The Norfolk and Waveney Therapeutics Advisory Group (TAG)

REPORT

April 2018 to March 2019

"Providing professional advice on the clinical efficacy, safety and cost effectiveness of new medicines and indications, and on prescribing responsibility across Norfolk and Waveney"

Contents

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REPORT OF ACTIVITIES - April 2018 to March 2019

Executive Summary

Introduction:

The Norfolk and Waveney Therapeutics Advisory Group, locally known as the "TAG", is an Area Prescribing Committee (APC) which was first established for Norfolk in 1995. Its objective is to promote rational, high quality, cost-effective prescribing across the whole of Primary and Secondary Care in the Norfolk and Waveney STP area.

During 2018-19 the TAG performed this work on behalf of Clinical Commissioning Groups (CCGs) in Norfolk and Waveney. The work of the committee was delivered as part of Prescribing and Medicines Optimisation services provided by Arden and Greater East Midlands (AGEM) Commissioning Support Unit (CSU) as commissioned by the Norfolk and Waveney CCGs.

Role of the TAG:

The TAG's role is to provide a forum for face-to-face discussion and agreement on county-wide implementation of national guidance on the use of medicines, including:

- NICE Technology Appraisal guidance and (Clinical) Guidelines
- Assessment of the clinical and cost-effectiveness of new drugs/indications and products.
- Payment by Results (PbR)-excluded ("non-national tariff") drugs.
- Resolution of issues regarding prescribing at the Primary and Secondary care interface.

The TAG's role in the local commissioning framework during 2018-19 was as described in the "**New Medicines Policy"** – *A Policy and Procedure for introducing New Medicines and indications across Clinical Commissioning Groups (CCGs) in Norfolk and Great Yarmouth & Waveney*.

The policy is available via: *Link*

Remit and process:

- The TAG worked to its **Terms of Reference (Appendix 1)**.
- The TAG made its recommendations using either a consensus approach or the **Decision-Making Framework (Appendix 2)** as necessary.
- TAG members were asked to complete and maintain a **Declaration of Interests Form (Appendix 3)**.

To make robust decisions about the relative merits of different therapies, the TAG considered in general:

- How clinically effective the treatment is
- The risk of adverse reactions
- How cost-effective the treatment is
- How it compares with current treatments
- and where (if at all) the proposed new medicine would fit into current treatment pathways

These points were all related to the group of patients most likely to receive the medicine, were it to be recommended for use.

Consultation:

Key stakeholders are identified and consulted when drugs within specialist areas are discussed.

As many views as possible are sought and then considered during the TAG meetings.

When felt appropriate, and requested by the proposing organisation's TAG representative, specialists are occasionally invited to attend TAG meetings to contribute to the meeting or to make presentations.

Supporting the Commissioning process:

The TAG's recommendations were presented to subsequent meetings of the Norfolk and Waveney CCGs' **Drugs & Therapeutics Committee (D&TC)**. Recommendations on CCG-commissioning responsibility issues and then taken forward to the CCGs' **Joint Strategic Commissioning Committee (JSCC)**.

The flowchart in **Appendix 4** illustrates the TAG's role in advising commissioners on the managed entry of new drugs and indications in the local health economy during 2018-19.

Communicating TAG Recommendations and the CCGs' Commissioning Decisions:

The D&TC/JSCC's commissioning decisions were then communicated to local NHS providers and key stakeholders e-mails, using **Commissioning Statements** and the **Summary of recommendations of the TAG and the D&TC**.

The **TAG Recommendations Report** was then updated and the latest changes publicised via the **Norfolk & Waveney Prescriber** newsletter.

- During 2018/19 the **TAG Recommendations Report** and its companion **Table** were available for local NHS Healthcare Practitioners to access via the Knowledge Management Service via http://nww.knowledgeanglia.nhs.uk/ .

- D&TC/JSCC Commissioning Decisions were ultimately recorded in the **Combined Commissioned Drugs List** which is available to local NHS Healthcare Practitioners via the Knowledge Management Service at http://nww.knowledgeanglia.nhs.uk/

- **Commissioned Pathways** and **Policy Statements** supported by the D&TC/JSCC were also published.

- TAG Recommendations and D&TC Commissioning Decisions were also communicated and implemented in Primary Care via the ***ScriptSwitch*** **IT Prescribing Support System**. GPs were notified of any relevant TAG recommendations at the point of prescribing. The system was updated following each TAG meeting and D&TC/JSCC meetings.

The Norfolk & Waveney Prescriber Newsletter:

During 2018-19 ***The Norfolk & Waveney Prescriber*** newsletter was published in its revised style and format, with both e-mail and web-based distribution.

Four editions of the Norfolk & Waveney Prescriber newsletter were published from April 2018 to March 2019 and included leading articles on TAG recommendations and CCG commissioning decisions.

The newsletter was widely circulated to prescribers and healthcare practitioners in primary and secondary care across the local health economy.

Editions of The Prescriber are available at: *Link*.

TAG Recommendations 2018/19:

Headlines: 278 recommendations to commissioners

- **55** recommendations regarding **New Drugs & Indications**
- **105** recommendations relating to **NICE Guidance**
- **78** recommendations related to **Interface issues and Miscellaneous Guidance**
- **15** recommendations related to **East of England Priorities Advisory Committee (EoE PAC)** policies
- **6** recommendations related to **NHS England Specialised Commissioning Group (NHSE SCG)** policies
- **19** recommendation related to **Regional Medicines Optimisation Committees (RMOCs)**

Details of all the **TAG's Recommendations for 2018-19** are listed in **Section 1** (from **Page 10 onwards).**

TAG Membership during 2018/19

TAG members included representatives from the following organisations

- Arden and GEM Commissioning Support Unit (CSU)
- Cambridgeshire Community Services NHS Trust
- East Coast Community Healthcare CIC
- Great Yarmouth and Waveney CCG
- HealthWatch Norfolk
- The James Paget University Hospital NHS Foundation Trust
- The Norfolk & Norwich University Hospital NHS Foundation Trust
- Norfolk & Suffolk NHS Foundation Trust
- Norfolk and Waveney Local Medical Committee
- Norfolk Community Health & Care NHS Trust
- Norfolk Local Pharmaceutical Committee
- North Norfolk CCG
- Norwich CCG
- Public Health England (Norfolk County Council)
- The Queen Elizabeth Hospital, King's Lynn NHS Foundation Trust
- South Norfolk CCG
- West Norfolk CCG

TAG Meetings Attendance 2018/19

- TAG meetings are held bi-monthly, usually on the first Thursday of the odd months of the year. Dates and times of meetings are set on an annual basis.
- **Six meetings** were held during May 2018 to March 2019.
- The following table reports on the attendance rates of TAG members, their roles, and representative organisations during 2018-19 (*compared with 2017-18*).

Role	Member Organisation	TAG Meetings Attendance 2018-19 *(2017-18)*
Consultant in Public Health	Public Health England - Norfolk	0 out of 6 *(0)*
Deputy Medical Director	Norfolk & Suffolk Foundation Trust	1 out of 1 *(-)*
GP Prescribing Lead	West Norfolk CCG	0 out of 5 *(0)*
Community Pharmacist	Norfolk LPC	3 out of 6 *(0)*
Associate Chief Pharmacist	The Queen Elizabeth Hospital	4 out of 6 *(4)*
Medical Director	Norfolk LMC	1 out of 3 *(-)*
Chief Pharmacist	Norfolk & Suffolk Foundation Trust	5 out of 6 *(3)*
Head of Prescribing & Medicines Management	Great Yarmouth & Waveney CCG	4 out of 6 *(6)*
Clinical Director of Pharmacy Service / Chief Pharmacist	Norfolk & Norwich University Hospital	5 out of 6 *(4)*
Medical Director	Norfolk and Waveney LMC	1 out of 6 (from Sept 2018)
GP Prescribing Lead	North Norfolk CCG	5 out of 6 *(3)*
Highly Specialist Pharmacist HIV	Cambridgeshire Community Services NHS Trust	1 out of 6 (*1*)
TAG Lead Pharmacist	Arden and GEM CSU	6 out of 6 *(6)*
DT&MMC Chair	Norfolk & Norwich University Hospital	6 out of 6 *(6)*
GP Prescribing Lead	Norwich CCG / Local Medical Committee	6 out of 6 *(6)*
D&TC Chair	The Queen Elizabeth Hospital	6 out of 6 *(5)*
GP Representative	South Norfolk CCG	6 out of 6 (*6*)
Deputy Head of Prescribing & Medicines Management / Prescribing Adviser	Arden and GEM CSU – Norwich and South Norfolk CCGs	5 out of 6 *(5)*
Head of Prescribing & Medicines Management	Norfolk Community Health and Care	5 out of 6 *(4)*
Lay Member	HealthWatch - Norfolk	5 out of 6 (*5*)
Head of Prescribing & Medicines Management	East Coast Community Healthcare CIC	0 out of 6 *(0)*
D&TC Chair	The James Paget University Hospital	2 out of 6 *(0)*
TAG Chair	Norwich GP	5 out of 6 *(6)*
Pharmacist Prescribing Adviser	Arden and GEM CSU - North Norfolk & West Norfolk CCGs	5 out of 6 *(6)*
Prescribing Adviser – Interface / High Cost Drugs	Arden and GEM CSU	5 out of 6 *(5)*

Costs of running the TAG

Financial Year 2018-19:

- The work of the TAG was managed and delivered by the TAG Lead Pharmacist which was a salaried role, employed during 2018-19 by Arden and GEM Commissioning Support Unit (CSU).
- Most TAG members are funded by their employers to attend meetings as part of their salaried roles, representing NHS organisations, or other representative bodies e.g. Norfolk LPC and Norfolk and Waveney LMC.
- The member from HealthWatch Norfolk is a volunteer role.

Meeting Accommodation & Parking:

Due to inadequate car-parking available at NHS venues to accommodate the TAG's large membership, TAG meetings were held at a suitable non-NHS venue, located centrally in the county with quick access to major routes and suitable parking.

The overall cost of using this venue during 2018/19 was **£472.80** for the six meetings.

The costs of the venue were shared by each CCG in Norfolk and Waveney, paid for on a rotational basis.

General Conclusion

During **2018-2019**, the **Norfolk and Waveney Therapeutics Advisory Group (TAG)** continued to provide robust recommendations on the safe, clinical and cost-effective use of medicines to the Norfolk and Waveney CCGs for the benefit of the Norfolk and Waveney STP-wide population.

There was broad representation from Primary and Secondary Care NHS Trusts, Clinical Commissioning Groups (CCGs), and other stakeholders. TAG meetings were generally well attended across the membership.

The TAG's work became even more important during the development of the work of the CCGs across the STP area, their local priorities, the emphasis on QIPP, and as healthcare resources continue to be increasingly limited.

The meetings of the TAG continue to provide an important local forum for face-to-face interactions which help to facilitate and maintain good working relations across several healthcare sectors.

It is hoped that this **Report** is helpful to all interested parties.

Any comments on this document are welcomed by the TAG Lead Pharmacist.

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1. TAG Recommendations 2018/19

The TAG developed a range of guidance on the appropriate and cost-effective use of medicines during 2018/19 as follows:

A. *New Drugs & Indications*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
May 2018	**NNUH Application:** Dimethyl fumarate (*Skilarence*®) ***NB*** QEH application and the proposed treatment pathway for psoriasis considered and supported by the TAG in March 2018 – recommended as Red (Hospital only). The QEH estimated use in 10 patients per year, costing £47,000, saving £6,625 compared with current treatment with apremilast. CCG-commissioning responsibility Current **Double Red** classification under review pending confirmation of a commissioning decision by the CCGs' JSCC (April 2018 meeting). *This has since been confirmed as being supported by the JSCC.*		Dimethyl fumarate (*Skilarence*®) for treatment of moderate to severe plaque psoriasis in adults – *as per* NICE TA 475 and for additional use	The TAG considered the NNUH's application and discussed how dimethyl fumarate would be placed in the psoriasis treatment pathway with respect apremilast. Apremilast is more effective for nail treatment whereas dimethyl fumarate is more effective in hand and foot psoriasis. Both drugs would be positioned ahead of biologics. Patients will be selected according to NICE criteria which places DMF alongside apremilast. There may also be a small subgroup of patients (that transfer from apremilast) where the use of a biologic agent is contraindicated. The TAG agreed to support the NNUH's application and reaffirmed the previous recommendation of Red (Hospital only). The treatment pathway to be sent to the D&TC for confirmation.	The NNUH's application states that an estimated 27 patients per year will require treatment with *Skilarence*®. Annual cost of *Skilarence*® per patient: £4,643 Annual cost for 27 patients: £125,356 Annual costs of treating 27 patients using current treatment options Fumaderm: £171,477 Apremilast: £144,787 *The D&TC was advised that since local dermatology specialists also wish to switch between different treatment options for psoriasis, the treatment pathway was not finalised and would be brought to the June 2018 D&TC meeting.* *The D&TC therefore did not make any decision regarding the NNUH's application and the TAG's recommendation at the May 2018 meeting.*

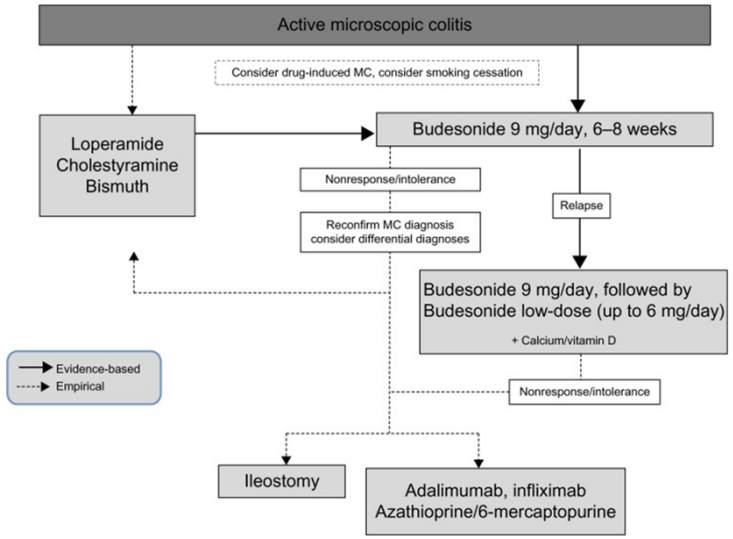
TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
May 2018	**NNUH Application:** CCG-commissioning responsibility Currently **Double Red / not commissioned** pending submission and approval of a business application and confirmation of its place in the local treatment pathway	Dexamethasone (*Ozurdex*®) intravitreal implant	For treatment of non-infectious uveitis – *as per* NICE TA 460 (July 2017), and also for use beyond NICE criteria.	The TAG considered the NNUH's application as per NICE TA 460 which also proposed use in both eyes (administered separately to mitigate the risk of endophthalmitis occurring after insertion) in patients presenting with bilateral uveitis with contraindications to anti-TNF and/or if there has been a positive response to unilateral application on previous occasions. The NNUH had sought information from the manufacturer and had provided evidence to support such use if required. The application also proposed replacement implantation sooner than 6 monthly where the treatment has not remained effective for that time period. Around a third of patients may need replacement at 4 months (3 implants per year) rather 6-monthly. These uses would be outside of NICE criteria. The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital use only).	The NNUH's application states that an estimated 12 patients will require treatment with *Ozurdex*®. Annual cost of *Ozurdex*® per patient: £2,088 - £3,132 Annual cost for 12 patients: £25,056 - £37,584 The annual costs above are based upon the 12 patients being treated unilaterally at intervals of either 4 or 6 months. Trial data indicate that ~30% of cases need retreating < 6 months which makes the anticipated cost £29,232. *The D&TC noted that the application included proposals for use of intravitreal dexamethasone implants outside of NICE TA 460. A review of the pathway and proforma would be required to accommodate such extended use which would need to be audited.* *The D&TC agreed that more information is required from the Trust regarding the proposed use outside of NICE TA 460 but agreed to support commissioning as* Red (Hospital only) *for use strictly in line with* NICE TA 460*.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
May 2018	**NNUH Application:** CCG-commissioning responsibility Currently Green (GP prescribable following specialist recommendation) (January 2017).	Ticagrelor (*Brilique*®)	For prolonged dual antiplatelet therapy for up to 3 years post MI – as per NICE TA 420 NICE TA 420 Resource impact report - *Link*	The TAG considered the NNUH's application and clarified that the proposed patient numbers equate to those for the NNUH's catchment population plus the fact that the NNUH is a tertiary centre which may receive referrals from elsewhere across the county. However the estimated number of patients are lower than those estimated by NICE due to the NNUH cardiologists' wish to use in a more considered way. Older People's Medicine numbers have also been included but are low due to the increased risk of bleeding. The TAG recommended that the dosage regimen and duration of treatment must be specified in the specialist's letter to the GP. The TAG also noted that if treatment is continued beyond a year, then the dose should be revised from 90mg OD to 60mg BD for a maximum of 3 years of extended treatment. GPs would have to set up repeats with a limited and specified number of authorisations in order to ensure safe and appropriate prescribing. The TAG reaffirmed a traffic light classification of Green (GP prescribable following specialist recommendation) providing that the dosage regimen and duration	The NNUH's application states that a NICE estimates that 260 patients per year will require prolonged dual antiplatelet therapy for up to 3 years post MI with ticagrelor. However the NNUH predicts that this figure is likely to be closer to 150 patients. Annual cost of *Brilique*® 60mg BD per patient: £709.80 Annual cost for 260 patients: £184,548. (*Annual cost for 150 patients: £106,470*) The above figure(s) is an annual rate. Cumulative costs will plateau at **£319,410 annually by the end of Year 3**, assuming steady numbers of patients who take the full treatment course and survive post MI. *The D&TC noted the NNUH cardiologists' considered estimation of patient numbers and was concerned about the financial impact of this treatment of primary care prescribing expenditure. To be referred for consideration by the JSCC.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
				of treatment is specified in specialists' letters to GPs.	
May 2018	**NNUH Application:** Currently **Double Red** pending submission and approval of a business application and confirmation of its place in the local treatment pathway (Sep 2017)	Eluxadoline (*Triberzi*®)	As a third line option for diarrhoea predominant irritable bowel syndrome (IBS-D) - as per NICE TA 471	The TAG considered the NNUH's application and proposed treatment pathway and agreed to support revising the traffic light classification to Green (GP prescribable following specialist recommendation) in line with the proposed treatment pathway and the first 4 weeks are prescribed by the specialist. **Future demand:** The NNUH state that because of the lack of efficacy of other currently available treatments for IBS-D, there is considerable unmet need for effective treatments. Demand may increase due to a considerable number of currently unsuccessfully treated patients who are not being seen in either primary or secondary care. Using the NICE costing resource template the estimated patient population is 206 of which 77 are likely to withdraw therapy within the first 4 weeks giving an ongoing population of 129 patients.	The NNUH's application states that an estimated 50 patients per year will require treatment with *Triberzi*®, but also points out that it is likely that there is considerable unmet need in these cases of IBS-D in the community. Annual cost of *Triberzi*® per patient: £1,149.75 Annual cost for 50 patients: £57,487.50. If patients stay on treatment long term, these annual costs will accumulate. *The D&TC noted that there is an estimated initial dropout rate of ~37% within the first 4 weeks of starting treatment due to adverse effects, and supported the TAG's recommendation that the initial prescription should be provided by the specialist.* *The D&TC therefore supported the TAG's recommendation.* *To be referred for consideration by the JSCC.*
May 2018	**NNUH Application:** ***Follow-up*** **January 2018:** The TAG	Roflumilast (*Daxas*®)	For maintenance treatment of severe COPD associated with chronic bronchitis in adults with history of	**May 2018:** The NNUH submitted info on patient numbers based on the NICE resource impact statement as follows:	

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	considered the NNUH's application but deferred making a decision pending further information from the Trust regarding criteria for use, stopping, and realistic patient numbers. Currently **Double Red** pending submission and approval of a business application and confirmation of its place in the local treatment pathway (Sept 2017)		frequent exacerbations as add on to bronchodilator treatment – *as per* NICE TA 461	***No significant resource impact is anticipated*** *We (NICE) do not expect this guidance to have a significant impact on resources; that is, it will be less than £5m per year in England (or £9,100 per 100,000 population). This is because the expected uptake of the technology is small because the therapy should only be started by specialists in secondary care, and the unit cost for the intervention is small.* The NNUH reported that there is limited interest within the Trust's specialists in using roflumilast apart from consultant who has had brief experience of using it elsewhere in the country and would like to have it available as an option. However they are unable to identify criteria of when and how they would decide to use roflumilast or how they would decide to stop it if not beneficial. Adverse effects related to the treatment make it a less desirable option for many physicians. Despite protracted discussion on how criteria for starting / stopping treatment might be agreed and whether it was appropriate to recommend use within hospital only to start with, the TAG felt unable to comment on the application and as the sub-group	**May 2018:** *The D&TC noted the TAG*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
				of patients could not be identified concerned were expressed around the numbers. The TAG felt unable to consider this any further until more information is received from the clinician. The TAG recommended that the current traffic light classification of **Double Red (Not recommended for routine use)** be maintained. A request would be made to the STP respiratory working group to review the evidence for this treatment to see if a sub-group of patients can be identified.	*recommendation but did not agree that the STP respiratory group was the appropriate forum to refer this issue to.* *The D&TC instead recommended that the East of England PAC be approached to provide guidance on criteria for use and review of treatment with roflumilast for severe COPD.* *The current classification of **Not commissioned** was therefore recommended to be maintained.*
May 2018	**Alignment of the Commissioned Drug Therapies List (March 2018) and the TAG recommendations database**	Various	*Drugs / Indications on the March 2018 Combined Commissioned Drug Therapies List that have not been considered by TAG (mostly NHSE commissioning responsibility)* / for consideration and approval to be added to the TAG's database – CCG-commissioning responsibility items highlighted	**Acamprosate and disulfiram for alcohol misuse:** PHE commissioning responsibility with service and prescribing provided by Change Grow Live (CGL) – should not be prescribed by the GP – classify as Red (Specialist only)? *To be confirmed by the D&TC.* All other recommendations supported by the TAG.	*The D&TC noted and supported the TAG's recommendations and also confirmed that prescribing of treatments for alcohol misuse, including acamprosate and disulfiram (and also nalmefene) are the responsibility of the specialist since PHE has not commissioned alcohol services from GPs practices – classified as* Red (Specialist only).
May 2018	**MHRA Safety Update:**	Daclizumab (Zinbryta▼): suspension and recall for safety reasons; review patients as soon as possible and start alternative therapy *	Noted by the TAG		* *The D&TC also noted the suspension of* Daclizumab (Zinbryta▼)*, which is* NHSE commissioning responsibility *and is currently classified as* Red (Hospital only) *– the D&TC agreed that it was*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
					appropriate to revise the classification to **Double Red (Not recommended for routine use)** *until further information is available.*
July 2018	**Therapeutics Advisory Group:** **QEH Application:** ***NB*** Currently classified as Green (GP prescribable following specialist recommendation) for Crohn's disease (January 2018). CCG-commissioning responsibility	*Budenofalk*® (3mg capsules and 9mg granules) for collagenous colitis in adults	The QEH Gastroenterologists considered that there was a lower risk of side effects with this treatment than with prednisolone, which is unlicensed and is not within current guidance. There is evidence of effectiveness, it is a licensed indication, and *Budenofalk*® is a more cost effective brand (11% lower cost) than *Entocort*® (currently in use). The TAG therefore recommended a traffic light classification of Green (GP prescribable following specialist recommendation) for *Budenofalk*® (3mg capsules and 9mg granules) for collagenous colitis in adults. **Proposed treatment pathway:**  European Microscopic Working Group algorithm for the treatment of collagenous colitis.	The QEH have stated that an estimated 25 patients per year will require treatment with *Budenofalk*®. Cost of using *Budenofalk*® capsules for 25 patients in primary care: £3,752.50 (capsules) saving £455.00 compared with *Entocort*® (£4,207.50. *The D&TC supported the TAG's recommendation and the QEH's application.*

<table>
<tr><th>TAG Meeting Date</th><th>Reason for review by the TAG</th><th>Drug name (Brand name)</th><th>Indication for use</th><th>TAG Recommendation</th><th>Commissioning Decision by the N&W D&TCG</th></tr>
<tr>
<td>July 2018</td>
<td>Therapeutics Advisory Group:
<u>NCHC Application</u>:

CCG-commissioning responsibility

These devices have been in use locally over the last 10 years but had not been formally commissioned.

The devices had been discussed at the Norfolk & Waveney Prescribing Reference Group (PRG) where concern had been expressed about occasional requests for use in inappropriate situations.

Currently Double Red / not commissioned pending submission and approval of business applications and confirmation of its</td>
<td>Trans Anal Irrigation (TAI) for Chronic Constipation and Faecal Incontinence (NCHC Adult Continence Service) - as an option as per agreed treatment pathways

3 types of device, 2 manual and 1 electric:
• IryPump S (B Braun Medical)
• Peristeen Anal Irrigation System (Coloplast)
• Qufora IrriSedo Mini (MacGregor Healthcare Ltd)

<table>
<tr><th>Product name (manufacturer)</th><th>Description</th><th>Components/Accessories</th><th>Number of uses</th><th>Monthly (30 day on alternate day</th></tr>
<tr><td>IryPump S
(B Braun Medical)
http://www.bbraun.co.uk/cps/rde/xchg/cw-bbraun-en-gb/hs.xsl/products.html?prid=PRID00007571</td><td>A high-volume cone system with an electrical pump.[7]</td><td>IryPump S (electrical pump, water container, power supply)
IryCone+ (cone and tubing)
Carrying case
The starter kit also includes accessories needed if being used to irrigate via a stoma.</td><td>The power unit has a three year warranty.
The water container has a six month warranty (but does not need to be replaced routinely at six months).
The IryCone is reusable after cleaning. It should be replaced every three months.[8]</td><td>Average monthly system is £34.78
*Based on three use (1 IryPump S IryCone+, 1 repl IryPump water c use is discontinu the average mon increases.</td></tr>
<tr><td>Peristeen anal irrigation system
(Coloplast)
www.coloplast.co.uk/peristeen-anal-irrigation-system-en-gb.aspx</td><td>A high-volume rectal catheter system with a manual pump.[9]</td><td>Control unit (includes pump)
Rectal catheters (available in regular and small sizes)
Water bag
Tubing
Strap</td><td>The control unit can be used 90 times (six months usage if used on alternate days).[10]
Water bags can be used 15 times.
Rectal catheters are single use.[9]</td><td>Average monthly system is £144.1
*Based on six mo (1 Peristeen syst Peristeen access If use is discontir the average mon increases.</td></tr>
<tr><td>Qufora IrriSedo Mini System
(MacGregor Healthcare Ltd)
www.macgregorhealthcare.com/products/quforamini/index.html</td><td>A low-volume cone system with a manual pump.
It is designed for people who need a small amount of water to irrigate.[11]</td><td>Pump
Cones
Waste bags</td><td>Up to 30 days use for the pump.
Cones are for single use.[12]</td><td>15 irrigation set
£59</td></tr>
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</td>
<td>The proposed use is mainly in neurology patients with spinal cord injury, and in patients with bowel dysfunction, as a last resort following failure of all other conservative treatments.

NICE recommendations (March 2018) for use of the electric pump (the most expensive option) are not suitable for all patients, particularly those with spinal injury who have flaccid bowel, and for whom manual (TAI) pumps would be more suitable. Each proposed option has pros and cons for different patients ← see table.

TAI is considered for such patients where conservative treatments such as diet and fluid; lifestyle alteration; laxatives or constipating drugs, followed by digital stimulation; suppositories and biofeedback are first tried within a formal treatment pathway but have been ineffective. TAI is therefore an option for patients before more invasive treatment options including Antegrade Colonic Irrigation (ACE), Sacral Nerve Stimulation, Sacral Anterior Root Stimulation and Stoma are considered.

The TAG agreed to support the application and recommended a traffic light classification of Green</td>
<td>The NCHC’s application states chronic constipation / faecal incontinence affects an estimated 3.1 to 3.6 men and women aged 60 to 89 per 100,000 population.

An additional patient groups include younger patients with neurological conditions such as spina bifida or Hirschprung’s disease, spinal cord injury, multiple sclerosis, and Parkinson’s Disease can all result in neurogenic bowel dysfunction (NBD).

Average monthly cost:

IryPump S: £34.78 (if at least 3 years’ use)

Peristeen Anal Irrigation System: £144.15 (if at least 6 months’ use)

Qufora IrriSedo Mini:

£59 (15 irrigation set)

The D&TC noted total 2017/18 expenditure on TAI in primary care across the CCGs (£157,400 for Norfolk; £39,000 for GY&W)).
It was acknowledged that most of the costs related to a single product currently recommended by specialists in the acute trust.

In contrast the NCHC service recommends a variety of products, selected depending on individual patient need, for</td>
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TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	place in a treatment pathway (July 2017). A request was made to local specialists at different Provider Trusts to bring forward their applications and proposed treatment pathways to the TAG, to clarify what is being used and under which criteria. The NCHC adult continence service has met this request, to seek approval for their recommended use of TAI products.			(GP prescribable following specialist recommendation) for use in patients managed by the NCHC Adult Continence Service.	*a smaller number of patients.* *The D&TC noted that the acute trust recommends use in adults and in children, and that separate treatment pathways for these patient groups were being developed.* *The D&TC therefore agreed to support the use of TAI for adults manged by the NCHC continence service as* Green (GP prescribable following specialist recommendation).
July 2018	**Therapeutics Advisory Group:** **NNUH / JPUH *proposed* Interim Commissioning Agreement:** Proposal (as an alternative to the IFR route) to cover a local patient cohort until the EoE PAC publishes its final	**Continual Glucose Monitoring (CGM)** Devices: *Dexcom G5* (when alarms are appropriate) *Enlite* sensor, in conjunction with the sensor augmented *Medtronic minimed* 640G insulin pump	For Children with Diabetes as per specified criteria in three key areas: **1.** Children less than 2 years of age – *estimate no more than 1 patient per CCG; treatment would continue until age 5 years*. **2.** Children with 1 or more episodes of	The TAG considered the potential time delay in finalising the commissioning position if the final PAC recommendations did not meet the deadline for being considered at the next available meetings of the DTC and JSCC, and the impact it would have on patient care and the need to make further submissions to the IFR Panel. The TAG therefore	**Actual patient numbers to date are:** **1.** 1 child under the age of 2 **2.** 7-8 patients **3.** 10 patients

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	commissioning recommendations – due following the July 2018 PAC meeting at the earliest		severe hypoglycaemia per year resulting in cognitive impairment requiring external assistance, despite optimal diabetes care – *estimate 3% of caseload; review at 6 months and then every 12 months; trial without after 3 years – flash glucose monitoring may be required at this review* **3.** Children with persistent loss of hypoglycaemia awareness or where the child is unable to communicate – *estimate 4% of caseload; review at 6 months and then every 12 months; trial without after 3 years – flash glucose monitoring may be required at this review*	recommended that the application be supported pending the publication of the PAC's guidance. To be discussed further at the next D&TC together with the (latest version of the) PAC's recommendations, if available, and an appropriate traffic light classification related to this treatment to be considered.	**Costs:** Maximum 53 sensors will be provided /12 month period (which must be worn at least 70% of the time)

<table>
<tr><th>TAG Meeting Date</th><th>Reason for review by the TAG</th><th>Drug name (Brand name)</th><th>Indication for use</th><th>TAG Recommendation</th><th>Commissioning Decision by the N&W D&TCG</th></tr>
<tr>
<td>July 2018</td>
<td>JPUH / NNUH Interim proposal - Financial Assessment of providing CGM in children:

Total costs referred to are based on 100% sensor utilisation and replacement of transmitter and reader at end of warranted life.

Currently patients test their blood glucose with lancets and test strips more than 10 times/day. Dexcom is licensed to replace test strip blood glucose tests. There is therefore a cost saving in lancet strip/test costs for patients using Dexcom:</td>
<td colspan="2">
Current costs
Cost per lancet 0.04
Annual cost (10/day) 146.00
Cost per test strip: £0.29 0.29
Annual cost (10/day) 1,058.50
Total current lancet/test strip cost 1,204.50

Reduced lancet/test strip costs for patients using Dexcom
Cost per lancet 0.04
Annual cost (2/day) 29.20
Cost per test strip 0.29
Annual cost (2/day) 211.70
New total lancet/test strip cost 240.90
</td>
<td>
Intervention costs:
<table>
<tr><th></th><th>Current Cost</th><th>CGM Cost Option 1</th><th>CGM Cost Option 2</th><th>Increase cost for Option 1</th><th>Increase cost for Option 2</th></tr>
<tr><td>Start-up Cost</td><td></td><td>330</td><td></td><td>330</td><td>-</td></tr>
<tr><td>Run Cost</td><td>1,205</td><td>4,399</td><td>4,690</td><td>3,194</td><td>3,485</td></tr>
<tr><td>Total Yr 1 Cost/patient</td><td>1,205</td><td>4,729</td><td>4,690</td><td>3,524</td><td>3,485</td></tr>
<tr><td>Total Yr 1 Cost/20 Patients</td><td>24,090</td><td>94,578</td><td>93,790</td><td>70,488</td><td>69,700</td></tr>
<tr><td>Total Yr 1 Cost/20/CCG</td><td>8,030</td><td>31,526</td><td>31,263</td><td>23,496</td><td>23,233</td></tr>
</table>
Assumptions
Option 1 is using DEXCOM
Option 2 uses ENLITE

Current cost for option includes 2 strips/day
Current cost for option 2 includes 10 strips/day

Current demand that falls under the criteria are 20 patients per year
At NNUH cost per CCG is split out equally between the three main CCG's for the NNUH
Assumed VAT is unrecoverable

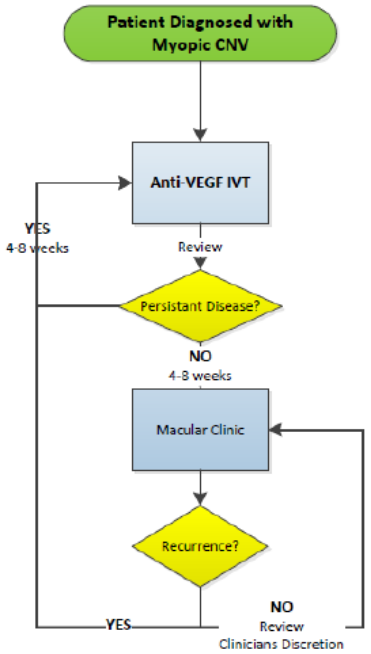
Potential other savings
• £300–£1,600 for each avoided hospital admission with hypoglycemia
• £80-£240 for each avoided Accident & Emergency attendance

The D&TC was advised that the EoE PAC did not finalise its guidance at the July 2018 meeting due to outstanding queries regarding costs and stopping criteria related to the patients' age.

It was also reported that the Department of Health has decided that the procurement of insulin pumps, enteral feeds and Continual Glucose Monitoring (CGM) (amongst other items) will be managed under a new national strategy, which will remove the issue from local level decision makers' responsibility.

The CSU's Interface Pharmacist will therefore meet with the Local clinicians to agree a way forward for their patients.
</td>
<td></td>
</tr>
<tr>
<td>July 2018</td>
<td>Therapeutics Advisory Group:
QEH Application and proposed</td>
<td colspan="2">Aflibercept (Eylea®) for myopic choroidal neovascularisation (CNV) in adults – as per NICE TA 486 which states:
• Ranibizumab is already recommended by NICE</td>
<td>QEH's proposed treatment algorithm:
One single dose intravitreal injection Aflibercept. Additional doses may be administered if</td>
<td>The QEH estimate use in 15 patients per year.

Annual cost (assuming 50%</td>
</tr>
</table>

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	<u>treatment pathway</u>: CCG-commissioning responsibility Currently **Double Red / Not commissioned** pending the submission and approval of a locally developed business application for its use and confirmation of its place in the local treatment pathway Requested as an alternative to ranibizumab - to be used according to NICE TA 486.	for treating choroidal neovascularisation. An indirect comparison of aflibercept and ranibizumab shows that both drugs provide similar overall health benefits. The total costs of aflibercept are the same as or less than those of ranibizumab. • Because it is has similar costs and overall health benefits to ranibizumab, aflibercept is also recommended as a cost-effective option for treating choroidal neovascularisation. Choroidal neovascularization (CNV) is one of the most important vision-threatening complications of pathologic myopia and occurs in 5–10% of myopic patients (up to 3% of general population), with a positive correlation between risk and degree of myopia. Among myopic patients with pre-existing CNV, more than 30% will develop CNV in the fellow eye within 8 years .Without treatment, the long term prognosis of myopic CNV is poor; approximately 90% of patients will have a VA of 6/60 or less after 5 years.		visual and/or anatomic outcomes indicate that the disease persists. The interval between two doses should not be shorter than one month. Recurrences should be treated as a new manifestation of the disease. The schedule for monitoring should be determined by the treating physician.  The TAG agreed to support the QEH's application and recommended a traffic light classification of Red (Hospital/Specialist only)	of patients need 2nd dose): £11528.00 (22 packs) **Net saving** (compared with equivalent cost of ranibizumab): £225.28 *The D&TC agreed to support the application as* Red (Hospital / Specialist only) *and acknowledged that this is another extension in the treatment of eye disease. Monitoring of aflibercept in line with NICE TA 486 will be undertaken via a proforma.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
July 2018	**Therapeutics Advisory Group:** **Treatment Pathway / GP Prescribing Decision Support Tool: – *review***	Oral Anticoagulant Therapy	For Stroke prevention in Atrial Fibrillation	Reviewed and updated in line with current SPCs and guidance on crushing medicines. Hyperlinks checked and updated. The TAG agreed that the changes were acceptable and that the revised pathway and prescribing support tool should be published.	*Noted and supported by the D&TC*
July 2018	**Prescribing Reference Group / Therapeutics Advisory Group:** ***Draft* GP Prescribing Guidance** **May 2018:** The TAG recommended that GP prescribing and monitoring guidance for amiodarone be developed to support local use in primary care under the new CCGs' primary care drug monitoring LES. 2 possible versions have been developed for consideration by TAG.	Amiodarone	For supraventricular and ventricular arrhythmias	Amiodarone had been flagged as a treatment the required additional attention in terms of monitoring arrangements. The need for annual ECG monitoring also to be flagged on the front page of the document. The TAG agreed to adopt the version of the document that the PRG had supported as it was in the existing TAG format. Final version to be published on Knowledge Anglia.	*Noted and supported by the D&TC.* *The D&TC also recommended that amiodarone should be classified as Level 3 under the CCGs' Local Enhanced Service agreement with GP practices for monitoring drug treatments in primary care.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
July 2018	**Therapeutics Advisory Group:** ***Draft* GP Physical Health Monitoring Guidance**	Antipsychotics (various)	Physical Health monitoring related to prescribing in adults with psychoses (and related disorders)	The NSFT and GY&W CCG had discussed and adapted Cambs and Peterborough CCG's guidance. An additional statement needed to be made to include ECG for specialist baseline tests. The TAG supported the guidance which would sit alongside the shared care LES information on Knowledge Anglia.	*Noted by the D&TC.* *The D&TC also acknowledged that the monitoring to be undertaken by GPs under the CCGs' Local Enhanced Service agreement for monitoring drug treatments in primary care would be classified as Level "0" since GPs are already funded under the QoF.*
July 2018	**Cambs & Peterborough CCG:** **Shared Care Agreement:** Not previously classified by the TAG. No current commissioning position regarding use of dapsone for any indication.	Dapsone	For Dermatitis Herpetiformis and other Dermatoses	Requested to be considered by the TAG since may be adopted by Trusts outside Norfolk and Waveney that interface with local GP practices. Dapsone has significant monitoring requirements which would not be funded under the current local enhance service guidelines. It was considered that the agreement would therefore not be considered for adoption locally. The TAG also decided that no new (Red) classification should be agreed for use of dapsone.	*Noted and supported by the D&TC*
July 2018	**Cambs & Peterborough CCG:** **Shared Care Agreement:**	Bosentan	For Digital Ulcers in Systemic Sclerosis	The TAG was asked to consider the document since it may be adopted by Trusts outside Norfolk and Waveney that interface with local GP practices. Bosentan has significant	*Noted and supported by the D&TC*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	Currently classified as Red (Hospital use only) (Sept 2015) since is NHSE– commissioning responsibility			monitoring requirements which would not be funded under the current local enhanced service guidelines. The TAG therefore agreed that the agreement should not be considered for adoption locally and that the current classification of Red (Hospital use only) for bosentan would be maintained.	
July 2018	**Therapeutics Advisory Group:** Goserelin (*Zoladex*®) is currently classified as Green (Suitable for GPs to prescribe following specialist recommendation) for this indication.	Goserelin (*Zoladex*®) and other LHRH analogues (but *not* degarelix - which is currently **Double Red (Not recommended for routine use)**)	For use in prostate cancer	The TAG confirmed the view that goserelin and other cost-effective LHRH analogues (but not degarelix) should be classified as Green (Suitable for GPs to prescribe following specialist recommendation) for use in prostate cancer	*The D&TC noted and supported the TAG's recommendations*
July 2018	**Therapeutics Advisory Group:** **Prescribing Support document – *Review Link to current version***	Summary of guidance and clinical practice on the use of Anti-platelets to prevent occlusive vascular events		Updated in line with NICE TA 420 (Dec 16) and updated RCP Stroke guidelines 5th edition (Oct 16) Noted and supported by the TAG.	*Noted and supported by the D&TC*
July 2018	**Therapeutics Advisory Group:** **NNUH Application: (May 2018)** ***NB*** QEH application and the proposed treatment pathway for psoriasis considered and supported by the TAG in March 2018 –	Dimethyl fumarate (*Skilarence*®) for treatment of moderate to severe plaque psoriasis in adults – *as per* NICE		**May 2018:** The TAG considered the NNUH's application and discussed how dimethyl fumarate would be placed in the psoriasis treatment	**May 2018:** The NNUH's application states that an estimated 27 patients per year will require treatment with *Skilarence*®.

