The Norfolk and Waveney Therapeutics Advisory Group (TAG)

REPORT

April 2017 to March 2018

"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 2017 to March 2018

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 across all of Norfolk and Waveney.

During 2017-18 the TAG performed this work on behalf of Clinical Commissioning Groups (CCGs) in the Norfolk and Waveney area. The work of the committee was delivered as part of Prescribing and Medicines Management services provided at that time by the NEL Commissioning Support Unit (Anglia).

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 Appraisals 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 2017-18 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 by using 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 Commissioning Group (D&TCG).

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 2017-18.

Communicating TAG Recommendations and CCG Commissioning Decisions:

The D&TCG's commissioning decisions were then communicated to commissioning bodies and key stakeholders via letters / e-mails, using the **Summary of TAG Recommendations and D&TCG Commissioning Decisions**.

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

- During 2017/18 the **TAG Recommendations Report** was available to local NHS Healthcare Practitioners via the Knowledge Management Service at http://nww.knowledgeanglia.nhs.uk/ .

- D&TCG Commissioning Decisions were recorded in the **Combined Commissioned Drugs List** which was available to local NHS Healthcare Practitioners via the Knowledge Management Service at and also via **Commissioning Statements** , **Commissioned Pathways** and **Policy Statements** supported by **Norfolk & Waveney CCG Drugs & Therapeutics Commissioning Group (D&TCG)** from January 2016 up to March 2018.

- TAG Recommendations and D&TCG 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 Drugs & Therapeutics Commissioning Group meeting.

The Norfolk & Waveney Prescriber Newsletter:

During 2017-18 ***The Norfolk & Waveney Prescriber*** newsletter was published in its revised style and format, with both e-mail and web-based distribution.

Six two-monthly editions of the Norfolk & Waveney Prescriber newsletter were published from April 2017 to March 2018 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 2017/18:

Headlines: 318 recommendations to commissioners

- **50** recommendations regarding **New Drugs & Indications**
- **149** recommendations relating to **NICE Guidance**
- **103** recommendations related to **Interface issues and Miscellaneous Guidance**
- **14** recommendations related to **East of England Priorities Advisory Committee (EoE PAC)** policies
- **1** recommendation related to **NHS England Specialised Commissioning Group (NHSE SCG)** policies
- **1** recommendation related to **Regional Medicines Optimisation Committees (RMOCs)**

Details of all the **TAG's Recommendations for 2017-18** are listed in **Section 1** (from **Page 10 onwards).**

TAG Membership during 2017/18

TAG members included representatives from the following organisations

- Cambridgeshire Community Services NHS Trust
- East Coast Community Healthcare CIC
- Great Yarmouth and Waveney CCG
- HealthWatch Norfolk
- NEL CSU (Anglia) (Commissioning Support Unit)
- 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)
- South Norfolk CCG
- The James Paget University Hospital NHS Foundation Trust
- The Norfolk & Norwich University Hospital NHS Foundation Trust
- The Queen Elizabeth Hospital, King's Lynn NHS Foundation Trust
- West Norfolk CCG

TAG Meetings Attendance 2017/18

- 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 2017 to March 2018.
- The following table reports on the attendance rates of TAG members, their roles, and representative organisations during 2017–18 (*compared with 2016-17*).

Role	Member Organisation	TAG Meetings Attendance 2017-18 *(2016-17)*
Community Pharmacist	Norfolk LPC	0 out of 6 *(2)*
Assistant Chief Pharmacist	The Queen Elizabeth Hospital	4 out of 6 *(5)*
Chief Pharmacist	Norfolk & Suffolk Foundation Trust	3 out of 6 *(4)*
GP / Medical Adviser (left February 2018	Great Yarmouth & Waveney CCG	3 out of 5 *(6)*
Head of Prescribing & Medicines Management	Great Yarmouth & Waveney CCG	6 out of 6 *(3)*
Clinical Director of Pharmacy Services	Norfolk & Norwich University Hospital	4 out of 6 *(5)*
GP Prescribing Lead	North Norfolk CCG	3 out of 6 *(4)*
Highly Specialist Pharmacist HIV	Cambridgeshire Community Services NHS Trust	1 out of 6 (*1*)
TAG Lead Pharmacist	NEL CSU Anglia	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 *(5)*
Consultant in Public Health	Public Health England - Norfolk	0 out of 6 *(3)*
D&TC Chair	The Queen Elizabeth Hospital	5 out of 6 *(6)*
Clinical Pharmacy Manager	Norfolk & Suffolk Foundation Trust	3 out of 6 *(3)*
GP Representative	South Norfolk CCG	6 out of 6 (*6*)
Deputy Head of Prescribing & Medicines Management / Prescribing Adviser	NEL CSU Anglia	5 out of 6 *(3)*
Assistant Director / Head of Prescribing & Medicines Management	Norfolk Community Health and Care	4 out of 6 *(3)*
Lay Member	HealthWatch - Norfolk	5 out of 6 (*6*)
Head of Prescribing & MM	East Coast Community Healthcare CIC	0 out of 6 *(0)*
D&TC Chair	The James Paget University Hospital	0 out of 6 *(3)*
TAG Chair	Norwich GP / Local Medical Committee	6 out of 6 *(6)*
Pharmacist Prescribing Adviser	NEL CSU Anglia - North Norfolk	6 out of 6 *(6)*
Prescribing Adviser – Interface / High Cost Drugs	NEL CSU Anglia	5 out of 6 *(6)*
GP Prescribing Lead	West Norfolk CCG	0 out of 6 *(2)*

Costs of running the TAG

Financial Year 2017-18:

- The work of the TAG is managed and delivered by the TAG Lead Pharmacist which is a salaried role, employed during 2017-18 by NEL Commissioning Support Unit (CSU).
- The majority of 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 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 2017/18 was **£467.40** 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 **2017-2018**, 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 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 CCGs and their local priorities, the emphasis on QIPP, and as healthcare resources became 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 2017/18

The TAG developed a range of guidance on the appropriate and cost-effective use of medicines during 2017/18 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 2017	**Central Norfolk CCGs and NNUH Joint Application:** **Draft Shared Care Proposal:** Currently classified as Red (Hospital only)	Denosumab (*Xgeva*®)	For prevention of skeletal related events in adults with bone metastases from solid tumours, other than prostate - in line with **NICE TA 265**	**January 2017:** Proposed as an alternative to IV zoledronic acid infusions, to be given in primary care by monthly subcutaneous injection under a Local Enhanced Service agreement, to ease current service pressures. The TAG supported the shared care proposal subject to minor amendments, and recommended a revised classification of Amber (Option for GP prescribing under an approved shared care agreement). **March 2017:** The Shared Care Agreement has not yet been published as no confirmation has been received from CCGs regarding the LES. No information was available to advise the TAG of any progress on this. **May 2017:** The TAG was advised that no further information had been received from the central Norfolk CCGs' commissioning body. The LMC are also conferring with the CCGs regarding GP workload	**January 2017:** *The D&TCG recommended that details on how to order the treatment direct from the designated supplier (Movianto) should be added to the shared care document.* *The D&TCG otherwise supported the TAG's recommendation of* Amber (Option for GP prescribing under an approved shared care agreement) ***in principle*** *but subject to local CCGs finalising the Local Enhanced Service agreement. CCG D&TCG members to feedback regarding when this happens.* **March & May 2017:** *The D&TCG was advised that there was no update regarding the LES and agreed that the TAG should keep this item as a Matter Arising.*