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	recommended as Red (Hospital only). The QEH estimated use in 10 patients per year, costing less compared with current treatment with apremilast. CCG-commissioning responsibility Current **Double Red** classification under review pending confirmation of a commissioning decision by the CCGs' JSCC (April 2018 meeting). *This has since been confirmed as being supported by the JSCC.*		TA 475 and for additional use	pathway with respect apremilast. Apremilast is more effective for nail treatment whereas dimethyl fumarate is more effective in hand and foot psoriasis. Both drugs would be positioned ahead of biologics. Patients will be selected according to NICE criteria which places DMF alongside apremilast. There may also be a small subgroup of patients (that transfer from apremilast) where the use of a biologic agent is contraindicated. The TAG agreed to support the NNUH's application and reaffirmed the previous recommendation of Red (Hospital only). The treatment pathway to be sent to the D&TC for confirmation.	Annual cost of *Skilarence*® per patient was compared with the costs of treatment with Fumaderm. *The D&TC was advised that since local dermatology specialists also wish to switch between different treatment options for psoriasis, the treatment pathway was not finalised and would be brought to the June 2018 D&TC meeting.* **July 2018:** The D&TC was advised that the psoriasis treatment pathway had been updated and published on Knowledge Anglia in May 2018 for dimethyl fumarate to be used as a non-biosimilar option, as an alternative to apremilast before biologics, in line with NICE TA 475 and the QEH and the NNUH's applications. Already classified as Red (Hospital only) following the JSCC's decision in April 2018.
July 2018	**Therapeutics Advisory Group: NNUH Application: (May 2018)** CCG-commissioning	Dexamethasone (*Ozurdex*®) intravitreal implant	For treatment of non-infectious uveitis – *as per* NICE TA 460 (July 2017), and also for use beyond NICE criteria.	**May 2018:** The TAG considered the NNUH's application as per NICE TA 460 which also proposed use in both eyes (administered separately to mitigate the risk of endophthalmitis occurring after	The NNUH's application stated that an estimated 12 patients will require treatment with *Ozurdex*®. Annual cost of *Ozurdex*® was noted, based on patients being treated unilaterally at intervals of either 4 or 6

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	responsibility Currently **Double Red / not commissioned** pending submission and approval of a business application and confirmation of its place in the local treatment pathway			insertion) in patients presenting with bilateral uveitis with contraindications to anti-TNF and/or if there has been a positive response to unilateral application on previous occasions. The NNUH had sought information from the manufacturer and had provided evidence to support such use if required. The application also proposed replacement implantation sooner than 6-monthly where the treatment has not remained effective for that time period. Around a third of patients may need replacement at 4 months (3 implants per year) rather 6-monthly. These uses would be outside of NICE criteria. The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital use only).	months. Trial data indicate that ~30% of cases need retreating < 6 months. **May 2018:** *The D&TC noted that the application included proposals for use of intravitreal dexamethasone implants outside of NICE TA 460. A review of the pathway and proforma would be required to accommodate such extended use which would need to be audited.* *The D&TC agreed that more information is required from the Trust regarding the proposed use outside of NICE TA 460 but agreed to support commissioning as Red (Hospital only) for use strictly in line with NICE TA 460.* **July 2018:** *The D&TC was advised that a separate treatment pathway for uveitis is not required due to there being only a small number of patients affected.* *The D&TC confirmed the previous position which had already been communicated to the Trusts - commissioned as Red (Hospital only) for use strictly in line with NICE TA 460*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
Sept 2018	**Therapeutics Advisory Group:** **NNUH Application:** Currently classified as **Double Red / Not commissioned** until a local business application for its use is supported following a positive NICE TA related to the treatment (*TAG recommendation May 2017*)	Dupilumab (*Dupixent*®) for treating moderate to severe atopic dermatitis after topical treatments - as per **NICE TA 534 (August 2018)** which states: Recommended as an option for treating moderate to severe atopic dermatitis in adults, only if: • the disease has not responded to at least 1 other systemic therapy, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are contraindicated or not tolerated • dupilumab is provided according to the commercial arrangement. • Stop dupilumab at 16 weeks if the atopic dermatitis has not responded adequately. An adequate response is: ○ at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started and ○ at least a 4 point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started. When using the EASI, healthcare professionals should take into account skin colour and how this could affect the EASI score, and make the clinical adjustments they consider appropriate.		The NNUH's application states that an estimated 10 patients per year will require dupilumab and costs are as follows: **Cost* per dose:** Noted by the TAG **Number of doses per course:** 26 injections per year **Cost per course:** Noted by the TAG **Total Annual Cost (10 patients):** Noted by the TAG Prices* are exclusive of VAT if provided via homecare. Also assumes no dropout at 16 week assessment but the trials indicate that this could be around 25%. The TAG recommended that the Eczema Area and Severity Index (EASI) score should be used for the starting criteria and that treatment could be commenced at EASI ≥16. The TAG otherwise supported the business case and recommended a traffic light classification of Red (Hospital / Specialist use only).	*The D&TC noted that the East of England Priorities Advisory was also discussing entry and continuation criteria for dupilumab, in consultation with consultant dermatologists, and are considering the following options:* *Entry criteria:* *1. EASI score of 7.1 or above (as per accepted definition of moderate to severe disease cited in NICE documents)* *2. EASI score of 16 or above (as per entry criteria used in pivotal trials used for licensing and quoted in the SPC)* *3. EASI score of 16 or above* *4. EASI score 7.1 and above AND a POEM score of 8 or above* *Continuation Criteria:* *As per NICE:* • *at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started and* • *at least a 4 point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started.* *The D&TC noted the above information and agreed that a considered approach in line*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
					with other EoE CCGs, using measurable and consistent assessment tools, regarding criteria for use of dupilumab, was appropriate. *The D&TC therefore decided to wait on the PAC's decisions and to maintain the current* **Double Red / Not commissioned** *position in the interim.*
Sept 2018	**Therapeutics Advisory Group:** **NNUH Application:** *Guselkumab was recommended through the NICE fast track appraisal process which expects that funding to implement this guidance will be provided by commissioners 30 days after publication.* *Currently classified as* Double Red / Not commissioned *pending submission and approval of a business*	Guselkumab (*Tremfya*®) for treating moderate to severe plaque psoriasis - as per **NICE TA 521 (June 2018)**		The TAG considered the NNUH's application in conjunction with an update of the local specialist treatment pathway for psoriasis which specifies that *Guselkumab, along with Ustekinumab, Secukinumab, Brodalumab, or Ixekizumab, are possible second line choices where an anti-TNF is contraindicated or not tolerated, depending on patient factors, co-morbidities and cost. The lowest cost option should be chosen, taking into account route of administration, dose and cost per dose. Prior approval through BluTeq is required for each of these agents before initiation*. The TAG therefore recommended a revised traffic light of Red (Specialist only), and to support the NNUH's application.	The NNUH application estimates 3 to 5 patients per year will require guselkumab with costs as follows: **Cost* per dose:** Noted by the D&TCG **Number of doses per course:** 7 – year 1 **Cost per patient per year:** Noted by the D&TCG **Total Annual Cost (3 to 5 patients):** Noted by the D&TCG The above patient numbers and costing is based on it being placed as an alternative to ixekizumab in the current CCG pathway for severe psoriasis. *Costs are exclusive of VAT, assuming that guselkumab will be provided via homecare. *Noted and supported by the*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	application and confirmation of its place in the local treatment pathway (TAG - July 2018)				*D&TCG.*
Sept 2018	**Therapeutics Advisory Group:** **Norfolk and Waveney CCGs Specialist Treatment Pathway – *update* August 2018** Updated to incorporate the most recently commissioned NICE-recommended treatment options. Current version - *Link*		**Specialist treatment of Rheumatoid Arthritis:** The TAG was advised that the pathway had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified. The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated. Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist. The TAG otherwise agreed with the treatment pathway in principle.		*Noted and supported by the D&TC*
Sept 2018	**Therapeutics Advisory Group:** **Norfolk and Waveney CCGs Draft Treatment Pathway – *update* August 2018** Updated to incorporate the most recently commissioned NICE-recommended treatment options, including guselkumab (commissioning yet to be finalised). Current version - *Link*		**Specialist treatment of Psoriasis:** The TAG was advised that the updated pathway incorporates the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments. Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice. The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally. Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.		*Noted and supported by the D&TC*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
Sept 2018	**Therapeutics Advisory Group:** **March 2018:** Previous Green (GP prescribing following specialist initiation) classification revised to **Double Red (Not recommended for routine use)** for initiating treatment courses in new or previous patients following reports of serious liver injury and an EU review of its use.	Ulipristal acetate (*Esmya*®)	For intermittent treatment of moderate to severe symptoms of uterine fibroids: – *Revisit* **August 2018:** The MHRA published updated guidance regarding new restrictions to licensed use and increased requirements for liver function monitoring before, during, and after treatment as follows: **Restricted indication and new contraindication** • Esmya is now indicated for: ○ the intermittent treatment of moderate to severe symptoms of uterine fibroids in women of reproductive age who are not eligible for surgery ○ one treatment course of pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age • Esmya treatment is to be initiated and supervised by physicians experienced in the diagnosis and treatment of uterine fibroids • Esmya is contraindicated in women with underlying liver disorders **Liver function monitoring** • **Before initiation of each treatment course:** perform liver function tests; do not initiate Esmya in women with baseline ALT or AST more than 2-times the upper limit of normal [ULN] • **During the first 2 treatment courses:** perform liver function tests every month • **For further treatment courses:** perform LFTs once before each new course and when clinically indicated • **At the end of each treatment course:** perform LFTs after 2-4 weeks • Stop Esmya treatment and closely monitor women with ALT or AST more than 3-times ULN; consider the need for		*The D&TC noted and supported the TAG's recommendation to revise the* **Double Red (Not recommended for routine use)** *classification to* Red (Hospital / Specialist only)*.* *The D&TC decided that in view of the safety issues and increased monitoring requirements, prescribing and monitoring responsibility should remain with the hospital for a period of at least 12 months before reconsidering whether a shared care approach was appropriate and that GPs should resume clinical responsibility for Esmya.* *The D&TC therefore recommended that EPACT data should be checked to ensure that GPs were not continuing to prescribe, and that previously agreed GP prescribing guidance should be withdrawn for the time being.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
			specialist hepatology referral The TAG agreed that the classification should be revised to Red (Hospital / Specialist only) until such time as a shared care agreement could be developed. The previously agreed GP Prescribing Guidance document could form the basis of a new shared care agreement.		
Sept 2018	**Therapeutics Advisory Group: (following previous) NNUH Application:**	Roflumilast (*Daxas*®) for maintenance treatment of severe COPD associated with chronic bronchitis in adults with history of frequent exacerbations as add on to bronchodilator treatment – *as per* NICE TA 461 **January 2018:** The TAG considered the NNUH's application but deferred making a decision pending further information from the Trust regarding criteria for use, stopping, and realistic patient numbers. **May 2018:** The NNUH submitted info on patient numbers based on the NICE resource impact statement: The TAG was unable recommend a change in the current Double Red traffic light classification but suggested that the STP respiratory working group be considered to agree a patient sub-group for this treatment. **May 2018:** *The D&TC did not agree that the STP respiratory group was the appropriate forum to refer this issue to and recommended instead that the EoE PAC be approached to provide guidance on the criteria for use and review of treatment with roflumilast for severe COPD* **July 2018:** Noted by the TAG. *The DTC requested that the PAC be approached on this issue.* **September 2018:** The PAC had responded to state that they were unable to undertake this piece of work as it was not a priority for their work plan. Hertfordshire CCGs commissioning policy for roflumilast cited as an example of what had been agreed elsewhere. Roflumilast could be given only to patients who have had more than two admissions in the previous 12 months. The hospital to provide it for the first 3 months, and if patients tolerated treatment, prescribing responsibility could then be transferred to primary care.		*The COPD data and NICE estimated was not available for DT&C to consider.* *To be returned at a future meeting.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
		Annual data checks would be needed to show that hospital admissions were not increasing. It was considered that stopping criteria would still be difficult to determine as the disease is progressive. AGEM CSU Business Intelligence unit to be asked to provide the number of patients admitted to hospital for COPD exacerbations 3 times or more in the preceding 12 months to see if they are comparable with NICE estimates. ***The figures to be considered by the D&TC in September 2018.***			
Sept 2018	**Therapeutics Advisory Group:** **<u>NNUH Application</u>:** CCG-commissioning responsibility These devices have been in use locally over the last 10 years but had not been formally commissioned. The devices had been discussed at the Norfolk & Waveney Prescribing Reference Group (PRG) where concern had been expressed about occasional requests for use in inappropriate situations.	**Trans Anal Irrigation (TAI) for Chronic Constipation and Faecal Incontinence in Paediatrics (NNUH Service) - *as an option as per agreed treatment pathways*** Patients who mayy require treatment with TAI after conservative management in Primary Care are referred into the Paediatric Colorectal Surgery or Gastroenterology team at the NNUH for a clinical decision on the next appropriate step. Patients include those with anorectal malformations, Hirschsprung's disease, spina bifida or other syndromic conditions. Others may have severe functional constipation and soiling unresponsive to laxatives/suppositories. TAI is considered where a stepped approach to treat bowel dysfunction has been followed, i.e. diet and fluid / lifestyle alteration / laxatives, followed by suppositories or enemas. Failure of medical management involving multiple laxatives, multiple trials of macrogols, disimpaction regimens and advice, leads to referral to secondary care for further assessment. TAI is minimally invasive,and is considered the next step after failure of the conservative medical management treatments. The specialist Paediatric colorectal multi-disciplinary team may recommend use, as per the proposed pathway, following clinical assessment and investigation into underlying causes, and before considering more invasive and permanent surgical solutions such as Antegrade continence enema (ACE) and Stoma. Use of two manual devices is requested:		The NNUH Paediatric department has 34 patients on its database. 15 of these have an anorectal malformation, Hirschsprung's disease, Spina Bifida or other syndromic cause. The rest have severe functional constipation or faecal incontinence unresponsive to laxatives/suppositories 11 paediatric patients currently use TAI (1 is weaning off). Another 11 patients have an ACE. 6 patients need to start as per the proposed pathway. A further 5 children may require TAI in the future. Another 1 has recently moved away. ***Around 5, and no more than 10, new cases are expected per year.*** **Average monthly cost:** **Peristeen Anal Irrigation System:** £144.15 (if at least 6

<table>
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<tr>
<td></td>
<td>Currently Double Red / not commissioned pending submission and approval of business applications and confirmation of its place in a treatment pathway (July 2017).
A request was made to local specialists at different provider Trusts to bring forward their applications and proposed treatment pathways to the TAG, to clarify what is being used and under which criteria. The NNUH paediatrics service has met this request, to seek approval for their use.</td>
<td colspan="3">
Irrigation Systems Cost per month analysis from PrescQIPP Summary of Irrigation Systems based on Drug Tariff price July 2016
<table>
<tr><td>Peristeen anal irrigation system
(Coloplast)
www.coloplast.co.uk/peristeen-anal-irrigation-system-en-gb.aspx</td><td>A high-volume rectal catheter system with a manual pump.[9]</td><td>Control unit (includes pump)
Rectal catheters (available in regular and small sizes)
Water bag
Tubing
Strap</td><td>The control unit can be used 90 times (six months usage if used on alternate days).[10]
Water bags can be used 15 times.
Rectal catheters are single use.[9]</td><td>Average monthly c system is £144.15
*Based on six mon (1 Peristeen syster Peristeen accessor If use is discontinu the average montl increases.</td></tr>
<tr><td>Qufora IrriSedo Mini System
(MacGregor Healthcare Ltd)
www.macgregorhealthcare.com/products/quforamini/index.html</td><td>A low-volume cone system with a manual pump.
It is designed for people who need a small amount of water to irrigate.[11]</td><td>Pump
Cones
Waste bags</td><td>Up to 30 days use for the pump.
Cones are for single use.[12]</td><td>15 irrigation set
£59</td></tr>
</table>
Support programs and services for healthcare professionals and patients:

Peristeen Advisor Nurse - a dedicated Advisor Nurse provides clinical support to HCP’s and patients to aid adherence to the suggested treatment. This includes clinic and home visits prior and during the initiation phase as well as troubleshooting and review visits afterwards
Coloplast Care program - Supports patients in the initial months of using Peristeen, when most support and encouragement is needed.
A Paediatric Constipation Nurse Specialist is already available in the NNUH and works closely with paediatric gastroenterology and paediatric colorectal surgery. They can provide support for use of Peristeen in a clinic environment as well as other TAI products.

The TAG agreed to support the application and recommended a traffic light classification of Green (GP prescribable following specialist recommendation).
</td>
<td>months’ use)
Qufora IrriSedo Mini:
£59 (15 irrigation set)

Recent expenditure (January to May 2018) on TAI systems in primary care by CCG for all indications / patients are:
WN CCG: £13,794.06
Norw CCG: £12,810.93
GY&W CCG: £17,093.36
NN CCG: £19,739.03
SN CCG: £16,095.53
Total (5/12): £79,532.91
The D&TC noted and supported the NNUH’s application for use of TAI in paediatrics.</td>
</tr>
<tr>
<td>Sept 2018</td>
<td>Therapeutics Advisory Group:
<u>Cambridge University Hospitals / Cambs & Peterborough CCG Draft Share Care Guideline</u>:</td>
<td>Penicillamine (Distamine®) for use in Wilson’s disease (as recommended by a specialist centre – CUH / Addenbrooke’s Hospital))</td>
<td>The TAG considered that such a shared care agreement could not easily be adopted locally due to the significant level of monitoring involved.
If a local patient requires</td>
<td>Noted and supported by the D&TC as Red (Hospital use only) with specific reference to possible recommended use by the CUH Trust (Addenbrooke’s Hospital) – to</td>
</tr>
</table>

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	CCG-commissioning responsibility Not previously classified by the TAG for any indication. No historical commissioning position regarding use of penicillamine (although it had been prescribed by GPs in years gone by, following specialist recommendation, who received funding for monitoring the treatment under a previous LES).		(*Considered by the TAG since may be adopted by Trusts in neighbouring CCGs that interface with local practices, who may be approached to prescribe it.*)	treatment with penicillamine this would have to be managed on an individual basis. However it was acknowledged that a written guideline to support its use would be good clinical practice. The TAG therefore decided to recommend a traffic light classification of Red (Hospital use only) with specific reference to possible recommended use by the CUH Trust (Addenbrooke's Hospital) – to support GPs who may be approached to prescribe this treatment.	*support GPs who may be approached to prescribe this treatment.*
Sept 2018	**Therapeutics Advisory Group:** **Cambridge University Hospitals / Cambs & Peterborough CCG *Draft* Share Care Guideline:** Not previously classified by the TAG. No current commissioning position for stiripentol.	Stiripentol (*Diacomit*®)	For SCN1A related and Severe Myoclonic Epilepsies in Infancy (*Considered by the TAG since may be adopted by Trusts in neighbouring CCGs that interface with local practices, who may be approached to prescribe it.*)	The TAG was advised that there had been five cases approved for funding via the IFR-Drugs Panel. Two for the QEH and three for the NNUH. The TAG agreed that for the time being stiripentol should be classified as **Double Red (Not recommended for routine use)** with any requests for funding to be made via the IFR-Drugs Panel.	*Noted and supported by the D&TC as* **Double Red (Not recommended for routine use)** *Not recommended for commissioning*
Nov 2018	**Therapeutics Advisory Group:**	Risperidone for short term management of	**May 2013:** The TAG noted NICE CG 158 and recommended Shared Care to support Primary Care prescribing of risperidone where treatment is required beyond 6 weeks' use.		

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<tr><td></td><td>NSFT request for review of traffic light classification:
– as per NICE CG 158 (March 2013)
- Antisocial behaviour and conduct disorder in children and young people: recognition, intervention and management</td><td>severely aggressive behaviour in young people with a conduct disorder who have problems with explosive anger and severe emotional dysregulation and who have not responded to psychosocial interventions</td><td colspan="2">The D&TCG commissioned risperidone as Red (Hospital / Specialist use only) for the specified indication, pending an approved Shared Care Agreement.
July 2018: Following the NSFT's request that the traffic light classification should be in line with other antipsychotic treatments (i.e. Green (GP prescribing following specialist initiation / recommendation)), a document detailing different treatments and indications for use of risperidone in children and young people to be produced for the TAG to consider.
CCG lead mental health commissioner to be contacted regarding who commissions the various services for children and adolescents.
September 2018: No progress to date.
November 2018: Update on progress?
Information on use of Risperidone within the NSFT CAMHS during 2017-18 in 7 individual cases with specialist neurodevelopmental disorder patient group (out of around 100 children and young people who have received medication overall):
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<tr><td>ADHD, ASD and Tourette's</td><td>Tics and settling</td></tr>
<tr><td>ADHD, ASD and aggression</td><td>Aggression and settling</td></tr>
<tr><td>ADHD, some ASD, proper psychosis last year ?2nd spiked drink</td><td>Psychosis, settling</td></tr>
<tr><td>ASD, psychotic features at start of viral illness as it turns out</td><td>Short-term management</td></tr>
<tr><td>ADHD, ASD</td><td>Aggression and settling</td></tr>
<tr><td>ADHD, ASD, aggressive outbursts evening</td><td>Settling and aggression</td></tr>
</table>
The TAG noted the data and acknowledged the relatively infrequent use of risperidone for these patients. The TAG debated issues regarding ease of access to treatment by</td><td>Noted by the D&TC</td></tr>
</table>

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
			patients and their carers, the level of on-going monitoring recommended by NICE CG 158 where treatment is continued or where there are dosage changes, and whether GPs could provide that level of care. Practical issues regarding possible use of FP10HP forms were also discussed. The specialist service to be asked to consider these issues and return the item to the TAG with more detailed proposals for further consideration.		
Nov 2018	**Therapeutics Advisory Group:** **NNUH Discussion document:** View on the CCGs' strategy of using edoxaban as first line DOAC option across a number of clinical indications	Direct Oral Anticoagulants – Comparison	**July 2018:** The TAG agreed that if switching between DOACs is to take place then there should be clear guidance on how that should happen. *An independent review of class effect and switching to be sought.* **September 2018:** • Information from the *Lixiana*® SPC regarding switching from dabigatran, rivaroxaban and apixaban to edoxaban included in the draft July 18 TAG notes. • Overview by *Thrombosis Canada* also provided for consideration by the TAG. • BMJ study on comparative safety of DOACs - *Link* The TAG decided that a further critical review of the available evidence should be undertaken. **November 2018:** UKMi evidence review and related papers provided for the TAG's consideration. The TAG considered the information provided and acknowledged that the available studies cannot completely address whether DOACs are interchangeable across all indications for all patients – the choice of treatment is determined by the clinical condition and any relevant co-morbidities or circumstances affecting an individual patient. However for the majority of patients with either AF or VTE, edoxaban is a reasonable option where the effective full treatment dose of 60mg can be used safely, wrt renal function. A switching protocol in use by GY&W CCG would be shared with a view to developing a cross STP version as part of policy	*The D&TC also noted recently highlighted concerns regarding the clinical effectiveness of edoxaban at lower doses, and also additional cautions in the SPC regarding use in patients with CrCl>95ml/min.* *The D&TC agreed that a consistent approach to reviewing and optimising use of DOACs in primary care was needed.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
			development, in consultation with local specialists.		
Nov 2018	**Therapeutics Advisory Group:** **NNUH Application:** Currently classified as **Double Red / Not commissioned** pending submission and approval of a business application	**Collagenase Clostridium Histolyticum (CCH) (*Xiapex*®) for treatment of Dupuytren's contracture in adult patients with a palpable cord -** as per NICE TA 459**:** The NNUH's application states that an estimated* 90 patients per year will require treatment. The TAG noted the comparative costs versus current therapy. The TAG considered the NNUH's application and agreed to support use in line with the application and proposed treatment pathway, with a recommended traffic light classification of Red (Hospital use only).			*The D&TC noted and supported the application.* *The treatment would be monitored as a High Cost Drug and would be provided via Outpatients.*
Nov 2018	**Therapeutics Advisory Group:** **NNUH Application:** No previous TAG recommendation for use in this clinical indication. Treatment regimen proposed involves fewer injections than recommended in the manufacturer's SPC.	Collagenase Clostridium Histolyticum (*Xiapex*®) for treatment of Peyronie's Disease The NNUH's application states that an estimated 5 to 10 patients per year will require treatment. The TAG noted the with comparative costs versus current therapy. The TAG considered the NNUH's application and agreed to support use in line with the application and proposed treatment pathway, with a recommended traffic light classification of Red (Hospital use only).			*The D&TC considered likely numbers of patients accessing this treatment and whether they would also go on to require surgery. The treatment was proposed to improve surgical outcomes, if necessary following the injection.* *The D&TC considered whether it would be prudent to cap patient numbers in line with those estimated in the application.* *To be highlighted to the JSCC as not being a NICE-recommended indication for use.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
Nov 2018	**Therapeutics Advisory Group: Interface Issue:** Recent (un-commissioned) use by local cardiology services noted, leading to concerns about increased risk of bleeding in patients	Combined use of anticoagulant and antiplatelet therapies in cardiology	**March 2018:** An evidence review and related EU guidelines submitted by the NNUH DTMMC were considered by TAG but no agreement was reached. **July 2018:** An independent evidence review was received from EAMIS. NNUH cardiologist, Dr Alisdair Ryding, attended the TAG to talk to his proposals. A Task & Finish group to be set up to finalise proposals for the CCGs to consider commissioning. **September 2018:** No progress to date **November 2018:** The Task & Finish Group had met during October 2018 and had drawn up a document laying out the proposed drug combinations for specified clinical indications depending on individual patient bleeding risk, with durations of use and likely patient numbers for one but not all the local acute Trusts. Prospective drug costs would be calculated once the patient data was provided and the document would be completed and submitted to the D&TC.		*To be submitted to the December 2018 D&TC.*
Nov 2018	**Therapeutics Advisory Group: Interface Issue:** NICE TA 217 (update June 2018) Donepezil, galantamine, rivastigmine, memantine for Alzheimer's disease - partially updated by NG97 on dementia (replaces NICE TA111).	Donepezil, galantamine, rivastigmine, memantine, for Dementia / Alzheimer's Disease *Links* to current shared care agreements for AChEIs and memantine	**September 2018:** The TAG was asked to reconsider in more detail the updated and new recommendations in the above guidance that will impact on current commissioned arrangements for prescribing and monitoring drug treatments for patients with dementia. The TAG noted that in Suffolk dementia drugs have been classified as "Green" since 2015. ***Suffolk GP Prescribing Guidance*** (*same guidance used across both CCGs*) to be shared and a Task & Finish Group set up to take this item forward – led by EJ. *EJ has since proposed that this work is discussed by the STP Dementia Group*. **November 2018:** The TAG requested that a proposed treatment pathway be submitted for consideration to enable to group to consider revising the current position regarding drug treatment for		*Noted by the D&TC.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	NICE NG 97 (June 218): Dementia: *assessment, management and support for people living with dementia and their carers* **Drug recommendations:** NICE TA 217: *Link* & NG97: *Link*		Dementia / Alzheimer's Disease.		
Nov 2018	**Therapeutics Advisory Group:** **NCH&C Application:** ***Draft* Share Care proposal:** **Currently classified / commissioned as:** Red (Hospital / Specialist use only) for use only in breakthrough pain in cancer as a third-line treatment option – *since March 2010*. The maximum recommended	Transmucosal fentanyl (*Abstral*®) for breakthrough cancer pain in patients on regular strong opioids – **Background:** In 2010 the TAG agreed that *Abstral*® (sublingual tablets) is the immediate-release (I-R) fentanyl formulation of choice. Other immediate-release fentanyl preparations including buccal tablets, lozenges/lollipops, and intranasal spray, are not recommended for routine use (**Double**	Following problems occurring recently with patients having difficulties obtain the drug via the hospital, the TAG was asked to consider an NCH&C shared care proposal, with estimated costing information, to facilitate prescribing by GPs with a view to improving access for patients and their carers. Data on current prescribing of I-R Fentanyl products (outside of current commissioning arrangements) by GPs is also provided. The TAG was concerned that the dosage threshold of current use of morphine for consideration Abstral® stated in the shared care proposal was too low, despite being that specified in the manufacturer's SPC. The TAG advised that the wording of any shared care proposal should be clear that GPs would not carry out any dosage titration. The TAG felt that logistical solutions other than GP prescribing under shared care, could be used to improve access to the treatment, and that other options should be investigated. The TAG noted the disparity in the numbers of patients being	

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	number of daily doses must *not* be exceeded. Background analgesia to be adjusted if more than 4 episodes of breakthrough pain are experienced a day.	**Red / Not recommended for routine use – Not commissioned**). The TAG had also supported possible use under a shared care agreement with Palliative Care specialists i.e. Amber (option for shared care with a written agreement) - *Abstral*® has remained as Red (Hospital use only) until a shared care agreement is proposed by local Palliative Care consultants, and approved by TAG.	given Abstral® across the county, with high use in central Norfolk and minimal use in the west and eastern areas, and recommended that this should also be investigated. The TAG did not support the shared care proposal at the moment and maintained the current Red (Hospital use only) classification		*Noted and supported by the D&TC*
Nov 2018	**Therapeutics Advisory Group:** **Interface Issue:** - as recommended by the **Joint Trust (JPUH, NNUH & QEH) Guideline for Adult Testosterone Replacement and Monitoring** (*last reviewed Jan 2017*) **- *Link***	Testosterone	(Long term) monitoring of patients on testosterone: A local GP has noted that the Joint Trust guideline states under **Follow up and monitoring** (*page 7-8*): *all testosterone patients to have annual Digital Rectal Examination (DRE) and PSA thereafter, plus FBC and LFTs.* The GP has suggested that it is likely that GPs are *not following* this *post discharge* from the Trust service.	The TAG acknowledged the information provided and was advised that the NNUH's specialists' view is that (follow-up) DRE may not be necessary for most patients. The joint guideline is also planned to be updated. This item will therefore be returned to the TAG in due course. The TAG did not make any additional recommendations regarding this issue.	*Noted by the D&TC*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
			The TAG is asked to consider whether this level of long term monitoring in Primary Care, is clinically appropriate / necessary. *Clarification* is needed regarding whether this is actually being / should be provided in primary care. ***NB*** the QEH state that they provide blood tests for patients *under their care* and also offer the DRE which is sometimes refused. The NNUH reportedly ask GPs to undertake the DRE.		
Nov 2018	**Therapeutics Advisory Group:** **NNUH Application:** Currently classified as **Double Red / Not commissioned** until a local business application for its use is supported following a positive NICE TA related to the treatment (*TAG recommendation May 2017*)	Dupilumab (*Dupixent*®) For treating moderate to severe atopic dermatitis after topical treatments - as per **NICE TA 534 (August 2018)** which states: Recommended as an option for treating moderate to severe atopic dermatitis in adults, only if: • the disease has not responded to at least 1 other systemic therapy, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are contraindicated or not tolerated • dupilumab is provided according to the commercial arrangement. • Stop dupilumab at 16 weeks if the atopic dermatitis has not responded adequately. An adequate response is: ○ at least a 50% reduction in the Eczema Area	**September 2018:** The NNUH's application states that an estimated 10 patients per year will require dupilumab. The TAG recommended that the Eczema Area and Severity Index (EASI) score should be used for the starting criteria and that treatment could be commenced at EASI ≥16. The TAG otherwise supported the business case and recommended a traffic light classification of Red (Hospital / Specialist use only).	*The D&TC noted that the East of England Priorities Advisory Committee (PAC) was also discussing entry and continuation criteria for dupilumab, in consultation with consultant dermatologists, and are considering the following options:* *Entry criteria:* *1. EASI score of 7.1 or above (as per accepted definition of moderate to severe disease cited in NICE documents)* *2. EASI score of 16 or above (as per entry criteria used in pivotal trials used for licensing*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
		and Severity Index score (EASI 50) from when treatment started and ○ at least a 4 point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started. When using the EASI, healthcare professionals should take into account skin colour and how this could affect the EASI score, and make the clinical adjustments they consider appropriate.		**November 2018:** The TAG noted the D&TC's decision to await the PAC's which were likely to result in a lower threshold for initiation of treatment with dupilumab than previously discussed, and also acknowledged the frustration and concerns within the Trusts that this has led to further delays in the CCGs commissioning this treatment. The TAG also noted that the CCGs, in common with NHS England, increasingly find that they are unable to afford to commission some treatments in the current financial climate.	*and quoted in the SPC)* *3. EASI score of 16 or above* *4. EASI score 7.1 and above AND a POEM score of 8 or above* *Continuation Criteria:* *As per NICE:* • *at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started and* • *at least a 4 point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started.* *The D&TC noted the above information and agreed that a considered approach in line with other EoE CCGs, using measurable and consistent assessment tools, regarding criteria for use of dupilumab, was appropriate.* *The D&TC therefore decided to await the PAC's decisions and maintained the* **Double Red / Not commissioned** *position in the interim.* **November 2018:** *The TAG's concerns were noted by the D&TC. The D&TC agreed that it should be recommended to the JSCC that dupilumab should be commissioned for use by the*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
					NNUH in line with NICE guidance and as per the criteria agreed by the East of England Priorities Advisory Committee (PAC), with applications for use to be managed via BlueTeq. Review after 6 months to check that use is in line with the NNUH's business application.
Nov 2018	**Therapeutics Advisory Group: <u>(following previous) NNUH Application</u>:**	Roflumilast (*Daxas*®)	For maintenance treatment of severe COPD associated with chronic bronchitis in adults with history of frequent exacerbations as add on to bronchodilator treatment – *as per* NICE TA 461 **January 2018:** The TAG considered the NNUH's application but deferred making a decision pending further information from the Trust regarding criteria for use, stopping, and realistic patient numbers. **May 2018:** The NNUH submitted info on patient numbers based on the NICE resource impact statement: The TAG was unable recommend a change in the current Double Red traffic light classification but suggested that the STP respiratory working group be considered to agree a patient sub-group for this treatment. **May 2018:** *The D&TC did not agree that the STP respiratory group was the appropriate forum to refer this issue to and recommended instead that the EoE PAC be approached to provide guidance on the criteria for use and review of treatment with roflumilast for severe COPD* **July 2018:** Noted by the TAG. *The DTC requested that the PAC be*	**September 2018:** *The COPD data and NICE estimated was not available for DT&C to consider.* *To be returned to a future D&TC meeting.* **October 2018:** Based on the numbers seen the D&TC agreed to the NICE criteria. The hospital should

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
			approached on this issue. **September 2018:** The PAC had responded to state that they were unable to undertake this piece of work as it was not a priority for their work plan. Hertfordshire CCGs commissioning policy for roflumilast cited as an example of what had been agreed elsewhere. Roflumilast could be given only to patients who have had more than two admissions in the previous 12 months. The hospital to provide it for the first ***3 months***, and if patients tolerated the treatment, prescribing responsibility could then be transferred to primary care. Annual data checks would be needed to show that hospital admissions were not increasing. It was considered that stopping criteria would still be difficult to determine as the disease is progressive. AGEM CSU Business Intelligence unit to be asked to provide the number of patients admitted to hospital for COPD exacerbations 3 times or more in the preceding 12 months to see if they are comparable with NICE estimates. ***The figures to be considered by the D&TC in September 2018.***		provide the ***first month*** of treatment and a request be made for the specialists to audit some of the frequent fliers who are admitted 5 times or more in a 12 month period.
Jan 2019	**Therapeutics Advisory Group:** Recent (un-commissioned) use by local cardiology services noted, leading to concerns about increased risk of bleeding in patients	Combined use of anticoagulant and antiplatelet therapies in cardiology	**March 2018:** An evidence review and related EU guidelines submitted by the NNUH DTMMC were considered by TAG but no agreement was reached. **July 2018:** An independent evidence review was received from EAMIS. NNUH cardiologist, Dr Alisdair Ryding, attended the TAG to talk to his proposals. A Task & Finish group to be set up to finalise proposals for the CCGs to consider commissioning. **September 2018:** No progress to date **November 2018:** The Task & Finish Group had met during October 2018 and had drawn up a document laying out the proposed drug combinations for specified clinical indications depending on		*The D&TC was advised that the data would be submitted to the February 2019 meeting.*

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<tr><td></td><td></td><td></td><td colspan="2">individual patient bleeding risk, with durations of use and likely patient numbers for one but not all the local acute Trusts. Prospective drug costs would be calculated once the patient data was provided and the document would be completed and submitted to the D&TC.

January 2019: in the absence of real data from Primary Care, figures extrapolated from local Trust data will be submitted to the D&TC. The TAG to see the final output from these discussions in March 2019.</td><td></td></tr>
<tr><td>Jan 2019</td><td>Therapeutics Advisory Group:

NSFT request for review of traffic light classification:

– as per NICE CG 158 (March 2013)
- Antisocial behaviour and conduct disorder in children and young people: recognition, intervention and management</td><td>Risperidone for short term management of severely aggressive behaviour in young people with a conduct disorder who have problems with explosive anger and severe emotional dysregulation and who have not responded to psychosocial interventions</td><td colspan="2">May 2013: The TAG noted NICE CG 158 and recommended Shared Care to support Primary Care prescribing of risperidone where treatment is required beyond 6 weeks' use. The D&TCG commissioned risperidone as Red (Hospital / Specialist use only) for the specified indication, pending an approved Shared Care Agreement.

July 2018: Following the NSFT’s request that the traffic light classification should be in line with other antipsychotic treatments (i.e. Green (GP prescribing following specialist initiation / recommendation)), a document detailing different treatments and indications for use of risperidone in children and young people to be produced for the TAG to consider.

CCG lead mental health commissioner to be contacted regarding who commissions the various services for children and adolescents.

September 2018: No progress to date.

November 2018: Update on progress?

Information on use of Risperidone within the NSFT CAMHS during 2017-18 in 7 individual cases with specialist neurodevelopmental disorder patient group (out of around 100 children and young people who have received medication overall):

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<tr><td>ADHD, some ASD, proper psychosis last year ??2nd spiked drink</td><td>Psychosis, settling</td><td>Medium, now stopped</td></tr>
<tr><td>ASD, psychotic features at start of viral illness as it turns out</td><td>Short-term management</td><td>Short, stopped</td></tr>
<tr><td>ADHD, ASD</td><td>Aggression and settling</td><td>Long-term</td></tr>
<tr><td>ADHD, ASD, aggressive outbursts evening</td><td>Settling and aggression</td><td>Long-term</td></tr>
</table>
The TAG noted the data and acknowledged the relatively infrequent use of risperidone for these patients. The TAG debated issues regarding ease of access to treatment by patients and their carers, the level of on-going monitoring recommended by NICE CG 158 where treatment is continued or where there are dosage changes, and whether GPs could provide that level of care. Practical issues regarding possible use of FP10HP forms were also discussed.
The specialist service to be asked to consider these issues and return the item to the TAG with more detailed proposals for further consideration.
January 2019: No update on progress was available from the NSFT.
CCG members advised the TAG on the need to liaise with the local Children’s commissioner regarding the treatment pathway and prescribing responsibility, and also with contract manager regarding the possibility of adding a clause to clarify interface prescribing issues.</td><td>Noted by the D&TC</td></tr>
<tr><td>Jan 2019</td><td>Therapeutics Advisory Group: Interface Issue:
NICE TA 217 (update June 2018)
Donepezil, galantamine,</td><td>Donepezil, galantamine, rivastigmine, memantine, for Dementia / Alzheimer’s Disease</td><td>September 2018:
The TAG was asked to reconsider in more detail the updated and new recommendations in the above guidance that will impact on current commissioned arrangements for prescribing and monitoring drug treatments for patients with dementia.
The TAG noted that in Suffolk dementia drugs have been classified as “Green” since 2015. Suffolk GP Prescribing Guidance (same guidance used across both CCGs) to be</td><td></td><td></td></tr>
</table>

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	rivastigmine, memantine for Alzheimer's disease - partially updated by NG97 on dementia (replaces NICE TA111). NICE NG 97 (June 218): Dementia: *assessment, management and support for people living with dementia and their carers* **Drug recommendations:** NICE TA 217: *Link* & NG97: *Link*	*Links* to current shared care agreements for AChEIs and memantine	shared and a Task & Finish Group set up to take this item forward – led by EJ. *EJ has since proposed that this work is discussed by the STP Dementia Group*. **November 2018:** The TAG requested that a proposed treatment pathway be submitted for consideration to enable to group to consider revising the current position regarding drug treatment for Dementia / Alzheimer's Disease. **January 2019:** No update on progress was available from the NSFT.		*The D&TC acknowledged the need for investment in primary care to support GPs in assessing and managing their patients with dementia.*
Jan 2019	**Therapeutics Advisory Group:** **NNUH Application and proposed treatment algorithm:** Currently classified as **Double Red / Not commissioned**	Ixekizumab (*Taltz* ®) for psoriatic arthritis - as per NICE TA 537 which states: Recommended as an option, alone, or with methotrexate, for treating active psoriatic arthritis in adults, only if: • it is used as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (recommendations 1.1 and 1.2) or • the person has had a tumour necrosis factor (TNF)-alpha inhibitor but their disease has not responded within the first 12 weeks or has	The TAG was advised that ixekizumab is an alternative to secukinumab within the current treatment pathway, is of similar cost and offers benefits in slightly better adverse effects profile and marginally faster onset of action. Secukinumab has not been used widely within the NNUH to date since most patients are currently managed on biosimilar anti-TNFs.	The NNUH's application estimates use of ixekizumab in up to 10 patients per year; use would be long term. The treatment is cost-neutral compared to current therapy - only patients eligible for secukinumab or ustekinumab would be treated, and the presumption remains that the cheapest drug will be selected.

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	until a local business application for its use is supported following a positive NICE TA related to the treatment (*TAG recommendation Sept 2018*)	stopped responding after the first 12 weeks or • TNF-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE's technology appraisal guidance as above). • Assess the response to ixekizumab after 16 weeks of treatment. Only continue treatment if there is clear evidence of response, defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria. • People whose disease has a Psoriasis Area and Severity Index (PASI) 75 response but whose PsARC response does not justify continuing treatment should be assessed by a dermatologist, to determine whether continuing treatment is appropriate based on skin response (as described in NICE's technology appraisal guidance as above, recommendation 1.3). Ixekizumab is only recommended if the company provides it according to the commercial arrangement.		The proposed treatment algorithm had been updated in line with NICE TA 537, and was supported by the TAG. The TAG supported the business application and recommended a revised traffic light classification of Red (Hospital/Specialist only).	*Noted and supported by the D&TC with acknowledgement that the commissioned treatment pathway requires revision.*
Jan 2019	**Therapeutics Advisory Group:**	***Review of treatment algorithm*:**	**Primary Care Treatment of Refractory Symptomatic Chronic Constipation in Adults** ***Link*** to current version (last reviewed in Nov 2015).	The TAG noted and agreed the updated algorithm.	*Noted and supported by the D&TC.*
Jan 2019	**Therapeutics Advisory Group:**	***Review of treatment algorithm*:**	**Management of constipation-predominant irritable bowel syndrome (IBS-C) in primary care in**	The TAG supported the revisions made and also recommended that Faecal Immunochemical Tests (FIT), which check for risk of bowel cancer, should be	*Noted and supported by the D&TC.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
			Norfolk & Waveney ***Link*** to current version (last reviewed in Nov 2014).	added under the section on atypical features to eliminate this as a cause of abdominal pain, especially in older patients.	
Jan 2019	**Therapeutics Advisory Group:**	***Review of treatment algorithm*:**	**Management of Opioid-Induced Constipation** ***Link*** to current version (last reviewed in February 2016).	The TAG noted and agreed the updated algorithm.	*Noted and supported by the D&TC.*
Jan 2019	**Therapeutics Advisory Group:**	***Review of treatment algorithm*:**	**Managing mild-moderate flares of Ulcerative Colitis in Outpatients or Primary Care** ***Link*** to current version (last reviewed in January 2016).	The TAG recommended that clarification on which mesalazine product should be used was needed, but otherwise agreed continued use of the algorithm.	*Noted and supported by the D&TC.*
Jan 2019	**Therapeutics Advisory Group:**	**Review of GP Guidelines:**	**TAG Guidelines for Primary Care Prescribers with competence in the treatment of Opioid Dependence: – *Use of Sublingual Buprenorphine*** ***Link*** to current version (last reviewed in Nov 2016).	The TAG acknowledged the on-going need for this document since some local GPs do prescribe for patients with opioid dependence under the Local Enhanced Service commissioned by Public Health, or independently. Patient numbers / prescription items to be investigated and returned to the TAG. The document also to be shared with the current local service provider, Change, Grow, Live (CGL).	*The D&TC noted the summary of costs and items of S/L buprenorphine issued by GPs prescribing within and outside the Public Health LES to date during 2018-19.* *The CCGs are unable to seek reimbursement for prescribing costs for those operating outside the LES. The D&TC recommended that these practices are written to on this matter to highlight the cost implications for the CCGs.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
Jan 2019	**Therapeutics Advisory Group:**	**Review of GP Prescribing Guidance:** Re-classified from Amber to Green in March 2013. The Trust provides at least 2 weeks' supply following in-patient admission.	**Lamotrigine for Bipolar Depression in adults aged 18 years and over** ***Link*** to current version (last reviewed in May 2015). View from NSFT that this document may no longer necessary since the titration regimens are similar to (but slightly longer than) those for epilepsy. See an example SPC.	The TAG considered whether separate guidance for use of lamotrigine in bipolar depression is still necessary, and agreed that the document may now be withdrawn from use.	*Noted and supported by the D&TC.*
Jan 2019	**Therapeutics Advisory Group:**	**Review of GP Prescribing Guidance:** Re-classified from Amber to Green in May 2014. No GP monitoring or special prescribing responsibilities are involved.	**Sodium Clodronate in Plasma Cell Myeloma** ***Link*** to current version (last considered in May 2014). (207 items issued across 22 practices in last 12 months)	The TAG considered whether separate guidance for use of Sodium Clodronate in Plasma Cell Myeloma is still necessary, and agreed that the document may now be withdrawn.	*Noted and supported by the D&TC.*
Jan 2019	**Therapeutics Advisory Group:**	**Review of Shared Care Prescribing Agreement:**	**Sildenafil for use in severe secondary Raynaud's phenomenon** ***Link*** to current version (last considered in January 2017).	The TAG considered the revised document and agreed that it would be reasonable to downgrade the traffic light classification from Amber to Green. The document to be retained and adapted as GP Prescribing Guidance. No changes to initiation and handover were discussed by the TAG.	*The D&TC noted and supported the change in classification providing that current arrangements for transferring prescribing responsibility are maintained.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
Mar 2019	**Therapeutics Advisory Group:** **QEH Application:** Currently classified as **Double Red / Not commissioned** until a local business application for its use is submitted and supported.	*Jorveza*® (Budesonide) 1mg orodispersible tablets	For treatment of eosinophilic oesophagitis in adults older than 18 years of age	The TAG noted that *Jorveza*® is a newly licensed option for a rare condition that occurs in a small number of people, which has been treated to date using budesonide nebules, off-label, mixed to form a slurry to coat the oesophagus. The Trusts consider that it is necessary to use a licensed product, where available. The TAG considered that the evidence presented indicated that *Jorveza*® was as effective as the current treatment option and debated whether a more expensive licensed option should necessarily be used. It was noted that there are occasions where treatments of lower cost and equivalent effectiveness have continued to be used off-label instead of a more expensive licensed option. The TAG acknowledged that the evidence provided indicated higher patient preference for using *Jorveza*® compared with the slurry prepared from the nebules. The TAG also debated how the 6-week treatment course for *Jorveza*® might be managed if an additional 6-week course was deemed necessary as confirmed by histology. In order to avoid patients having to return to	*The D&TC acknowledged that the proposed treatment schedule would mean that a GPs would be asked to prescribe only a single (follow-up) 6-week treatment course per patient, for a very small number of cases. The D&TC therefore requested sight of*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
				hospital, the TAG agreed it was reasonable to recommend a traffic light classification of Red (Hospital/Specialist use only) for the first six weeks of treatment, and Green (GP prescribing following Specialist initiation/recommendation) if an additional six weeks of treatment is required. This would be a one-off, acute prescription from the GP. The TAG noted the price differential between the current and the proposed treatment options.	*the QEH Trust's planned GP communication letter regarding use of Jorveza® before agreeing to recommend that it is commissioned as per the TAG's recommendations.* *Once approved the letter would have to be used across all the Acute Trusts to ensure a consistent approach.*
Mar 2019	**Therapeutics Advisory Group:** **NNUH Application:** Business application submitted following 2 successful IFR applications	Biosimilar adalimumab	For treatment of peripheral spondyloarthritis	The TAG was advised that the proposed use of biosimilar adalimumab was outside of current NICE guidance, for a very small number of patients who are significantly disabled by spondyloarthropathy in the lower limbs. Patients would have been treated with 3 DMARDs before being considered for a biologic agent. The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital/Specialist use only).	*Noted and supported by the D&TC.*
Mar 2019	**Therapeutics Advisory Group:** **NNUH Application:**	Brodalumab (*Kyntheum*®)	For moderate to severe adult plaque psoriasis – as per NICE TA 511 Proposes use as 4th line	The TAG was advised that brodalumab is proposed as biologic option for consideration alongside ixekizumab, guselkumab and secukinumab in	*The NNUH's application estimated that they would use this treatment in 13 patients per year. The cost was equivalent to using*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
			treatment for moderate to severe adult plaque psoriasis defined by PASI 10 or more and DLQI 10 or more, after failure of topical and systemic treatment such as MTX and cyclosporine, as an alternative to biological therapies, apremilast and dimethyl fumarate	the local treatment pathway as 3rd line treatment options after cost-effective anti-TNFs and ustekinumab. The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital/Specialist use only).	*secukinumab.* *Noted and supported by the D&TC.*
Mar 2019	**Therapeutics Advisory Group:** **NNUH Application:**	Hydrocortisone granules in capsules for opening (*Alkindi*®) (0.5mg, 1mg & 2mg capsules)	For cortisol replacement therapy for children (0-6 years) with adrenal insufficiency	The TAG supported the proposal for use of a product that would deliver more consistently accurate dose, compared with administering portions of tablets dissolved in water for use, in a young patient group, and at a more cost-effective price than using oral liquid specials. Once older than 6 years, standard tablets can be used to provide necessary dosages. The TAG agreed to support the application and recommended a traffic light classification of Green (GP prescribing following Specialist initiation/recommendation).	*Noted and supported by the D&TC.*
Mar 2019	**Therapeutics Advisory Group:** **Joint Acute Trusts / CSU Application:** Currently classified as **Double Red /**	Tofacitinib (*Xeljanz*®) *(oral JAK inhibitor)*	For treating active psoriatic arthritis after inadequate response to DMARDs – as per NICE TA543 The application proposes that tofacitinib would only	The TAG was advised that the application aimed to clarify proposed criteria for use of tofacitinib, which is a mid-priced treatment option (costs >£3.5k but <£8k per patient per year) between biosimilar anti-TNFs and	

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	Not commissioned pending submission and approval of a business application (November 2018)		be used before anti TNFs as follows: *Tofacitinib may be useful first line over Adalimumab in specific clinical circumstances where biosimilar Adalimumab cannot be used:* • *True needle phobia* • *Severe bacterial infection* • *MS/demyelination* • *Severe heart failure* • *Active malignancy*	the non-biosimilar options. Any first-line (biologic) use of tofacitinib would be audited against the agreed criteria. The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital/Specialist use only).	*Around 40 patients across the CCGs would be likely to be treated.* *Noted and supported by the D&TC.*
Mar 2019	**Therapeutics Advisory Group:** **Joint Acute Trusts / CSU Application:** Currently classified as **Double Red / Not commissioned** pending submission and approval of a business application (January 2019)	Tofacitinib (*Xeljanz*®)	For treating moderate to severe ulcerative colitis – as per NICE TA 547 (but after biosimilar adalimumab)	The TAG was advised that although NICE TA 547 implied that tofacitinib could be used first-line ahead of adalimumab, the cost-modelling was based on the price of *Humira*® rather than biosimilars. Biosimilar adalimumab remains as the recommended first-line biologic treatment option for this indication. Tofacitinib would however be cheaper than 2nd line options infliximab and to a greater extent, vedolizumab. The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital/Specialist use only).	*Noted and supported by the D&TC.*
Mar 2019	**Therapeutics**	Ferric maltol	Treatment of mild to	The TAG considered the revised	*The D&TC supported the*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
	Advisory Group: **Joint NNUH / CSU Application: - *Resubmission*** Currently classified as **Double Red / Not commissioned** following previous submissions for use (Sept – Nov 2017) which were not supported by the D&TC on the basis of a lack of evidence to justify its additional costs compared with standard care with other oral iron salts.	(*Feraccru*®)	moderate Iron Deficiency Anaemia (IDA) in patients with IBD that are intolerant of oral iron	application, which proposed restricted use of this oral chelated iron product in a small number of patients with inflammatory bowel disease with iron deficiency anaemia who cannot tolerate standard oral iron salts and who then require IV iron infusions (~30 patients). Patients often require 2 day case appointments to complete the required IV treatment. The TAG agreed to support the revised application and recommended a traffic light classification of Green (GP prescribing following Specialist initiation/recommendation) for a 12 week course only in patients with IBD who had been unable to tolerate 2 other oral iron preparations.	*revised application for use in principle.* *However due to concerns that use of Ferric maltol (Feraccru®) would become widespread in primary care as a general treatment for iron deficiency anaemia, the D&TC recommended a revised classification of* Red (Hospital/Specialist use only)*, where the specialist provides the complete treatment course.*
Mar 2019	**Therapeutics Advisory Group:** **Joint NNUH/CSU Application: - *Resubmission***	Colesevelam (*Cholestage*l®)	In bile acid malabsorption causing diarrhoea *(off-label use)*	The TAG considered the revised application which included additional information to support use. Patient numbers are small and stable. The TAG agreed to re-support the revised application and again recommended a traffic light classification of Green (GP prescribing following Specialist initiation/recommendation) for 3rd line use to control diarrhoea caused by bile acid malabsorption providing the specialist prescribes the first 8	*The D&TC agreed to support the revised application, and also the TAG's recommendation. The D&TC recommended that this should apply to use initiated by the NNUH only, with the number of patients to be treated to be capped at the 15 people who have already identified by that Acute Trust.* *The other Acute Trusts had not submitted any patient numbers when consulted regarding the revised*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
				weeks of treatment for any new patients.	*application.*
Mar 2019	**Therapeutics Advisory Group:** **Review of GP Guidelines:** ***Link*** to current version (last reviewed in Nov 2016).	**TAG Guidelines for Primary Care Prescribers with competence in the treatment of Opioid Dependence: – *Use of Sublingual Buprenorphine*** **March 2019:** The TAG was provided with: • data illustrating prescribing of buprenorphine for opioid dependence by local GP practices over a 12 month period. • Communications from the DoH and Change, Grow, Live (CGL) regarding a change from using sublingual formulations to *Espranor*® (buprenorphine as oral lyophilisate, for dissolution on the tongue) NB *Espranor*® is *not interchangeable* with other buprenorphine products and has a different dose regimen from sublingual buprenorphine products.		**January 2019:** The TAG acknowledged the on-going need for this document since some local GPs do prescribe for patients with opioid dependence under the Local Enhanced Service commissioned by Public Health, or independently. Patient numbers / prescription items to be investigated and returned to the TAG. The document also to be shared with the current local service provider, Change, Grow, Live (CGL). **March 2019:** The TAG noted that CGL is now prescribing *Espranor*® (buprenorphine as an oral lyophilisate which dissolves on the tongue) to manage rising costs of generic sublingual buprenorphine, which is not interchangeable due to differences in dosage regimen. The TAG supported continued use of the revised document which had been updated in line feedback from CGL. The CSU has been encouraging more practices to sign up to the LES in order for prescribing costs	**January 2019:** *The D&TC noted the summary of costs and items of S/L buprenorphine issued by GPs prescribing within and outside the Public Health LES to date during 2018-19.* *The CCGs are unable to seek reimbursement for prescribing costs for those operating outside the LES. The D&TC recommended that these practices are liaised with on this matter to highlight the cost implications for the CCGs.* **March 2019:** *The D&TC supported on-going use of the document for practices with competency, working within the LES.*

TAG Meeting Date	Reason for review by the TAG	Drug name (*Brand name*)	Indication for use	TAG Recommendation	Commissioning Decision by the N&W D&TCG
				to be recharged appropriately.	
Mar 2019	**Therapeutics Advisory Group:** Currently classified as Red (Hospital / Specialist use only) (November 2016)	**Guanfacine prolonged-release (*Intuniv*®)**	**For children aged 6-17yr with ADHD for whom stimulants are not suitable, not tolerated or have been shown to be ineffective** Issues regarding transfer of care of young people on guanfacine to the local adult ADHD services. Differences in formulary status between NCH&C (on-formulary) and the NSFT (non-formulary) are highlighting problems regarding growing number of patients initiated by NCH&C who are staying on treatment into adulthood (of 52 NCHC patients on guanfacine, 4 are turning 18 years old in the near future).	The TAG was advised that NCH&C are seeing these patients every 3 months and are prescribing guanfacine for them. However GP practices have reported being approached to take over prescribing responsibility for patients as they turn 18 and are still using the treatment. The children and adult ADHD teams are meeting in March 2019 and will be asked what plans are place for de-prescribing for these patients. Feedback to be reported to the next TAG meeting in May 2019.	*Noted by the D&TC.*

1. TAG / DTC Recommendations 2018/19

B. *NICE Guidance*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
May 2018	**NICE TA 508 (March 2018)** Recommended as an option by NICE.	Autologous chondrocyte implantation using chondrosphere (Spherox®)	For treating symptomatic articular cartilage defects of the knee	The TAG acknowledged **NICE TA 508 (March 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NICE TA 509 (March 2018)** Recommended by NICE only if provided within the commercial access agreement.	Pertuzumab (*Perjeta*®)	(with trastuzumab and docetaxel) for treating HER2-positive breast cancer	The TAG acknowledged **NICE TA 509 (March 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NICE TA 510 (March 2018)** Recommended as an option by NICE within the Cancer Drugs Fund.	Daratumumab (*Darzalex*®)	As monotherapy for treating relapsed and refractory multiple myeloma	The TAG acknowledged **NICE TA 510 (March 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NICE TA 511 (March 2018)** Recommended by NICE as an option for treating plaque psoriasis in adults, only if: • the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and • the disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and long-		Brodalumab (*Kyntheum*®) for treating moderate to severe plaque psoriasis	The TAG acknowledged **NICE TA 511 (March 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment, pending submission of an application for its use and agreement on its place in the treatment pathway.	*Noted and supported by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
	wave ultraviolet A radiation), or these options are contraindicated or not tolerated and • the company provides the drug with the discount agreed in the patient access scheme.				
May 2018	**NICE TA 512 (March 2018)** Recommended as an option by NICE.	Tivozanib (*Fotivda*®) *N.B. Oral formulation*	For treating advanced renal cell carcinoma	The TAG acknowledged **NICE TA 512 (March 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NICE TA 513 (March 2018)** Recommended as an option by NICE.	Obinutuzumab (*Gazyvaro*®)	For untreated advanced follicular lymphoma	The TAG acknowledged **NICE TA 513 (March 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NICE TA 514 (March 2018)** Not recommended by NICE	Regorafenib (*Stivarga*®)	For previously treated advanced hepatocellular carcinoma	The TAG acknowledged **NICE TA 514 (March 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NICE TA 515 (March 2018)** Not recommended by NICE	Eribulin (*Halaven*®)	For treating locally advanced or metastatic breast cancer after 1 chemotherapy regimen	The TAG acknowledged **NICE TA 515 (March 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NICE TA 516 (March 2018)** Recommended as an option by NICE.	Cabozantinib (*Cometriq*®) *NB Oral formulation*	For treating medullary thyroid cancer	The TAG acknowledged **NICE TA 516 (March 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
May 2018	**NICE TA 517 (April 2018)** Recommended as an option by NICE for use within the Cancer Drugs Fund.	Avelumab (*Bavencio*®)	For treating metastatic Merkel cell carcinoma	The TAG acknowledged **NICE TA 517 (April 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NICE TA 518 (April 2018)** Recommended as an option by NICE.	Tocilizumab (*RoActemra*®)	For treating giant cell arteritis	The TAG acknowledged **NICE TA 518 (April 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NICE TA 519 (April 2018)** Recommended as an option by NICE for use within the Cancer Drugs Fund.	Pembrolizumab (*Keytruda*®)	For treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy	The TAG acknowledged **NICE TA 519 (April 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC.*
May 2018	**NG 87 (March 2018)** *This guideline updates and replaces NICE guideline CG72 (September 2008) and NICE technology appraisal guidance 98 (2006).* Regarding medication, NICE has made several new recommendations under sections 1.7.3 to 1.7.29.	Attention deficit hyperactivity disorder: diagnosis and management Includes recommendations on: • 1.1 Service organisation and training • 1.2 Recognition, identification and referral • 1.3 Diagnosis • 1.4 Information and support • 1.5 Managing ADHD • 1.6 Dietary advice • 1.7 Medication • 1.8 Maintenance and monitoring • 1.9 Adherence to treatment		The TAG acknowledged **NG 87 (March 2018)** and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval – this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine. The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and	*Noted by the D&TC - to be drawn to the JSCC's attention regarding local service level agreements.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		• 1.10 Review of medication and discontinuation		returned for the TAG's consideration in due course.	
May 2018	**NG 88 (March 2018)** *This guideline updates and replaces NICE guideline CG44 (January 2007).* CCG-commissioning responsibility	Heavy menstrual bleeding: assessment and management	Includes recommendations on: • history, physical examination and tests • investigating causes • information for women • management	The TAG acknowledged **NG 88 (March 2018)** but did not make any new recommendations related to drug management options.	*Noted by the D&TC.*
May 2018	**NG 89 (March 2018)** *This guideline updates and replaces NICE guideline CG92 (January 2010).*	Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism Includes recommendations on: • risk assessment • giving information and planning for discharge • all patients • interventions for people with acute coronary syndromes or acute stroke or for acutely ill patients • interventions for people with renal impairment • interventions for people with cancer • interventions for people having palliative care • interventions for people admitted to critical care • interventions for people with psychiatric illness • interventions when using anaesthesia • interventions for people having orthopaedic surgery • interventions for people having CNS surgery • interventions for people with major trauma • interventions for people having abdominal, thoracic or head and neck surgery • interventions for people having cardiac or vascular surgery		The TAG acknowledged **NG 89 (March 2018)** and was advised that the guidance was being considered by local acute trusts' thromboembolism committees.	*Noted by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		• interventions for pregnant women and women who gave birth or had a miscarriage or termination of pregnancy in the past 6 weeks			
May 2018	**NG 90 (March 2018)** *Updates and replaces NICE guideline PH8 (January 2008)* PHE commissioning responsibility	Physical activity and the environment	Includes recommendations on: • strategies, policies and plar environment • active travel • public open spaces	The TAG noted **NG 90 (March 2018)**	*Noted by the D&TC.*
May 2018	**NG 91 (March 2018)** 2-page visual summary Links to Norfolk and GYW CCGs Antibiotic Formularies CCG-commissioning responsibility	Otitis media (acute): antimicrobial prescribing	Includes recommendations on: • managing acute otitis media, including advice when an antibiotic is not needed • choice of antibiotic when a back-up or immediate prescription is needed • self-care.	The TAG was advised that West Norfolk CCG is leading on developing a strategy for Antimicrobial Stewardship across the Norfolk and Waveney CCGs' area. The TAG acknowledged **NG 91 (March 2018)**	*Noted by the D&TC.* *This guidance to be promoted via The Prescriber newsletter.*
May 2018	**NICE NG 92 (March 2018)** *This guideline updates and replaces NICE guidelines PH1 (March 2006) and PH10 (February 2008).* PHE commissioning responsibility	Stop smoking interventions and services Includes recommendations on: • commissioning and providing stop smoking interventions and services • monitoring stop smoking services • evidence-based stop smoking interventions • engaging with people who smoke • advice on e-cigarettes • people who want to quit • people who are not ready to quit		The TAG noted **NICE NG 92 (March 2018)**	*Noted by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		• telephone quitlines • education and training • campaigns to promote awareness of local stop smoking services • closed institutions • employers			
May 2018	**NICE NG 93 (March 2018)**	Learning disabilities and behaviour that challenges: service design and delivery Includes recommendations on: • strategic planning and infrastructure • enabling person-centred care and support • early intervention and support for families and carers • services in the community • housing and related support • services for children and young people • carers' breaks services • making the right use of inpatient services • staff skills and values		The TAG noted **NICE NG 93 (March 2018)**	*Noted by the D&TC.*
May 2018	**NICE NG 94 (March 2018)**	Emergency and acute medical care in over 16s: service delivery and organisation Includes recommendations on: • first points of contact with emergency and acute care services • alternatives to hospital care • services within hospitals • ward rounds, transfers and discharges • monitoring and managing hospital bed capacity		The TAG noted **NICE NG 94 (March 2018)**	*Noted by the D&TC.*
May 2018	**NICE NG 95 (April 2018)**	Lyme disease – diagnosis and management		The TAG noted that this guidance does not cover the	*Noted by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
	visual summary	Includes recommendations on: • being aware of Lyme disease • symptoms and history taking • which tests to use and when • treatment with antibiotics • treatment and support for ongoing symptoms • managing Lyme disease in pregnant women and their babies • information for people with Lyme disease		management of chronic Lyme disease which is felt to be a problematic area of care. The TAG otherwise acknowledged **NICE NG 95 (April 2018)**	*NG95 and the issue of management of chronic Lyme Disease to be raised at the Eastern Pathology Alliance*
May 2018	**NICE NG 96 (April 2018)**	Care and support of people growing older with learning disabilities Includes recommendations on: • overarching principles • organising and delivering services • identifying and assessing care and support needs • planning and reviewing care and support • identifying and managing health needs • end of life care • staff skills and expertise		The TAG noted **NICE NG 96 (April 2018)**	*Noted by the D&TC.*
May 2018	**NICE HST 7 (February 2018)**	Strimvelis for treating adenosine deaminase deficiency – severe combined immunodeficiency (ADA-SCID)	Recommended by NICE as an option for treating adenosine deaminase deficiency–severe combined immunodeficiency (ADA–SCID) when no suitable human leukocyte antigen-matched related stem cell donor is available. ***(Available only in Italy at present)***	The TAG noted **NICE HST 7 (February 2018)** and although recommended as an option by NICE, decided to classify this NHSE-commissioning responsibility treatment as **Double Red (Not recommended for routine use)** in order to avoid local clinicians being given the impression that it is available for	*Noted by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
				use locally by the NHS.	
May 2018	**Medtech innovation briefings** **NICE MIB 140 (February 2018)**	Coban 2 compression bandage for venous leg ulcers • The **innovative aspect** is that it is thinner than 4-layer bandages. This aims to improve mobility and convenience. • The intended **place in therapy** would be as an alternative to current compression bandages in selected people with venous leg ulcers. • The **main points from the evidence** summarised in this briefing are from 3 studies (2 RCTs and 1 observational study) including a total of 1,456 adults with venous leg ulcers. The evidence is limited in quantity and quality. One randomised study showed that Coban 2 slipped significantly less than 4-layer bandages. Coban 2 shown to be as effective for wound healing as other compression bandages. • There are no studies showing better wound healing than 4-layer bandages. • **Cost** of Coban 2 is £8.24 per unit (excluding VAT). The **resource impact** would likely be similar to standard care (£4 to £15 depending on size of bandage).		The TAG noted **NICE MIB 140 (February 2018)** but did not agree any recommendations for a "traffic light" classification for the treatment. The TAG recommended that the briefing be referred to the Norfolk and Waveney Prescribing Reference Group for further consideration, to be compared with current standard care for the treatment of venous leg ulcers.	*The D&TC noted the briefing and were of the opinion that in view of there being unlikely additional costs imposed by this product, and also a 2-layer bandaging option already being listed on the local wound care formulary, that it was not necessary to refer this guidance elsewhere.*
July 2018	**NICE TA 520 (May 2018)** Recommended as an option by NICE	Atezolizumab (*Tecentriq*®)	For treating locally advanced or metastatic non-small-cell lung cancer after chemo.	The TAG acknowledged **NICE TA 520 (May 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC*
July 2018	**NICE TA 521 (June 2018)** Recommended as an option by NICE under specified criteria. Guselkumab has	Guselkumab (*Tremfya*®) for treating moderate to severe plaque psoriasis in adults, only if: • the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and • the disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are		The TAG acknowledged **NICE TA 521 (June 2018)** discussed the process for commissioning a NICE Fast track drug. The TAG would usually recommend a classification of **Double Red (Not recommended for routine**	*The D&TC confirmed that the interim position for this treatment is* **Double Red (Not recommended for routine use) / Not commissioned** *pending the submission of a business application from local*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
	been recommended through the **fast track appraisal process**. NICE states that NHS England and commissioning groups have committed to providing funding to implement this guidance 30 days after publication (**i.e. by 13th July 2018**).	contraindicated or not tolerated and • the company provides the drug according to the commercial arrangement. Stop guselkumab at 16 weeks if there is inadequate response. Adequate response is defined as: • a 75% reduction in the PASI score (PASI 75) from when treatment started or • a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.		**use)**, pending submission of a business application and agreement on the place in the treatment pathway is reached, when a CCG-commissioning responsibility treatment is recommended as an option for use by NICE. This was not specified by the TAG at the meeting in view of discussions regarding commissioning a NICE fast track drug, and will therefore need to be decided by the D&TC.	*provider Trusts and agreement on its place in the treatment pathway for psoriasis.*
July 2018	**NICE TA 522 (June 2018)** Pembrolizumab (*Keytruda*®) Recommended as an option by NICE within the Cancer Drugs Fund.	Pembrolizumab (*Keytruda*®)	For untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable	The TAG acknowledged **NICE TA 522 (June 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC*
July 2018	**NICE TA 523 (June 2018)** Recommended as an option by NICE.	Midostaurin (*Rydapt*®)	For untreated FLT3-mutation-positive acute myeloid leukaemia in adults	The TAG acknowledged **NICE TA 523 (June 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC*
July 2018	**NICE TA 524 (June 2018)** Recommended as an option by NICE.	Brentuximab vedotin (*Adcetris*®)	For treating CD30-positive Hodgkin lymphoma in adults with relapsed or refractory disease	The TAG acknowledged **NICE TA 524 (June 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
July 2018	**NICE TA 525 (June 2018)** Recommended as an option by NICE.	Atezolizumab (*Tecentriq*®)	For treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy	The TAG acknowledged **NICE TA 525 (June 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC*
July 2018	**NICE TA 526 (June 2018)** Recommended by NICE as an option	Arsenic trioxide (*Trisenox*®)	For treating acute promyelocytic leukaemia (characterised by the presence of the t[15;17] translocation or the PML/RAR-alpha gene) in adults	The TAG acknowledged **NICE TA 526 (June 2018))** and recommended a traffic light classification of Red (Hospital/Specialist only)	NHSE--commissioning responsibility *Noted by the D&TC*
July 2018	**NICE TA 527 (June 2018)**	Beta interferons (*Avonex*®, *Betaferon*®, *Extavia*®, *Rebif*®) and glatiramer acetate (*Copaxone*®) for treating multiple sclerosis: **1.1 Interferon beta-1a** is recommended as an option for multiple sclerosis only if: • the person has relapsing–remitting multiple sclerosis and • the companies provide it according to commercial arrangements. **1.2 Interferon beta-1b (Extavia)** is recommended as an option for treating multiple sclerosis, only if: • the person has relapsing–remitting multiple sclerosis and has had 2 or more relapses within the last 2 years ***or*** • the person has secondary progressive multiple sclerosis with continuing relapses and • the company provides it according to the commercial arrangement. **1.3 Glatiramer acetate** is recommended as an option for multiple sclerosis, only if: • the person has relapsing–remitting multiple sclerosis and • the company provides it according to the commercial arrangement. **1.4 Interferon beta-1b (Betaferon)** is not recommended as an		The TAG acknowledged the **NICE TA 527 (June 2018)** and recommended traffic light classifications of Red (Hospital / Specialist only) for 1.1, 1.2 and 1.3 and **Double Red (Not recommended for routine use)** for 1.4	NHSE--commissioning responsibility *Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		option for treating multiple sclerosis.			
July 2018	**NICE Final Appraisal Determination (June 2018):** Recommended by NICE as an option *(The final TA is expected to be published on 1st August 2018)* ***NB*** Dupilumab has already been in use via the NHS EAMS (Early Access to Medicines Scheme) – there is therefore an expectation that the TA should be implemented within 30 days of its publication. CCG-commissioning responsibility	Dupilumab (*Dupixent*®)	For treating moderate to severe atopic dermatitis after topical treatments in combination with topical corticosteroids, in adults only if: • the disease has not responded to at least 1 other systemic therapy, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are contraindicated or not tolerated • the company provides dupilumab according to the commercial arrangement • Stop dupilumab at 16 weeks if the atopic dermatitis has not responded adequately. An adequate response is: ○ at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started and ○ at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started.	Currently classified as **Double Red (Not recommended for routine use)** until a local business application for its use is supported following a positive NICE TA related to the treatment (*TAG recommendation May 2017*) A local Trust business case would be expected at Sept 2018 TAG, which would be a few days after the 30 day deadline set for commissioning this treatment (assuming that the NICE TA remains positive and is published to time as planned). The NNUH have one patient who they wish to treat with dupilumab. An application had been submitted to the IFR-Drugs Panel for this patient but it was expected that it may be declined if the patient was considered not to meet the criteria for exceptionality. The Trust would also be a wish to try and treat this patient ahead of the agreement of dupilumab's place in a treatment pathway. The JSCC's process for commissioning "Fast track" NICE-recommended treatments has yet to be ascertained. The TAG would usually	*The D&TC confirmed that the interim position for this treatment is* **Double Red (Not recommended for routine use) / Not commissioned** *pending the submission of a business application from local provider Trusts and agreement on its place in the treatment pathway for atopic dermatitis.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
				recommend a classification of **Double Red (Not recommended for routine use)**, pending submission of a business application and agreement on the place in the treatment pathway is reached, when a CCG-commissioning responsibility treatment is recommended as an option for use by NICE. This was not specified by the TAG at the meeting in view of the above discussion, and will therefore need to be decided by the D&TC.	
July 2018	**NICE TA 217 (update June 2018)** and **NICE NG 97 (June 218) -** This TA has been partially updated by NG97 on dementia and replaces NICE TA111. CCG-commissioning responsibility	Donepezil, galantamine, rivastigmine, memantine / Dementia: assessment, management and support for people living with dementia and their carers for Alzheimer's disease Pharmacological recommendations include: **1.1** AChE Inhibitors - donepezil, galantamine and rivastigmine as monotherapies are recommended as options for managing mild to moderate Alzheimer's disease under all conditions specified in **1.4** and in recommendation 1.5.5 of NG97 on dementia. **1.2** Memantine monotherapy is recommended as an option for managing Alzheimer's disease for people with: • moderate Alzheimer's disease who are intolerant of or have a contraindication to AChE Inhibitors **or** • severe Alzheimer's disease. Treatment should be as specified in recommendation 1.5.5 in NG97. **1.3** Updated and replaced by recommendation 1.5.5 in NG97.		An initial document which summarised the major changes in NICE's recommendations and mapped them against current commissioned positions to advise the TAG of the extent of the changes recommended by NICE (see under **Item 7.11**). The TAG agreed that the current classifications and criteria for use should be maintained pending review and further discussion by the TAG. Work was needed to ascertain how the Trusts would wish to use the treatments following NG 97 and also how the specialist service would be provided. To be discussed with the CCGs'	*The NICE guidance was acknowledged by the D&TC.* *The committee noted in particular* **1.6: Medicines that may cause cognitive impairment** *which highlighted the need to consider increased anticholinergic burden related to some medicines used long term and the associated risk of cognitive impairment.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		1.4 Treatment with an AChE inhibitor (donepezil, galantamine or rivastigmine), should normally be started with the drug of lowest acquisition cost (taking into account required daily dose and the price per dose once shared care has started). However, an alternative AChE Inhibitor could be prescribed if it is considered appropriate when taking into account adverse event profile, adherence, medical comorbidity, possibility of drug interactions and dosing profiles		Lead Mental Health Commissioner. Details of what is currently commissioned, what is new and possible traffic light changes, should come back to the next meeting for further discussion. Review of the current shared care agreements for dementia treatments. This item to be returned to the September 2018 meeting for further discussion.	
July 2018	**Medtech innovation briefings - NICE MIB 145 (May 2018)**	Point-of-care diagnostic testing in primary care	For strep A infection in sore throat	The TAG noted **NICE MIB 145 (May 2018)** and suggested that this be forwarded to the Anti-Microbial Stewardship Committee for their consideration.	*Noted by the D&TC*
Sept 2018	**NICE TA 492 (Update July 2018)** Recommended by NICE as an option within the Cancer Drugs Fund **July 2018:** The European Medicines Agency restricted the use of atezolizumab for untreated urothelial carcinoma. It should now only be used in adults with high levels of PD-L1.	Atezolizumab (*Tecentriq*®)	For untreated PD-L1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable only if: • their tumours express PD-L1 at a level of 5% or more and • the conditions of the managed access agreement for atezolizumab are followed. There is a managed access agreement, which includes a patient access scheme for	The TAG noted **NICE TA 492 (Update July 2018)** and reaffirmed a traffic light classification of Red (Specialist only)	NHSE-commissioning responsibility *Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
	See summary of product characteristics.		atezolizumab.		
Sept 2018	**NICE TA 522 (Update July 2018)** Recommended by NICE as an option within the Cancer Drugs Fund	Pembrolizumab (*Keytruda*®)	For untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable only if: • their tumours express PD-L1 with a combined positive score of 10 or more • pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier if the disease progresses and • the conditions of the managed access agreement for pembrolizumab are followed.	The TAG noted **NICE TA 522 (Update July 2018)** and reaffirmed a traffic light classification of Red (Specialist only)	NHSE-commissioning responsibility *Noted by the D&TC*
Sept 2018	**NICE TA 528 (July 2018)** Recommended by NICE as an option within the Cancer Drugs Fund	Niraparib (*Zejula*®) for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer only if: • they have a germline BRCA mutation and have had 2 courses of platinum-based chemotherapy or • they do not have a germline BRCA mutation and have had 2 or more courses of platinum-based chemotherapy and • the conditions in the managed access agreement for niraparib are followed.		The TAG noted **NICE TA 528 (July 2018)** and recommended a traffic light classification of Red (Specialist only)	NHSE-commissioning responsibility *Noted by the D&TC*
Sept 2018	**NICE TA 529 (July**	Crizotinib (*Xalkori*®)	For treating ROS1-positive	The TAG noted **NICE TA 529**	NHSE-commissioning