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 related payments for participation in shared care. Clarification regarding shared care funding streams is awaited. **July 2017:** The TAG acknowledged that this item could not move forward at the moment pending the further discussions around the management of shared care arrangements in their entirety within the local economy.	**July 2017:** *No further progress to date on this issue - noted by the D&TCG.*
May 2017	**Therapeutics Advisory Group:** **QEH Proposed Treatment Policy:**	2 years of either 6-monthly IV zoledronic acid infusions (4 doses), or daily oral ibandronate.	Adjuvant use to improve survival in post-menopausal women with breast cancer receiving chemotherapy	**March 2017:** The TAG considered the QEH application and recommended that the key reference cited is provided for the TAG to consider. The TAG would also welcome similar applications from oncology specialists at the other acute trusts if interested in this model of care. The item was otherwise deferred until the next meeting. **May 2017:** The TAG reconsidered the QEH's application alongside the key reference and agreed to support the application. The TAG recommended traffic light classifications of Green (GP prescribable following consultant recommendation) for daily oral ibandronate and Red (Hospital use only) for 6-monthly IV zoledronic acid infusions (4	**March 2017:** *Noted by the D&TCG. Viewed as being a useful initiative that could be taken up other Trusts. The D&TCG awaits further progress on this item.* **May 2017:** *The D&TCG noted and supported the TAG's recommendations and decided to commission adjuvant use of 2 years of either 6-monthly IV zoledronic acid infusions (4 doses), or daily oral ibandronate, to improve survival in post-menopausal women with breast cancer receiving chemotherapy as* Red (Hospital use only) *and* Green (GP prescribable following consultant recommendation) *respectively.*

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
				doses) as adjuvant treatment to improve survival in post-menopausal women with breast cancer receiving chemotherapy for 2 years.	*The D&TCG also recommended that GP prescribing systems and processes should ensure that such use of ibandronic acid is not stopped in advertently or continued beyond two years inappropriately by clearly stating the Indication and duration of use along with an appropriate stop date on the patient's record.*
May 2017	**Therapeutics Advisory Group:** **NNUH & QEH Joint Guideline: Antibiotic Management of Diabetes Related Foot Infections in Adults**	Various antibiotics	Management of Diabetes Related Foot Infections in Adults	The TAG was advised that feedback had been sent to the authors recommending that additional text regarding the need to monitor LFTs in patients on long-term fusidic acid for osteomyelitis. The guideline is already hyperlinked from the Primary Care Antibiotic Formulary in Norfolk. The TAG otherwise supported the guidance.	*Noted by the D&TCG*
May 2017	**Therapeutics Advisory Group:** **N&W GP Prescribing Information:**	Sodium oxybate	For treatment of adult narcoleptic patients with cataplexy who were already on treatment prior to July 2013	Guidance last reviewed July 2013. Three patients remain on treatment in Norfolk (North Norfolk, West Norfolk & Norwich CCGs). The TAG recommended that the prescribing information could be withdrawn from use on Knowledge Anglia.	*Noted and supported by the D&TCG*

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 2017	**Therapeutics Advisory Group:** **JPUH Application:** *Revised application with additional information on patient numbers and costs has been deferred until Sept 2017. A new application from the NNUH may also be available by that time.*	Alirocumab (*Praluent*®) and Evolocumab (*Repatha*®)	For treating primary hypercholesterolaemia and mixed dyslipidaemia - as specified in NICE TAs **393** and **394**	**July 2017:** **Draft Primary Care Lipid Treatment Pathway:** No work had yet been done to create local documentation, but it was considered that examples from other areas could perhaps be adapted for local use through the Prescribing Reference Group.	*Noted by the D&TCG.*
July 2017	**Therapeutics Advisory Group:** **Revised GP Prescribing Guidance:** **Adjuvant Bisphosphonates to improve survival in post-menopausal women with breast cancer receiving chemotherapy** 2 years' of either 6-monthly IV zoledronic acid infusions (4 doses), classified as Red (Hospital	2 years daily oral ibandronate.	Adjuvant use to improve survival in post-menopausal women with breast cancer receiving chemotherapy	**May 2017:** The TAG reconsidered the QEH's application alongside the key reference and agreed to support the application. The TAG recommended traffic light classifications of Green (GP prescribable following consultant recommendation) for daily oral ibandronate and Red (Hospital use only) for 6-monthly IV zoledronic acid infusions (4 doses) as adjuvant treatment to improve survival in post-menopausal women with breast cancer receiving chemotherapy for 2 years.	**May 2017:** *The D&TCG decided to commission adjuvant use of 2 years of either 6-monthly IV zoledronic acid infusions (4 doses), or daily oral ibandronate, to improve survival in post-menopausal women with breast cancer receiving chemotherapy as* Red (Hospital use only) *and* Green (GP prescribable following consultant recommendation) *respectively.* *The D&TCG also recommended that GP prescribing systems and processes should ensure that such use of ibandronic acid is*

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	only), or daily oral ibandronate, classified as Green (GP prescribable following specialist recommendation) in May 2017.			**July 2017:** Previous GP guidance for use of oral ibandronic acid for prevention of skeletal events in patients with breast cancer and bone metastases had been updated to incorporate newly supported indication. This was supported by the TAG. The TAG also recommended that the Trusts specialists should be asked to develop a standard letter to GPs which states that treatment should only be given for two years; that the treatment should stop after 2 years and that a blood test should be carried out after 12 months.	*not stopped in advertently or continued beyond two years inappropriately by clearly stating the Indication and duration of use along with an appropriate stop date on the patient's record.* **July 2017:** *Noted and supported by the D&TCG.*
July 2017	**Therapeutics Advisory Group:** **<u>NNUH application</u>:** **Proposal for Treat and Extend (T&E)** **1.** "prn" regimen verses a "treat and extend" protocol. **2.** Wet AMD Flow Diagram of treatment options **3.** Wet AMD Treat & Extend Management flow diagram	Aflibercept (*Eylea*®) and Ranibizumab (*Lucentis*®)	For treatment of Wet Age-related Macular Degeneration (AMD)	It was suggested that drug costs can be captured and activity costs could potentially be monitored if a piece of work was done with the Trusts, and by NHS Business Intelligence to make sure that all parties are using consistent coding. Ophthalmology would need to demonstrate that the T&E protocol was working by reducing the number of visits required and containing the costs. New patients would also need to be factored into that equation. It was suggested that perhaps Public Health might be in a position to carry out a piece of work to monitor this.	*The D&TCG noted the TAG's discussions and recommendations, and was advised that close financial monitoring of use of the treatments will be undertaken via the BlueTeq system.* *The D&TCG was advised to request a report on the savings made through use of the Treat & Extend regimen after one year's data has been captured.* *Modified versions of the wet AMD and DMO treatment pathways to include use of T&E will be circulated to the local clinicians.* *The D&TCG agreed to*