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
	2018) Recommended by NICE as an option within the Cancer Drugs Fund		advanced non-small-cell lung cancer, only if the conditions in the managed access agreement are followed	**(July 2018)** and recommended a traffic light classification of Red (Specialist only) for this treatment.	responsibility *Noted by the D&TC*
Sept 2018	**NICE TA 530 (July 2018)** **Not recommended** by NICE	Nivolumab (*Opdivo*®)	For treating locally advanced unresectable or metastatic urothelial cancer after platinum-containing chemotherapy	The TAG noted **NICE TA 530 (July 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this treatment.	NHSE-commissioning responsibility *Noted by the D&TC*
Sept 2018	**NICE TA 531 (July 2018)** Recommended as an option by NICE	Pembrolizumab (*Keytruda*®) for untreated PD-L1-positive metastatic non-small-cell lung cancer (NSCLC) in adults whose tumours express PD-L1 (with at least a 50% tumour proportion score) and have no epidermal growth factor receptor- or anaplastic lymphoma kinase-positive mutations, only if: • pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier in the event of disease progression and • the company provides pembrolizumab according to the commercial access agreement		The TAG noted **NICE TA 531 (July 2018)** and recommended a traffic light classification of Red (Specialist only) for this treatment.	NHSE-commissioning responsibility *Noted by the D&TC*
Sept 2018	**NICE TA 532 (July 2018)** **July 2017:** Classified as **Double Red (Not recommended for routine use)** following a positive scientific opinion being issued for Oxervate eye drops under the NHS England Early Access to Medicines Scheme (EAMS). **July 2018:** Cenegermin is **not recommended** by NICE for treating moderate or severe neurotrophic keratitis in adults.		Cenegermin (*Oxervate*®) for treating neurotrophic keratitis	The TAG noted **NICE TA 532 (July 2018)** and reaffirmed a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment.	*Noted and supported by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
Sept 2018	**NICE TA 533 (July 2018)** Recommended by NICE as an option	Ocrelizumab (*Ocrevus*®)	For treating relapsing-remitting multiple sclerosis in adults, only if: • alemtuzumab is contraindicated or otherwise unsuitable and • the company provides ocrelizumab according to the commercial arrangement.	The TAG noted **NICE TA 533 (July 2018)** and recommended a traffic light classification of Red (Specialist only) for this treatment	NHSE-commissioning responsibility *Noted by the D&TC*
Sept 2018	**NICE TA 534 (August 2018)** Recommended by NICE as an option	Dupilumab (*Dupixent*®) for treating moderate to severe atopic dermatitis, only if: • the disease has not responded to at least 1 other systemic therapy, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are contraindicated or not tolerated • dupilumab is provided according to the commercial arrangement. • Stop dupilumab at 16 weeks if the atopic dermatitis has not responded adequately. An adequate response is: ○ at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started and ○ at least a 4 point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started. When using the EASI, healthcare professionals should take into account skin colour and how this could affect the EASI score, and make the clinical adjustments they consider appropriate.		The TAG noted **NICE TA 534 (August 2018)** and recommended a traffic light classification of Red (Specialist only) for this CCG-commissioning responsibility treatment, as per the application submitted concurrently by the NNUH.	*Noted but not yet supported by the D&TC*
Sept 2018	**NICE TA 535 (August 2018)**	Lenvatinib (*Lenvima*®) and sorafenib (*Nexavar*®) for treating progressive, locally advanced or metastatic differentiated thyroid cancer (papillary, follicular or Hürthle cell) in adults		The TAG noted **NICE TA 535 (August 2018)** and recommended a traffic light	NHSE-commissioning responsibility

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
	Recommended as options by NICE	whose disease does not respond to radioactive iodine, only if: • they have not had a tyrosine kinase inhibitor before or • they have had to stop taking a tyrosine kinase inhibitor within 3 months of starting it because of toxicity (specifically, toxicity that cannot be managed by dose delay or dose modification). • Lenvatinib and sorafenib are recommended only if the companies provide them according to the commercial arrangements.		classification of Red (Specialist only) for this treatment.	*Noted by the D&TC*
Sept 2018	**NICE TA 536 (August 2018)** Recommended by NICE as an option	Alectinib (*Alecensa*®)	For untreated ALK-positive advanced non-small-cell lung cancer (NSCLC), only if the company provides alectinib according to the commercial arrangement	The TAG noted **NICE TA 536 (August 2018)** and recommended a traffic light classification of Red (Specialist only) for this treatment.	NHSE-commissioning responsibility *Noted by the D&TC*
Sept 2018	**NICE TA 537 (August 2018)** Recommended by NICE as an option. Assess the response to ixekizumab after 16 weeks of treatment. Only continue treatment if clear evidence of response, defined as improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria. People whose disease has a PASI 75 response but whose PsARC response does not justify continuing treatment should be assessed by a dermatologist, to determine whether continuing treatment is appropriate based on skin response (as per NICE TA on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis, 1.3).		Ixekizumab (*Taltz*®) for treating active psoriatic arthritis after inadequate response to DMARDs, used alone or with methotrexate, only if: • it is used as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (recommendations 1.1 and 1.2) or • the person has had a tumour necrosis factor (TNF)-alpha inhibitor but their disease has not responded within the first 12 weeks or has	The TAG noted **NICE TA 537 (August 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment pending the submission of a business application and confirmation of its place in the locally commissioned psoriatic arthritis treatment pathway.	*Noted and supported by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
			stopped responding after the first 12 weeks or • TNF-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis). • the company provides it according to the commercial arrangement.		
Sept 2018	**NICE TA 538 (August 2018)** Recommended by NICE as an option	Dinutuximab beta (*Qarziba*®)	For treating high-risk neuroblastoma in people aged 12 months and over whose disease has at least partially responded to induction chemotherapy, followed by myeloablative therapy and stem cell transplant, only if: • they have not already had anti-GD2 immunotherapy and • the company provides dinutuximab beta according to the commercial arrangement.	The TAG noted **NICE TA 538 (August 2018)** and recommended a traffic light classification of Red (Specialist only) for this treatment.	NHSE-commissioning responsibility *Noted by the D&TC*
Sept 2018	**NICE TA 539 (August 2018)** Recommended by NICE as an option	Lutetium (177Lu) oxodotreotide (*Lutathera*®)	For treating unresectable or metastatic, progressive, well-differentiated (grade 1 or grade 2), somatostatin receptor-positive gastroenteropancreatic	The TAG noted **NICE TA 539 (August 2018)** and recommended a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
			neuroendocrine tumours (NETs) in adults, only if: • the company provides it according to the commercial arrangement	treatment.	
Sept 2018	**NICE NG 98 (June 2018)**	Hearing loss in adults: Assessment and management Includes recommendations on: • assessment and referral • removing earwax • investigation using MRI • treating idiopathic sudden sensorineural hearing loss • assessment and management in audiology services • hearing aids and assistive listening devices, including follow-up in audiology services • information and support.		The TAG noted **NICE NG 98 (June 2018)**	*Noted by the D&TC*
Sept 2018	**NICE NG 99 (July 2018)**	Management of Brain tumours (primary) and brain metastases in adults Includes recommendations on: • investigation of suspected glioma, meningioma and brain metastases • management of suspected glioma, meningioma and brain metastases • follow-up and supportive care • neurorehabilitation • surveillance for late-onset side effects of treatment.		The TAG noted **NICE NG 99 (July 2018)**	*Noted by the D&TC*
Sept 2018	**NICE NG 100 (July 2018)**	Management of Rheumatoid arthritis in adults: Includes new and updated recommendations on: • investigations following diagnosis • treat-to-target strategy and initial pharmacological		The TAG noted **NICE NG 100 (July 2018)**	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		management • symptom control and monitoring and also: • investigations for diagnosis and referral from primary care • non-pharmacological management and the multidisciplinary team • communication and education			
Sept 2018	**NICE NG 101 (July 2018)**	**Early and locally advanced breast cancer: Diagnosis and management:** **Includes new and updated recommendations on:** • surgery to the breast and axilla • breast reconstruction • diagnostic assessment and adjuvant therapy planning • endocrine therapy • adjuvant chemotherapy for invasive breast cancer • bisphosphonate therapy • radiotherapy • primary systemic therapy • lymphoedema • lifestyle **Existing recommendations:** • referral, diagnosis and preoperative assessment • providing information and psychological support • complications of local treatment and menopausal symptoms • follow-up The TAG noted **NICE NG 101 (July 2018)**			*Noted by the D&TC*
Sept 2018	**NICE NG 102 (August 2018)**	Community pharmacies:	Promoting health and wellbeing Includes recommendations on: • health and wellbeing hub • overarching principles of	**NICE NG 102 (August 2018)**	Community pharmacies:

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
			good practice • awareness raising and providing information • advice and education • behavioural support • referrals and signposting		
Sept 2018	**NICE NG 103 (August 2018)**	Flu vaccination: Increasing uptake Includes recommendations on: • using a multicomponent approach • raising awareness • offering vaccination • increasing uptake among eligible groups in primary and secondary care • audit, monitoring and feedback • vaccination in carers • increasing uptake in health and social care staff		The TAG noted **NICE NG 103 (August 2018)**	*Noted by the D&TC*
Sept 2018	**Medtech innovation briefings - NICE MIB 152 (July 2018)**	Remote ECG interpretation consultancy services For cardiovascular disease: • The **technologies** described in this briefing are remote electrocardiogram (ECG) interpretation consultancy services. They are used for assisting in diagnosing and decision-making for people with cardiovascular disease. • The **innovative aspects** are that with remote ECG interpretation, a person does not need to travel to hospital for a consultation with a cardiologist, potentially providing quicker and more accurate diagnoses. • The intended **place in therapy** would be to replace referrals to secondary care for interpreting ECGs from people with suspected cardiovascular disease. • The **main points from the evidence** summarised in this briefing are from 4 UK pilot studies including 26,320 adults		The TAG noted **NICE MIB 152 (July 2018)**	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		and children in primary care. The studies show that remote ECG interpretation consultancy services may reduce the number of unnecessary referrals to secondary care and reduce costs for the NHS. • **Key uncertainties** around the evidence or technology are that the economic benefits are not yet clear and there is a lack of evidence for clinical outcomes. Published evidence of clinical utility is only available for 1 out of 6 services in this briefing. • The **cost** of the services in this briefing ranges from £3 to £195 per report (excluding VAT). The **resource impact** may be cost saving because of reductions in secondary care referrals.			
Nov 2018	**NICE TA 540 (September 2018)** Not recommended by NICE for treating relapsed or refractory classical Hodgkin lymphoma in adults who have had autologous stem cell transplant and brentuximab vedotin. Recommended by NICE as an option within the Cancer Drugs Fund for the restricted indication.	Pembrolizumab (*Keytruda*®) for	Recommended for treating relapsed or refractory classical Hodgkin lymphoma in adults who have had brentuximab vedotin and cannot have autologous stem cell transplant, only if: • pembrolizumab is stopped after 2 years of treatment or earlier if the person has a stem cell transplant or the disease progresses and • the conditions in the managed access agreement for pembrolizumab are followed. • There is a managed access agreement, which includes a patient access scheme for atezolizumab.	The TAG noted **NICE TA 540** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** in adults who have had autologous stem cell transplant and brentuximab vedotin, and Red (Hospital / Specialist use only) in adults who have had brentuximab vedotin and cannot have autologous stem cell transplant as per criteria specified by NICE, for this treatment.	NHSE-commissioning responsibility *Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
Nov 2018	**NICE TA 541 (September 2018)** Recommended by NICE as an option only if the company provides it according to the commercial arrangement	Inotuzumab ozogamicin (*Besponsa*®) for treating relapsed or refractory B-cell acute lymphoblastic leukaemia	• Recommended by NICE as an option for treating relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukaemia in adults. • People with relapsed or refractory Philadelphia-chromosome-positive disease should have had at least 1 tyrosine kinase inhibitor.	The TAG noted **NICE TA 541 (September 2018)** and recommended a traffic light classification of Red (Hospital / Specialist use only) for this treatment.	NHSE-commissioning responsibility *Noted by the D&TC*
Nov 2018	**NICE TA 542 (October 2018)** Recommended by NICE for those at	Cabozantinib (*Cabometyx*®)	For untreated advanced renal cell carcinoma in adults only if: • The condition is intermediate- or poor-risk as defined in the International Metastatic Renal Cell Carcinoma Database Consortium criteria • the company provides cabozantinib according to the commercial arrangement	The TAG noted **NICE TA 542 (October 2018)** and recommended a traffic light classification of Red (Hospital / Specialist use only) for this treatment.	NHSE-commissioning responsibility *Noted by the D&TC*
Nov 2018	**NICE TA 543 (October 2018)** Recommended by NICE as an option. ***Link*** to the current locally commissioned treatment pathway for psoriatic arthritis	Tofacitinib (*Xeljanz*®) for treating active psoriatic arthritis in adults after inadequate response to DMARDs only if: • it is used as described in NICE TA 199 - treatment of psoriatic arthritis (1.1 and 1.2) or • the person has had a tumour necrosis factor (TNF)-alpha inhibitor but their disease has not responded within the first 12 weeks or has stopped responding after 12 weeks or • TNF-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE TA 199 -		The TAG noted **NICE TA 543 (October 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** pending the submission of a business application and confirmation of place in the local treatment pathway for this CCG-commissioning responsibility	The deadline for commissioning this treatment within 3 months of its date of publication is 02 January 2019. *Noted and supported by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		treatment of psoriatic arthritis). Tofacitinib is only recommended if the company provides it according to the commercial arrangement. **1.2** Assess the response to tofacitinib after 12 weeks: • Only continue treatment if there is clear evidence of response, defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria. • People whose disease has a Psoriasis Area and Severity Index (PASI) 75 response but whose PsARC response does not justify continuing treatment should be assessed by a dermatologist, to determine whether continuing treatment is appropriate based on skin response (as described in NICE TA 199 - treatment of psoriatic arthritis, recommendation 1.3).		treatment.	
Nov 2018	**Nov 2018**	Dabrafenib (*Tafinlar*®) with trametinib (*Mekinist*®)	For adjuvant treatment of resected BRAF V600 mutation-positive melanoma, only if the company provides dabrafenib and trametinib with the discounts agreed in the commercial arrangements.	The TAG noted **NICE TA 544 (October 2018)** and recommended a traffic light classification of Red (Hospital / Specialist use only) for these treatments.	NHSE-commissioning responsibility *Noted by the D&TC*
Nov 2018	**NICE NG 104 (September 2018)** Covers managing acute and chronic pancreatitis in children, young people and adults.	Pancreatitis	Includes recommendations on: • Information and support • Identifying the cause of acute and chronic pancreatitis • Nutrition support in acute and chronic pancreatitis • Managing complications in acute and chronic pancreatitis	The TAG noted **NICE NG 104 (September 2018)**	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
			• Referral and follow-up		
Nov 2018	**NICE NG 106 (September 2018)**	Chronic heart failure in adults: diagnosis and management	Includes recommendations on: 1.1 Team working in the management of heart failure 1.2 Diagnosing heart failure 1.3 Giving information to people with heart failure 1.4 Treating heart failure with reduced ejection fraction 1.5 Treating heart failure with reduced ejection fraction in people with chronic kidney disease 1.6 Managing all types of heart failure 1.7 Monitoring treatment for all types of heart failure 1.8 Interventional procedures 1.9 Cardiac rehabilitation 1.10 Palliative care	The TAG noted **NICE NG 106 (September 2018)**	*The D&TC was advised that the STP Cardiovascular Disease (Circulation) workstream is looking at this guidance under Rightcare.* *The D&TC also noted that use of metolazone, which is no longer licensed in the UK and must be imported from outside the EU, is still being recommended by local specialist heart failure services. Community pharmacies are able to source but charge variable fees to the NHS for doing so. To be taken forward for discussion with the Trusts.*
Nov 2018	**NICE NG 107 (October 2018)** - covers renal replacement therapy (dialysis and transplantation) and conservative management for people with CKD stages 4 and 5.	Renal replacement therapy and conservative management	Includes recommendations on: • indications for starting dialysis • planning and choosing treatments • switching or stopping treatments • recognising symptoms • diet and fluids • information, education and support • coordinating care	The TAG noted **NICE NG 107 (October 2018)**	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
Nov 2018	**NICE NG 108 (October 2018)** - covers decision-making in people ≥16 years who may lack capacity now or in the future. It aims to help health and social care practitioners support people to make their own decisions where they have capacity to do so. It also helps practitioners to keep people who lack capacity at the centre of the decision-making process.	Decision-making and mental capacity	Includes recommendations on: • supporting decision-making • advance care planning • assessing mental capacity to make specific decisions at a particular time • best interests decision-making This guideline should be read in conjunction with the Mental Capacity Act 2005. It is not a substitute for the law or relevant Codes of Practice. It does not cover Deprivation of Liberty Safeguards processes.	The TAG noted **NICE NG 108 (October 2018)**	*Noted by the D&TC*
Nov 2018	**NICE NG 109 (October 2018)** - sets out an antimicrobial prescribing strategy for LUTI (cystitis) in children, young people and adults who do not have a catheter which aims to optimise antibiotic use and reduce antibiotic resistance.	Urinary tract infection (lower): antimicrobial prescribing	Includes recommendations on: • treatment for women who are not pregnant • treatment for men and pregnant women • treatment for children and young people under 16 years • reassessment and referral • choice of antibiotic • self-care • managing asymptomatic bacteriuria 3-page visual summary also available	The TAG noted **NICE NG 109 (October 2018)**	*Implementation of this guidance is being covered under the local antimicrobial stewardship strategy (AMS).* *Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
Nov 2018	**NICE NG 110 (October 2018)** - sets out an antimicrobial prescribing strategy for acute prostatitis which aims to optimise antibiotic use and reduce antibiotic resistance.	Prostatitis (acute): antimicrobial prescribing	Includes recommendations on: • managing acute prostatitis, including treatment, reassessment and referral • choice of antibiotic • self-care. 2-page visual summary also available	The TAG noted **NICE NG 110 (October 2018)**	*Implementation of this guidance is being covered under the local antimicrobial stewardship strategy (AMS).* *Noted by the D&TC*
Nov 2018	**NICE NG 111 (Oct 18)** - sets out an antimicrobial prescribing strategy for acute pyelonephritis (upper UTI) in children, young people and adults who do not have a catheter which aims to optimise antibiotic use and reduce antibiotic resistance	Pyelonephritis (acute): antimicrobial prescribing	Includes recommendations on: • managing acute pyelonephritis, including treatment, reassessment and referral • choice of antibiotic • self-care. 3-page visual summary also available	The TAG noted **NICE NG 111 (October 2018)**	*Implementation of this guidance is being covered under the local antimicrobial stewardship strategy (AMS).* *Noted by the D&TC*
Nov 2018	**NICE NG 112 (Oct 18)** - sets out an antimicrobial prescribing strategy for preventing recurrent urinary tract infections in children, young people and adults who do not have a	Urinary tract infection (recurrent): antimicrobial prescribing	Includes recommendations on: • referral and seeking specialist advice • treatment for women who are not pregnant • treatment for men and pregnant women • treatment for children and young people under 16 years	The TAG noted **NICE NG 112 (October 2018)**	*Implementation of this guidance is being covered under the local antimicrobial stewardship strategy (AMS).* *Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
	catheter which aims to optimise antibiotic use and reduce antibiotic resistance.		• reassessment • self-care • choice of antibiotic prophylaxis. 2-page visual summary also available		
Nov 2018	**NICE HST 8 (October 2018)** Recommended only if the company provides burosumab according to the commercial arrangement.	Burosumab (*Crysvita*®)	For treating X-linked hypophosphataemia (XLH) with radiographic evidence of bone disease in children aged 1 year and over, and in young people with growing bones	The TAG noted **NICE HST 8 (Oct 18)** and recommended a classification of Red (Hospital / Specialist use only) for this treatment.	NHSE-commissioning responsibility *Noted by the D&TC*
Nov 2018	**Medtech innovation briefings** **NICE MIB 161 (October 2018)**	**myAIRVO2** for the treatment of chronic obstructive pulmonary disease: • The **technology** described in this briefing is myAIRVO2. It is designed to warm and humidify respiratory gases used for nasal high-flow therapy. This briefing focuses on its potential use in a community setting. • The **innovative aspects** are that myAIRVO2 is designed to allow the delivery of nasal high-flow therapy in a community setting. It is also designed to allow clinicians to titrate flow and oxygen independently from one another and does not need a sealed interface. • The intended **place in therapy** would be as well as standard management in the home or long term care environment for people with COPD having nasal high-flow oxygen therapy. • The **main points from the evidence** summarised in this briefing are from 5 studies, 1 randomised controlled trial and 4 randomised crossover trials including a total of 232 adults. They show that myAIRVO2 is at least as effective as non-humidified and unwarmed gases in patients with COPD and has the potential to reduce hospital admissions. • **Key uncertainties** around the evidence relate to the lack of follow-up to show the long-term positive effects of myAIRVO2 and the generalisability to UK NHS practice. There are also uncertainties around which patient group nasal high-flow therapy would most benefit in a community setting and if it should be used with or instead of current treatments. • The **cost** of myAIRVO2 is £2,475 per unit (excluding VAT). The overall resource impact is uncertain because there is no published evidence assessing the resource consequences of		*Noted by the D&TC* *To be highlighted with the Clinical Policy Development Group.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		myAIRVO2 in a community setting. More information on this would be helpful. The TAG noted **NICE MIB 161 (October 2018)**			
Nov 2018	**Medtech innovation briefings** **NICE MIB 162 (October 2018)**	**gammaCore** for cluster headache: • The **technology** described in this briefing is gammaCore which is a handheld, patient-controlled, non-invasive vagus nerve stimulator. It is used as a daily preventative measure for cluster headache and can be used to treat pain during a headache. • The **innovative aspects** compared with other vagus nerve stimulators is that gammaCore is applied to the surface of the neck rather than surgically implanted. • The intended **place in therapy** would be as well as standard care, most likely where standard treatments for cluster headache are ineffective, not tolerated or contraindicated. It would be prescribed by neurologists who provide specialist headache services. • The **main points from the evidence** summarised in this briefing are from 5 studies: 3 RCTs, 1 open-label randomised trial and 1 cohort study including a total of 465 people. They show that use of gammaCore alongside standard care may be more effective than standard care only in treating cluster headaches. • **Key uncertainties** around the evidence and technology are that people with episodic and chronic cluster headaches respond differently to treatment with gammaCore. The optimal use of gammaCore in the different populations is unclear. • The **cost** of gammaCore treatment is £625 for 93 days (exclusive of VAT). The resource impact would be more than standard care, except where it replaces current treatments. The TAG noted **NICE MIB 162 (October 2018)**			*Noted by the D&TC*
Jan 2019	**NICE TA 547 (November 2018)** Recommended by NICE as an option only if the company provides tofacitinib with the discount agreed in the commercial arrangement	Tofacitinib (*Xeljanz*®)	For moderately to severely active ulcerative colitis in adults when: • conventional therapy or a biological agent cannot be tolerated • or the disease has responded inadequately or lost response to treatment.	The TAG noted **NICE TA 547 (November 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** pending the submission of a business application and confirmation of place in the local treatment pathway for this CCG-commissioning responsibility treatment.	The deadline for commissioning this treatment within 3 months of its date of publication is 28 February 2019. *Noted and supported by the D&TC*
Jan	**NICE TA 549**	Denosumab (XGEVA®)	For preventing skeletal-related	The TAG noted **NICE TA 549**	*Noted and supported by the*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
2019	**(December 2018)** (*terminated appraisal*)		events in multiple myeloma. *NICE is **unable to make a recommendation** about this treatment because no evidence submission was received from Amgen. The company has confirmed that it does not intend to make a submission because denosumab is unlikely to be used at this point in the treatment pathway*.	**(December 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	*D&TC*
Jan 2019	**NICE NG 113 (November 2018)** 3-page visual summary also available	Urinary tract infection (catheter-associated): antimicrobial prescribing	Includes recommendations on: • treatment • advice when an antibiotic prescription is given • reassessment • referral and seeking specialist advice • self-care • choice of antibiotic • prevention	The TAG noted in particular that NG 113 recommends that Antibiotic treatment is not routinely needed for asymptomatic bacteriuria (in people with a catheter), and also that drinks enough fluids to avoid dehydration should be encouraged, which reinforces current policy and messages being communicated. The TAG otherwise noted **NICE NG 113 (November 2018)**	*Noted by the D&TC*
Jan 2019	**NICE NG 114 (December 2018)** This guideline sets out an antimicrobial prescribing strategy to optimise antibiotic use and reduce antibiotic resistance.	Chronic obstructive pulmonary disease (acute exacerbation): antimicrobial prescribing	Includes recommendations on: • treatment • reassessment • referral and seeking specialist advice • choice of antibiotic 2-page visual summary also available	The TAG noted recent data analysis which indicates that patients who request >3 COPD rescue packs a year (which should not be on their repeat prescription list) and related hospital admission rates which show increased in-year death rates in frequent attenders with COPD exacerbations, should be prioritised for review of their	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
				treatment. The TAG also noted the increased risks of using oxygen therapy in an environment where people are smoking. The TAG otherwise noted **NICE NG 114 (December 2018)**	
Jan 2019	**NICE NG 115 (December 2018)** This guideline aims to help people with COPD to receive a diagnosis earlier so that they can benefit from treatments to reduce symptoms, improve quality of life and keep them healthy for longer. See also Local Guidance	Chronic obstructive pulmonary disease in over 16s: Diagnosis and Management	Includes *new* recommendations on: • incidental findings on chest X-rays or CT scans • prognosis • inhaled therapies • prophylactic antibiotics • oxygen therapies • managing pulmonary hypertension and cor pulmonale • lung volume reduction procedures • self-management and exacerbation plans. Contains *existing* recommendations on: • diagnosing COPD using symptoms, spirometry and other tests • managing stable COPD using nebulisers, oral therapy and pulmonary rehabilitation • multidisciplinary management of stable COPD, including physiotherapy, occupational	Of particular note is that when managing stable COPD, LAMA or LABA as monotherapy are now no longer recommended by NICE, i.e. if a patient using a SABA or SAMA remains breathless or has exacerbations (a decision not based on severity measured by FEV1), the next step is to offer a combination of LAMA+LABA or LABA+ICS. The TAG was advised that the STP RightCare Respiratory Group would consider the place of this guidance with respect to guidance issued in 2018 and current agreed clinical practice. The TAG noted **NICE NG 115 (December 2018)**.	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
			therapy, nutrition and palliative care • managing exacerbations of COPD in primary care and in hospital.		
Jan 2019	**NICE NG 116 (December 2018)** This guide aims to improve quality of life by reducing symptoms of PTSD such as anxiety, sleep problems and difficulties with concentration. Recommendations also aim to raise awareness of the condition and improve coordination of care.	Post-traumatic stress disorder in children, young people and adults	This guideline includes new and updated recommendations on: • access to care and supporting transitions between services • principles of care, including providing support and information • management of PTSD in children, young people and adults* • care for people with PTSD and complex needs. Contains existing recommendations on: • recognition of PTSD • assessment and coordination of care • language and culture • disaster planning ***Regarding Drug therapy see:** **1.6.14** *Do not offer drug treatments for the prevention or treatment of PTSD in children and young people aged under 18 years.* **[2018]** **1.6.24** *Do not offer drug treatments, including benzodiazepines, to prevent PTSD in adults*. **[2018]** **1.6.25** *Consider venlafaxine[2] or a selective serotonin reuptake inhibitor (SSRI), such as sertraline[3] for adults with a diagnosis of PTSD if the person has a preference for drug treatment. Review this treatment regularly.* **[2018]** **1.6.26** *Consider antipsychotics such as risperidone[4], in addition to psychological therapies to manage symptoms for adults with a diagnosis of PTSD if:* • *they have disabling symptoms and behaviours, for example severe hyperarousal or psychotic symptoms* ***and*** • *their symptoms have not responded to other drug or psychological treatments.* *Antipsychotic treatment should be started and reviewed regularly by a specialist (see how to use antipsychotic*		*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
			medication in NICE's guideline on psychosis and schizophrenia in adults). **[2018]** The TAG noted **NICE NG 116 (December 2018)**		
Jan 2019	**NICE NG 117 (December 2018)** - sets out an antimicrobial prescribing strategy for managing & preventing acute exacerbations of bronchiectasis (non-cystic fibrosis). It aims to optimise antibiotic use and reduce antibiotic resistance. Evidence review	Bronchiectasis (non-cystic fibrosis), *acute exacerbation*: antimicrobial prescribing	Includes recommendations on: • treatment • reassessment • referral and seeking specialist advice • choice of antibiotic for treatment • prevention. See also 3-page visual summary of the recommendations, including tables to support prescribing decisions.	The TAG noted **NICE NG 117 (December 2018)**, and its related Evidence review, with respect to the emergence of antibiotic resistance, and considered whether continued use of a local shared care agreement for nebulised colomycin was appropriate. It was agreed that local specialists should be asked for their views on this issue to feedback to the TAG.	*The D&TC recommended that the issue of long-term use of nebulised colistin in patients with non-CF bronchiectasis is also referred for consideration by the Antimicrobial Steering Group, which is next due to meet in mid February 2019.* *The TAG's recommendations were otherwise noted by the D&TC.*
Jan 2019	**Medtech innovation briefings** **NICE MIB 164 (December 2018)**	**Axonics sacral neuromodulation system for overactive bladder and faecal incontinence:** • Axonics is currently the only **rechargeable** system and is designed to need less frequent surgical replacement than current non-rechargeable systems. • It is an **alternative** to non-rechargeable sacral neuromodulation devices for people with urinary or faecal dysfunction, who would be offered sacral neuromodulation in line with current NICE guidance. • The **evidence** summarised in the briefing is from 1 multicentre, post-marketing study in 51 adults with overactive bladder and 1 case series involving 5 people with faecal incontinence, which indicates that Axonics may provide effective sacral neuromodulation therapy, and that most people were satisfied with rechargeable therapy. It was not compared with any other treatment. • **Key uncertainty** around the technology is that the available evidence is *limited in quantity and quality*, especially for use in faecal incontinence. Well-designed, comparative studies with larger numbers of patients and longer follow-up would be helpful to confirm equivalence to standard care. • The **cost** of the Axonics sacral neuromodulation system is £475 for the trial phase, £9,210 for a permanent implant and £6,500 for a replacement implant (all excluding VAT).			*Noted and supported by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		• The **resource impact** would be similar for initial implantation but, if Axonics is shown to need replacing less often than current systems, there could be less resource use via fewer procedures and associated complications. There is no relevant published evidence to support this. The TAG noted **NICE MIB 164 (December 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** until a local business application for its use is supported for this technology.			
Jan 2019	**Medtech innovation briefings** **NICE MIB 165 (December 2018)**	**Cerebrotech Visor for detecting stroke:** • The **technology** uses bioimpedance measurements for early detection of stroke subtypes to allow appropriate management, including mechanical thrombectomy. • The **innovative aspects** are that it uses an established physiological measurement for a new indication, it's portable and can be used in pre-hospital settings. • The likely **place in therapy** is uncertain. It would most likely be used in a pre-hospital setting or in a hospital setting where immediate CT imaging is not available. • The **main points from the evidence** summarised in this briefing are from 1 US cohort including a total of 248 adult patients in hospital. They show that the Visor system may be more accurate than diagnostic scales in diagnosing patients with severe ischaemic stroke. • **Key uncertainties** re the evidence are that it is limited to a validation study, which was done in a setting with a different care pathway from the NHS. • The **cost** is £50,000 per unit (exclusive of VAT). • The **resource impact** would be a potentially substantial additional cost to standard care. Any test which allows earlier management thereby reducing stroke-related disability could save costs, but there is no evidence on the Visor system to determine this. The TAG noted **NICE MIB 165 (December 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** until a local business application for its use is supported for this technology.		*Noted and supported by the D&TC.*
Jan 2019	**Medtech innovation briefings** **NICE MIB 166 (December 2018)**	**Galaxy UNYCO for temporary stabilisation of lower limb fractures:** • The **technology** is a single-use device used for temporary stabilisation of lower limb fractures of the femur, tibia, ankle and foot. • The **innovative aspects** are that it is claimed to be less invasive than other external fixation devices and is designed to reduce procedure time and the risk of deep bone infection. • The intended **place in therapy** would be in place of current external fixation devices for people with complex lower limb fractures needing temporary stabilisation. Use in current NHS			*Noted and supported by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		clinical practice is likely to be rare. • The **main points from the evidence** summarised in this briefing are from 5 studies (including a total of 13 adults) in a hospital setting (in France, Germany, Italy and Switzerland), 4 case studies and 1 observational study, only 1 of which has been published in a peer-reviewed journal. They suggest that Galaxy UNYCO can provide effective temporary fixation for tibial and ankle fractures. • **Key uncertainties** around the low quantity of evidence are that there is no direct comparative evidence to determine if patient outcomes would be different to those having other forms of fixation, such as bicortical fixation. • The **cost** is £1,600 to £2,000 per unit. The cost of standard external fixation (reusable) is about £2,400. • The **resource impact** would be an increase in costs compared with standard care. The TAG noted **NICE MIB 166 (December 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** until a local business application for use of this technology is supported.		
NICE Guidance: NHS England Commissioning Responsibility					
Jan 2019	**NICE TA 545 (November 2018)** Recommended by NICE as an option, only if the company provides gemtuzumab ozogamicin according to the commercial arrangement.	Gemtuzumab ozogamicin (*Mylotarg*®) (with daunorubicin and cytarabine)	For untreated de novo CD33-positive acute myeloid leukaemia, except acute promyelocytic leukaemia, in people 15 years and over, only if: • they start induction therapy when either the cytogenetic test confirms that the disease has favourable, intermediate or unknown cytogenetics (that is, because the test was unsuccessful) or when their cytogenetic test results are not yet available *and* • they start consolidation therapy when their cytogenetic test confirms that the disease has favourable, intermediate	The TAG noted **NICE TA 545 (November 2018)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
			or unknown cytogenetics (because the test was unsuccessful)		
Jan 2019	**NICE TA 546 (November 2018)** **Not recommended by NICE**	Padeliporfin (*Tookad*®)	For untreated localised (unilateral, low-risk) prostate cancer	The TAG noted **NICE TA 546 (November 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	*Noted by the D&TC*
Jan 2019	**NICE TA 548 (December 2018)** (*Terminated appraisal*)	Decitabine (*Dacogen*®)	For untreated acute myeloid leukaemia. *NICE is **unable to make a recommendation** about the use of this treatment in the NHS because no evidence submission was received from Janssen, but will review this decision if the company decides to make a submission.*	The TAG noted **NICE TA 548 (December 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	*Noted by the D&TC*
Jan 2019	**NICE TA 550 (December 2018)** **Not recommended** by NICE	Vandetanib (*Caprelsa*®) *NB oral formulation*	For treating aggressive and symptomatic medullary thyroid cancer in adults with unresectable, locally advanced or metastatic disease	The TAG noted **NICE TA 550 (December 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	*Noted by the D&TC*
Jan 2019	**NICE TA 551 (December 2018)** Recommended by NICE as an option, only if the company provides it according to the commercial	Lenvatinib (*Lenvima*®) *NB oral formulation*	For untreated advanced, unresectable hepatocellular carcinoma in adults, only if: • they have Child–Pugh grade A liver impairment and an Eastern Cooperative Oncology Group (ECOG)	The TAG noted **NICE TA 551 (December 2018)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
	arrangement		performance status of 0 or 1		
Jan 2019	**NICE TA 552 (December 2018)** Recommended by NICE as an option, only if the company provides it according to the commercial arrangement	Liposomal cytarabine–daunorubicin (*Vyxeos*®)	For untreated therapy-related acute myeloid leukaemia or acute myeloid leukaemia with myelodysplasia-related changes in adults	The TAG noted **NICE TA 552 (December 2018)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*
Jan 2019	**NICE TA 553 (December 2018)** Recommended by NICE as an option for use within the Cancer Drugs Fund, only if the conditions in the managed access agreement are followed	Pembrolizumab (*Keytruda*®)	For adjuvant treatment of resected melanoma with high risk of recurrence - stage III melanoma with lymph node involvement in adults who have had complete resection	The TAG noted **NICE TA 553 (December 2018)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*
Jan 2019	**NICE TA 554 (December 2018)** Recommended by NICE as an option for use within the Cancer Drugs Fund, only if the conditions in the managed access agreement are followed	Tisagenlecleucel (*Kymriah*®)	For treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years	The TAG noted **NICE TA 554 (December 2018)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*
Mar 2019	**NICE NG 118 (January 2019)**	Renal and ureteric stones: assessment and management	Includes recommendations on: • diagnostic imaging • managing pain	The TAG noted **NICE NG 118 (January 2019)**	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
	This guideline aims to improve the detection, clearance and prevention of stones, so reducing pain and anxiety, and improving quality of life.		• medical expulsive therapy • surgical treatments, including shockwave lithotripsy • Stenting before and after treatment • metabolic testing • preventing recurrence, including dietary and lifestyle advice, potassium citrate and thiazides.		
Mar 2019	**NICE NG 119 (January 2019)** This guideline aims to improve health and wellbeing, promote access to services and support participation and independent living.	Cerebral palsy in adults	Includes recommendations on: • access to services and ongoing review • support with communication, vocational skills and independent living, electronic assistive technology and physical activity • managing spasticity and dystonia • assessing and monitoring bone and joint disorders, mental health problems, difficulties with eating and nutrition, respiratory disorders and pain ***Regarding Drug therapy see:** **1.3.9** *Do not offer diazepam for spasticity in adults with cerebral palsy, except in an acute situation when spasticity is causing severe pain or anxiety.* **1.3.10** *Do not rapidly withdraw muscle relaxant drugs, particularly if adults with cerebral palsy have taken them for more than 2 months or at a high dosage. Reduce the dosage gradually to avoid withdrawal symptoms.* **1.3.20** *Do not prescribe levodopa to manage dystonia in adults with cerebral palsy, except in the rare situation when it is used as a therapeutic trial to identify dopa-responsive dystonia.* **1.3.21** *Do not rapidly withdraw enteral drugs for treating dystonia, particularly if adults with cerebral palsy have taken them for more than 2 months or at a high dosage. Reduce the dosage gradually*		*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
			to avoid withdrawal symptoms. The TAG noted **NICE NG 119 (January 2019)** and acknowledged the above *Do Not Do's"*		
Mar 2019	**NICE NG 120 February 2019)**	Cough (acute): antimicrobial prescribing This guideline sets out an antimicrobial prescribing strategy for acute cough associated with an upper respiratory tract infection or acute bronchitis in adults, young people and children. It aims to limit antibiotic use and reduce antibiotic resistance.	Includes recommendations on: • treatment • reassessment • referral and seeking specialist advice • self-care • choice of antibiotic 2-page visual summary of the recommendations, including tables to support prescribing decisions, also available.	The TAG was advised that all local CCGs have recently met national targets for reducing Items/STARPUs The TAG otherwise noted **NICE NG 120 February 2019).**	*Noted by the D&TC*
Mar 2019	**Medtech innovation briefings** **NICE MIB 169 (January 2019)**	**RT300 for spinal cord injury rehabilitation** • **RT300** is a functional electrical stimulation (FES) integrated cycling system. It is used to start muscle contraction to stimulate trunk and limb muscles in people with spinal cord injury. • It combines FES with a cycle ergometer, allowing stimulation of muscles in the trunk and arms or legs during a cycling motion as part of rehabilitation or physical activity for people with spinal cord injury. The combined motor and electrical stimulation system adjusts resistance and speed to make sure stimulation is safe for optimal treatment. The system links to a database to store and monitor performance data. • The intended **place in therapy** would be as well as standard rehabilitation care for people with spinal cord injuries. This would start in specialist spinal injuries units but can be given in any setting. • The **main points from the evidence** in the briefing are from 6 studies (3 randomised trials and 3 observational studies), including a total of 103 patients (43 adults and 60 children) in the US and Canada. Limited evidence shows that using RT300 may be associated with an improvement in quality of life and an increase in muscle volume compared with passive cycling systems or pre-treatment baseline. • **Key uncertainties** around the evidence or technology are that the study results may not be generalisable to the NHS. The studies were small and the comparative studies used a passive			*The D&TC was advised that the CCGs' Clinical Policy Development Group may have future involvement in reviewing the use of such devices.* *Otherwise noted and supported by the D&TC.* *Not recommended for commissioning, pending the submission of a local business application which is supported for commissioning by the CCGs.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
		cycling system from the same manufacturer. • The **cost** of RT300 ranges from £14,995 to £21,995 per unit with 6-channel stimulations (exclusive of VAT) plus an annual service charge of £495. An extra 6-channel stimulation unit costs £6,995. • The **resource impact** is unclear because of a lack of evidence and uncertainty in the standard care pathway and which people may benefit. The TAG noted **NICE MIB 169 (January 2019)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** until a local business application for its use is supported for this technology.			
Mar 2019	**NICE TA 555 (January 2019)** Regorafenib (*Stivarga*®) Recommended by NICE as an option, only if the company provides regorafenib (*Stivarga*®) according to the commercial arrangement	For treating advanced unresectable hepatocellular carcinoma in adults who have had sorafenib, only if: • they have Child–Pugh grade A liver impairment and an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1	The TAG noted **NICE TA 555 (January 2019)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*
Mar 2019	**NICE TA 556 (January 2019)** Darvadstrocel (*Alofisel*®) **Not recommended by NICE**	For treating complex perianal fistulas in adults with non-active or mildly active luminal Crohn's disease	The TAG noted **NICE TA 556 (January 2019)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	*Noted by the D&TC*
Mar 2019	**NICE TA 557 (January 2019)** Pembrolizumab (*Keytruda*®) Recommended by NICE as an option for use within the Cancer Drugs Fund, only if the company provides pembrolizumab according to the managed access agreement	For untreated, metastatic, non-squamous non-small-cell lung cancer (NSCLC) in adults whose tumours have no epidermal growth factor receptor (EGFR)- or anaplastic lymphoma kinase (ALK)-positive mutations, only if: • pembrolizumab is stopped	The TAG noted **NICE TA 557 (January 2019)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
			at 2 years of uninterrupted treatment or earlier if disease progresses		
Mar 2019	**NICE TA 558 (January 2019)** Nivolumab (*Opdivo*®) Recommended by NICE only if the conditions in the managed access agreement are followed		For the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease	The TAG noted **NICE TA 558 (January 2019)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*
Mar 2019	**NICE TA 559 (January 2019)** Axicabtagene ciloleucel (*Yescarta*®) Recommended by NICE as an option, for use within the Cancer Drugs Fund, only if the conditions in the managed access agreement are followed		For treating relapsed or refractory diffuse large B-cell lymphoma or primary mediastinal large B-cell lymphoma in adults after 2 or more systemic therapies	The TAG noted **NICE TA 559 (January 2019)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*
Mar 2019	**NICE TA 560 (February 2019)** Axicabtagene ciloleucel (*Yescarta*®) (*terminated appraisal*) NICE is unable to make a recommendation about the use of this treatment in the NHS because no evidence submission was received from Roche; NICE will review this decision if the company decides to make a submission. Bevacizumab (*Avastin*®) with carboplatin, gemcitabine and paclitaxel		For treating the first recurrence of platinum-sensitive advanced ovarian cancer	The TAG noted **NICE TA 560 (February 2019)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	*Noted by the D&TC*
Mar 2019	**NICE TA 561 (February 2019)** Venetoclax (*Venclyxto*®) with rituximab Recommended by NICE as an option, only if the company provides it according to the commercial arrangement.		For treating chronic lymphocytic leukaemia in adults: • who have had at least 1 previous therapy	The TAG noted **NICE TA 561 (February 2019)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	D&TC Commissioning Recommendation
Mar 2019	**NICE TA 562 (February 2019)** Encorafenib (*Braftovi*®) with binimetinib (*Mektovi*®) Recommended by NICE as an option, only if the company provides encorafenib and binimetinib according to the commercial arrangements.		For treating unresectable or metastatic BRAF V600 mutation-positive melanoma in adults	The TAG noted **NICE TA 562 (February 2019)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*
Mar 2019	**NICE TA 563 (February 2019)** Abemaciclib (*Verzenios*®) Recommended by NICE as an option, only if the company provides it according to the commercial arrangement.		For treating locally advanced or metastatic, hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer as first endocrine-based therapy in adults.	The TAG noted **NICE TA 563 (February 2019)** and recommended a traffic light classification of Red (Hospital / Specialist use only)	*Noted by the D&TC*
Mar 2019	**NICE TA 564 (February 2019)** (*terminated appraisal*) Dabrafenib (*Tafinlar*®) with trametinib (*Mekinist*®) NICE is unable to make a recommendation about the use of this treatment in the NHS because no evidence submission was received from Novartis; NICE will review this decision if the company decides to make a submission.		For treating advanced metastatic BRAF V600E mutation-positive non-small-cell lung cancer	The TAG noted **NICE TA 564 (February 2019)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	*Noted by the D&TC*

1. TAG Recommendations 2018/19

C. *Interface Issues & Miscellaneous Guidance (including work by the Prescribing Reference Group)*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
May 2018	**Shared Care Agreement: *Review*** Update required regarding giving varicella vaccination prior to starting methotrexate ***Link*** to current version	Methotrexate for the treatment of Rheumatoid Arthritis, Juvenile Arthritis, Connective Tissue Disease, Felty's Syndrome, Psoriasis and Crohn's Disease	**March 2018:** The NNUH Rheumatology Service identified the need to protect prospective methotrexate patients who have no immunity against chickenpox. The TAG was advised that patients already on methotrexate would not acquire effective immunity from live vaccines such as varicella. The hospital rheumatology service does not have staff trained to administer vaccinations and therefore requests that this is undertaken by the GP practice, prior to methotrexate being started. Although supportive of the clinical need in principle, the TAG was uncertain whether GPs would be able to provide and administer the vaccine for this indication if such use was not covered by the Green Book, and recommended that advice is sought from PHE on this matter before agreeing to amend the document. **May 2018:** The TAG was advised that PHE Immunisation Lead had no strong view on how this should be managed and did not object to GPs prescribing the varicella vaccine where clinically indicated. Recent are very small. The vaccine is significantly cheaper than the immune globulin (~£50 per dose verses £2000). The TAG therefore recommended that an addition be made to the shared care agreement to state that GPs could be asked to vaccinate patients before commencing on methotrexate, if identified by the Rheumatology service.		**May 2018:** *The D&TC noted and supported the TAG's recommendations.*
May 2018	**Therapeutics Advisory Group:** **Summary of Guidance and Clinical Practice on Antiplatelets – *Update*** Updated to incorporate NICE	Various	Various	The TAG noted and supported the updated summary.	*Noted by the D&TC.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
	TA420 (Dec16)				
May 2018	**Prescribing Reference Group:** *Xultophy*® (*100 units/ml insulin degludec + 3.6 mg/mL liraglutide solution for injection in a pre-filled pen*)		For diabetes mellitus	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification to this treatment on the basis that combination products are not generally supported and also that this is an expensive product compared with other treatment options: The TAG agreed to support the PRG's recommendation.	*Noted and supported by the D&TC as* **Double Red (Not recommended for routine use)**. *Not recommended for commissioning.*
May 2018	**Prescribing Reference Group:** *Onexila® XL* prolonged-release tablets – various strengths (Oxycodone once daily modified-release formulation)		Analgesia – opioid appropriate	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification to this treatment on the basis of a risk of inappropriate prescribing if confused with 12 hour BD MR preps i.e. Longtec, Oxycontin. Prescribing by brand to avoid confusion between different formulations is also recommended. The TAG agreed to support the PRG's recommendation.	*Noted and supported by the D&TC as* **Double Red (Not recommended for routine use)** *- Not recommended for commissioning*
May 2018	**Prescribing Reference Group:** **Prescribing Advice**		(Updated) Advice on drug interactions with simvastatin and atorvastatin - *Link*	The TAG noted and agreed to support the PRG's updated prescribing guidance document.	*Noted and supported by the D&TC.*
May 2018	**Prescribing Reference Group:** **Prescribing Advice**		Appropriate prescribing for phenylketonuria (PKU) - *Link*	The TAG noted and agreed to support the PRG's updated prescribing guidance document.	*Noted and supported by the D&TC.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
May 2018	**Prescribing Reference Group:** **Prescribing Resource**		COPD – Inhaler types and devices - *Link*	The TAG noted the prescribing information resource.	*Noted and supported by the D&TC.*
May 2018	**Prescribing Reference Group:** **Primary Care Guideline**		COPD (Norfolk CCGs) - *Link*	The TAG noted the primary care COPD guideline	*Noted and supported by the D&TC.*
May 2018	**Prescribing Reference Group:** **Primary Care Guideline**		Diagnosis and Management of Vitamin D Deficiency in Adults in Primary Care - *Link*	The TAG noted the primary care guideline	*Noted and supported by the D&TC.*
May 2018	**Prescribing Reference Group:** **Formulary updates**		**Gastrointestinal** **Asthma** **COPD**	The TAG noted the updated formularies	*Noted and supported by the D&TC.*
May 2018	**Prescribing Reference Group:**	***Key Message Bulletins*** – *Updates*	• **Bulletin 34: Antimicrobial prescribing guidance to reduce risk of *C. difficile*** • **Bulletin 18: Inhaler Spacer Devices**	Noted and supported by the TAG	*Noted by the D&TC.*
July 2018	**Prescribing Reference Group:** **Prescribing Advice**	Prescribing Resources for Primary Care regarding use of opioids: Key Message Bulletins / Prescribing Guidance / Patient contract / Pain Diary / Patient Information Leaflet		The TAG noted and agreed to support these new resources for publication in Knowledge Anglia and promotion to local prescribers.	*Noted and supported by the D&TC*
July 2018	**Prescribing Reference Group (PRG):**	Dexibuprofen (*Seractil®*)	Analgesia / musculoskeletal pain	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification to this treatment due to a lack of evidence of additional benefit over standard care with ibuprofen to justify its additional cost. The TAG agreed to support the PRG's recommendation.	*Noted and supported by the D&TC as* **Double Red (Not recommended for routine use)** *Not recommended for commissioning*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
July 2018	**Prescribing Reference Group (PRG):**	Tadalafil: 10mg & 20mg strength tablets	As required (PRN) use in erectile dysfunction	PRG recommendation that the TAG considers applying a **Double Green (Suitable for GPs to initiate and prescribe)** classification to these products for prn use in erectile dysfunction as per SLS criteria, and that they should be substituted in the Urology Formulary in place of vardenafil (max 4 doses per month to be supplied on the NHS). The TAG agreed to support the PRG's recommendation.	*Noted and supported by the D&TC as* **Double Green (Suitable for GPs to initiate and prescribe)** *for prn use in erectile dysfunction as per SLS criteria.* *Also supported to be substituted in the Urology Formulary in place of vardenafil (max 4 doses per month to be supplied on the NHS).*
Sept 2018	**Prescribing Reference Group:**	Rupatadine 10mg tablets	H1 receptor antagonist (is also a potent platelet-activating factor (PAF) inhibitor)	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification to this treatment due to a lack of evidence of sufficient additional benefit over standard care with other antihistamines to justify its additional cost. The TAG agreed to support the PRG's recommendation.	*Noted and supported by the D&TC as* **Double Red (Not recommended for routine use)** *Not recommended for commissioning*
Sept 2018	**Prescribing Reference Group:**	Capsaicin patches - *Qutenza®*	For peripheral neuropathic pain	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification for this product as an interim measure, in the absence of a formal application for use from local pain services, to ensure that GPs are not approached to prescribe it. The TAG noted that there are a small number of patients who benefit from this treatment and	*Noted and supported by the D&TC as* Red (Hospital use only)

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
				recommended a traffic light classification of Red (Hospital / Specialist use only) to meet this need.	
Sept 2018	**Prescribing Reference Group:** *To support the local Nutrition Formulary*	Vitamin B Co / Co Strong tablets	For time-limited use (10 days) only in re-feeding syndrome	PRG recommendation that the TAG supports restricted use only of Vitamin B Co / Co strong tablets, by specialists, for 10 days only in re-feeding syndrome and considers applying a Red (Hospital / Specialist use only) classification for restricted use only. No longer supported for prescribing in primary care. The TAG agreed to support the PRG's recommendation.	*Noted and supported by the D&TC.* *Also incorporated in local guidance regarding self-care and over the counter purchasing of items.*
Sept 2018	**Prescribing Reference Group:** *To support a revision of local Allergies Formulary* Currently classified as **Double Red (Not recommended for routine use)** (Nov 2015)	*Dymista®* Nasal Spray (fluticasone propionate / azelastine HCl)	For moderate to severe seasonal and perennial rhinitis, if monotherapy with antihistamine or corticosteroid is inadequate	PRG recommendation that the TAG supports a re-classification for this product to **Double Green (Suitable for GPs to initiate and prescribe)** for use only where all other options have been exhausted, since it is now cheaper than prescribing the components separately. The TAG agreed to support the PRG's recommendation.	*The D&TC considered the PRG and TAG's recommendations but felt that Dymista® was still a relatively expensive treatment compared with other more cost effective alternatives.* *The D&TC did not support revising the* **Double Red** *classification and recommended that the item be returned to the PRG.*
Nov 2018	**Prescribing Reference Group:** Currently **Double Red (Not recommended for**	***Feraccru®*** **capsules** (containing 231.5mg ferric maltol - equivalent to 30mg ferrous iron)	Licensed indication recently extended to treatment of iron deficiency in adults.	PRG recommendation that the TAG considers reviewing and updating the **Double Red (Not recommended for routine use)** classification to this treatment in	*Noted and supported by the D&TC as* **Double Red (Not recommended for routine use)**

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
	routine use) for treatment of iron deficiency anaemia in IBD (i.e. previous licensed indication) (Nov 2017)			line with its revised licensed indication. The TAG supported the PRG's recommendation.	*Not recommended for commissioning*
Nov 2018	**Prescribing Reference Group:**	**Pentosan polysulfate sodium 100mg capsules - Elmiron®:**	For treatment of bladder pain syndrome / Interstitial Cystitis characterized by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification for this product as an interim measure, until a formal application for use is submitted via usual processes. The TAG supported the PRG's recommendation.	*Noted and supported by the D&TC as* **Double Red (Not recommended for routine use)** *Not recommended for commissioning*
Nov 2018	**Prescribing Reference Group:**	***ActiPatch*® -** a pulsed electromagnetic stimulator product marketed	For relief of musculoskeletal pain	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification for this product as an interim measure, until a formal application for use is submitted via usual processes. The TAG supported the PRG's recommendation.	*Noted and supported by the D&TC as* **Double Red (Not recommended for routine use)** *Not recommended for commissioning*
Nov 2018	**Prescribing Reference Group:** **Primary Care Formularies:–** *updated and published*	Allergies Cardiovascular Diabetes / Diabetes Non Specialist Treatment Pathway Emollient Primary Care Pathway Skin		Noted and supported by the TAG.	*Noted and supported by the D&TC*
Jan 2019	**Therapeutics Advisory Group:**	**Review of Shared Care Prescribing Agreement:**	**Mycophenolate Mofetil for the treatment of autoimmune conditions** ***Link*** to current version (last	The TAG supported the changes to the wording in the document to clarify that use for Interstitial Lung Disease is not limited to patients	*Noted and supported by the D&TC.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
			considered in July 2017).	under Papworth's care, and also agreed that the document could be re-dated for next review in January 2021.	
Jan 2019	**Therapeutics Advisory Group:**	**Review of Shared Care Prescribing Agreement:**	**Nebulised Colistin for Bronchiectasis (Non-Cystic Fibrosis)** ***Link*** to current version (last considered in Nov 2015).	The TAG supported continued use of the revised document in the interim but also recommended that local specialists be consulted regarding the appropriateness of long term use of antibiotics in view of the risk of antimicrobial resistance post the publication of **NICE NG 117 (December 2018),** and its related Evidence review.	*The D&TC recommended that the issue of long-term use of nebulised colistin in patients with non-CF bronchiectasis is also referred for consideration by the Antimicrobial Steering Group, which is next due to meet in mid February 2019.* *Otherwise noted and supported by the D&TC.*
Jan 2019	**Therapeutics Advisory Group:**	**Review of Shared Care Prescribing Agreement:**	**Denosumab (*Prolia*®) for treatment of osteoporosis in post-menopausal women at increased risk of fractures** ***Link*** to current version (last considered in January 2017).	The TAG supported continued use of the revised document.	*Noted and supported by the D&TC.*
Jan 2019	**Therapeutics Advisory Group:**	**Review of Shared Care Prescribing Agreement:**	**Sacubitril valsartan (*Entresto*®) for treating symptomatic chronic heart failure with reduced ejection fraction** ***Link*** to current version (last considered in September 2016).	The TAG supported continued use of the revised document.	*Noted and supported by the D&TC.*
Jan 2019	**Therapeutics Advisory Group:**	**Review of Shared Care Prescribing Agreement:**	**Triptorelin for the treatment of precocious puberty, menorrhagia and**	The TAG supported the changes to the wording in the document, and continued use of the shared	*Noted and supported by the D&TC.*

<table>
<tr><th>Date</th><th>Reason for review by the TAG</th><th>Drug</th><th>Indication for Use</th><th>TAG Recommendation</th><th>D&TCG Commissioning Decision</th></tr>
<tr><td></td><td></td><td></td><td>dysmenorrhoea in children
Link to current version (last considered in January 2017).</td><td>care agreement.</td><td></td></tr>
<tr><td>Jan 2019</td><td>Prescribing Reference Group:
EoE PAC Guidance Statement:
Commissioning recommendations for specified Medical devices (Aug18)
Items not previously classified locally</td><td colspan="3"><table>
<tr><th>Device:</th><th>PAC view:</th><th>PRG view:</th></tr>
<tr><td>Vaginal dilators or trainers,
e.g. Femmax®, Ameille Care® and Ameille Comfort®:</td><td>Recommended for women following vaginal reconstruction surgery or following pelvic radiotherapy when recommended by an appropriate Secondary Care Specialist.</td><td>The PAC’s view was supported in principle but the TAG is recommended to classify as Double Red (Not recommended for routine use), until a formal application for their use is submitted to the PRG from local stakeholders.</td></tr>
<tr><td>Jaw rehabilitation devices,
e.g. Therabite®</td><td>Recommended for patients following head and neck radiotherapy or head and neck surgery when recommended by an appropriate Secondary Care Specialist.</td><td>The PAC’s view was supported in principle but the TAG is recommended to classify as Double Red (Not recommended for routine use), until a formal application for their use is submitted to the PRG from local stakeholders.</td></tr>
</table></td><td>The TAG considered the PRG’s recommendation but agreed that in view of these devices already being used and issued by the hospital, a more pragmatic recommendation is Red (Hospital use only).

The TAG considered the PRG’s recommendation but agreed that in view of these devices already being used and issued by the hospital for a specific patient group, a more pragmatic recommendation is Red (Hospital use only).</td><td>Noted and supported by the D&TC.

Noted and supported by the D&TC.</td></tr>
<tr><td>Jan 2019</td><td>Prescribing Reference Group:</td><td>NSAID plasters:
e.g. Flector Tissugel medicated plaster 140mg (diclofenac)
Voltarol 140mg medicated plaster (diclofenac)
Nurofen Joint & Muscular Pain Relief medicated plaster 200mg (ibuprofen)</td><td>The PRG requests that the TAG considers applying a Double Red (Not recommended for routine use) classification for these products since all, apart from Flector Tissugel medicated plasters, are available over the counter and may be purchased for short term use for sprains and strains as part of self care.
Systemic diclofenac is not supported due to increased risk</td><td>The TAG supported the PRG’s recommendation and agreed that the traffic light classification for NSAID plasters should be Double Red (Not recommended for routine use).</td><td>Noted and supported by the D&TC as Double Red (Not recommended for routine use)
- Not recommended for commissioning</td></tr>
</table>

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
			of adverse effects. NSAID plasters are not suitable for long term use and are more costly than standard care.		
Jan 2019	**Prescribing Reference Group:**	*Jorveza*® 1mg orodispersible tablets: SPC (Licensed alternative to budesonide "slurry")	For treatment of eosinophilic oesophagitis PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification for this product as an interim measure, until a formal application for its use is submitted via usual processes.	The TAG supported the PRG's recommendation.	*Noted and supported by the D&TC as* **Double Red (Not recommended for routine use)** *pending the submission of a business application.*
Jan 2019	**Prescribing Reference Group:** **Primary Care Formularies:–** *updated and published*	• Respiratory Formulary - Asthma • Respiratory Formulary – COPD • Antibiotics Formulary and Antibiotic Quick Reference Guide		Noted and supported by the TAG.	*Noted and supported by the D&TC.*
Jan 2019	***"Key Message"*** **Bulletins - *Updates***	• **Summary table: Asthma Inhaler types and devices** • **Summary table: COPD Inhaler types and devices** • **Bulletin 18: Inhaler Spacer Devices** • **Summary table: Blood Glucose Meters and Test Strip Cost Comparison**		Noted and supported by the TAG.	*Noted and supported by the D&TC.*
Jan 2019	**Primary Care Guidance: - *For information***	• **Asthma Primary Care Guideline – *New*** Guideline produced by the Norfolk & Waveney RightCare Respiratory Group based on the PCRS – UK Consensus of current national guidelines: BTS/SIGN Sept 2016 and NICE NG80 Nov 2017		Noted and supported by the TAG.	*Noted and supported by the D&TC.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
		• **Management of Acute Asthma in Primary Care** - Produced by the Norfolk & Waveney RightCare Respiratory Group based on BTS/SIGN Sept 2016. ***New*** summary of national guidance to support primary care clinicians.			
March 2019	**Therapeutics Advisory Group: Interface Issue:** Recent (un-commissioned) use by local cardiology services noted, leading to concerns about increased risk of bleeding in patients	Combined use of anticoagulant and antiplatelet therapies in cardiology	**March 2018:** An evidence review and related EU guidelines submitted by the NNUH DTMMC were considered by TAG but no agreement was reached. **July 2018:** An independent evidence review was received from EAMIS. NNUH cardiologist, Dr Alisdair Ryding, attended the TAG to talk to his proposals. A Task & Finish group to be set up to finalise proposals for the CCGs to consider commissioning. **September 2018:** No progress to date **November 2018:** The Task & Finish Group had met during October 2018 and had drawn up a document laying out the proposed drug combinations for specified clinical indications depending on individual patient bleeding risk, with durations of use and likely patient numbers for one but not all the local acute Trusts. Prospective drug costs would be calculated once the patient data was provided and the document would be completed and submitted to the D&TC. **January 2019:** in the absence of real data from Primary Care, figures extrapolated from local Trust data will be submitted to the D&TC. The TAG to see the final output from these discussions in March 2019. **March 2019:** The TAG was advised that because the February 2019 D&TC meeting was no quorate, a commissioning decision would not be taken until the March 2019 D&TC meeting. It was also noted that for this patient group, the cardiologists would prefer to use a licensed, evidence-based DOAC such as rivaroxaban.		*The D&TC was advised that the data would be submitted to the February 2019 meeting.* **March 2019:** *The D&TC noted the report and recommended that a clinical protocol be produced to support clinicians who are managing the on-going care of patients who taking these drug combinations as recommended by cardiology specialists.*
Mar 2019	**Therapeutics Advisory Group:** **NSFT request for review of traffic light classification:**	Risperidone for short term management of severely aggressive behaviour in young people with a conduct disorder who have problems with explosive	**May 2013:** The TAG noted NICE CG 158 and recommended Shared Care to support Primary Care prescribing of risperidone where treatment is required beyond 6 weeks' use. The D&TCG commissioned risperidone as Red (Hospital / Specialist use only) for the specified indication, pending an approved Shared Care Agreement.		

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<tr><th>Date</th><th>Reason for review by the TAG</th><th>Drug</th><th>Indication for Use</th><th>TAG Recommendation</th><th>D&TCG Commissioning Decision</th></tr>
<tr><td></td><td>– as per NICE CG 158 (March 2013) - Antisocial behaviour and conduct disorder in children and young people: recognition, intervention and management</td><td>anger and severe emotional dysregulation and who have not responded to psychosocial interventions</td><td colspan="2">July 2018: Following the NSFT's request that the traffic light classification should be in line with other antipsychotic treatments (i.e. Green (GP prescribing following specialist initiation / recommendation)), a document detailing different treatments and indications for use of risperidone in children and young people to be produced for the TAG to consider.
CCG lead mental health commissioner to be contacted regarding who commissions the various services for children and adolescents.
September 2018: No progress to date.
November 2018: Update on progress?
Information on use of Risperidone within the NSFT CAMHS during 2017-18 in 7 individual cases with specialist neurodevelopmental disorder patient group (out of around 100 children and young people who have received medication overall):
<table>
<tr><th>Diagnosis reason</th><th>Reason</th><th>Duration</th></tr>
<tr><td>Mixed neurodevelopmental, so ASD, ADHD, anxiety</td><td>Aggression mostly</td><td>Long-terr</td></tr>
<tr><td>ADHD, ASD and Tourette's</td><td>Tics and settling</td><td>Long-terr</td></tr>
<tr><td>ADHD, ASD and aggression</td><td>Aggression and settling</td><td>Long-terr</td></tr>
<tr><td>ADHD, some ASD, proper psychosis last year ?2nd spiked drink</td><td>Psychosis, settling</td><td>Medium, stopped</td></tr>
<tr><td>ASD, psychotic features at start of viral illness as it turns out</td><td>Short-term management</td><td>Short, stc</td></tr>
<tr><td>ADHD, ASD</td><td>Aggression and settling</td><td>Long-terr</td></tr>
<tr><td>ADHD, ASD, aggressive outbursts evening</td><td>Settling and aggression</td><td>Long-terr</td></tr>
</table>
The TAG noted the data and acknowledged the relatively infrequent use of risperidone for these patients. The TAG debated issues regarding ease of access to treatment by patients and their carers, the level of on-going monitoring recommended by NICE CG 158 where treatment is continued or where there are dosage changes, and whether GPs could provide that level of care. Practical issues regarding possible use of FP10HP forms were also discussed.
The specialist service to be asked to consider these issues and return the item to the TAG with more detailed proposals for further</td><td></td></tr>
</table>

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
			consideration. **January 2019:** No update on progress was available from the NSFT. CCG members advised the TAG on the need to liaise with the local Children's commissioner regarding the treatment pathway and prescribing responsibility, and also with contract manager regarding the possibility of adding a clause to clarify interface prescribing issues. **March 2019:** The TAG noted that the issues of concern under this item would be managed as part of wider STP-led pathway review work, and therefore agreed to remove it from the TAG's agenda until commissioning arrangements for this patient group were clarified. No change to the current traffic light classification were agreed.		*Noted by the D&TC.*
Mar 2019	**Therapeutics Advisory Group: Interface Issue:** NICE TA 217 (update June 2018) Donepezil, galantamine, rivastigmine, memantine for Alzheimer's disease - partially updated by NG97 on dementia (replaces NICE TA111). NICE NG 97 (June 218): Dementia: *assessment, management and support for people living with dementia and their carers* **Drug recommendations:**	Donepezil, galantamine, rivastigmine, memantine, for Dementia / Alzheimer's Disease *Links* to current shared care agreements for AChEIs and memantine	**September 2018:** The TAG was asked to reconsider in more detail the updated and new recommendations in the above guidance that will impact on current commissioned arrangements for prescribing and monitoring drug treatments for patients with dementia. The TAG noted that in Suffolk dementia drugs have been classified as "Green" since 2015. ***Suffolk GP Prescribing Guidance*** (*same guidance used across both CCGs*) to be shared and a Task & Finish Group set up to take this item forward – led by EJ. *EJ has since proposed that this work is discussed by the STP Dementia Group*. **November 2018:** The TAG requested that a proposed treatment pathway be submitted for consideration to enable to group to consider revising the current position regarding drug treatment for Dementia / Alzheimer's Disease. **January 2019:** No update on progress was available from the NSFT. **March 2019:** The TAG noted that this item was be managed as part of wider STP-led pathway review work, and therefore agreed to remove it from the TAG's agenda until commissioning arrangements for this patient group were clarified. No changes to the current traffic light classifications were agreed.		**January 2019:** *The D&TC acknowledged the need for investment in primary care to support GPs in assessing and managing their patients with dementia.* **March 2019:** *The D&TC noted the TAG's position and also discussed how to influence dementia specialists initiating patients on costly rivastigmine transdermal patches. To be raised at NSFT's DTC meeting, and with Mental Health commissioners.* *The D&TC also recommended that the TAG revisits to current recommendation that memantine is restricted to use as monotherapy only, in view of the*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
	NICE TA 217: *Link* & NG97: *Link*				*recommendations within to the 2018 NICE guidance which support adjunctive use with an AChEI.*
Mar 2019	**Therapeutics Advisory Group:** ***Review of* Shared Care Agreement:**	Nebulised Colistin	For Pseudomonas aeurginosa infection in Bronchiectasis (Non-Cystic Fibrosis) **January 2019:** The TAG supported continued use of the revised document in the interim but also recommended that local specialists be consulted regarding the appropriateness of long term use of antibiotics in view of the risk of antimicrobial resistance post the publication of **NICE NG 117 (December 2018)**, and its related Evidence review.	**January 2019:** In view of NICE NG 117 (December 2018), and its related Evidence review regarding the risk of antimicrobial resistance related to long term use of antimicrobials, TAG Trust representatives to confer with respiratory specialist / microbiologist colleagues regarding their views for return to the next meeting. **March 219:** The TAG considered feedback received from the QEH and the NNUH respiratory specialists which recommended on-going use of the Shared Care Agreement in adults and in children, and also in line with recently published BTS Guidance for Bronchiectasis in Adults, and until a consensus national view by respiratory specialists is available. The TAG also noted that whilst the BTS guidance relates to adults, the local shared care agreement covered use of nebulised colistin in both adults and children, and felt that more work was required on this matter. The TAG agreed that it is necessary to ensure that nebulised colistin is being used only for appropriate reasons.	**January 2019:** *The D&TC recommended that the issue of long-term use of nebulised colistin in patients with non-CF bronchiectasis is also referred for consideration by the Antimicrobial Steering Group, which is next due to meet in mid February 2019.* *Otherwise noted and supported by the D&TC.* **March 2019:** *The D&TC was advised that NG 117 had involved input from a respiratory specialist, contrary to what had been assumed by local specialists. The same evidence had been considered by NICE and the BTS, from which each review body had drawn different conclusions regarding the risks associated with long term use of antimicrobials. It was not thought that there was evidence that such use of nebulised colistin in bronchiectasis necessarily reduced admissions. The*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
				Since this issue is also likely to apply in other areas beyond the Norfolk and Waveney, the TAG recommended that the EoE PAC is requested to consider reviewing this issue.	*EoE PAC to be requested to consider reviewing this issue which would result in respiratory specialists being consulted with on any draft PAC recommendations. The local Antimicrobial Steering Group also to be requested to take a view on this matter.*
Mar 2019	**Therapeutics Advisory Group:** **Shared Care Agreements – *revisit*** ***Link*** to current SCA for Children and adolescents with ADHD (last considered in March 2017). ***Link*** to current SCA for atomoxetine for Children and adolescents with ADHD (last considered in March 2017). ***Link*** to current SCA for Adults with ADHD (last considered in May 2016).	• **Methylphenidate** • **Dexamfetamine** • **Lisdexamfetamine** • **Atomoxetine** **May 2018:** The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine and possibly to dexamfetamine and guanfacine.	**For treatment of Attention Deficit/Hyperactivity Disorder (ADHD)** • Review of local SCAs post NG 87 required • SN CCG has advised that an STP-wide review of the all-age NDD pathway is in progress, due for completion at the end of April19, which will include management of ADHD. • Reports of local specialists who are inconsistently supporting bioequivalence for use of cost-effective m-r methylphenidate products by switching patients back to *Concerta*®.	**March 2019:** The NSFT TAG representative had requested that the adult Shared Care Agreement be revisited by the TAG, but no comments had been submitted by local specialists. The agreements for adults and children are overdue for review. To be reviewed and returned to the ADHD specialists in NSFT and NCH&C for comment ahead on the next TAG meeting in May 2019. NSFT and NCH&C TAG representatives also to draw their specialist colleagues' attention to the London Medicines Information Service's review of the pharmacokinetic profiles of extended-release methylphenidate products to encourage clinicians and patients to support use of cost-effective products.	*The D&TC noted the TAG's recommendations.*
Mar	**Prescribing**	**Probiotics (e.g. *VSL#3;***	• The CCGs' Self Care policy	The TAG acknowledged the	*Noted and supported by*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
2019	**Reference Group:**	***Vivomixx*) for ileoanal pouchitis** These products were on the N&W DROP List and have been **Double Red (Not recommended for routine use)** for any indication since Nov15.	(October 2018) lists an exemption for use under ACBS criteria for maintenance of antibiotic induced remission of ileoanal pouchitis in adults. • From January 2019, these products have been removed from the Drug Tariff, and are therefore unable to be prescribed or reimbursed on the NHS. For acknowledgement by the TAG and recommendation for the CCGs' self-care policy to be amended in this regard.	update provided by the PRG and agreed that the traffic light classification of **Double Red (Not recommended for routine use)** was still appropriate and applied also to use for ileoanal pouchitis since the prescribing on the NHS is no longer possible. The CCGs' Self Care policy requires updating in this respect.	*the D&TC as* **Double Red (Not recommended for routine use)** *- Not recommended for commissioning* *The D&TC recommended that the Prescribing Reference Group be asked to revisit and revise the Self Care policy in this respect.*
Mar 2019	**Prescribing Reference Group:**	**Primary Care Formularies:–** *updated and published* • Formulary: Skin • Emollient Pathway		Noted and supported by the TAG.	*Noted and supported by the D&TC.*
Mar 2019	***"Key Message"* Bulletins - *Updates***	• Key Message Bulletin 37: Ondansetron • Key Message Bulletin 16: Quetiapine		Noted and supported by the TAG.	*Noted and supported by the D&TC.*
Mar 2019	**Primary Care Guidance: - *For information***	• COPD Rescue Packs: Quick Reference Guide – *NEW from the* Norfolk & Waveney Rightcare Respiratory Group • Suggested Guidance on Monitoring Drugs in Primary Care - ***Update***		Noted and supported by the TAG.	*Noted and supported by the D&TC*
Mar 2019	**Care Homes – Best Practice Guidance – *NEW*** and ***Updates***	• Care Home Best Practice Guidance No.32: Antibiotics - NEW • Care Home Best Practice Guidance No. 30: Lithium - NEW • Care Home Best Practice Guidance No. 29: Cellulitis - NEW • Care Home Best Practice Guidance No. 28: Anaphylactic reactions - emergency treatment advice - NEW • Care Home Best Practice Guidance No. 27: Influenza vaccine - NEW • Care Home Best Practice Guidance No. 26: Medicines		Noted and supported by the TAG.	*Noted and supported by the D&TC*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
		Reconciliation - UPDATE • Care Home Best Practice Guidance No. 20: COPD - UPDATED • Care Home Best Practice Guidance No. 5: Analgesic Patches - UPDATED • Care Home Best Practice Guidance No. 4: Crushing or opening medication			

1. TAG Recommendations 2018/19

D. *NHS East of England Priorities Advisory Committee (PAC)*

Since 2011 the TAG has considered output from the **East of England Priorities Advisory Committee (PAC)** for acknowledgement and ratification. One TAG member represents the Norfolk and Waveney area on the PAC, which is part of the PrescQIPP programme.