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
	4. West Suffolk Hospital – Treatment Pathway for Age Related Macular Degeneration (ARMD) Treat and Extend studies - *abstracts*			The TAG agreed to recommend the clinical appropriateness of the potential of following a Treat and Extend protocol. The arrangements of how this would be implemented would be for the commissioners to determine. The TAG members also recommended that a review should be carried out to see if the protocol was cost effective, if it was commissioned.	*commission use of* Aflibercept (*Eylea*®) and Ranibizumab (*Lucentis*®) for treatment of Wet Age-related Macular Degeneration (AMD) under a treat and extend regimen as Red (Hospital use only).
July 2017	**Therapeutics Advisory Group:** **<u>NNUH application</u>:** **Proposal for Treat and Extend** **1.** "prn" regimen verses a "treat and extend" protocol. **2.** DMO Flow Diagram of treatment options **3.** DMO Treat & Extend Management flow diagram **4.** Modified Suffolk Treatment Pathways for Diabetic Macular Oedema (DMO)	Aflibercept (*Eylea*®) and Ranibizumab (*Lucentis*®)	For treatment of Diabetic Macular Oedema (DMO)	Drug costs could be captured and activity costs potentially be monitored if a piece of work was done with the Trusts, and by NHS Business Intelligence to make sure that all parties are using consistent activity coding. Ophthalmology would need to demonstrate that the T&E protocol was working if it reduced the number of visits required and contained costs. New patients would also need to be factored in. It was suggested that Public Health might be in a position to carry out a piece of work to monitor this. The TAG agreed to recommend the clinical appropriateness of the potential of following a Treat and Extend protocol. The arrangements of how this would be implemented to be determined by commissioners. The TAG members also	*The D&TCG noted the TAG's discussions and recommendations, and was advised that close financial monitoring of use of the treatments will be undertaken via the BlueTeq system.* *The D&TCG was advised to request a report on the savings made through use of the Treat & Extend regimen after one year's data has been captured.* *Modified versions of the wet AMD and DMO treatment pathways to include use of T&E will be circulated to the local clinicians.* *The D&TCG agreed to commission use of* Aflibercept (*Eylea*®) and Ranibizumab (*Lucentis*®) for treatment of Diabetic Macular Oedema (DMO) under a treat and extend regimen as Red

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 that a review is carried out to see if the protocol was cost effective, if T&E was commissioned.	(Hospital use only).
July 2017	**Therapeutics Advisory Group:** **<u>NNUH application & Treatment Pathway</u>:** The application is for the use of Golimumab as a third line anti-TNF agent in patients where neither adalimumab nor infliximab can be used either due to the presence of anti-drug antibodies (ADA) or adverse drug reactions (ADR).	Golimumab (*Simponi*®)	For induction of remission, with or without steroids, in patients with Crohn's disease colitis with moderate-severe disease as a third-line anti-TNF after failure of or adverse reaction to two previous agents (*unlicensed indication; no current NICE guidance supporting use*)	The TAG supported the NNUH's application and proposed pathway (with amendments regarding the order of use of ustekinumab and vedolizumab as per NICE guidance), and recommended a traffic light classification of Red (Hospital/Specialist only).	*The D&TCG noted the TAG's recommendation and decided to classify this treatment as* **Double Red (Not recommended for routine use)** *in the interim, until the treatment pathway has been clarified and resubmitted.*
July 2017	**Therapeutics Advisory Group:** **<u>NNUH application & Treatment Pathway</u>:** **(*submitted pre final NICE guidance*)** NICE are due to publish their Technology Appraisal Guidance for Ustekinumab for moderately to severely active Crohn's disease after previous treatment in July 2017. **NICE Final Appraisal Determination (April 2017) states:** **1.1** *Ustekinumab is recommended, within its marketing authorisation, as an option for treating moderately to severely active*	Ustekinumab (*Stelara*®) for treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies.	The treatment pathway would be amended to place ustekinumab ahead of vedolizumab in line with the NICE FAD on ustekinumab. Local clinicians have previously always indicated a preference for ustekinumab over vedolizumab. Once the pathway was amended it would be shared with QEH and JPUH. The TAG supported the NNUH's	*The D&TCG noted the TAG's recommendation and decided to classify this treatment as* **Double Red (Not recommended for routine use)** *in the interim, until the NICE TA has been published and the draft treatment pathway clarified and resubmitted.*

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
	Crohn's disease, for adults who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-alpha inhibitor or have medical contraindications to such therapies. **1.2** *The choice of treatment between ustekinumab or another biological therapy should be made on an individual basis after discussion between the patient and their clinician about the advantages and disadvantages of the treatments available. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose).*			application and proposed pathway with the above amendments, and recommended in principle a traffic light classification of Red (Hospital/Specialist only).	
July 2017	**Therapeutics Advisory Group:** **NNUH application and proposed Biological Treatment Pathway for psoriasis:** *The NNUH has been confirmed as a specialist centre for the treatment of psoriasis.*	Apremilast (*Otezla*®), Secukinumab (*Cosentyx*®) and ixekizumab (*Taltz*®)*	Treatment of moderate to severe plaque psoriasis (in line with NICE TAs 419, 350 and 442)	Current classifications for apremilast and for secukinumab, and for ixekizumab for use in moderate to severe plaque psoriasis are **Double Red (not recommended for routine use)** The TAG supported the NNUH's application and proposed pathway with recommended amendments, and recommended revised traffic light classifications. The D&TCG is asked consider re-classifying these treatments to Red (Hospital/Specialist only) if used in line with NICE TA 419, NICE TA 350 and NICE TA 442 respectively (**although a business application for ixekizumab has yet to be submitted*).	*The D&TCG noted the TAG's recommendations and decided to maintain the classifications as* **Double Red (Not recommended for routine use)** *in the interim, until the draft treatment pathway has been clarified and resubmitted.*

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 2017	**Therapeutics Advisory Group:** **JPUH Application:** *A revised application, along with JPUH Formulary applications; the NICE Resource Impact template for GY&W CCG population; Lipid Modification Pathways for FH and N-FH; Fourier Study Summary, was submitted*	Alirocumab (*Praluent*®) and Evolocumab (*Repatha*®)	For treating primary hypercholesterolaemia and mixed dyslipidaemia - as specified in NICE TAs **393** and **394**	**September 2017:** The TAG considered the revised application and supporting information and was advised that patient numbers would be around 250 patients a year across the Norfolk & Waveney area at around £5k per head. Due to concerns regarding the threshold for use of the drugs, it was agreed that the treatment pathway was key to managing the number of patients being referred to a specialist service. The TAG recommended that a meeting be arranged with specialists from local trusts to see if a cross-county pathway could be developed in order to achieve a compromise between the NICE TAs and affordability within the local health economy.	*Noted and supported by the D&TCG.*
Sept 2017	**Therapeutics Advisory Group:** **QEH Application:** **Shared Care *Proposal*** Currently classified as Red (Hospital only) (November 2015). Confirmed as being CCG-commissioning responsibility (*TAG database to be*	Tolvaptan (*Jinarc*®)	For use in Autosomal Dominant Polycystic Kidney Disease – *as per* NICE TA 358 *(October 2015)* Most of these patients will be pre-dialysis; the monthly monitoring for 18 months is more frequent than is currently undertaken in CKD 2-4. The hospital specialists wish to retain prescribing	There are relatively few patients with ADPKD (local only been charged for 1 across N&W in the last year). The monitoring would have to be set up as a paid service in primary care to save on hospital OPAs, but at a fee lower than the cost of an OPA. The TAG was also advised that tolvaptan may only be prescribed registered prescribers. It was also noted that the proposal's author currently works across	*Noted and supported by the D&TCG.* Tolvaptan (*Jinarc*®) for use in Autosomal Dominant Polycystic Kidney Disease – *as per* NICE TA 358 to remain as Red (Hospital / Specialist use only) with the specialist responsible for prescribing and monitoring the treatment.