The TAG considered the following information from the PAC:

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
May 2018	**East of England Priorities Advisory Committee (PAC):** **PAC Guidance Statement:** January 2018 Insulin glargine 300 units/ml (*Toujeo*®) for Diabetes mellitus CCG-commissioning responsibility Currently commissioned in Norfolk and Waveney as Green (GP prescribable following specialist recommendation) for a specific group of adults with diabetes mellitus who are using Humulin R500 insulin who require greater than 200 units of insulin per day, with poor glycaemic control defined as having an HbA1c of greater than 75mmol/mol (March 2016)	The TAG considered the PAC's guidance which recommended against *routine use* in diabetes due to safety concerns with the use of high strength insulins. PAC-recommended criteria for restricted use in adults aged ≥18 years of age are: • Patients with significant hypoglycaemia, despite optimal adjustments of lifestyle (eliminating any contributory factors), diet (undertaken structured education, e.g. DAFNE), and basal insulin/multiple daily injections and who fulfil the criteria for insulin pump therapy. • "Chaotic patients" who may be at significant risk of diabetic ketoacidosis (DKA) or hyperosmolar hyperglycaemic state (HHS) if daily basal insulin is missed, despite optimal adjustments of lifestyle, and diet and optimising basal insulin/multiple daily injections. • Patients with psychological problems (e.g. eating disorders or patients with intermittent compliance issues with insulin injections), who are not supervised by a daily carer and do not qualify to receive district nurse injections of daily insulin glargine, and who may be at significant risk of DKA or HHS if daily basal insulin is missed. • Patients with a diagnosed allergy to either insulin detemir or insulin degludec. The PAC also recommended that:	The QEH has 80 patients who are either already on or who would now meet the PAC's criteria for using *Toujeo*®. **The PAC's guidance states that:** • Insulin glargine 300 units/ml is currently higher cost than biphasic insulin and some analogue basal insulins. Insulin glargine 100 units/ml is included in the PbR tariff. *Toujeo*® costs £291.20 per year based on 30 units per day. • Whilst insulin glargine 300 units/ml appears to be cheaper than *Lantus*® 100 units/ml, in the clinical trials a 10-18% increase in dose using *Toujeo*® was required compared to *Lantus*®, with the overall cost being similar (however the insulin glargine 100 units/ml biosimilar *Abasaglar*®, which costs £256.84 p.a. based on 30 units a day, would be cheaper). • The estimated activity costs for an uncontrolled diabetic, experiencing severe hypoglycaemic episodes which result in at least one hospital admission per month, is approximately £18,000 per year. *The D&TC noted that a higher than expected number of patients in West Norfolk had been identified by the QEH and queried whether the recommended criteria for use had been met.* *Although additional cost implications are not high,*	

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
		• Insulin glargine 300 units/ml (Toujeo®) could be considered for patients with severe insulin resistance requiring large daily doses of insulin (≥3units/kg/ day), where treatment is initiated by a Consultant Diabetologist ~~in a tertiary centre specialising in insulin resistance~~. • All patients should be managed by the initiating specialist team for a minimum of three months or until stable. Patients should be returned to their previous treatment if no improvement in overall disease control from baseline is demonstrated. The TAG agreed to accept the PAC's recommendations as stated above, in addition to the previously commissioned criteria for use, and to maintain the classification as Green (GP prescribable following specialist initiation) where the initial dose titration and monitoring is closely supervised by the initiating specialist for the first three months or until stable, as per the above-listed criteria for use.		*the D&TC was concerned that use outside of the recommended criteria would escalate if not strictly followed.* *The D&TC supported that PAC's criteria, with the amendments recommended by the TAG, with the proviso that local practitioners must adhere to them, that* ***the specialist will provide the first prescription supply****, and that use of Toujeo will be monitored.*	
May 2018	**East of England Priorities Advisory Committee (PAC):** **PAC Guidance Statement: *Update* v3** (January 2018) Insulin degludec (*Tresiba*®) for Diabetes mellitus CCG-commissioning responsibility Currently commissioned in Norfolk and Waveney as: **Double Red (Not recommended for routine use)** for routine use in Type 1 diabetes mellitus, and any use in Type 2 diabetes	The TAG considered the PAC's *revised* guidance, which now recommended restricted use in type 2 diabetes and included amendments to the recommended criteria for use, as follows: 1. Insulin degludec is not recommended for routine use in adults or children with either type 1 or type 2 diabetes. 2. Insulin degludec 100 units/ml may be of benefit in certain patients with type 1 or type 2 diabetes who fulfil the following criteria: • Patients with significant hypoglycaemia, despite optimal adjustments of lifestyle (eliminating any contributory factors), diet (undertaken structured education, e.g. DAFNE), and basal insulin/multiple daily injections and who fulfil the criteria for insulin pump therapy.		The NNUH has a total of 30 patients (20 with T1DM and 10 with T2DM) identified as being suitable to start treatment with insulin degludec. The QEH has 120 patients who are either already on or who would now meet the PAC's criteria for using insulin degludec. The current cost for biphasic insulin is approximately £30 per pack, or £0.41 for 30 units and £150 per year, based on 30 units per day; for insulin glargine (long acting basal insulin) the cost is £0.83 for 30 units and £302.12 per year, versus £0.93 for 30 units or £339.25 per year for insulin degludec. Additional costs for moving patients meeting the criteria for use to insulin degludec are therefore approximately £37 to £190 per patient per year depending on the patient's current therapy.	

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
	and as Green (GP prescribable following specialist recommendation) for Restricted use in Type 1 Diabetes mellitus - consultant initiation only	• "Chaotic patients" who may be at significant risk of diabetic ketoacidosis (DKA) or hyperosmolar hyperglycaemic state (HHS) (previously known as hyperosmolar non – ketotic diabetic state or hyper HONK) if daily basal insulin is missed, despite optimal adjustments of lifestyle, and diet and optimising basal insulin/multiple daily injections. • Patients with psychological problems (e.g. eating disorders or patients with intermittent compliance issues with insulin injections), who are not supervised by a daily carer and do not qualify to receive district nurse injections of daily insulin glargine, and who may be at significant risk of DKA or HHS if daily basal insulin is missed. • Patients with a diagnosed allergy to either insulin glargine or insulin detemir. 3. High strength insulin degludec 200 units/ml is not recommended for routine use. It should be considered for patients with severe insulin resistance requiring large daily doses of insulin (≥3 units/kg/day), where treatment is initiated by a Consultant Diabetologist ~~in a tertiary centre specialising in insulin resistance~~. 5. Insulin degludec should be initiated by a consultant Diabetologist only and is NOT suitable for initiation by GPs or other prescribers in primary care unless under the supervision of a specialist. It is recommended that the initial dose titration and monitoring is closely supervised by a specialist team. 6. All patients should be managed by the initiating specialist team for a minimum of three months or until stable. Patients should be returned to previous treatment if no improvement in overall disease control from baseline is demonstrated. The TAG agreed to accept the PAC's recommendations as stated above, to revise the	The cost of treating the 150 patients identified by the NNUH and the QEH with insulin degludec in primary care would be around £50,900 p.a. which may be an increase of anything from £5550 to £28,500 p.a. depending on each patient's current insulin regimen. *The D&TC noted that the extended criteria relate to T-2 diabetes.* *The D&TC supported that PAC's criteria, with the TAG's recommended amendments, providing that local practitioners adhere to them, and that* ***the specialist provides the first prescription****.*	

<table>
<tr><th>Date of TAG meeting</th><th>Recommending body</th><th>Drug</th><th>Indication for Use</th><th>TAG Recommendation</th><th>N&W CCGs - D&TCG Decision</th></tr>
<tr><td></td><td></td><td colspan="2"><u>Double</u> Red (Not recommended for routine use) classification to for routine use in Type 1 and Type 2 diabetes mellitus, and to extend the classification as Green (GP prescribable following specialist recommendation) where the initial dose titration and monitoring is closely supervised by the initiating specialist for the first three months or until stable, as per the above-listed criteria for use, including use in Type 2 diabetes.</td><td></td><td></td></tr>
<tr><td>May 2018</td><td>East of England Priorities Advisory Committee (PAC):
<u>PAC Recommendations</u>:
Flash Glucose Scanning system (FGS) (including Freestyle Libre®) for adults with Type 1 diabetes
(version considered by PAC on 30th April 2018)

CCG-commissioning responsibility</td><td colspan="2">The PAC’s recommendations were as follows:
Freestyle Libre® is an innovative device Flash Glucose Scanning system (FGS) that has the potential to improve quality of life for patients and support self-management. However, currently there are significant limitations in available clinical trial data and economic analysis, and routine commissioning for all patients is therefore not recommended.
PAC supports a managed entry of FGS to allow real world data on use and outcomes to be collected in order to inform future policy.
FGS is recommended for the patient groups outlined below in line with the criteria and general funding recommendations set out in sections 2 and 3 (of the full document).
Routine funding for any other indication is currently considered a low priority and is not recommended.
Funding for patients who are currently self-funding who do not fulfil the criteria is not recommended.
PAC recommends that funding is initially made available for these patient groups for a time limited period of 1 year. Funding should be provided for a maximum of 26 sensors per patient per year and should be reviewed after 6 months. Continued</td><td colspan="2">The PAC document includes estimated patient numbers and cost impact for each of the recommended patients groups as follows:
1. Pre- / Pregnancy:<table><tr><td>Estimated·%·diabetes·population¤</td><td colspan="3">1.8%·T1DM·and·0.07%·T2DM¤</td></tr><tr><td>No.·patients·per·100,000·total·population·(all·ages)¤</td><td colspan="3">9¤</td></tr><tr><td rowspan="3">Additional·cost·per·100,000·total·population,·per·year·using·FGS·and·continuing·to·BG·test·4·times·per·day¶
¤</td><td>¤</td><td>Most·cost·effective·strips¤</td><td>Average·cost·strips¤</td></tr><tr><td>Excluding·VAT¤</td><td>£3,618¤</td><td>£2,682·¤</td></tr><tr><td>Including·VAT¤</td><td>£5,256¤</td><td>£4,320¤</td></tr></table>2. Type 1 diabetics who meet <u>NICE TA151</u> criteria for CSII<table><tr><td>Estimated·%·diabetes·population¤</td><td colspan="3">1.2%·–·3.8%·of·T1DM·population¤</td></tr><tr><td>No.·patients·per·100,000·total·population·(all·ages)·using·upper·end·of·estimate·3.8%¤</td><td colspan="3">16¤</td></tr><tr><td rowspan="3">Additional·cost·per·100,000·total·population·per·year·using·FGS·and·continuing·to·BG·test·4·times·per·day·(upper·end·of·estimate·3.8%)¶
¤</td><td>¤</td><td>Most·cost·effective·strips¤</td><td>Average·cost·strips¤</td></tr><tr><td>Excluding·VAT¤</td><td>£6,432¤</td><td>£4,768¤</td></tr><tr><td>Including·VAT¤</td><td>£9,344¤</td><td>£7,680¤</td></tr></table>3. People with co-morbidities or who are on treatments which are associated with changes in nutrient intake or insulin sensitivity</td></tr>
</table>

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision

funding beyond this initial 6 months is not automatic, and prior approval of funding beyond this time will only be granted where there is evidence of achievement of treatment goals specified for each criteria and a statement of rationale from the diabetologist that cessation of FGS would reverse this benefit. Funding for treatment should be discontinued as per circumstances specified in the full document.

- It is recommended that audit data is collected and that funding recommendations are reviewed to include new evidence on cost effectiveness, actual patient numbers and affordability.
- FGS should be initiated, managed and supplied by a consultant led specialist Diabetes team. GP prescribing is not recommended.
- Due to the high cost of testing strips and the use of the inbuilt FreeStyle Libre meter for testing blood glucose or ketones is not currently recommended.

Summary for criteria recommended for funding:

All recommendations apply to patients with Type 1 diabetes only unless otherwise specified (see section 3 in the full document for details).

1. **Pregnancy:**
   - **1.1** Pre-Pregnancy Care (PPC) for women with Type 1 diabetes in a recognised PPC pathway
   - **1.2** Pre-Pregnancy Care (PPC) for women with Type 2 diabetes on an intensive insulin regime, in a recognised PPC pathway.
   - **1.3** Pregnancy care for women with Type 1 diabetes
   - **1.4** Pregnancy care for women with preconception Type 2 diabetes on an intensive insulin regimen

Estimated·%·diabetes·population¤	0.5%·of·T1DM·population¤		
No.·patients·per·100,000·total·population·(all·ages)¤	2¤		
Additional·cost·per·100,000·total·population,·per·year·using·FGS·and·continuing·to·BG·test·4·times·per·day¶ ¤	¤	Most·cost·effective·strips¤	Average·cost·strips¤
	Excluding·VAT¤	£804¤	£596¤
	Including·VAT¤	£1,168¤	£960¤

4. Frequent (>2 per year) hospital admissions (inpatient episodes) with Diabetic Ketoacidosis (DKA) with HbA1c >69 mmol/mol despite intensive clinical intervention.

Estimated·%·diabetes·population¤	0.5%·of·T1DM·population¤		
No.·patients·per·100,000·total·population·(all·ages)¤	2¤		
Additional·cost·per·100,000·total·population,·per·year·using·FGS·with·no·change·to·baseline·BG·testing·frequency¶ ¤	¤	Most·cost·effective·strips¤	Average·cost·strips¤
	Excluding·VAT¤	£1,820¤	£1,820¤
	Including·VAT¤	£2,184¤	£2,184¤

Cost of FreeStyle Libre vs blood glucose testing:

Cost of BG testing	Most cost effective strips	Average EoE cost per strip
Cost per pack	£9.99 for 50	£12.37
Cost per strip	£0.20	£0.25
Cost per lancet	£0.03	£0.03
Total cost per test	**£0.23**	**£0.28**

FreeStyle Libre costs	Excluding VAT	Including VAT
Sensor x1 (14 days)	£35	£42
1 year cost (sensors only)	£910	£1,092

Cost impact of FreeStyle Libre:

It is not possible to accurately state the number of patients that will be eligible for each of the proposed criteria. Cost impact estimates are based on estimated patient numbers provided by East of England Diabetologists.

Based on feedback from clinicians, it is assumed people who test BG frequently are testing on average 10 times per day. Where a reduction in

<table>
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<tr><td></td><td></td><td colspan="2">2. People with Type 1 diabetes who meet NICE TA151 criteria for Continuous Subcutaneous Insulin Infusion (CSII) and are in a recognised pathway prior to CSII.
3. People with co-morbidities or who are on treatments which are associated with changes in nutrient intake or insulin sensitivity resulting in marked fluctuations of blood glucose levels that make the diabetes management very challenging. This includes patients with anorexia nervosa, PEG feeding, and people with Cystic-Fibrosis related Diabetes.
4. Frequent hospital admissions (>2 per year) with Diabetic Ketoacidosis (DKA) with HbA1c >69 mmol/mol despite intensive clinical intervention.

The TAG considered the PAC's recommendations, which were accepted in principle by the committee. The TAG also acknowledged the importance of the patient contract being followed. The TAG recommended a traffic light classification of Green to cover supply of the sensors by GPs – is this appropriate?</td><td colspan="2">blood glucose testing is expected using FreeStyle Libre, an average reduction from 10 to 4 tests per day has been assumed as per NICE recommendations. Impact of reducing BG testing to 0.5 tests per day is shown for comparative purposes:
<table><tr><th colspan="3">Cost per patient per year</th></tr><tr><td></td><td>Most cost effective strips</td><td>Average EoE cost per strip</td></tr><tr><td>10 BG tests per day</td><td>£847</td><td>£1020</td></tr><tr><td>4 BG tests per day</td><td>£339</td><td>£408</td></tr><tr><td>0.5 BG tests per day using</td><td>£42</td><td>£51</td></tr><tr><td colspan="3">Excluding VAT</td></tr><tr><td>FreeStyle Libre (sensors only)</td><td colspan="2">£910</td></tr><tr><td>FreeStyle Libre (sensors only) and BG testing 4 times per day</td><td>£1,249</td><td>£1,318</td></tr><tr><td>Additional cost of using FreeStyle Libre and BG testing 4 times per day vs BG testing 10 times per day</td><td>£402</td><td>£298</td></tr><tr><td>FreeStyle Libre (sensors only) and BG testing 0.5 times per day</td><td>£952</td><td>£961</td></tr><tr><td>Additional cost of using FreeStyle Libre and BG testing 0.5 per day vs BG testing 10 times per day</td><td>£105</td><td>-£59</td></tr><tr><td colspan="3">Including VAT</td></tr><tr><td>FreeStyle Libre (sensors only)</td><td colspan="2">£1,092</td></tr><tr><td>FreeStyle Libre (sensors only) and BG testing 4 times per day</td><td>£1,431</td><td>£1,500</td></tr><tr><td>Additional cost of using FreeStyle Libre and BG testing 4 times per day vs BG testing 10 times per day</td><td>£584</td><td>£480</td></tr><tr><td>FreeStyle Libre (sensors only) and BG testing 0.5 times per day</td><td>£1,134</td><td>£1,143</td></tr><tr><td>Additional cost of using FreeStyle Libre and BG testing 0.5 per day vs BG testing 10 times per day</td><td>£287</td><td>£123</td></tr></table>
The D&TC acknowledged that the numbers of patients estimated by the specialist clinicians under each agreed criteria for use are small.
The D&TC debated the classification for prescribing responsibility of the sensors – Specialist (Red – possible Homecare provision?) as recommended by the PAC, versus GP (Green – specialist recommendation) as recommended by the TAG. The D&TC was uncertain regarding the hospital / specialist's ability to prescribe on-going supplies and any related activity costs to the CCGs, and agreed to investigate further to ensure that the</td></tr>
</table>

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<tr><td></td><td></td><td></td><td></td><td>most cost-effective process was recommended.
The issue would be queried with specialist contacts at the PAC and also raised at the next (May 2018) NIDDM and NCH&C D&T meeting and returned to the June 2018 D&TC meeting to ensure that an informed recommendation is made to the JSCC.</td><td></td></tr>
<tr><td>May 2018</td><td>East of England Priorities Advisory Committee (PAC):
<u>PAC Recommendations</u>:
Flash Glucose Scanning system (FGS) (including Freestyle Libre®) for children and young people with type 1 diabetes age 4 up to the age of 19
(version considered by PAC on 30th April 2018)

CCG-commissioning responsibility</td><td colspan="2">The PAC’s recommendations were as follows:
1. Freestyle Libre® is an innovative device Flash Glucose Scanning system (FGS) that has the potential to improve quality of life for patients and support self-management. However, currently there are significant limitations in available clinical trial data and economic analysis, and routine commissioning for all patients is not recommended.
2. PAC supports a managed entry of FGS to allow real world data on use and outcomes to be collected in order to inform future policy.
3. FGS is recommended for the patient groups outlined below in line with the criteria and general funding recommendations set out in sections 2 and 3 of the full document.
4. PAC recommends that funding is initially made available for these patient groups for a time limited period of 1 year. It is recommended that audit data is collected and that funding recommendations are reviewed to include new evidence on cost effectiveness, actual patient numbers and affordability.
5. Routine funding for any other indication is currently considered a low priority and is not recommended.
6. Funding for patients who are currently self-funding who do not fulfil the criteria is not recommended.
7. PAC recommends that funding is initially made available for these patient groups for a time limited period of 1 year. Funding should be provided for a maximum of 26 sensors per patient per year and</td><td colspan="2">The PAC document includes estimated patient numbers and cost impact for each of the recommended patients groups as follows:
1. Children who have recently developed hypoglycaemia unawareness (< 3 months onset) [a,b,c]<table><tr><td>Estimated·%·Paediatric·Caseload¤</td><td colspan="2">2%¤</td></tr><tr><td>No.·patients·per·100,000·total·population·(all·ages)¤</td><td colspan="2">1.2¤</td></tr><tr><td rowspan="2">Additional·cost·per·100,000·total·population·per·year·using·FGS·and·continuing·to·BG·test·5·times·per·day¶¤</td><td>Excluding·VAT¤</td><td>Including·VAT¤</td></tr><tr><td>£317→¤</td><td>£535¤</td></tr></table>2. Children who have disabling hypoglycaemia without loss of hypo awareness.<table><tr><td>Estimated·%·Paediatric·Caseload¤</td><td colspan="2">5%¤</td></tr><tr><td>No.·patients·per·100,000·total·population·(all·ages)¤</td><td colspan="2">3¤</td></tr><tr><td rowspan="2">Additional·cost·per·100,000·total·population·per·year·using·FGS·and·continuing·to·BG·test·5·times·per·day¶¤</td><td>Excluding·VAT¤</td><td>Including·VAT¤</td></tr><tr><td>£792¤</td><td>£1,338¤</td></tr></table>3. Children where adequate frequency of blood glucose monitoring is unachievable due to diagnosed behavioural or mental health disorders, where there are significant concerns about the safety of the individual, and poor metabolic control<table><tr><td>Estimated·%·Paediatric·Caseload¤</td><td colspan="2">1%¤</td></tr><tr><td>No.·patients·per·100,000·total·population·(all·ages)¤</td><td colspan="2">0.6¤</td></tr><tr><td rowspan="2">Additional·cost·per·100,000·total·population·per·year·using·FGS·with·no·change·to·baseline·BG·testing·frequency¶¤</td><td>Excluding·VAT¤</td><td>Including·VAT¤</td></tr><tr><td>£546¤</td><td>£655¤</td></tr></table>4. Children with co-morbidities or who are on treatments which are associated with changes in nutrient intake or insulin sensitivity resulting in marked fluctuations of blood glucose levels that make the diabetes management difficult.</td></tr>
</table>

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision

should be reviewed after 6 months. Continued funding beyond this initial 6 months is not automatic, and prior approval of funding beyond this time will only be granted where there is evidence of achievement of treatment goals specified for each criteria and a statement of rationale from the diabetologist that cessation of FGS would reverse this benefit. Funding for treatment should be discontinued as per circumstances specified in the full document.

8. FGS should be initiated, managed and supplied by a consultant led specialist Diabetes team. GP prescribing is not recommended.
9. The use of FreeStyle Libre blood glucose testing strips using the inbuilt meter should be considered locally.
10. Due to the high cost of testing strips the use of the inbuilt FreeStyle Libre meter for testing ketones is not currently recommended.

Summary for criteria recommended for funding:

All recommendations apply to patients with Type 1 diabetes only unless otherwise specified (see section 3 in the full document for details).

1. Children who have recently developed hypoglycaemia unawareness (< 3 months onset) [a,b,c].

   a Score >4 on the Clarke hypoglycaemia unawareness questionnaire

   b Score ≥4 on the Gold hypoglycaemia unawareness Likert scale

   c Evidence of incidentally detected hypo episodes from downloaded blood glucose data/ significant hypoglycaemia lasting >15 minutes confirmed by diagnostic Continuous Glucose Monitoring (CGM) or diagnostic FGS provided by the diabetes specialist team, that occurred during the waking

Estimated·%·Paediatric·Caseload¤	1%¤	
No.·patients·per·100,000·total·population·(all·ages)¤	0.6¤	
Additional·cost·per·100,000·total·population·per·year·using·FGS·and·continuing·to·BG·test·5·times·per·day¶¤	Excluding·VAT¤	Including·VAT¤
	£158¤	£268¤

5. Frequent (>2 per year) hospital admissions (inpatient episodes) with Diabetic Ketoacidosis (DKA) with HbA1c > 69 mmol/mol despite intensive clinical intervention

Estimated·%·Paediatric·Caseload¤	1%¤	
No.·patients·per·100,000·total·population·(all·ages)¤	0.6¤	
Additional·cost·per·100,000·total·population·per·year·using·FGS·with·no·change·to·baseline·BG·testing·frequency¶¤	Excluding·VAT¤	Including·VAT¤
	£546¤	£655¤

6. Children who meet the current NICE criteria for Continuous Subcutaneous Insulin Infusion (CSII) therapy and who are on recognised insulin pump pathway, where a successful trial of FGS may avoid the need for pump therapy if clinically appropriate

Estimated·%·Paediatric·Caseload¤	2%¤	
No.·patients·per·100,000·total·population·(all·ages)¤	1.2¤	
Additional·cost·per·100,000·total·population·per·year·using·FGS·and·continuing·to·BG·test·5·times·per·day¶¤	Excluding·VAT¤	Including·VAT¤
	£317¤	£535¤

7. Children with extreme phobia towards finger prick blood test which adversely affect metabolic control

Estimated·%·Paediatric·Caseload¤	2%¤	
No.·patients·per·100,000·total·population·(all·ages)¤	1.2¤	
Additional·cost·per·100,000·total·population·per·year·using·FGS·with·no·change·to·baseline·BG·testing·frequency¶¤	Excluding·VAT¤	Including·VAT¤
	£1,092¤	£1,310¤

8. Children who are unable to achieve an HbA1c target of <58 mmol/mol despite intensive clinical intervention to optimise therapy and persistent (>6 months) intensive blood

<table>
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<tr><td></td><td></td><td colspan="2">day which the patients were unaware.
2. Children who have disabling hypoglycaemia [d] without loss of hypo awareness
d Disabling hypoglycaemia is defined as the repeated and unpredictable hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life and is manifested by one or more of the following features:
• High frequency of blood glucose testing (≥ 8 tests per day)
• High frequency of blood glucose testing during night that disturbs sleep
• Persistent efforts to maintain high blood glucose levels in excess of the recommended maximum target in order to avoid hypoglycaemic episodes, that adversely affect metabolic control.
3. Children where adequate frequency of blood glucose monitoring is unachievable due to diagnosed behavioural or mental health disorders where there are significant concerns about the safety of the individual, and poor metabolic control.
4. Children with co-morbidities or who are on treatments which are associated with changes in nutrient intake or insulin sensitivity resulting in marked fluctuations of blood glucose levels that make the diabetes management very challenging. This includes patients with anorexia nervosa, PEG feeding, and children with Cystic-Fibrosis related Diabetes.
5. Frequent hospital admissions (>2 per year) with Diabetic Ketoacidosis (DKA) and HbA1c >69 mmol/mol despite intensive clinical intervention.
6. Children who meet the current NICE criteria for insulin pump therapy who are on pump pathway,</td><td colspan="2">glucose monitoring (blood glucose tests ≥ 8/ day).

<table>
<tr><td>Estimated·%·Paediatric·Caseload¤</td><td colspan="2">3%¤</td></tr>
<tr><td>No.·patients·per·100,000·total·population·(all·ages)¤</td><td colspan="2">1.7¤</td></tr>
<tr><td>Additional·cost·per·100,000·total·population·per·year¶
using·FGS·and·continuing·to·BG·test·5·times·per·day¶
¤</td><td>Excluding·VAT¤
£449¤</td><td>Including·VAT¤
£758¤</td></tr>
</table>

Cost of FreeStyle Libre vs blood glucose testing:
The frequency of BG testing in children using FGS is not yet known. East of England Paediatric Diabetes Network clinicians have confirmed that they will not be advocating the use of Flash monitoring readings to replace blood glucose testing when calculating bolus doses of insulin, or where hypoglycaemia is suspected.
To estimate cost impact, it has been assumed that the minimum number of daily blood glucose tests recommended by NICE (5 tests per day) will continue to be performed. In clinical practice, the number of daily BG tests performed may be less, further offsetting the cost of FGS provision. The impact of reducing to an average of 0.5 tests per day is shown for comparison only.
<table>
<tr><th>Cost of BG testing using Aviva test strips</th><th>Per pack</th><th>Per test</th></tr>
<tr><td>Aviva Test strips:</td><td>£16.09 for 50</td><td>£0.32</td></tr>
<tr><td>Lancets (average cost East of England CCGs)</td><td>£3.29 for 100</td><td>£0.03</td></tr>
<tr><td>Average cost per test</td><td></td><td>£0.35</td></tr>
</table>

<table>
<tr><th>FreeStyle Libre costs</th><th>Excluding VAT</th><th>Including VAT</th></tr>
<tr><td>Sensor x1 (14 days)</td><td>£35</td><td>£42</td></tr>
<tr><td>1 year cost (sensors only)</td><td>£910</td><td>£1,092</td></tr>
</table>

Cost impact of FreeStyle Libre:
It is not possible to accurately estimate the number of patients that will be eligible for each of the proposed criteria. Cost impact estimates are based on patient numbers estimated by the Eastern Paediatric Diabetes Network. To estimate patient numbers in each cohort, we have estimated an approximate prevalence of 244 children with Type 1 diabetes per 100,000 children under the age of 19. This equates to approximately 58 children per 100,000 of the general population of all ages. PAC have assumed children who are testing BG frequently e.g. because of disabling hypoglycaemia, are testing an average of 10 times per day. Where a reduction in blood glucose testing is</td></tr>
</table>

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<tr><td></td><td></td><td>where a successful trial of FGS may avoid the need for insulin pump therapy if clinically appropriate.
7. Children with extreme phobia towards finger prick blood test which adversely affect metabolic control defined as:
• Children who have good concordance with insulin treatment but who have significant needle phobia despite psychological/play therapy interventions, and who are BG testing <5 times a day resulting in poor metabolic control (HbA1c > 69 mmol/mol).
8. Children who are unable to achieve the HbA1c target of <58 mmol/mol despite intensive clinical intervention to optimise therapy and persistent (>6 months) intensive blood glucose monitoring (blood glucose tests ≥ 8/ day that is clinically appropriate, on the recommendation of the diabetes specialist team).
The TAG considered the PAC's recommendations, which were accepted in principle by the committee. The TAG also acknowledged the importance of the patient contract being followed. The TAG recommended a traffic light classification of Green to cover supply of the sensors by GPs – is this appropriate?</td><td>expected as a result of using FreeStyle Libre, an average reduction from 10 tests per day to 5 tests per day as per current NICE recommendations has been assumed. Impact of reducing BG testing to 0.5 tests per day is shown for comparison only:
<table>
<tr><th colspan="3">Cost per patient per year</th></tr>
<tr><td>10 BG tests per day using Aviva test strips</td><td colspan="2">£1,291</td></tr>
<tr><td>5 BG tests per day using Aviva test strips</td><td colspan="2">£646</td></tr>
<tr><td>0.5 BG tests per day using Aviva test strips</td><td colspan="2">£65</td></tr>
<tr><td>FreeStyle Libre (sensors only)</td><td>Excluding VAT*
£910</td><td>Including VAT**
£1,092</td></tr>
<tr><td>FreeStyle Libre (sensors only) and BG testing 5 times per day</td><td>£1,556</td><td>£1,738</td></tr>
<tr><td>Additional cost of using FreeStyle Libre and BG testing 5 times per day vs BG testing 10 times per day</td><td>£264</td><td>£446</td></tr>
<tr><td>FreeStyle Libre (sensors only) and BG testing 0.5 times per day</td><td>£975</td><td>£1,157</td></tr>
<tr><td>Additional cost of using FreeStyle Libre and BG testing 0.5 per day vs BG testing 10 times per day</td><td>-£317</td><td>-£135</td></tr>
</table>
*VAT would not be added if supplied on FP10 prescription however an unknown handling fee may be levied by community pharmacies increasing the overall cost
**Supplies made via secondary care would be subject to 20% VAT

The D&TC acknowledged that the numbers of patients estimated by the specialist clinicians under each agreed criteria for use are small.
The D&TC debated the classification for prescribing responsibility of the sensors – Specialist (Red – possible Homecare provision?) as recommended by the PAC, versus GP (Green – specialist recommendation) as recommended by the TAG. The D&TC was uncertain regarding the hospital / specialist's ability to prescribe on-going supplies and any related activity costs to the CCGs, and agreed to investigate further to ensure that the most cost-effective process was recommended.</td><td></td></tr>
<tr><td>May 2018</td><td>East of England Priorities Advisory Committee (PAC):
<u>PAC Recommendations</u>:</td><td>The TAG considered the PAC's recommendations which were as follows:
1. Levothyroxine monotherapy is the treatment of choice for</td><td>The D&TC noted and supported the PAC and the TAG's related</td><td></td></tr>
</table>