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
	amended).		responsibility but would like GPs to take on responsibility for long term blood monitoring (monthly serum Cr / eGFR, K+ and LFTs, bilirubin, INR for 18 months, and if stable, 3-monthly thereafter). Patients are required to arrange and communicate their monitoring appointments and results.	both the QEH, and at the Addenbrookes' Hospital, Cambridgeshire, where tolvaptan has been commissioned as shared care and GPs are paid a monitoring fee. The TAG acknowledged that GPs are generally happy to provide phlebotomy services (for which they are remunerated) but that the specialist must be responsible for monitoring the treatment where they retain prescribing responsibility. The document was therefore declined as a shared care agreement but was agreed to provide useful information for GPs regarding tolvaptan. The content could therefore be used in-Trust and also be communicated to GPs when their patients are initiated on treatment. The TAG therefore decided to maintain the current classification of Red (Hospital/Specialist only), with blood sampling possibly being carried out in primary care but responsibility for monitoring the results to remain with the specialist.	
Sept 2017	**Therapeutics Advisory Group:** **QEH Application:** Current TAG	Ixekizumab (*Taltz*®)	As a third line option for treating moderate to severe plaque psoriasis as per NICE TA 442	The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of	*Noted and supported by the TAG.* Ixekizumab (*Taltz*®) is commissioned as a third 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
	classification **Double Red (Not recommended for routine use / Not commissioned)** pending clarification regarding the local treatment pathway for psoriasis.		(April 2017)	biologics in plaque psoriasis. The TAG agreed to support the pathway and to recommend revising the classification for use of Ixekizumab (*Taltz*®) from **Double Red (Not recommended for routine use** to Red (Hospital/Specialist only) as a third line option for treating moderate to severe plaque psoriasis in line with **NICE TA 442** (April 2017) and the local treatment pathway.	option for treating moderate to severe plaque psoriasis in line with **NICE TA 442** , as specified in the local treatment pathway as Red (Hospital/Specialist only).
Sept 2017	**Therapeutics Advisory Group:** **NNUH Application:** Infliximab is recommended in national and international protocols for the management of Grade 3-4 immune-related adverse effects of immunotherapy for melanoma with Ipilimumab, Pembrolizumab and Nivolumab.	Infliximab	For immunotherapy toxicity (colitis) – Iinfliximab is recommended for immune-related colitis refractory to high doses of corticosteroids and is widely adopted in oncology treatment centres nationally for this indication. The aim is to limit exposure to very high steroid doses, and to avoid life-threatening toxicity.	The TAG was advised that the NNUH DTMMC had considered that the level of supporting evidence for such use is relatively poor due to small case numbers (n=8), despite it being recommended in specialist guidelines. To date it had not been necessary to use infliximab in patients whose symptoms had settled without this intervention, however the request was made since the patients would not meet criteria for funding via the IFR process. Infliximab was preferred to high dose steroids due to faster response rate and risk of adverse effects. In view of the limitations of using alternative treatment (high-dose steroids), the TAG agreed to support the application (on a majority basis only) as Red (Hospital/Specialist only),	*Despite the limited evidence base the D&TCG acknowledged that this treatment was recognised as accepted practice within the specialism and would be used only after careful consideration by local specialists and following positive diagnosis of severe colitis.* *The D&TCG therefore agreed to commission use of infliximab for immunotherapy toxicity (colitis) as* Red (Hospital/Specialist only) *on this basis.*

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
				providing that such support would not be considered by the Trusts to set a precedent for future applications with similar paucity of supporting data. The TAG also recommended a **Prescriber's Rating of 4. Possibly helpful – *the product has minimal additional value, and should not change prescribing habits except in rare circumstances***	
Sept 2017	**Therapeutics Advisory Group:** **NNUH Application:** Currently **Double Red (Not recommended for routine use / Not commissioned)** for hypercholesterolaemia (May 2008). The NNUH proposes initiation and assessment of effectiveness in hospital with transfer to primary care if beneficial.	Colesevelam (*Cholestagel*®)	As a third-line option for (unlicensed) use in bile salt malabsorption causing diarrhoea: Colesevelam would be used as third line therapy in patients with choloretic diarrhoea whose symptoms are not controlled by opiates (e.g. loperamide) and who are intolerant of cholestyramine	The TAG considered the application and supporting evidence and was concerned at the low quality of data available. It was felt that a potentially large number of people could end up on this treatment, long term, as a result of intolerance or unwillingness to adhere to treatment with the first and second line options, cholestyramine and colestipol (which has recently been unavailable). The TAG noted that NICE evidence summary esuom22 (Oct 2013) indicated that only low level evidence to support use in this indication was available. A TAG recommendation regarding this item is deferred until more evidence to support use is provided.	*The D&TCG noted the TAG's discussions regarding the application for this treatment and decided to apply a classification of* **Double Red (Not recommended for routine use / Not commissioned)** *to this indication for use of colesevelam until such time as it is approved.*

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 2017	**Therapeutics Advisory Group:** **NNUH Application & Treatment Pathway:** Currently **Double Red (Not recommended for routine use / Not commissioned)** (July 2017)	Ferric maltol (*Feraccru*®)	For iron deficiency anaemia (mild-moderate) in adult patients with inflammatory bowel disease that are intolerant or have failed 1st line oral iron agents.	The TAG was advised that where other iron preparations are not effective / not tolerated, the next treatment option is IV iron infusion. *Feraccru*® is significantly more expensive than standard oral iron preparations but is cheaper and less invasive than administering IV iron. The TAG was concerned about the low quality of supporting evidence provided with this application (2 placebo-controlled RCTs), and also noted that the SMC had published their decision not to commission use of this treatment. The TAG therefore agreed that a revised recommendation regarding this item is deferred until more evidence to support such use is provided particularly regarding the effectiveness and tolerability of *Feraccru*® compared to other iron salts.	*Noted and supported by the D&TCG.*
Sept 2017	**Therapeutics Advisory Group:** **NNUH Application:** **Shared Care *Proposal*** Currently classified as Red (Hospital only) (March 2017); supported as Amber (option	Ulipristal acetate (*Esmya*®)	For intermittent treatment of moderate to severe symptoms of uterine fibroids	The TAG was advised that there was a potential saving to the health economy of £120k if prescribing of ulipristal was supported in primary care. The shared care proposal had been developed to clarify the GPs responsibilities regarding use of ulipristal for this indication. The specialist would provide **3 months of treatment** then	*Noted and supported by the D&TCG.*

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
	for GP prescribing under shared care) pending approval of shared care agreement			review to assess its effectiveness, liaise with the GP. The treatment would be given intermittently depending of the patient's needs. The TAG otherwise accepted the information provided and recommended that the re-classification be revised to Green (GP prescribing following specialist initiation) with the first **3 months** of treatment being prescribed in hospital to assess effectiveness. The shared care proposal to be modified to become GP prescribing guidance to be sent out with hospital letters for GPs and published on Knowledge Anglia for reference.	
Sept 2017	**Therapeutics Advisory Group:** **NNUH Application:** **NICE ES9 (March 2017) Opicapone for Parkinson's disease with end of dose motor fluctuations** was also provided for the TAG's reference.	Opicapone (*Ongentys*®)	As adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease (PD) and end-of-dose motor fluctuations who cannot be stabilised on those combinations	The TAG noted that the application had been costed against the prices of branded alternative products rather than the cheaper generic options which are currently in use in primary care in Norfolk & Waveney. The TAG therefore deferred making any recommendation on this item and requested that the application is revised with recalculated comparative costs for treatments provided in primary care.	*The D&TCG noted the TAG's discussions regarding the application for opicapone and decided to apply a classification of* **Double Red (Not recommended for routine use / Not commissioned)** *until such time as its use is approved.*

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 2017	**Therapeutics Advisory Group:** **Draft N&W CCGs Policy Statement:** Long-standing agreement between commissioners and the NNUH and QEH to consider use of rituximab first line before going on to the more expensive drugs, eltrombopag and romiplostim. Policy statement has been developed and commissioning statement agreed to formalise this position. The JPUH has also been asked to consider adopting the policy.	Rituximab	In the treatment of Immune (idiopathic) Thrombocytopenic Purpura (ITP)	The TAG considered feedback on the draft policy from local specialists and was advised that the previous version had been updated by mapping against a policy from the EoE PAC which had unintentionally changed the tone of the policy to suggest that rituximab would be used first-line in all cases. It was agreed that draft policy would be revisited and another version sent out for further consultation if necessary.	*Noted by the D&TCG.*
Nov 2017	**Therapeutics Advisory Group:** **NNUH Application:**	Ustekinumab (*Stelara*®)	Dose escalation of treatment for severe psoriasis with inadequate response to initial ustekinumab regimen	The TAG considered the advice and evidence submitted to support this application for increased doses and/or frequency of administration of ustekinumab (in line with licensed doses in the manufacturer's SPC and as recommended in the British Association of	*The D&TCG noted and supported the TAG's recommendation and decided to commission use of* ustekinumab (*Stelara*®) *in a dose escalation regimen for treatment for severe psoriasis with inadequate response to initial ustekinumab regimen as*

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
				Dermatologists (BAD) guidelines for biologic therapy for psoriasis 2017), in a small number of patients who have only partially responded to standard treatment with ustekinumab. The aim to optimise treatment without having to change the agent used. The TAG agreed to support the application and recommended a classification of Red (Hospital/Specialist only) for consideration by the CCGs.	Red (Hospital/Specialist only).
Nov 2017	**Therapeutics Advisory Group:** **JPUH Application:** *A revised application, along with JPUH Formulary applications; the NICE Resource Impact template for GY&W CCG population; Lipid Modification Pathways for FH and N-FH; Fourier Study Summary, was submitted*	Alirocumab (*Praluent*®) and Evolocumab (*Repatha*®)	For treating primary hypercholesterolaemia and mixed dyslipidaemia - as specified in NICE TAs **393** and **394**	**September 2017:** The TAG considered the revised application and supporting information and was advised that patient numbers would be around 250 patients a year across the Norfolk & Waveney area at around £5k per head. Due to concerns regarding the threshold for use of the drugs, it was agreed that the treatment pathway was key to managing the number of patients being referred to a specialist service. The TAG recommended that a meeting be arranged with specialists from local trusts to see if a cross-county pathway could be developed in order to achieve a compromise between the NICE TAs and affordability within the local health economy. **November 2017:**	*The D&TCG was advised that a meeting between CCG representatives and local lipidology specialists regarding implementing local use of the PCSK-9 inhibitors was planned for November 2017.*

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
				Costing information provided by the manufacturer of evolocumab (Amgen) had been passed to the CCGs, which indicates that actual costs of using the treatment would be much lower than previously thought. The TAG was also advised that meetings were taking place between the CCGs and the Trusts' lipidology specialists during November 2017 to discuss a treatment pathway and likely numbers and costs of using PCSK-9 inhibitors. The TAG also recommended that the Trusts should work together on finalising a joint treatment pathway.	
Nov 2017	**Therapeutics Advisory Group:** **NNUH Application:** Currently **Double Red (Not recommended for routine use / Not commissioned)** for hypercholesterolaemia (May 2008). The NNUH proposes initiation and assessment of effectiveness in hospital with transfer to primary	Colesevelam (*Cholestagel*®)	As a third-line option for (unlicensed) use in bile salt malabsorption causing diarrhoea: Colesevelam would be used as third line therapy in patients with choloretic diarrhoea whose symptoms are not controlled by opiates (e.g. loperamide) and who are intolerant of cholestyramine	**September 2017:** The TAG considered the application and supporting evidence and was concerned at the low quality of data available. It was felt that a potentially large number of people could end up on this treatment, long term, as a result of intolerance or unwillingness to adhere to treatment with the first and second line options, cholestyramine and colestipol (which has recently been unavailable). The TAG noted that NICE evidence summary esuom22 (Oct 2013) indicated that only low level evidence to support use in	**September 2017:** *The D&TCG noted the TAG's discussions and decided to apply a classification of* **Double Red (Not recommended for routine use / Not commissioned)** *until such time as its use is approved.* **November 2017:** *The D&TCG considered the information provided by the NNUH and the TAG's revised recommendation, but decided that given the quality of the available evidence, the lack of clarity regarding patient numbers and how intolerance to previous options had been*

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
	care if beneficial.			this indication was available. A TAG recommendation regarding this item is deferred until more evidence to support use is provided. **November 2017:** The TAG noted detail of the RCT referred to by the NNUH in the original application and was advised that the patient numbers quoted in the application had been confirmed by the specialist, based on patients who had already responded to the treatment. The TAG agreed pragmatic support for colesevelam as third-line use in this patient group, and that a shared care approach was reasonable where use was limited to use in patients who remain uncontrolled having tried standard treatment with an opioid (loperamide) and with a bile salt sequestrant (cholestyramine). The specialist should prescribe the first 8 weeks' of treatment to allow transfer of care, having assessed the patient's response within 4 weeks. The TAG therefore recommended a revised traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement).	*defined, plus the current financial cost pressures faced by the CCGs, who have other compelling interests to fund, it is not currently possible to commission use of this drug for this indication.* *The D&TCG therefore decided not to support the TAG's recommendations and that the treatment would remain as* **Double Red (Not recommended for routine use) / Not commissioned**.