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
	Liothyronine for all indications *(supported by the PAC on Monday 30th April 2018)* CCG-commissioning responsibility Currently commissioned in Norfolk and Waveney as follows: **Liothyronine / L-tri-iodothyronine sodium (T3)** — Long term for treatment of Hypothyroidism — 6.2.2 — Anti-thyroid drugs — **Double Red** — Not recommended for routine use / Not commissioned **Liothyronine / L-tri-iodothyronine sodium (T3)** — Niche, short-term use for up to three months in patients awaiting surgery pre-cancer therapy — 6.2.2 — Antithyroid drugs — **Red** — Hospital / Specialist only **Liothyronine/L-tri-iodothyronine sodium (T3)** — Patients with thyroid cancer following thyroid surgery, pre- and post radio iodine ablation — 6.2.2 — Antithyroid drugs — **Red** — Hospital / Specialist only		hypothyroidism. There is no consistent evidence to support the routine use of liothyronine in the management of hypothyroidism, either alone or in combination with levothyroxine. **2.** Liothyronine for treatment of hypothyroidism is not recommended for routine funding unless one of the following criteria applies: **a.** Post thyroidectomy thyroid cancer patients. Patients who need to receive radioactive iodine treatment (Radioiodine Remnant Ablation RRA) after their surgery will initially be started on liothyronine due to its shorter half-life and therefore faster onset of action than levothyroxine. These patients will remain on liothyronine until the oncologist is confident that they will not need any more radioactive iodine at which point they are switched over to levothyroxine. Prescribing in these circumstances must remain with the secondary care specialist and GPs should not accept prescribing responsibility for these patients. **b.** In rare cases of levothyroxine induced liver injury, long term liothyronine prescribing may be supported but only after initiation and stabilisation by a secondary care specialist. Arrangements for **individual prior approval**, prescribing and supply should be agreed locally, ensuring that appropriate patient monitoring is in place. **3.** Initiation and prescribing of liothyronine for patients on levothyroxine who continue to suffer with symptoms despite adequate biochemical correction should remain in secondary care under the supervision of an accredited endocrinologist. **4.** Funding of unlicensed medicines e.g. Armour Thyroid for the treatment of hypothyroidism is not supported. **5.** Prescribers in primary care should not initiate or accept clinical responsibility for on-going prescribing of liothyronine for any new patient, including patients who are currently self-funding and obtaining supplies via private prescription or previously prescribed by a secondary care consultant, unless the criteria stated above are met and they have agreed to accept clinical responsibility for prescribing. **6.** CCGs should give consideration to providing guidance for GPs to switch existing patients to levothyroxine where	*recommendations regarding criteria for use of liothyronine.* *The D&TC was notified that a patient action group is currently lobbying CCGs on this matter. Facilitated by Health Watch Norfolk they had also requested that their comments on the PAC recommendations be considered by the TAG. Due to being submitted on the day of the meeting the TAG was unable to consider the information.* *The D&TC noted and agreed to support the PAC's and the TAG's related recommendations.* *The JSCC will also be requested to decide whether the patient action group's comments on the PAC's guidance should be considered by the TAG.*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
			clinically appropriate, with support from a consultant NHS endocrinologist where necessary or agree arrangements for appropriate review by a consultant NHS endocrinologist These recommendations will be reviewed (by the PAC) in the light of new evidence of clinical and cost effectiveness. The TAG supported the PAC's recommendations which were broadly in line with previous local commissioning decisions – additional recommendations are highlighted above which were recommended to be classified as **Red (Hospital/Specialist use only)**.		
July 2018	**East of England Priorities Advisory Committee (PAC):** **PAC Guidance Statement:** Revised May 2018 CCG-commissioning responsibility	Insulin glargine 300 units/ml (*Toujeo*®)	Diabetes mellitus	**May 2018:** The (January 2018) PAC guidance statement was supported by the TAG, subject to the text on page 8 where it states that one click of the device delivers a volume of 0.01ml (3 units) being corrected. **July 2018:** The TAG noted the revised PAC Guidance Statement which had been updated regarding the number of units delivered per click of the delivery device.	*The TAG / D&TC's recommendations from May 2018 regarding Insulin Toujeo® were supported by the JSCC in June 2018.* **July 2018:** *Noted by the D&TC*
July 2018	**East of England Priorities Advisory Committee (PAC):** **PAC Guidance Statements:**	Insulin *Toujeo*® / Insulin Degludec (*Tresiba*®) for Diabetes mellitus	**May 2018:** The (January 2018) PAC guidance statement was supported by the TAG, apart from the recommendation regarding initiation by a tertiary centre only for severe insulin resistance.		*The TAG / D&TC's recommendations from May 2018 regarding Insulin Toujeo and Insulin*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
			The TAG queried the reasons for this restriction which would not be practical for Norfolk patients. **July 2018: The had PAC responded:** • *This was added as it had been agreed as a possible option with the national specialist insulin resistance centre at Addenbrookes by C&P CCG, before these patients try unlicensed and imported U500 insulin.* • *The service has fed back that they prefer, and have had good outcomes with insulin degludec 200iu in these patients, but wish to retain the option of possibly using Toujeo in certain patients.* The TAG otherwise noted the revised statements.		*Degludec (Tresiba®) were supported by the JSCC in June 2018.* **July 2018:** *Noted by the D&TC*
Sept 2018	**East of England Priorities Advisory Committee (PAC):** **PAC Guidance Statement:** Published July 2018 CCG-commissioning responsibility Currently classified as **Double Red (Not recommended for routine use)** – November 2017	Faster acting insulin aspart (*Fiasp*®)	For use in adults and children with diabetes mellitus **The PAC's recommendations include:** **1.** Faster acting insulin aspart (Fiasp®) is *not* recommended for *routine* prescribing in primary or secondary care. **2.** It may be of benefit in certain patients under specified criteria, only if first line use of conventional insulin aspart or insulin lispro has been tried and failed **3.** It should be initiated by a specialist diabetes team / consultant diabetologist only **4.** Return to previous care if no overall improvement in	The TAG noted that the treatment may be used in certain circumstances which have been clearly defined by the PAC. Locally there had only been limited interest expressed in this therapy, some of which had been patient-led. It was therefore agreed that the current **Double Red (Not recommended for routine use)** classification should be maintained, pending the submission of a business case from local clinicians / providers.	*Noted and supported by the D&TC*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
			disease control, including HbA1c is seen after 6 months		
Nov 2018	**East of England Priorities Advisory Committee (PAC):** **PAC Guidance Statements:** Published on the PAC's website since the draft documents were considered and supported by the TAG in May 2018 CCG-commissioning responsibility	Flash Glucose Scanning system (FGS)	For use in adults (age 19 and older), ***and*** for children and young adults age 4 to (less than) 19, with type 1 diabetes Currently classified as **Double Red (Not recommended for routine use)** – since May 2017	The TAG noted the PAC's guidance statements and was advised that finance leads at the CCGs' Joint Commissioning and Contracting Executive (JCCE) committee had not supported the prospective costs of using the FGS product, Freestyle Libre, for use within the current financial year. This recommendation would be taken forward to the JSCC for a decision and final sign off.	*Noted by the D&TC, and recommended that if the CCGs decide not to fund use within this financial year then this decision should be communicated to local stakeholders.* *The D&TC also acknowledged NHS England's communication regarding a commitment to make Flash Glucose Monitoring more widely available to people with type 1 diabetes from April 1st 2019.*
Nov 2018	**East of England Priorities Advisory Committee (PAC):** ***Draft* PAC Statement:** ***NB:*** Cannabis (all forms, including nabilone) is currently classified as **Double Red (Not recommended for routine use)** – as per local	Cannabis-based medicinal preparations	**At the time of the TAG meeting, the PAC's *draft* document stated:** • Prescribing of (unlicensed) cannabis based medicinal preparations is restricted to clinicians listed on the Specialist Register of the General Medical Council. Prescribing by General	The TAG noted the PAC's draft statement in line with national guidance issued by NHS England and the Department of Health on 31st October 2018. The CCGs had already sent out a communication	*Noted by the D&TC*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
	policy (July 2011)		Practitioners (GPs) is not permitted. • Patients requesting prescriptions who are currently under the care of a specialist should be advised to discuss their treatment plan with the specialist. • Patients requesting prescriptions who are not currently under the care of a specialist should only be referred to specialist services where clinically appropriate and in line with current pathways. • Patients in secondary care must have tried all conventional treatments and not responded, before cannabis can be offered. • The specialist doctor in secondary care has to have an MDT which includes the chair of the hospital DTC before a decision to prescribe can be made.	to support local practices regarding access to medicinal cannabis. The TAG also acknowledged a letter from the NNUH Pain Management Centre which stated that they will not and cannot prescribe or recommend any Cannabis-based medicinal preparations to any patient referred with acute or chronic pain.	
Jan 2019	**East of England Priorities Advisory Committee (PAC):** ***Final* PAC Statement:** *published November 2018* ***NB:*** Cannabis (all forms, including nabilone) is currently classified as **Double Red (Not recommended for routine use)** – as per local policy (July 2011)	Unlicensed cannabis-based medicinal preparations - *prescribing in primary care*	**The PAC's final document states:** • Prescribing of unlicensed cannabis-based medicinal preparations is restricted to clinicians listed on the Specialist Register of the General Medical Council. Prescribing by General Practitioners (GPs) is not permitted. • Patients requesting prescriptions who are currently under the care of a specialist	The TAG was advised that despite previous communications from the local Trust Pain Services at the NNUH and the QEH that they would not wish to recommend use of medicinal cannabis for chronic pain, the Trusts have received GP referrals requesting access to the treatment. The TAG agreed that	*Noted by the D&TC.*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
			should be advised to discuss their treatment plan with the specialist. • Patients requesting prescriptions who are not currently under the care of a specialist should only be referred to specialist services where clinically appropriate and in line with current pathways. • Information for patients on the availability of cannabis-based medicinal products is available on the NHS website here	further clear communication was required to prevent inappropriate referrals. GY&W CCG to write a paper for the wider health economy to facilitate engagement with the JPUH pain service who have indicated interest in its use.	
Jan 2019	***Revised* PAC Guidance Statement:** *(published Nov18)*	Recommendations on the use of growth hormone devices in children v3 (Sept18)	Price review - Nordiflex pre-filled pen moved to group 2 For information & reconsideration for local adoption.	The long term position in Norfolk and Waveney is that somatropin (growth hormone) is commissioned for use only in secondary care, with no GP prescribing. The TAG noted that there is a cohort of paediatric patients who require clinical review regarding on-going need for treatment. The TAG supported continued use of the PAC's revised guidance document.	*Noted and supported by the D&TC.*
March 2019	**East of England Priorities Advisory Committee (PAC):** ***Draft Interim* PAC**	Doxylamine succinate 10mg plus pyridoxine	**The PAC's draft interim recommendations state:** • Prescribing of doxylamine plus	The TAG was advised that the PAC had met a few days before the TAG	*The D&TC noted the TAG's recommendations*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
	Recommendations:	hydrochloride 10mg delayed-release (*Xonvea*®) for the treatment of nausea and vomiting in pregnancy	pyridoxine (Xonvea®) for nausea and vomiting in pregnancy is NOT recommended in primary or secondary care. • There is a lack of information relating to safety and cost-effectiveness of doxylamine and pyridoxine in comparison with other recognised non-pharmacological and pharmacological ways to manage nausea and vomiting in pregnancy and hyperemesis gravidarum. • Patients presenting with nausea and vomiting in pregnancy should be managed in line with current Royal College of Obstetricians and Gynaecologists (RCOG) guidelines. • These recommendations will be reviewed in the light of new national guidance. For information & possible local adoption	meeting and has since issued another draft of their guidance which clarified that national guidance would also include a steer from an RMOC. It was noted that the PAC has experienced significant pressure from the manufacturer regarding the issue that *Xonvea*® is the sole licensed option in the UK for this indication. The TAG acknowledged that there is long term experience of using other medicines off-label for this condition. The TAG deferred making any recommendation for this product until the PAC issues its final interim guidance.	*and decided to apply an interim traffic light classification of* **Double Red (Not recommended for routine use) / Not commissioned** *for use of* Doxylamine succinate 10mg plus pyridoxine hydrochloride 10mg delayed-release (*Xonvea*®) for the treatment of nausea and vomiting in pregnancy.
March 2019	***Revised* PAC Guidance Statement:** *(published Jan19)* Currently classified as "Green (GP prescribable following specialist initiation) in line with locally agreed criteria for use" – last reviewed by the TAG in May 2018	**Insulin degludec (*Tresiba*®):** Recommendations for use in adults and children v3.1 (Nov18)	The PAC has amended the wording in these statements regarding use in patients with disabling hypoglycaemia, which now state: "*Patients with disabling hypoglycaemia (defined as the repeated and unpredictable occurrence of hypoglycaemia*	The TAG supported continued use of the PAC's revised guidance document with the proviso that the previous local agreement was maintained which related to wording on use for severe insulin resistance, which had been amended	*Noted and supported by the D&TC.*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
			that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life), despite optimal adjustments of lifestyle (eliminating any contributory factors), diet (undertaken structured education, e.g. DAFNE, DESMOND), and optimisation of basal insulin/multiple daily injections."	to facilitate use of insulin degludec by local acute trust consultant diabetologists for this indication, to avoid the need for unnecessary referral to tertiary centre specialists.	
March 2019	***Revised* PAC Guidance Statement:** *(published Jan19)* Currently classified as "Green (GP prescribable following specialist initiation) in line with locally agreed criteria for use" – last reviewed by the TAG in May 2018	**Insulin glargine (*Toujeo*®)** Recommendations for use in adults v1.2 (Nov18)	For information & reconsideration for local adoption	The TAG supported continued use of the PAC's revised guidance document with the proviso that the previous local agreement was maintained which related to wording on use for severe insulin resistance, which had been amended to facilitate use of Insulin glargine (*Toujeo*®) by local acute trust consultant diabetologists for this indication, to avoid the need for unnecessary referral to tertiary centre specialists.	*Noted and supported by the D&TC.*

1. TAG Recommendations 2018/19

E. *NHS England Specialised Commissioning / Early Access to Medicines Scheme (EAMS)*

From 2011 the TAG considered outputs from the former East of England SCG, for acknowledgement and ratification. Since 2013 then outputs received from Specialised Commissioning have been from NHS England.

During 2018/19 the TAG considered the following information:

Date of TAG Meeting	NHS England Item	Drug	Indication	TAG Recommendation / Action	N&W CCGs – D&TCG
Nov 2018	**NHS England:** **Commissioning Intentions: adalimumab (September 2018)**	Adalimumab	Various - following the loss of patent exclusivity for *Humira*®	The TAG acknowledged the document and noted that the citrate content of a product can cause injection site reactions for some patients. There was also concern that patients may be asked to switch between products more than once.	*Noted by the D&TC*
Nov 2018	**Department of Health & Social Care / NHSE:** **Guidance for clinicians - Gateway Publications clearance: 08539** The Government has announced plans to reschedule certain cannabis-based products for medicinal use, and has laid regulations in Parliament to that effect. Subject to annulment by either House of Parliament, those regulations will come into force on 1st November 2018.	Cannabis-based products for medicinal use **Main points:** • Under the proposed new regime, all cannabis-based products for medicinal use (except *Sativex*®) would be *unlicensed* medicines. • Due to the limited evidence base and unlicensed status, the DoH has restricted the decision to prescribe cannabis-based products for medicinal use to only clinicians listed on the General medical Council's Specialist Register (GMCSR). • Prescribing must be on a "named patient" basis. Rigorous and auditable safeguards re prescribing to be followed, with existing protocols on CDs • Cannabis-based products for medicinal use only		The TAG noted the national guidance.	*Noted by the D&TC*

Date of TAG Meeting	NHS England Item	Drug	Indication	TAG Recommendation / Action	N&W CCGs – D&TCG
	The letter provides support and guidance to clinicians following the re-scheduling. In particular, it sets out expectations of what this regulatory change will mean in practice for clinicians working in the NHS and in private practice in England.	to be prescribed for indications where there is clear published evidence of benefit or UK Guidelines, and in patients where there is a clinical need which cannot be met by a licensed medicine, and where established treatment options have been exhausted. • Specialist doctors on the GMCSR should only prescribe within their own area of practice and training (e.g. physicians for adults should not prescribe for children) and the decision to prescribe should be agreed by the multidisciplinary team.			
Jan 2019	**NHS England:**	Flash Glucose Scanning system (FGS) - *Freestyle Libre®*	***For information*** November 2018 - NHS England announced that Freestyle Libre will be "is available on prescription for all patients who qualify for it in line with NHS clinical guidelines" from 1st April 2019.	The TAG was advised that in view of NHS England's decision, local CCGs would no longer commission Freestyle Libre in line with the East of England PAC's guidance. Details of NHS England's clinical guidelines have yet to be published. Funding arrangements are likely to involve CCG budgets being top-sliced, costing around £750k across the area.	*The D&TC acknowledged that it was now necessary to wait on the detail of NHSE's intentions, to be able to finalise criteria for use and prescribing responsibility for this device.* *Noted by the D&TC*
Jan 2019	**NHS Clinical Commissioners / NHS England:**	Items which should not routinely be prescribed in primary care	*An update and a consultation on further guidance for CCGs* Closes 28 February 2019 - ***Link***	The TAG noted the consultation information and acknowledged the importance of individual responses to the consultation.	*Noted by the D&TC*

Date of TAG Meeting	NHS England Item	Drug	Indication	TAG Recommendation / Action	N&W CCGs – D&TCG
March 2019	**NHS England:**	The NHS Long Term Plan	***For information*** January 2019 - NHS England published its long term plan - **www.longtermplan.nhs.uk**.	Noted by the TAG.	*Noted by the D&TC*
March 2019	**NHS England:** **Briefing note**	Rescheduling of Gabapentin and Pregabalin as Schedule 3 Controlled Drugs from April 2019	***For information***	The TAG also noted that Schedule 2 & 3 Controlled Drugs will become prescribable via the Electronic Prescription Service (EPS) to facilitate the re-classification of gabapentin and pregabalin.	*Noted by the D&TC*

1. TAG Recommendations 2018/19

F. *Regional Medicines Optimisation Committees (RMOCs)*

From November 2017 the TAG considered outputs from the newly formed NHS England Regional Medicines Optimisation Committees (RMOCs) for acknowledgement and consideration of local implementation.

During 2018/19 the TAG considered the following information:

Date of TAG Meeting	RMOC	Drug	Indication	TAG Recommendation / Action	N&W CCGs – D&TC
May 2018	**RMOC Guidance statement:** **RMOC North (Oct 2017 meeting)** Standardising strengths of high risk, unlicensed oral liquids formulations for anti-TB medicines - *Link* NHSE	Ethambutol 400mg in 5ml Pyrazinamide 500mg in 5ml Isoniazid 50mg in 5ml for Tuberculosis	The TAG noted the RMOC guidance regarding these NHSE--commissioning responsibility treatments which states: • A 3-year work programme has generated a consensus supporting a standardised specification for each of the 3 main products Ethambutol 400mg in 5ml, Pyrazinamide 500mg in 5ml, Isoniazid 50mg in 5ml • These standardised products will be submitted for addition to the British Pharmacopoeia and BNF-C • NHS prescribers are encouraged to restrict prescribing of these three drugs to the three products listed above		*Noted by the D&TC.*
July 2018	**RMOC Position statement:** **RMOC London (April 2018 meeting)** ***Link***	Pan-regional antidotes and rarely used medicines (RUMs)	Access to and availability	The TAG noted the RMOC position statement regarding these NHSE--commissioning responsibility treatments	*Noted by the D&TC*

July 2018	**RMOC Briefing (May 2018):** ***Link***	Adalimumab Best value biological medicines - which summarised: • Advice on the next steps for practical advice in the context of homecare services • Progress to date in planning for the patent expiry of the originator adalimumab product Humira® in October 2018 • A clinical briefing sheet is provided as well as an adalimumab homecare patient record form	The TAG noted the RMOC briefing which reflected what is already being done locally. The TAG felt that there was no formal obligation to use the draft form where local processes were already in place.	*Noted by the D&TC*
July 2018	**RMOC Position statement:** **RMOC Midlands and East (April 2018 meeting)** Safety factors for local formulary decision-making (June 2018) - ***Link***	Insulin preparations • RMOC has reviewed the issues pertaining to safety considerations when adopting any insulin preparation onto a local formulary. • Guidance has been issued to formulary committees/ Area Prescribing Committees on this subject. • The guidance is also available as a checklist which is intended to be completed as part of the evidence-gathering process alongside clinical and cost-effectiveness data.	The TAG noted the RMOC position statement.	*Noted by the D&TC*
Sept 2018	**RMOC Resource:** **- *Link***	Adalimumab toolkit for commissioners and providers) **Resources include:** • RMOC briefing • Patient FAQ document • Patient letter template • Biosimilar Adalimumab Toolkit *(updated 27/7/18)* • Best Value Biologic Implementation Plan template (for local adaptation) • Template DTC application form for biosimilar adoption • Template Terms of Reference for Best Value Biologic Adalimumab Implementation Group • Best Value Biologic (including biosimilars) Savings Calculator & Tracker	Noted by the TAG	*Noted by the D&TC*

Sept 2018	**RMOC Advice (July 2018):** **-** *Link* Advice ratified by the Regional Medicines Optimisation Committee for adoption as local policy	Free of Charge (FOC) medicines schemes **The executive summary states:** 1.1 …defined as an arrangement where a UK licensed or unlicensed medicine is provided free of charge by the pharmaceutical company to an individual patient or an identified cohort of patients. 1.2 Commissioners and providers must only undertake a free of charge scheme if the principles outlined in this policy are followed. 1.3 Trusts or commissioners should *not* sign up to an FOC scheme which is solely offering a licensed medicine free of charge in advance of NICE approval.		Noted by the TAG	*Noted by the D&TC*
Nov 2018	**Midlands & East RMOC Update: September 2018** **-** *Link*	Adalimumab toolkit for commissioners and providers)	Includes: • Guidance on homely remedies in care homes • Sodium Oxybate • Biosimilars • Polypharmacy Antimicrobial Stewardship	Noted by the TAG	*Noted by the D&TC*
Nov 2018	**RMOC Briefing:** **-** *Link* The briefing summarises current aspects related to implementing best value biological medicines in the NHS.	Best Value Biologicals: Adalimumab - Update 4	Covers: • Supporting materials in one place • Procurement update • System incentives • Patient group engagement • Clinical engagement • Product update • Future products • Citrate content • Paediatric prescribing • Homecare / Homecare service injection training • Clinical questions	Noted by the TAG	*Noted by the D&TC*

<table>
<tr>
<td>Jan 2019</td>
<td><u>South RMOC</u>: Guidance - Prescribing of Liothyronine (v2 November 2018)</td>
<td>For noting and comparing against the previously classified indications for use with reference EoE PAC Guidance Statement (agreed May 2018):
<table>
<tr><th>Indications for liothyronine agreed in Norfolk and Waveney</th><th>Traffic Light currently in place</th><th>Traffic light recommended January 2019</th></tr>
<tr><td>ROUTINE use for long term for treatment of Hypothyroidism</td><td>Double Red</td><td>Double Red</td></tr>
<tr><td>RESTRICTED use for long term treatment in rare cases of levothyroxine-induced liver injury</td><td>Red</td><td>Green – for new patients, NHS Consultant to prescribe for 3 months then GP.
For existing patients, NHS consultant to review, then, if appropriate, to the GP.</td></tr>
<tr><td>RESTRICTED use for patients on levothyroxine for hypothyroidism who continue to suffer with symptoms despite adequate biochemical correction</td><td>Red</td><td>Green – for new patients, NHS Consultant to prescribe for 3 months then GP.
For existing patients, NHS Consultant to review, then, if appropriate, to the GP.</td></tr>
<tr><td>Niche, short-term use for up to three months in patients awaiting surgery pre-cancer therapy</td><td>Red</td><td>Red</td></tr>
<tr><td>Patients with thyroid cancer following thyroid surgery, pre- and post- radio iodine ablation</td><td>Red</td><td>Red</td></tr>
<tr><td>Armour thyroid and other unlicensed thyroid extract products, plus compounded thyroid hormones, iodine containing preparations, dietary supplementation: Not commissioned for any indication</td><td>Double Red</td><td>Additional text from RMOC guidance also supported by the TAG.
Double Red</td></tr>
<tr><td>Resistant depression</td><td>Not previously listed – added from RMOC guidance</td><td>Double Red pending an evidence-based business and costed application for use.</td></tr>
</table>
</td>
<td>The TAG considered the guidance from RMOC and reviewed the previously agreed traffic light classifications as recorded in the table in the previous column ←
The TAG also considered a document received by the D&TC in December 2018 from the Norfolk Thyroid Support Group (TSG), which listed concerns regarding the RMOC guidance on Liothyronine. The TAG noted the TSG's request that their document be considered but was unable to make any recommendations in the absence of clinical evidence to support the TSG's position submitted by a local specialist clinician, or any revised guidance from NHS England.</td>
<td>The D&TC noted and supported the TAG's:
revised recommendations for previously considered clinical indications,
and also the additional clinical indication and products which were not recommended for use.</td>
</tr>
</table>

Jan 2019	**Midlands & East RMOC Position Statement and template Policy: November 2018**	**Homely remedies For Use in Care Homes by adults**	*For information* See also - local Best Practice Guidance for Care Homes regarding Homely Remedies (Bulletin 8) - ***Link***	Noted by the TAG. To be passed to the local Care Home Group for their consideration.	*Noted by the D&TC*
Jan 2019	**RMOC/NHSE: STOMP Resources (Nov 2018)**	Stopping the overmedication of people with a learning disability, autism or both	For information and consideration for local adoption	The TAG noted that these resources were an example of good practice which would require high intensity input from Primary Care to replicate. The information to be referred to the STOMP Working Group led by South Norfolk CCG.	*Noted by the D&TC which also acknowledged the need to engage with the LMC when planning a strategy for implementing this initiative.*
Jan 2019	**RMOC Briefing:**	Best Value Biologicals: Adalimumab Update 5 - *Link*	*For information* Summarises current aspects related to implementing best value biological medicines in the NHS, with an update on the procurement process. Also - PrescQIPP Data Report on uptake of biosimilars across East Of England.	Noted by the TAG	*Noted by the D&TC*

<table>
<tr>
<td>Jan 2019</td>
<td><u>South RMOC Update</u>: November 2018
- <u>Link</u></td>
<td>Includes:
<table>
<tr><td>• Liothyronine</td><td>• National “Do Once” System</td></tr>
<tr><td>• Shared Care</td><td>• Medicines Safety</td></tr>
<tr><td>• Free of Charge Medicines Schemes</td><td>• Best value Biologicals</td></tr>
<tr><td>• Medicines Supply Routes Guidance</td><td>• Polypharmacy</td></tr>
<tr><td>• Botulinum Toxin</td><td>• Antimicrobial Stewardship</td></tr>
</table>
</td>
<td>Noted by the TAG</td>
<td>Noted by the D&TC.</td>
</tr>
<tr>
<td>Jan 2019</td>
<td><u>London RMOC Update</u>: December 2018
- <u>Link</u></td>
<td>Includes:
<table>
<tr><td colspan="2">• Heparinised saline versus normal saline to maintain patency of intravascular central catheters</td></tr>
<tr><td>• Pan-regional storage of antidotes</td><td>• Polypharmacy</td></tr>
<tr><td>• National Antidote Storage Audit 2018</td><td>• Medicines Compliance Aids</td></tr>
<tr><td>• Rarely Used Urgent Medicines (RUUMs)</td><td>• De-prescribing</td></tr>
<tr><td>• Best value biological medicine (BVBM)</td><td>• Antimicrobial Stewardship</td></tr>
</table>
</td>
<td>Noted by the TAG</td>
<td>Noted by the D&TC.</td>
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<table>
<tr>
<td>March 2019</td>
<td><u>London RMOC</u>:
Position Statement on:</td>
<td><u>heparinised saline for central venous catheter lock in adults</u>
(February 2019)</td>
<td>For information and consideration for local adoption:
The RMOC recommends there is no role for routine use of heparinised saline lock for the purpose of maintaining patency of a central venous catheter (CVC) in adults, and that sodium chloride 0.9% is suitable for locking CVCs in the majority of adult patients.</td>
<td>The TAG noted that the RMOC’s guidance referred to routine use of heparinised saline and that some examples of exceptional use were given.
TAG Trust representatives requested that the guidance be shared in-trust for a view before recommending traffic light classification.
Feedback to be returned to the TAG in May 2019.</td>
<td>Noted by the D&TC</td>
</tr>
<tr>
<td>March 2019</td>
<td><u>Midlands & East RMOC Update</u>:
January 2019 - Issue 1
<u>Link</u></td>
<td>Includes:
<table>
<tr><td>• Sodium Oxybate</td><td>• GLP-1 mimetics – impact on cardiovascular outcomes in diabetes</td></tr>
<tr><td>• Shared Care issues</td><td>• Antimicrobial Resistance and Stewardship</td></tr>
</table>
</td>
<td>Noted by the TAG</td>
<td>Noted by the D&TC</td>
</tr>
</table>

1. TAG Recommendations 2018/19

G. MHRA *Drug Safety Update* Bulletins

The TAG noted Drug Safety Update Bulletins from March 2018 to January 2019 and revised previous TAG guidance where appropriate.

MHRA/CHM *Drug Safety Update* - March – April 2018:

- Head lice eradication products: risk of serious burns if treated hair is exposed to open flames or other sources of ignition, e.g. cigarettes
- Esmya (ulipristal acetate) for uterine fibroids: do not initiate or re-start treatment; monitor liver function in current and recent users
- Daclizumab (Zinbryta▼): suspension and recall for safety reasons; review patients as soon as possible and start alternative therapy *
- Obeticholic acid (Ocaliva▼): risk of serious liver injury in patients with pre-existing moderate or severe hepatic impairment; reminder to adjust dosing according to liver function monitoring
- Valproate medicines (Epilim▼, Depakote▼): contraindicated in women and girls of childbearing potential unless conditions of Pregnancy Prevention Programme are met
- Daclizumab (Zinbryta▼) and risk of severe liver injury: new restrictions to use and strengthened liver monitoring
- Radium-223 dichloride (*Xofigo*▼): do not use with abiraterone and prednisone /prednisolone, following clinical trial signal of increased risk of death and fractures

MHRA/CHM *Drug Safety Update* - – May – June 2018:

- Braltus (tiotropium): risk of inhalation of capsule if placed in the mouthpiece of the inhaler
- Denosumab (Xgeva▼) for advanced malignancies involving bone: study data show new primary malignancies reported more frequently compared to zoledronate
- Denosumab (Xgeva▼) for giant cell tumour of bone: risk of clinically significant hypercalcaemia following discontinuation
- Dolutegravir (Tivicay▼, Triumeq▼, Juluca▼): signal of increased risk of neural tube defects; do not prescribe to women seeking to become pregnant; exclude pregnancy before initiation and advise use of effective contraception

MHRA/CHM Drug Safety Update - July - August 2018:

- Medicines taken during pregnancy: report suspected ADRs, including in the baby or child, on a Yellow Card
- Parenteral amphotericin B: risk of potentially fatal adverse reaction if formulations confused
- Eltrombopag (Revolade): reports of interference with bilirubin and creatinine test results
- Pressurised metered dose inhalers (pMDI): risk of airway obstruction if aspirate a loose object
- Darunavir boosted with cobicistat: avoid use in pregnancy due to risk of treatment failure and maternal-to-child transmission of HIV-1
- Valproate (Epilim▼, Depakote▼): new restrictions on use; pregnancy prevention programme to be put in place
- Valproate (Epilim▼, Depakote▼): new restrictions on use: pregnancy prevention programme; important actions for pharmacists
- Esmya (ulipristal acetate) and risk of serious liver injury: new restrictions to use and requirements for liver function monitoring before, during, and after treatment

MHRA/CHM Drug Safety Update - September – October 2018:

- Rivaroxaban (Xarelto▼) after transcatheter aortic valve replacement: increase in all-cause mortality, thromboembolic and bleeding events in a clinical trial
- Ritonavir-containing products: reports of interaction with levothyroxine leading to reduced thyroxine levels
- Ponatinib (Iclusig▼): reports of posterior reversible encephalopathy syndrome (PRES)
- Valproate Pregnancy Prevention Programme: actions required now from GPs, specialists, and dispensers
- Xofigo▼ (radium-223-dichloride): new restrictions on use due to increased risk of fracture and trend for increased mortality seen in clinical trial
- Daclizumab beta (Zinbryta▼): risk of immune-mediated encephalitis – some cases several months after stopping treatment
- Nusinersen (Spinraza▼): reports of communicating hydrocephalus; discuss symptoms with patients and carers and investigate urgently
- Transdermal fentanyl patches: life-threatening and fatal opioid toxicity from accidental exposure, particularly in children

MHRA/CHM Drug Safety Update - November – December 2018:

- Hydrochlorothiazide: Risk of non-melanoma skin cancer (basal cell carcinoma, squamous cell carcinoma)
- Support Yellow Card: improve the safety of medicines in pregnancy and breastfeeding, and in babies and children
- Systemic and inhaled fluoroquinolones: small increased risk of aortic aneurysm and dissection; advice for prescribing in high-risk patients
- Sildenafil (Revatio and Viagra): reports of persistent pulmonary hypertension of the newborn (PPHN) following in-utero exposure in a clinical trial on intrauterine growth restriction

MHRA/CHM Drug Safety Update - January – February 2019:

- Oral lidocaine-containing products for infant teething: only to be available under the supervision of a pharmacist
- Hydrocortisone muco-adhesive buccal tablets: should not be used off-label for adrenal insufficiency in children due to serious risks
- Emollients: new information about risk of severe and fatal burns with paraffin-containing and paraffin-free emollients
- Valproate medicines: are you in acting in compliance with the pregnancy prevention measures?
- Tapentadol (Palexia): risk of seizures and reports of serotonin syndrome when co-administered with other medicines
- Direct-acting antivirals for chronic hepatitis C: risk of hypoglycaemia in patients with diabetes
- Ipilimumab (Yervoy): reports of cytomegalovirus (CMV) gastrointestinal infection or reactivation
- SGLT2 inhibitors: reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum)
- Carbimazole: risk of acute pancreatitis
- Carbimazole: increased risk of congenital malformations; strengthened advice on contraception

2. Horizon Scanning for 2019/2020

An in-depth local analysis, using the national horizon scanning data and the NICE work plan, had been undertaken of new products and uses which are likely to impact on prescribing and medicines management in both Primary and Secondary Care for a 12 month period during 2019/20.

The work will be used by commissioners in consultation with local providers to aid financial planning and prioritisation work for the coming year.

The reports are also being used to form the TAG's **Work Programme for 2019/2020** and to inform the Norfolk and Waveney Clinical Commissioning Groups (CCGs) of likely cost pressures and associated financial risks from the introduction of new medicines and indications.

3. Future Work Programme for the TAG

Issues that may be considered by the TAG during 2019/20 include:

A. PRIMARY CARE IMPACT

New drugs / Indications in the pipeline that *may* impact on Primary Care:

- Anacetrapib for mixed dyslipidaemia and prevention of major coronary events, in combination with a statin – likely specialist initiation
- Betrixaban - Direct factor Xa inhibitor for Venous thromboembolism (VTE) prevention - first-line in medically ill patients – likely specialist initiation
- Bempedoic acid oral for hypercholesterolemia, adjunct to statins in patients with high cardiovascular risk or familial hypercholesterolaemia.
- Buprenorphine injection - Opioid-receptor partial agonist, given by once weekly or once monthly s.c. injection for opioid dependence
- Cebranopadol oral for chronic cancer pain, moderate-to-severe, in adults.
- Ciclosporin eye drops (*Verkasia*®) for severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.
- Clarithromycin/ lofazimine/ rifabutin oral for Crohn's disease, secondary to Mycobacterium avium paratuberculosis.
- Crisaborole topical (*Eucrisa*®) - Non-steroidal phosphodiesterase (PDE-4) inhibitor, formulated as a topical cream or ointment - for atopic dermatitis, mild-to-moderate.
- Dapagliflozin oral (*Forxiga*®) - Type 1 diabetes mellitus in adults – in combination with insulin (licence extension).
- DBV712 patch for peanut allergy in children aged 4 to 11 years.
- Delafloxacin injection and oral for Community acquired pneumonia.
- Deutetrabenazine oral for Tardive dyskinesia (TD) in adults.
- Edoxaban for the treatment of VTE associated with cancer (licence extension)
- Elagolix oral for Endometriosis-related pain, moderate-to-severe, in adult pre-menopausal women.
- Elobixibat oral for chronic idiopathic constipation
- Empagliflozin for prevention of cardiovascular death in type 2 diabetes mellitus
- Empagliflozin oral (Jardiance) - Type 1 diabetes in adults – in combination with insulin (licence extension).
- Empagliflozin/ linagliptin oral (Glyxambi®) - Type 2 diabetes mellitus in adults
- Erenumab injection for prophylaxis of migraine in adults who have at least 4 migraine days per month.
- Exenatide subdermal implant - Long-acting glucagon-like peptide 1 (GLP-1) agonist in an osmotic mini-pump implanted subdermally. Inserted initially for 3 months, then every 6 months for Type 2 diabetes mellitus.
- Fasinumab monthly s.c. injection for pain due to osteoarthritis.
- Fexapotide triflutate injection for benign prostatic hyperplasia
- Fremanezumab injection, for migraine, prevention in adults.
- Galcanezumab injection for Migraine, prevention in adults.
- Intepirdine oral - Serotonin 6 receptor (5-HT6) antagonist – for Lewy body dementia (no longer in development for Alzheimer's disease)
- Lasmiditan oral for acute migraine in adults.

- Lefamulin injection and oral for Community acquired pneumonia.
- Lesinurad for gout (2nd line) / Hyperuricaemia in gout, in combination with a xanthine oxidase inhibitor.
- Lifitegrast eye drops for dry eye disease.
- Netarsudil mesylate eye drops for elevated IOP in patients with open-angle glaucoma (OAG) or ocular hypertension (OH)
- Odanacatib (oral) for osteoporosis in postmenopausal women, primary or secondary prevention, when bisphosphonates are contra-indicated or not successful
- Paliperidone (Oral MR preparation) for schizophrenia in adolescents
- Patiromer oral (Veltassa®) for treatment of hyperkalaemia in adults.
- Racecadotril for chronic diarrhoea in children
- Rivaroxaban oral (Xarelto®) - Direct factor Xa inhibitor - Prevention of venous thromboembolism post-hospital discharge in high-risk, medically ill patients – licence extension
- Rivaroxaban oral for prevention of cardiovascular events in patients with heart failure (HF) and coronary artery disease (CAD) (licence extension).
- Rivaroxaban for the prevention of VTE in ambulatory cancer patients receiving chemotherapy and at high risk of VTE (licence extension).
- Romosozumab injection (Evenity®) for osteoporosis in men and postmenopausal women.
- Safinamide oral for Parkinson's disease (PD) early stage, adjunct to dopamine agonist therapy and for Parkinson's disease (PD), mid-late stage, adjunct therapy
- Secnidazole (oral) for Bacterial vaginosis in adult women
- SER-109 oral for Clostridium difficile infection - prevention of recurrence.
- Sodium zirconium cyclosilicate (Lokelma®) for (chronic) hyperkalaemia (oral preparation)
- Solithromycin for community acquired pneumonia
- Sotagliflozin oral for Type 1 diabetes mellitus in adults – in combination with insulin.
- Tanezumab injection for Osteoarthritis (OA) pain.
- Tasimelteon for insomnia
- Tecarfarin oral - Selective vitamin K epoxidase antagonist, eliminating CYP450-mediated drug interactions - Anticoagulation, in patients not suitable for DOAC therapy
- Ticagrelor oral for prevention of cardiovascular events in patients with type 2 diabetes mellitus and coronary artery disease (licence extension).
- Tiotropium bromide for asthma in children
- Trientine oral (Cuprior®) for treatment of Wilson's disease in adults, adolescents and children ≥ 5 years intolerant to D-penicillamine
- Valbenazine oral (Ingrezza®) for Tardive dyskinesia (TD) in adults
- Vorapaxar oral (Zontivity®) for reduction of atherothrombotic events in patients with a history of MI and no history of transient ischaemic attack or stroke

Review of Shared Care prescribing Agreements for:

- ADHD treatments – Adults
- Anagrelide for Adults with Essential Thrombocythaemia
- Azathioprine for use in Autoimmune Diseases
- Azathioprine in Ulcerative Colitis and Crohn's disease
- Ciclosporin in the treatment of Rheumatic and Dermatological diseases
- Circadin® for Sleep Disorders in Children
- Dementia – drugs for Alzheimer's disease and dementia with Lewy Bodies
- Dronedarone (Multaq®) for Non-Permanent Atrial Fibrillation (AF)
- Duloxetine in Moderate to Severe Stress Urinary Incontinence (SUI)
- Hydroxycarbamide for adults with myeloproliferative disorders needing cytoreduction
- Leflunomide in the treatment of rheumatoid or psoriatic arthritis
- LHRH Agonist Treatment in Gynaecology
- Low Molecular Weight Heparin (LMWH)
- Memantine for Alzheimer's Disease
- Mercaptopurine in Ulcerative Colitis and Crohn's disease
- Mycophenolate mofetil / Mycophenolic acid for Adult Renal Transplant Patients
- Naltrexone for Abstinence in Alcohol Use Disorder
- Riluzole for treatment of the amyotrophic lateral sclerosis form of Motor Neurone Disease
- Sirolimus for adult renal transplant patients
- Sulfasalazine for the Treatment of Inflammatory Arthritis and Inflammatory Bowel Disease
- Tacrolimus for adult renal transplant patients
- Tacrolimus use in Ulcerative Colitis
- Modified-Release Tapentadol (Palexia® SR) for severe chronic pain in patients who are intolerant of Modified-Release Morphine

3. Future Work Programme for the TAG (cont'd)

B. SECONDARY CARE IMPACT

New drugs / Indications in the pipeline that may arise in Secondary Care:

- AAI 101/ cefepime injection for severe, gram-negative infections, including complicated urinary tract infections in patients with limited options.
- Abicipar injection for Wet age-related macular degeneration.
- Alirocumab injection for cardiovascular event reduction in patients with dyslipidaemia (license extension).
- Amikacin liposomal inhalation for treatment of resistant non-tuberculous mycobacterial (NTM) lung disease caused by Mycobacterium avium complex (MAC).
- Andexanet alfa injection for reversal of Factor Xa inhibition in patients with life-threatening or uncontrolled bleeding and for patients requiring urgent or emergency surgery.
- Angiotensin II injection for treatment of hypotension in patients with septic or other distributive shock.
- AR101 oral for peanut allergy (Secondary care, specialised allergy service)
- Autologous osteoblastic cell therapy implantation for early stage non-traumatic osteonecrosis of the hip
- Brexanolone injection for moderate-to-severe postnatal depression (PND) (Specialist perinatal mental health services).
- Brilacidin injection for acute bacterial skin and skin structure infection.
- Canakinumab injection Anti-interleukin-1 beta monoclonal antibody, given by s.c. injection every three months for cardiovascular (CV) disease, secondary prevention of CV events post myocardial infarction (MI) in patients with elevated high sensitivity C-reactive protein (hsCRP) - licence extension.
- Caplacizumab injection for treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression.
- Cefiderocol injection for severe gram-negative infections in patients with limited options.
- Ciraparantag injection - Anticoagulant reversal in patients taking new oral anticoagulants (NOACs) and heparins.
- Delafloxacin injection and oral for Community acquired pneumonia / Acute bacterial skin and skin structure infections (ABSSSI).
- Dupilumab injection for atopic dermatitis, moderate-to-severe, in children aged 6 to 11 years who are inadequately controlled with topical therapies (licence extension).
- Dusquetide injection for mucositis, severe oral, in head and neck cancer patients receiving chemoradiation therapy.
- Eravacycline injection for treatment of complicated intra-abdominal infections (cIAI) in adults.
- Esketamine intranasal for treatment-resistant depression in adults who have not responded to two different antidepressants (mental health services).
- Fenfluramine oral for Dravet syndrome, add-on therapy in children aged 2 to 18 years (Specialised paediatric neurological services).

- Fluocinolone acetonide implant for non-infectious posterior uveitis, second-line (licence extension).
- Fremanezumab injection for episodic cluster headache in adults, prevention (licence extension).
- Galcanezumab injection for cluster headache in adults, prevention (licence extension).
- GC4419 injection for radiotherapy- and chemotherapy-induced severe oral mucositis in adults with head and neck cancer (Specialist cancer centres).
- Givosiran injection for porphyria, acute hepatic porphyrias.
- House dust mite allergen immunotherapy sublingual for persistent allergic rhinitis caused by house dust mites (HDM) in adults and adolescents.
- Iclaprim injection for acute bacterial skin and skin structure infections (ABSSSIs) due to gram-positive pathogens.
- Lefamulin injection and oral for Community acquired pneumonia.
- Levodopa inhaled for Parkinson's disease – add-on therapy to oral levodopa to enable patients to manage motor fluctuations.
- Mepolizumab injection for severe eosinophilic chronic obstructive pulmonary disease (COPD), add-on therapy in patients at high risk of exacerbations (licence extension).
- Meropenem/ vaborbactam injection for complicated urinary tract infections (UTI).
- Minocycline/ disodium edetate/ ethanol solution for adjunctive treatment of catheter-related bloodstream infections.
- Netarsudil mesylate eye drops for elevated IOP in patients with open-angle glaucoma (OAG) or ocular hypertension (OH)
- Oliceridine injection for moderate-to-severe acute postoperative pain in adults.
- Omadacycline injection and oral for community acquired bacterial pneumonia (CAP).
- Peramivir injection for treatment of acute uncomplicated influenza in adults and children aged >2 years.
- Piclidenoson oral for plaque psoriasis, moderate-to-severe.
- Plazomicin injection for resistant complicated urinary tract infections (UTI) and Enterobacteriaceae infections.
- Reltecimod injection for necrotising soft tissue infections.
- Remestemcel-L injection for Crohn's disease, moderate-to-severe, in patients who have previously failed at least one steroid, and at least one immunomodulator or biologic.
- Rexmyelocel-T injection for critical limb ischaemia.
- Risankizumab injection for plaque psoriasis, moderate-to-severe, in adults who are candidates for systemic therapy.
- Tavilermide eye drops for dry eyes.
- Thrombomodulin alfa injection for disseminated intravascular coagulation (DIC) in sepsis.

3. Future Work Programme for the TAG (cont'd)

B. SECONDARY CARE IMPACT

NICE DRUGS

Around **40 NICE-recommended treatments** are likely to come on line during 2019-20. Some have previously been refused by NICE on cost-effectiveness grounds but are likely to return under the Patient Access Scheme (PAS).

NICE drugs will be funded within three months of date of published approval.

NICE Technology Appraisal Guidance likely to be published in 2019-20:

- Atezolizumab for untreated, locally advanced or metastatic, triple negative, PD-L1 positive breast cancer
- Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer
- Avatrombopag and lusutrombopag for treating thrombocytopenia in people with chronic liver disease needing an elective procedure
- Avelumab with axitinib for untreated advanced or metastatic renal cell carcinoma
- Budesonide for treating active eosinophilic oesophagitis
- Cabozantinib for treating advanced hepatocellular carcinoma after prior therapy
- Canakinumab for preventing cardiovascular events after myocardial infarction in people with raised high-sensitivity C-reactive protein
- Cannabidiol for adjuvant treatment of seizures associated with Dravet syndrome
- Cemiplimab for treating cutaneous squamous cell carcinoma
- Clostridium botulinum neurotoxin type A for treating hypersalivation associated with neurological conditions
- Dacomitinib for untreated EGFR-positive non-small-cell lung cancer
- Dapagliflozin, in combination with insulin, for treating type 1 diabetes
- Durvalumab with tremelimumab for untreated non-small-cell lung cancer with no EGFR- or ALK-positive mutations
- Entrectinib for treating ROS1-positive locally advanced or metastatic non-small-cell lung cancer
- Fenfluramine for treating Dravet syndrome
- Idelalisib for treating follicular lymphoma refractory to 2 treatments
- Lanadelumab for preventing recurrent attacks of hereditary angioedema
- Larotrectinib for treating advanced solid tumours with TRK fusions
- Letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant
- Lung cancer (non-small-cell, EGFR and T790M positive, metastatic) - osimertinib
- Multiple myeloma - lenalidomide (post bortezomib) (part rev TA171)
- Multiple myeloma (newly diagnosed) - lenalidomide
- NBTXR-3 for treating soft tissue sarcoma

- Neratinib for treating early hormone receptor-positive HER2-positive breast cancer after adjuvant trastuzumab
- Nusinersen for treating spinal muscular atrophy
- Olaparib for maintenance treatment of ovarian, fallopian tube or peritoneal cancer that has a BRCA germline mutation after response to first-line platinum-based chemotherapy
- Osimertinib for untreated EGFR-positive non-small-cell lung cancer
- Palbociclib in combination with fulvestrant for treating advanced, hormone-receptor positive, HER2-negative breast cancer after endocrine therapy
- Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy
- Pembrolizumab for untreated recurrent or metastatic squamous cell carcinoma of the head and neck
- Pembrolizumab with carboplatin and paclitaxel for untreated squamous non-small-cell lung cancer
- Pentosan polysulfate sodium for treating interstitial cystitis
- Quizartinib for treating relapsed or refractory acute myeloid leukaemia
- Ribociclib in combination with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer
- Risankizumab for treating moderate to severe plaque psoriasis
- Rivaroxaban for preventing major cardiovascular events in people with coronary or peripheral artery disease
- Rucaparib for maintenance treatment of recurrent platinum-sensitive epithelial ovarian, fallopian tube and peritoneal cancer that has responded to platinum-based chemotherapy
- Short bowel syndrome - teduglutide
- Sodium zirconium cyclosilicate for treating hyperkalaemia
- Sotagliflozin, in combination with insulin, for treating type 1 diabetes
- Treosulfan with fludarabine for malignant disease before allogeneic stem cell transplant
- TYRX Absorbable Antibacterial Envelope for preventing infection from cardiac implantable electronic devices

3. Future Work Programme for the TAG (cont'd)

B. SECONDARY CARE IMPACT

Non-NICE Drugs

- Alicaforsen enema in Pouchitis, antibiotic-refractory or contraindicated
- Alirocumab for CV event reduction in patients with dyslipidaemia (license extension).
- Amikacin liposomal inhalation for the treatment of resistant non tuberculous mycobacterial (NTM) lung disease caused by Mycobacterium avium complex (MAC).
- Andexanet alfa for reversal of Factor Xa inhibition in patients with life-threatening or uncontrolled bleeding and for patients requiring urgent or emergency surgery.
- Angiotensin II injection for the treatment of hypotension in patients with septic or other distributive shock.
- Carbetocin injection (i/m) for the Prevention of postpartum haemorrhage (PPH) due to uterine atony after vaginal delivery
- Edoxaban for the treatment of VTE associated with cancer (licence extension)
- Fexapotide triflutate injection for benign prostatic hyperplasia
- NKTR-181 oral for Chronic low back pain in adult patients new to opioid therapy
- Remestemcel-L injection for Crohn's disease, moderate-to-severe, in patients who have previously failed at least one steroid, and at least one immuno-modulator or biologic
- Rivaroxaban for the prevention of VTE in ambulatory cancer patients receiving chemotherapy and at high risk of VTE (licence extension).
- Thrombomodulin alfa injection for the treatment of disseminated intravascular coagulation (DIC) in sepsis
- Ustekinumab for Ulcerative colitis, moderate-to-severe active disease, second-line (licence extension).

The National Cancer Drugs Fund

Cancer treatments became the commissioning responsibility of the NHS England Specialised Commissioning from April 2013. NHS England is also responsible for the operational management of the Cancer Drugs Fund (CDF) which was originally raised by top-slicing former PCT funds in 2010 and for which there was funding commitment until the end of March 2016.

NHS England then moved to a new operating model from 1 July 2016.

The main features of the model included:

- The CDF became a 'managed access' fund to include clear entry and exit criteria for drugs entering the fund.
- All new licensed cancer drugs will first be referred to NICE for appraisal. NICE will then make one of three recommendations:
  - that drug should be routinely commissioned – where there is clear evidence of the drugs clinical and cost effectiveness
  - that the drug should not be routinely commissioned- where there is clear evidence that the drug is not clinically and cost effective
  - that the drug should be considered for funding within the new CDF for a time limited period- where the clinical and cost effectiveness of the drug is uncertain

The National Cancer Drugs Fund list

A list of the National Institute for Health and Care Excellence (NICE) approved and baseline funded cancer drugs/indications with criteria for use can be accessed via:

https://www.england.nhs.uk/publication/national-cancer-drugs-fund-list/

APPENDIX 1

Terms of Reference for the TAG during 2018/19

Reference: New Medicines Policy (March 2014)

Accountability

- The TAG is established jointly by NHS CCGs in Norfolk and Waveney and is accountable to them.
- The TAG will report to NHS CCGs in Norfolk and Waveney on its recommendations on new
- The TAG reports recommendations to relevant service development groups to assist those groups' commissioning roles.

Probity

- TAG members are expected to follow the guidance contained in "NHS England Standards of *Business Conduct (Oct 2012)"* and local policy on sponsorship
- TAG members are expected abide by *"The Seven Principles of Public Life"* (Nolan Committee recommendations) attached.
- TAG members should take account of the principles described in the document *"Social Values Judgement: Principles for the development of NICE guidance"*.
- The TAG recommendations and related CCG commissioning decisions will be made publicly available through local NHS websites.
- An annual report on TAG recommendations and activities will be provided for CCG Boards.

Role

- The TAG will work within the NHS CCGs in Norfolk and Waveney 'Ethical & Commissioning Principles' Framework.
- The role of the TAG is to provide informed professional advice, after consideration of critically appraised evidence, to NHS CCGs in Norfolk and Waveney on the clinical and cost-effective use of medicines, dressings and other prescribable items such as those evaluated by the Advisory Committee on Borderline Substances (ACBS), herbal remedies etc. This includes:
  - advice on the managed introduction of new medicines and indications into practice – including the most appropriate method of implementing guidance produced for the NHS by NICE;
  - advice on the transfer of prescribing responsibility across the Primary / Secondary care interface.
- The professional advice will apply to the area covered by NHS CCGs in Norfolk and Waveney.
- The TAG does not make recommendations on individual cases nor consider the application of TAG advice in individual circumstances.
- Priority will be given to issues which are of relevance to more than one NHS Provider Trust or CCG.
- The TAG has no executive authority.
- NHS CCGs in Norfolk and Waveney look to the TAG for advice to underpin their joint process for the introduction of new medicines and indications.

Process

- The TAG will consult with relevant parties when developing policies and advice.
- The TAG can solicit advice from external experts and local networks e.g. Cardiac network.
- The work of the TAG may be supported by *ad hoc* working groups.
- Advice and recommendations are agreed by a quorate TAG.
- TAG recommendations will be agreed by the development of a consensus. A small number of objections may be accepted and these should be recorded in the meeting notes.
- TAG members should be mindful to represent a body of opinion, not merely their own opinion

Membership

Members are nominated by their organisations to provide informed professional advice.

NHS provider organisations are represented by a pharmacist and a senior clinician with responsibilities in medicines management – typically the Chair of a Trust's Drug and Therapeutics Committee. These organisations are encouraged to nominate deputies to attend in their absence to ensure appropriate input and balance.

- Senior medical representative from each member organisation (local CCGs & NHS Provider Trusts)
- Consultant/Specialist in Public Health Medicine
- TAG Lead Pharmacist
- Senior pharmacist representative from each member organisation (local CCGs and NHS Provider Trusts)
- Non-Medical Prescriber representative
- Mental Health Care Trust representatives
- Local Medical Committee representative.
- Local Pharmaceutical Committee representative.
- Lay representation from Patients' Fora.
- Clinical Pharmacologist (Academic representative).

Quorum

Seven members, or their deputies, to include the chair (or nominated deputy); three from primary care organisations and three from secondary care organisations.

Responsibilities of TAG members

- Accept ownership of TAG recommendations.
- Undertake work as necessary between meetings.
- Promote two-way communication between the TAG and relevant NHS colleagues / organisations.
- Take specific views from the TAG back to the member organisations for comment, and then to feed back the responses to the TAG, as appropriate.
- Commit to regular attendance of TAG meetings to ensure continuity and balance of input into decision-making.
- Be an enthusiastic, motivated and active participant in the committee.
- Declare prior to each meeting any outside interests, which might have a bearing on their actions, views and involvement in discussions within the committee.

Remit

New medicines and new indications for existing medicines

1. To consider the clinical and cost-effectiveness of new medicines and indications and other matters relating to prescribing responsibility (see below).
2. To consider guidance on medicines prepared for the NHS by NICE and other national and regional advisory bodies which may impact on patients within the Norfolk and Waveney area.
3. To consider the resource implications (staff, services and financial) of new medicines and indications to the NHS Norfolk and Waveney CCGs health economies.
4. To receive and consider proposals for the use of new medicines and indications as endorsed by NHS Provider Trust-based Drug and Therapeutics Committees (focused on secondary care medicines) or as proposed through Norfolk & Waveney CCGs (focused on primary care medicines).
5. To agree an estimate of the clinical and cost-effectiveness of a new medicine or indication and the extent to which this is supported by research-based evidence.
6. To agree advice on the place of a medicine in relation to the other methods of managing the proposed indication.
7. In relation to other medicines considered by the TAG and taking into account the prevailing circumstances, including financial circumstances and national recommendations and expectations:
    - to issue advice on the appropriate use of the medicine in Norfolk and Waveney and the reasons for this view;
    - to indicate those medicines which are considered to be of highest priority for introduction in the current commissioning cycle and the reasons for this view;
    - to indicate those medicines which are not considered of sufficient priority to recommend their use in Norfolk and Waveney and the reasons for this view.
8. To review policies in the light of changed circumstances, including new research evidence and guidance from the National Institute for Health and Care Excellence and/or the Department of Health, the MHRA/CHM.

Primary–Secondary care interface

1. To consider matters which affect the clinical and prescribing responsibility of medicines by GPs and consultants/specialists, e.g. licensed and proposed indications, evidence to support use, alternatives, side-effects, monitoring requirements, follow-up by consultants/specialists, use in a clinical trial, etc.
2. To develop and update general guidance on clinical and prescribing responsibilities across the primary–secondary care interface.
3. To advise on the initial and subsequent prescribing responsibility for specific medicines and the clinical role of GPs and consultants/specialists in the supervision and monitoring of the patient.
4. To receive and consider shared-care protocols (which document the above) for adoption in Norfolk and Waveney.
5. To advocate the preferred funding mechanism to support the implementation of TAG advice.
6. To review policies in the light of experience, changed circumstances, including new research evidence and guidance from the National Institute for Health and Care Excellence and/or the Department of Health, the MHRA/CHM.

Clinical trials

1. To consider and issue advice on the clinical and prescribing responsibility of GPs who are approached to prescribe a medicine which is being used as part of a clinical trial which may require significant investment in excess treatment costs and where the CCGs require additional clinical guidance in addition to the information considered by the D&TCG.
2. To develop general principles, but also provide advice on specific trials when not covered by the general principles.

Sponsorship

To develop and advise the local health economy on the probity of relationships between the pharmaceutical industry and the workings of the local health economy with a particular focus on ensuring that the choice of medicines used is not adversely influenced by such relationships.

Other issues

In relation to the issues described above, to receive and comment on guidelines which contain therapeutic advice.

Complaints and other feedback

- Feedback on TAG recommendations should be made to the Chairman who will refer to the CSU's Prescribing & Medicines Management Team for guidance on further handling.
- The TAG will reconsider its recommendations in the light of new information, new proposals for use, alternative interpretations or changed circumstances brought to its attention by informants or complainants.
- In the absence of such changed circumstances, TAG members will have their attention drawn to feedback or complaints by the Chairman.

Dissemination of advice

1. Through the meeting notes to members of the TAG and local stakeholders.
2. Through letters stating commissioning decisions to local NHS Provider Trusts from CCG Boards.
3. Through the "Norfolk & Waveney Prescriber" newsletter.
4. Through the "Traffic-light / TAG recommendations" document which is updated at least annually and usually between TAG meetings.
5. Through CCG and NHS Provider Trust intranets.
6. Through *ad hoc* communications where necessary.
7. Through reports to relevant groups involved in service development.
8. Through contributions to guidelines produced by others.
9. In CCG strategic delivery plans when appropriate.
10. In response to queries made to CCGs.

Implementation of advice

1. Through the commissioning processes of CCGs.
2. Through processes internal to CCGs and NHS Provider Trusts (e.g., Trust-based Drug and Therapeutics Committees, CCG/CSU-facilitated prescribing committees, clinical governance processes, audits etc).
3. Through the work of the CSU Prescribing and Medicines Management Teams.

APPENDIX 2

TAG Decision-Making Framework

"Traffic Light" Classifications

The final outcome of TAG recommendations is determined by commissioning decisions.

Double Red: Not recommended for routine use

- GPs would not ordinarily be expected to prescribe the medicine.
- GPs would not ordinarily receive money from any contingency funds held by their PCT if they chose to prescribe the medicine.
- Trust-based clinicians would not ordinarily be expected to use the medicine.
- Exceptional cases would still be considered initially via the Trust's DTC Chair.

Red: Hospital / Specialist use only

- Agreed criteria to determine which patients are treated and guideline for use.
- Need to agree funding arrangements: e.g. within tariff, excluded from tariff, pass-through payment.
- Could act, as a probationary period for new medicines for which there is immature or emerging data on effectiveness or cost-effectiveness. Also, for medicines for which the proven effective outcome is of uncertain or limited relevance.
- GPs would not ordinarily be expected to prescribe the medicine.
- GPs would not ordinarily receive money from any contingency funds held by their PCT if they chose to prescribe the medicine.

Amber: Option for Shared care

- Assessment and initiation by a specialist.
- Typically requires a specialist to modify or terminate treatment.
- Clinical and prescribing responsibilities are detailed in an agreed shared-care protocol.
- Suitable for a GP to prescribe ongoing treatment following an initial period of supply by the specialist as detailed in the shared-care protocol.

Green: GP prescribable at the request of Consultant/Specialist

- GPs may prescribe following recommendation by a specialist.
- Shared care protocol not required as with Amber classification.
- Hospital to supply when immediately necessary as an outpatient and on discharge, otherwise supplied by GP.

Double Green: Medicines considered suitable for GPs to initiate and prescribe

- GPs may take full responsibility for prescribing these medicines.

Summarised as:

Double Red	Not recommended for routine use
Red	Hospital only – Drugs for which the Trust is responsible for prescribing. GPs should not be expected or approached to prescribe
Amber	Shared care following hospital initiation under agreed shared-care protocol
Green	Specialist recommendation, GP prescribing
Double Green	GP prescribing

Decision-Making Framework for Recommendations on New Medicines and Indications

TAG Meeting Date: **Agenda Item:**

Medicine and Indication:

A) Hierarchy of Evidence

Methodology	Description	Levels of Available Evidence	Grade of Available Evidence
Systematic reviews	**Systematic review:** Review of a body of data that uses explicit methods to locate primary studies, and explicit criteria to assess their quality.	**1++** If high quality with a very low risk of bias	**A** – If at least one systematic review rated as 1++, and directly applicable to the target population
			B – If is extrapolated evidence
		1+ If well conducted with a (moderately) low risk of bias	**A** – If is part of a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
			B – If is extrapolated evidence
		1- If have a high risk of bias	**D**
Meta-analyses	**Meta-analysis:** A statistical analysis that combines or integrates the results of several independent clinical trials considered by the analyst to be "combinable" usually to the level of re-analysing the original data, also sometimes called: pooling, quantitative synthesis. Both are sometimes called "overviews".	**1++** If high quality with a very low risk of bias	**A** – If at least one meta-analysis rated as 1++, and directly applicable to the target population
			B – If is extrapolated evidence
		1+ If well conducted with a (moderately) low risk of bias	**A** – If is part of a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
			B – If is extrapolated evidence
		1- If have a high risk of bias	**D**

Methodology	Description	Levels of Available Evidence	Grade of Available Evidence
Randomised Controlled Trials (finer distinctions may be drawn within this group based on statistical parameters like the Confidence Intervals)	Individuals are randomly allocated to a Control Group and a group who receive a specific intervention. Otherwise the two groups are identical for any significant variables. They are followed up for specific end points.	**1++** If high quality with a very low risk of bias	**A** – If at least one RCT rated as 1++, and directly applicable to the target population
			B – If is extrapolated evidence
		1+ If well conducted with a (moderately) low risk of bias	**A** – If is part of a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
			B – If is extrapolated evidence
		1- If have a high risk of bias	**D**
Cohort studies	Groups of people are selected on the basis of their exposure to a particular agent and followed up for specific outcomes.	**2++** If are high quality, with a very low risk of confounding or bias and a high probability that the relationship is causal	**B** – If part of a body of evidence directly applicable to the target population, and demonstrating overall consistency of results
		2+ If have a low risk of confounding or bias and a moderate probability that the relationship is causal	**C** – If part of a body of evidence directly applicable to the target population and demonstrating overall consistency of results
			D – If is extrapolated evidence
		2- If have a high risk of confounding or bias and a significant risk that the relationship is not causal	**D**
Case-control studies	"Cases" with a condition are matched with "controls" without, and a retrospective analysis used to look for differences between the two groups.	**2++** If are high quality, with a very low risk of confounding or bias and a high probability that the relationship is causal	**B** – If part of a body of evidence directly applicable to the target population, and demonstrating overall consistency of results
		2+ If have a low risk of confounding or bias and a moderate probability that the relationship is causal	**C** – If part of a body of evidence directly applicable to the target population and demonstrating overall consistency of results
			D – If is extrapolated evidence
		2- If have a high risk of confounding or bias and a significant risk that the relationship is not causal	**D**

Methodology	Description	Levels of Available Evidence	Grade of Available Evidence
Cross-sectional studies	Survey or interview of a sample of the population of interest at one point in time	**3?**	**D**
Non-Analytic Studies: e.g. Case reports, Case Series	A report based on a single patient or subject; sometimes collected together into a short series	**3**	**D**
Expert opinion	A consensus of opinion from the good and the great	**4**	**D**
Anecdotal	Something a bloke told you after a meeting or in the bar	**5**	**D**

Adapted from Systematic reviews, *What are they and why are they useful?* ScHARR 2008.

Levels and Grades of evidence (Refn: Scottish Intercollegiate Guidelines Network (www.sign.ac.uk):

Level of evidence

1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+ Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1 - Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++ High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+ Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2 - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3 Non-analytic studies, e.g. case reports, case series
4 Expert opinion

Levels and Grades of evidence (Refn: Scottish Intercollegiate Guidelines Network (www.sign.ac.uk):

Grade of evidence

A At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.
B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+.
C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++.
D Evidence level 3, 4 or 5, or extrapolated evidence from studies rated as 2+.

B) To support the TAG in deciding if a Medication *should* be recommended for use

Criterion to be measured	← Tends to "poor"		Tends to "good" →	
Evidence:				
Grade of evidence in the papers reviewed ***(as per section A) Hierarchy of evidence)***	**D**	**C**	**B**	**A**
Are trial end-points Patient orientated outcomes (POOs) or Drug orientated outcomes (DOOs) / clinical outcomes or surrogate markers?	DOOs / Surrogate markers		POOs / Clinical outcomes	
Magnitude of clinical effect inferred from trials reviewed	Low:	Medium:		High:
Number Needed to Treat (NNT):	High:	Medium:		Low:
Clinical indication & treatment options:				
Licensed status?	Unlicensed:		Licensed:	
Novel drug or member of existing class?	Member of existing class:		Novel drug:	
Severity of Condition to be Treated	Trivial:	Medium:		Severe:
Comparative effectiveness with other medicines for the same condition	Poor:	Medium:		Good:
Safety:				
Risk of side-effects occurring	High:	Medium:		Low:
Severity of known side-effects	High:	Medium:		Low:
Concern regarding Possible Side Effects Not Yet Uncovered	High:	Medium:		Low:
Balance of Benefit To Harm (side effects toxicity interactions etc)	Poor:	Medium:		Good:
Numbers Needed to Harm (NNH):	Low:	Medium:		High::
Risk of clinically significant (Known) interactions	High:	Medium:		Low
Cost effectiveness:				
Cost per QALY (*where available*): *From April 2017 NICE applies a threshold range from £20k up to £100k per QALY for very rare conditions, with higher limits applied to highly specialised technologies commissioned by NHS England.*	Greater than NICE threshold:		Less than NICE threshold:	
Are there alternative, comparable and more cost effective interventions?	Yes:		No:	

Criterion to be measured	← Tends to "poor"		Tends to "good" →
Decision on whether the proposed treatment should be *recommended* for use (subject to final funding decisions):	**No**	**Possibly (with caveats):**	**Yes**

C) Prescriber's Rating – To assist the TAG in *clarifying* its recommendation for use of a medicine or treatment

Prescriber's Rating Definitions			***Recommended for use?***
1.	**Bravo!**	The drug is a major therapeutic advance in an area where previously no treatment was available.	***Yes***
2.	**A real advance**	The product is an important therapeutic innovation but has certain limitations.	
3.	**Offers an advantage**	The product has some value but does not fundamentally change present therapeutic practice.	
4.	**Possibly Helpful**	The product offers small additional value, and should not change prescribing habits except in rare circumstances.	***Possibly***
5.	**Judgement reserved**	The Committee postpones its judgement until better data and a more thorough evaluation of the drug are available.	***No***
6.	**Nothing New**	The product may be a new substance but is superfluous because it does not add to the clinical possibilities offered by previous products available. (In most cases these are "me-too" products).	
7.	**Not acceptable**	Product without evident benefit over others but with potential or real disadvantages.	
Prescriber's Rating agreed by the TAG		**Number:**	

With acknowledgement to Prescrire and NHS Suffolk D&TC

D) To assist the TAG in recommending *where* Prescribing Responsibility might rest in Norfolk and Waveney

Criterion		Red (Hospital / Specialist only)	Amber (Option for shared care)	Green (Specialist recommendation / initiation)	Double Green (Suitable for initiation in Primary Care)
Skills of the Prescriber	Experience Of The Condition	Specific	Specific	Specific	General
	Diagnosis	Specific	Specific	Specific	General
	Monitoring Progress Of Treatment	Difficult	Specific	General	General
Therapy	Patient Selection	Difficult	Specific	Specific	Easy
	Initiation Of Treatment	Difficult	Difficult	Easy	Easy
	Dose Titration	Difficult	Specific	Easy	Easy
	Monitoring Of Side Effects	Complex	Easy	Easy	Easy
	Method Of Administration	Complex	Normal	Normal	Normal
	Discontinuation Of Treatment	Complex	Complex	Easy	Easy
Recommended classification:					

References:
Jonsen A, Bentham In a box: Technology assessment and health care allocation. Law Med. Health Care. 1986;14:172-174
Suffolk Drugs & Therapeutics Committee – responsibility for prescribing, Hospital Trust or GP?
East of England Priorities Advisory Committee (PAC) - Documentation on requesting a PAC recommendation

E) Framework to assist Commissioners in deciding whether to fund the proposed treatment

D&TC / JSCC Meeting Date: **Agenda Item:**

Medicine and Indication:

TAG recommendation:

Criterion to be measured	Tends to "poor"		Tends to "good"
Cost effectiveness:			
Cost per QALY (*where available*): *From April 2017 NICE applies a threshold range from £20k up to £100k per QALY for very rare conditions, with higher limits applied to highly specialised technologies commissioned by NHS England.*	Greater than NICE threshold:		Less than NICE threshold:
Are there alternative, comparable and more cost effective interventions?	Yes:		No:
Priority:			
Is the treatment a national, or a local priority / directive?	Not a priority	Local priority	National & Local priority
Health needs and health outcomes or benefits to be gained	Low:	Medium:	High:
Equity and Health Equalities:			
Is this patient /clinical condition or patient subgroup being treated differently in relation to others?	Yes:		No:
To what extent will adopting the treatment narrow existing health inequalities?	Low:	Medium:	High:
Budgetary impact / Affordability:			
Level of confidence in the robustness of the proposed business case	Low:	Medium:	High:
Quality of assessment of total budgetary impact in the business case	Low:	Medium:	High:
Expected patient population (estimated proportion of people with this condition likely to be prescribed the medication under consideration – maximum and minimum uptake)			

Criterion to be measured	Tends to "poor"		Tends to "good"
Opportunity costs? *(Whether the treatment is cost saving or cash-releasing)*	No:		Yes – via….
Risks from not recommending for clinical use & funding:			
….including risks to patient or service / impact on other services	Low:	Medium:	High:
Implementation and achievability considerations			
Are necessary management resources available to implement the initiative?	No:	Not known:	Yes:
Does the workforce have the required skills to implement the initiative?	No:	Not known:	Yes:
Are necessary infrastructure and equipment available to implement the initiative?	No:	Not known:	Yes:
Can implementation take place within a reasonable timescale?	No:	Possibly:	Yes:
Does implementation depend on active cooperation from external stakeholders – outside commissioners' control?	Yes:	No	
Final decision on whether the proposed treatment should be funded:	**No**	**Possibly (with caveats):**	**Yes**

Appendix 3

NORFOLK & WAVENEY THERAPEUTICS ADVISORY GROUP (TAG)

Declaration of Actual & Potential Conflicts of Interest

This information will not be made public without permission

NHS England defines a Conflict of Interest as:

"*A set of circumstances by which a reasonable person would consider that an individual's ability to apply judgement or act, in the context of delivering, commissioning, or assuring taxpayer funded health and care services is, or could be, impaired or influenced by another interest they hold.*"

Title & Name:

Correspondence / E-mail Contact Address:

TAG Members and contributors are requested to declare any **actual** and all **potential** conflicts of interest arising from their contacts with grant-awarding bodies, the pharmaceutical industry or other commercial organisations. **Members should also declare interests relating to specific agenda items at each meeting for the meeting record.**

Declarations should include existing interests, those arising in the past year or planned for next year.

Declaration of Potentially Competing Interest (*See guidance notes overleaf*):

	Item	Company	Outline description/ Comments
1.	Shareholding and/or Company Directorship		
2.	Paid consultancy work either direct or via an agency or other third party		
3.	Occasional payments for lecturing; please identify regularity		
4.	Sponsorship of posts in clinical or research team(s)		
5.	Sponsorship for conferences or other educational events		
6.	Sponsorship of any other description (travel, materials to support practice, research)		
7.	Any other links (e.g. relatives) Or other potential areas of conflict		
8.	I have nothing to declare *(Please tick or "x" the box)*		

Signature: **Date:**

Action taken by TAG Chairman:

Date:

TAG Declaration of Interest Form – July 2018 v6 Originally adapted from NHS Cambs JPG DoI form; updated in line with NHS England – *Managing Conflicts of Interest in the NHS* (February 2017).

Appendix 3

NORFOLK & WAVENEY THERAPEUTICS ADVISORY GROUP (TAG)

Statement on Potentially Competing Interests

TAG members, reviewers and all those who provide comments are asked to declare to the Chairman of the TAG any competing interests relating to any item to be discussed, or on which they are making comment to TAG, by signing a 'Declaration of Potential Conflict of Interest' form in the format agreed by TAG. TAG members are personally responsible for declaring material interests at the beginning of each meeting and as they arise. Any new interests should be added to the member's individual Annual Declaration of Interest form which is available at meetings.

Only the existence of a potentially competing interest, the individual and/or organisation concerned and the nature of the interest need be recorded. The amount of any fees, grants etc. need not be disclosed.

It shall be for the Chairman to decide on the action to then be taken regarding participation in the discussion and subsequent decisions relating to that product or issue.

A record shall be kept by the TAG Lead Pharmacist of all declarations of potentially competing interests, and the related action taken by the Chairman

Competing interests exist when professional judgement concerning a primary interest may be influenced by a secondary interest and will be defined as per NHS England guidance and also in the manner used by the British Medical Journal:

"A competing interest exists when professional judgement concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It may arise when they have a financial or other interest that may influence – probably without their knowing – their interpretation of their decisions or those of others".

Conflict of interest is a state, not a behaviour, and exists whether or not judgement is actually influenced by competing interests. As such the Therapeutics Advisory Group (TAG) asks that potentially competing interests are declared by members, reviewers and those who provide comments. This information is for use within the group and *will not be disclosed without permission*.

The types of interest that should be declared include:

Personal Interests

Personal interests in an organisation (e.g. a pharmaceutical company) that may in any way gain or lose financially from work undertaken on behalf of the TAG. Personal interests include consultancies, fee-paid work or directly managed shareholdings (not shareholdings through unit trusts or similar).

Non-Personal Interests

Non-personal interests in an organisation that may in any way gain or lose financially from work undertaken on behalf of the TAG. Non–personal interests are those which benefit a department for which the member is responsible but not the member personally.

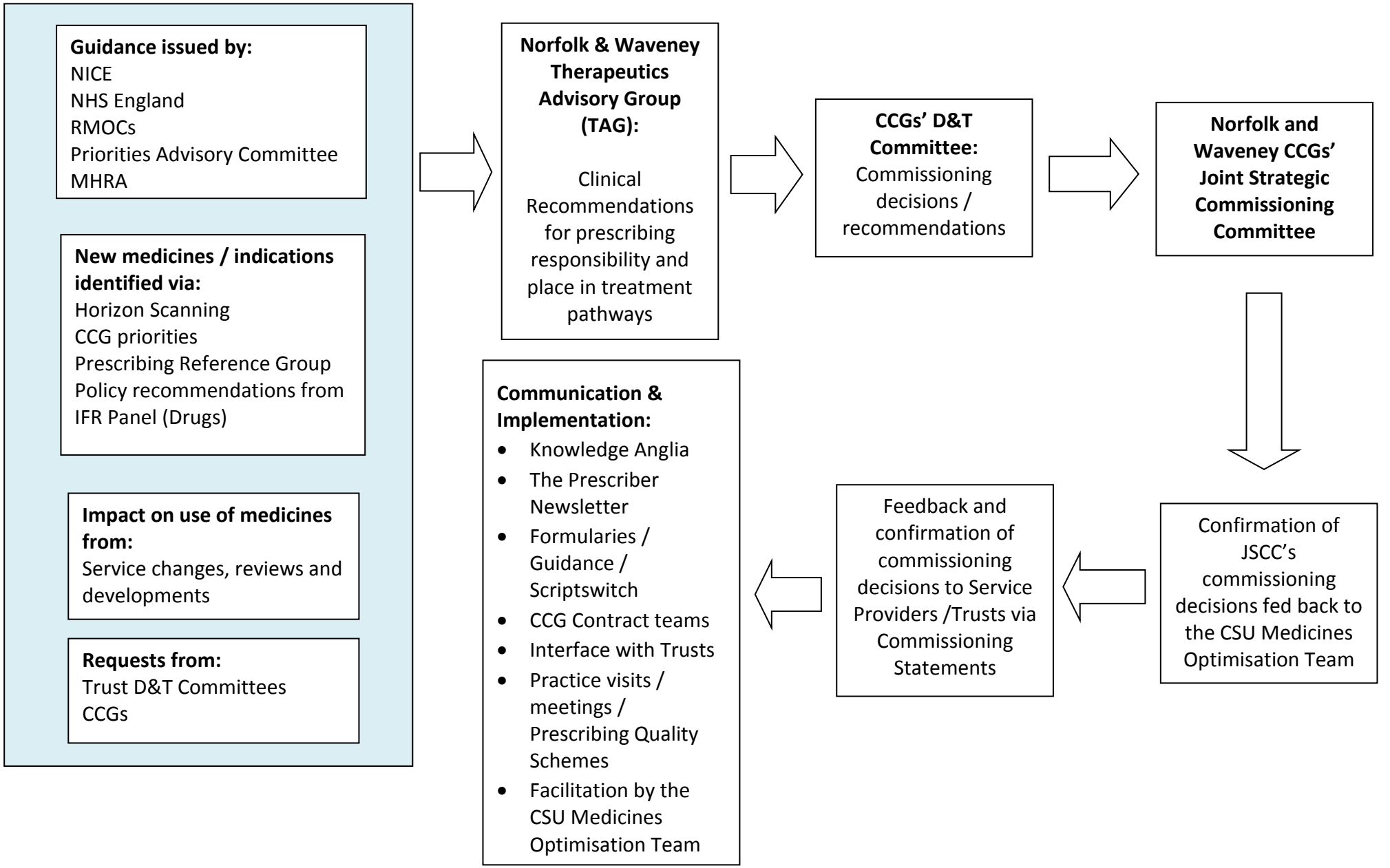
Examples of non-personal interests include fellowships, grants for the running of a unit or department, sponsorship of a post or member of staff, commissioned research or other work from staff in the unit and, sponsorship of attendance at scientific or similar meetings.

Other Potential Conflicts

We would also ask reviewers and those who provide comments to declare other potential conflicts of interest. For example, former employment in an organisation that may in any way gain or lose from work undertaken on behalf of the TAG, political or religious convictions which might influence conclusions, or academic or personal links with somebody whose interests may be affected by decisions made and advice given to/by the TAG.

Advice on potentially conflicting interests may be sought from the Chair of the TAG, Dr Ian Tolley, ian.tolley@nhs.net or from the TAG Lead Pharmacist fiona.marshall3@nhs.net

Appendix 4


Guidance issued by:
NICE
NHS England
RMOCs
Priorities Advisory Committee
MHRA
New medicines / indications identified via:
Horizon Scanning
CCG priorities
Prescribing Reference Group
Policy recommendations from IFR Panel (Drugs)
Impact on use of medicines from:
Service changes, reviews and developments
Requests from:
Trust D&T Committees
CCGs
Norfolk & Waveney Therapeutics Advisory Group (TAG):
Clinical Recommendations for prescribing responsibility and place in treatment pathways
CCGs' D&T Committee:
Commissioning decisions / recommendations
Norfolk and Waveney CCGs' Joint Strategic Commissioning Committee
Confirmation of JSCC's commissioning decisions fed back to the CSU Medicines Optimisation Team
Feedback and confirmation of commissioning decisions to Service Providers /Trusts via Commissioning Statements
Communication & Implementation:
• Knowledge Anglia
• The Prescriber Newsletter
• Formularies / Guidance / Scriptswitch
• CCG Contract teams
• Interface with Trusts
• Practice visits / meetings / Prescribing Quality Schemes
• Facilitation by the CSU Medicines Optimisation Team