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 2017	**Therapeutics Advisory Group:** **<u>NNUH Application & Treatment Pathway</u>:** Currently **Double Red (Not recommended for routine use / Not commissioned)** (July 2017)	Ferric maltol (*Feraccru*®)	For iron deficiency anaemia (mild-moderate) in adult patients with inflammatory bowel disease that are intolerant or have failed 1st line oral iron agents.	**September 2017:** The TAG was advised that where other iron preparations are not effective / not tolerated, the next treatment option is IV iron infusion. *Feraccru*® is significantly more expensive than standard oral iron preparations but is cheaper and less invasive than administering IV iron. The TAG was concerned about the low quality of supporting evidence provided with this application (2 placebo-controlled RCTs), and also noted that the SMC had published their decision not to commission use of this treatment. The TAG therefore agreed that a revised recommendation regarding this item is deferred until more evidence to support such use is provided, particularly regarding the effectiveness and tolerability of *Feraccru*® compared to other iron salts. **November 2017:** The TAG considered further information provided by the NNUH which aimed to clarify that ferric maltol is the next proposed treatment option in patients with clinically inactive disease after use of oral ferrous salt products have failed, either due to intolerance or inadequate response. The TAG agreed that	**September 2017:** *The D&TCG noted the TAG's discussions regarding the application for Feraccru® and decided to maintain the classification of* **Double Red (Not recommended for routine use / Not commissioned)** *until such time as its use is approved.* **November 2017:** The D&TCG considered the additional information provided by the NNUH, and the TAG's revised recommendation. The D&TCG felt that it was unclear whether the patients who are currently taking ferric maltol had tried all other ferrous salt alternatives, which are considerably cheaper than the proposed treatment, before being moved to Feraccru®. There were also outstanding questions regarding the status of the IV iron service currently provided in primary care. The D&TCG therefore felt that the case for using ferric maltol (*Feraccru*®) was not sufficiently proven to be able to justify introducing a new product to the local health economy which costs more than standard oral care and which may not necessarily reduce the costs of delivering

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
				use of ferric maltol was clinically acceptable, based on the available evidence, providing that all cost-effective oral ferrous salt products (i.e. sulphate, fumarate and gluconate) are tried before ferric maltol is used. The TAG also advised that if the local costs of running an IV iron service (which had been set up in primary care to treat patients found to be anaemic pre-operatively in order to ensure their fitness for surgery in a timely fashion) were greater than using ferric maltol in this specific patient group, then such use was reasonable. The TAG agreed to recommend a revised traffic light classification from **Double Red (Not recommended for routine use)** to Red (Hospital / Specialist use only) until the treatment pathway is finalised via the D&TCG.	IV iron in the future. Whilst the D&TCG appreciated the NNUH's intentions in proposing use of *Feraccru*®, the committee was not convinced that adding *Feraccru*® to local treatment pathway would save enough to justify its additional costs. The D&TCG therefore decided to maintain the current commissioned position of **Double Red (Not recommended for routine use / Not commissioned)**.
Nov 2017	**Therapeutics Advisory Group:** **NNUH Application:** **NICE ES9 (March 2017) Opicapone for Parkinson's disease with end of dose motor fluctuations** was also provided for the TAG's	Opicapone (*Ongentys*®)	As adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease (PD) and end-of-dose motor fluctuations who cannot be stabilised on those combinations	**September 2017:** The TAG noted that the application had been costed against the prices of branded alternative products rather than the cheaper generic options which are currently in use in primary care in Norfolk & Waveney. The TAG therefore deferred making any recommendation on this item and requested that the	**September 2017:** *The D&TCG noted the TAG's discussions regarding the application for opicapone and decided to apply a classification of* **Double Red (Not recommended for routine use / Not commissioned)** *until such time as its use is approved.* **November 2017:**

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
	reference.			application is revised with recalculated comparative costs for treatments provided in primary care. **November 2017:** The TAG considered the additional information received from the NNUH consultant neurologist which clarified that opicapone would be used only where entacapone / or its combinations are not tolerated or complied with, and where more expensive options such as tolcapone (which requires intensive hepatic monitoring), apomorphine, and DBS would next be considered. The TAG acknowledged that such use of opicapone could defer use of apomorphine and therefore save money. Use of opicapone could be audited if necessary. The TAG therefore recommended a traffic light classification of Green (Suitable for GPs to prescribe following specialist recommendation) for use of opicapone (*Ongentys*®) as adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease (PD) and end-of-dose motor fluctuations who cannot be stabilised on those combinations and have known intolerance or	*The D&TCG noted and supported the TAG's recommendations and agreed to revise the traffic light classification to* Green (Suitable for GPs to prescribe following specialist recommendation)*.*

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
				non-response to entacapone and its combinations.	
Nov 2017	**Shared Care Agreement:** **(*not yet commissioned*)**	Denosumab (*Xgeva*®)	For prevention of skeletal related events in adults with bone metastases from solid tumours other than prostate	**January to September 2017:** Supported by the TAG and approved for use by the N&W D&TCG – ***awaiting confirmation from the CCGs*** that the LES has started and that the shared care agreement can be published on Knowledge Anglia. **November 2017:** The TAG was advised that because HRG costs had changed it was likely that it would no longer be cost-effective for the CCGs to run a service in primary care, facilitated by the shared care agreement.	**November 2017:** *The D&TCG noted the updated information regarding the viability of having a local service in primary care using denosumab for this indication, and recommended that the item be removed from the TAG's future agendas since this is now unlikely to be commissioned by the CCGs.*
Jan 2018	**Therapeutics Advisory Group:** **Draft N&W CCGs Policy Statement:** Long-standing agreement between commissioners and the NNUH and QEH to consider use of rituximab first line before going on to the more expensive drugs, eltrombopag and romiplostim. Policy	Rituximab	In the treatment of Immune (idiopathic) Thrombocytopenic Purpura (ITP)	**November 2017:** The TAG considered feedback on the draft policy from local specialists and was advised that the previous version had been updated by mapping against a policy from the EoE PAC which had unintentionally changed the tone of the policy to suggest that rituximab would be used first-line in all cases. It was agreed that draft policy would be revisited and another version sent out for further consultation if necessary.	**January 2018:**

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
	statement has been developed and commissioning statement agreed to formalise this position. The JPUH has also been asked to consider adopting the policy.			**January 2018:** The TAG noted and supported the revised policy and was also advised that clinicians at the JPUH have agreed to adopt it.	*The D&TCG recommended that the policy to state that cost-effective biosimilar rituximab products should be used.* *The D&TCG otherwise supported the policy subject to this change and confirmed that the treatment is commissioned as* Red (Hospital only)*.*
Jan 2018	**Therapeutics Advisory Group:** **NSFT Application:** Further application to previously commissioned use **March 2015** - supported as a 3rd line option in adults with schizophrenia under the Early Intervention Treatment Pathway – currently commissioned as Green (GP prescribable following specialist recommendation) where the specialist prescribes for an initial period of 4	Lurasidone (*Lutada*®)	As a third antipsychotic option for schizophrenia in adults aged 18 years and over	The TAG considered the NSFT application and agreed to recommend a classification of Green (GP prescribable following specialist recommendation) where the consultant would initiate treatment and prescribe for the first 4 weeks of treatment, to assess patient response, before requesting that the GP continues prescribing.	*Noted and supported by the D&TCG.*

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.				
Jan 2018	**Therapeutics Advisory Group:** **NSFT Application:** A dose of 2mg may be continued for up to thirteen weeks.	Melatonin Prolonged Release (PR) (*Circadin*®)	As monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients aged 55 or over at the Julian Hospital, Norwich	The TAG acknowledged that the NSFT's application related to in-Trust use within a specialist dementia unit where patients can experience disrupted sleep patterns and exhibit symptoms of agitation and "sundowning syndrome" due to their environment and clinical condition. The TAG agreed to recommend a classification of Red (Hospital only) for use of Circadin® (melatonin prolonged release) for this specific use for the care of patients with dementia, and providing that the treatment is not continued beyond discharge from the service i.e. not to be recommended for continuation in primary care.	*Noted and supported by the D&TCG.* *Commissioned as* Red (Hospital use only) *for use by this specific indication.*
Jan 2018	**Therapeutics Advisory Group:** **NNUH Application:** Currently **Double Red (Not recommended for routine use) / Not commissioned** pending the submission of a business application and	Roflumilast (*Daxas*®)	For maintenance treatment of severe COPD (FEV1 post-bronchodilator < 50% predicted) associated with chronic bronchitis in adults with a history of frequent exacerbations, as add on to bronchodilator treatment. **NICE TA 461** (July 2017) states: *Roflumilast, as an add-on*	The TAG considered the NNUH's application and was advised by GP members that patient numbers meeting the criteria recommended by NICE are likely to be significantly greater that those estimated in the application. If patient numbers are likely to be greater than NICE predicts, the CCGs would request that local specialists agree further criteria for targeted and appropriate use of roflumilast in those likely to	*Noted by the D&TCG.* *Previous commissioning position maintained in the interim.*

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
	clarification of place in the treatment pathway. **For info:** • SMC review (August 2017) – not recommended COPD Primary Care Guideline for Norfolk CCGs - *Link*		*to bronchodilator therapy, is recommended as an option for treating severe COPD in adults with chronic bronchitis, only if:* • *the disease is severe, defined as a FEV_1 after a bronchodilator of <50% of predicted normal, and* • *the person has had ≥2 exacerbations in the previous 12 months despite triple inhaled therapy with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid.* *Treatment with roflumilast should be started by a specialist in respiratory medicine.*	benefit most from its use. The NNUH and QEH specialists to be asked to collaborate on this issue. Clear STOP criteria would also be necessary. The TAG recommended that use of roflumilast be restricted to hospital consultants. ***If*** commissioned as a Red drug, solutions on how patients would be provided with the treatment would have to be resolved to avoid unnecessary outpatient activity charges to CCGs. It was also recommended that any application for such use should be considered as part of the local STP work on the management of COPD. The NNUH is known to have a consultant nurse specialist involved in the STP process.	
Jan 2018	**Therapeutics Advisory Group:** **NNUH Application and proposed treatment algorithm:** Currently **Double Red (Not recommended for routine use) / Not**	Baricitinib (*Olumiant*®) for moderate to severe rheumatoid arthritis in adults **NICE TA 466 (August 2017) states:** **1.1** Baricitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults who have responded inadequately to intensive therapy with a combination of conventional DMARDs, only if: • disease is severe (a disease activity score [DAS28] of more than 5.1) and • the company provides baricitinib with the discount agreed under PAS.	*Noted and supported by the D&TCG – commissioned as* Red (Hospital use only). *The local Rheumatoid Arthritis treatment pathway to be amended in line with the application.* *The D&TCG also recommended monitoring for any inappropriate prescribing of this oral treatment in primary care.*	**Therapeutics Advisory Group:** **NNUH Application and proposed treatment algorithm:** Currently **Double Red (Not recommended for routine use) / Not commissioned** pending the submission of a business application and clarification of place in 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
	commissioned pending the submission of a business application and clarification of place in the treatment pathway.	**1.2** Baricitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if: • disease is severe (a DAS28 of > 5.1) and • they cannot have rituximab and • the company provides it with the discount agreed under PAS. The TAG noted that the cheapest appropriate treatment option within the treatment pathway for rheumatoid arthritis would be used for each patient. The TAG agreed to recommend that use of Baricitinib (*Olumiant*®) for moderate to severe rheumatoid arthritis in adults as per NICE TA 466 (August 2017) is classified as Red Hospital only).			treatment pathway.
Jan 2018	**Therapeutics Advisory Group:** **QEH Application:** Currently **Double Red (Not recommended for routine use) / Not commissioned** pending the submission of a business application and clarification of place in the treatment pathway.	Tofacitinib *(Xeljanz®)* for moderate to severe rheumatoid arthritis	**NICE TA 480 (October 2017) which states:** **1.1** Tofacitinib, with methotrexate, is recommended as an option for active rheumatoid arthritis in adults who have responded inadequately to intensive therapy with a combination of conventional DMARDs, only if: • disease is severe (DAS28 >5.1) and • the company provides tofacitinib with discount agreed under PAS. **1.2** Tofacitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults who have responded inadequately to, or who cannot have, other DMARDs, including at least 1 biologic, only if: • disease is severe (DAS28 >5.1) and • they cannot have rituximab and • the company provides tofacitinib with discount agreed under PAS. **1.3** Tofacitinib monotherapy can be used for adults where methotrexate is contraindicated or is not tolerated, when the	*Noted and supported by the D&TCG – commissioned as* Red (Hospital use only)*.* *The local Rheumatoid Arthritis treatment pathway to be amended in line with the application.* *The D&TCG also recommended monitoring for any inappropriate prescribing of this oral treatment 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
			criteria under 1.1 and 1.2 are met. **1.4** Continue treatment only if there is a moderate response (as per EULAR criteria) at 6 months after starting therapy. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained. The TAG noted that the cheapest appropriate treatment option within the treatment pathway for rheumatoid arthritis would be used for each patient. The TAG agreed to recommend that use of Tofacitinib *(Xeljanz®)* for moderate to severe rheumatoid arthritis in adults as per NICE TA 480 (October 2017) is classified as Red Hospital only).	
Jan 2018	**Therapeutics Advisory Group:** **JPUH Application:** *A revised application, along with JPUH Formulary applications; the NICE Resource Impact template for GY&W CCG population; Lipid Modification Pathways for FH and N-FH; Fourier Study Summary, was submitted*	Alirocumab (*Praluent®*) and Evolocumab (*Repatha®*) for treating primary hypercholesterolaemia and mixed dyslipidaemia - as specified in NICE TAs **393** and **394**	**September 2017:** The TAG considered the revised application and supporting information and was advised that patient numbers would be around 250 patients a year across the Norfolk & Waveney area at around £5k per head. Due to concerns regarding the threshold for use of the drugs, it was agreed that the treatment pathway was key to managing the number of patients being referred to a specialist service. The TAG recommended that a meeting be arranged with specialists from local trusts to see if a cross-county pathway could be developed in order to achieve a compromise between the NICE TAs and affordability within the local health economy. **November 2017:** Costing information provided by the manufacturer of evolocumab (Amgen) had been passed to the CCGs, which indicates that actual costs of using the treatment would be much lower than previously thought. The TAG was also advised that meetings were taking place between the CCGs and the Trusts' lipidology specialists during November 2017 to discuss a treatment pathway and likely numbers and costs of using PCSK-9 inhibitors. The TAG also	**September 2017:** *The D&TCG was advised that a meeting between CCG representatives and local lipidology specialists regarding implementing local use of the PCSK-9 inhibitors was planned for November 2017.* **January 2018:** The D&TCG had discussed this item at its December 2017 meeting and had supported a business case and treatment pathway for use of the treatments subject to details on potential costs being clarified. The D&TCG also debated how costs might be contained if actual use exceeded 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
			recommended that the Trusts should work together on finalising a joint treatment pathway. **January 2018:** The TAG was not provided with any update on this item.		numbers estimated in the Trust's business application. In progress and actions being chased.
March 2018	**Therapeutics Advisory Group:** **QEH Application:** Currently **Double Red** pending submission and approval of a business application and confirmation of its place in the local treatment pathway	Sarilumab (*Kevzara*®)	For moderate to severe rheumatoid arthritis in adults – as per NICE TA 485	Sarilumab is considered to be cost competitive as a third line option in line with tocilizumab and abatacept. The TAG considered and agreed to support the QEH's application along with the proposed treatment pathway and recommended a revised classification of Red (Hospital use only).	*Noted and supported by the D&TC.* *Recommended to be commissioned as* Red (Hospital use only) *in line with the agreed treatment pathway*.
March 2018	**Therapeutics Advisory Group:** **Specialist Treatment Pathway: *Update***	Various	Rheumatoid Arthritis	The TAG discussed the place of certolizumab as a possible first line option, and also the place of the newer but more costly oral JAK inhibitors (tofacitinib and baricitinib) where anti-TNFs or rituximab could not be used. The TAG agreed to support the draft treatment pathway as presented, and that any future recommendations for change should be returned to the TAG with supportive information for further consideration.	*Noted and supported by the D&TC.* *Treatment pathway for rheumatoid arthritis recommended to be commissioned.*
March 2018	**Therapeutics Advisory Group:** **QEH Application:**	Dimethyl fumarate (*Skilarence*®)	Severe psoriasis which has not responded to other non-biological	The TAG was advised that dimethyl fumarate would be used instead of (not added to)	*Noted and supported by the D&TC.* *Recommended to be*

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 **Double Red** pending submission and approval of a business application and confirmation of its place in the local treatment pathway		therapies, or when biological therapies cannot be taken.	apremilast. The TAG considered the QEH's application along with the proposed treatment pathway and agreed to recommend a revised classification of Red (Hospital use only).	*commissioned as* Red (Hospital use only) *in line with the agreed treatment pathway*.
March 2018	**Therapeutics Advisory Group:** **Specialist Treatment Pathway: *Update*** Current pathway (Dec17)	Various	Psoriasis	The TAG was advised that the place of dimethyl fumarate, which would be used rather than apremilast for certain areas of the body affected by the conditions, should be clear in the pathway. The TAG agreed to support the draft treatment pathway as presented, and that any future recommendations for change should be returned to the TAG with supportive information for further consideration.	*Noted and supported by the D&TC.* *Treatment pathway for psoriasis recommended to be commissioned.*
March 2018	**Therapeutics Advisory Group:** **Specialist Treatment Pathway: *Update*** Current pathway (July17)	Various	Psoriatic arthritis	The TAG was advise that ustekinumab was viewed by rheumatologists as being less effective for treating joints than for skin, as used by dermatology. For patients affected by both conditions the decision regarding which treatment to use would be affected by the more dominant aspect of their condition. In some cases with severe joint disease use of ustekinumab following secukinumab would not be	*Noted and supported by the D&TC.* *Revised treatment pathway for psoriatic arthritis recommended to be commissioned.*

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
				desirable. Use of apremilast would be preferred in those cases. The TAG agreed that this clinical preference to be added to the Notes within the draft treatment pathway.	
March 2018	**Therapeutics Advisory Group:** **<u>NNUH Evidence submission and proposals for approved treatment options</u>:** 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		The TAG considered and debated the evidence review and treatment proposals submitted by the NNUH cardiologists. The TAG was unable to agree support for the proposals based on the information provided but decided on the following actions: • An independent evidence review to be requested from local medicines information services • Local pharmacologist to be approached for views regarding the TAG's concerns regarding efficacy and safety of the proposed treatment regimens • NNUH lead cardiologist to be invited to attend the next TAG meeting to explain the rationale for the proposed treatment regimens	*The D&TC noted and supported the TAG's recommendations for taking this issued forward.*

1. TAG Recommendations 2017/18

B. *NICE Guidance*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
May 2017	**NICE TA 434 (March 2017)** ***Terminated appraisal*** - no evidence submission was received from Bristol–Myers Squibb.	Elotuzumab (*Empliciti*®)	For previously treated multiple myeloma.	The TAG acknowledged **NICE TA 434 (March 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**.	SCG-commissioning responsibility *Noted by the D&TCG*
May 2017	**NICE TA 435 (March 2017)** ***Terminated appraisal*** - no evidence submission was received from Gilead.	Tenofovir alafenamide fumarate (*Vemlidy*®)	For treating chronic hepatitis B.	The TAG acknowledged **NICE TA 435 (March 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	SCG-commissioning responsibility *Noted by the D&TCG*
May 2017	**NICE TA 436 (March 2017)** ***Terminated appraisal*** - no evidence submission was received from Roche.	Bevacizumab (*Avastin*®)	For treating epidermal growth factor receptor mutation-positive non-small-cell lung cancer.	The TAG acknowledged **NICE TA 436 (March 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	SCG-commissioning responsibility *Noted by the D&TCG*
May 2017	**NICE TA 437 (March 2017)** ***Terminated appraisal*** - no	Ibrutinib (*Imbruvica*®) with bendamustine and rituximab	For treating relapsed or refractory chronic lymphocytic leukaemia	The TAG acknowledged **NICE TA 437 (March 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)**	SCG-commissioning responsibility *Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	evidence submission was received from Janssen-Cilag.		after systemic therapy		
May 2017	**NICE TA 438 (March 2017)** ***Terminated appraisal*** - no evidence submission was received from Roche.	Alectinib (*Alecensa*®)	For previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer.	The TAG acknowledged **NICE TA 438 (March 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this treatment.	SCG-commissioning responsibility *Noted by the D&TCG*
May 2017	**NICE TA 439 (March 2017)** Recommended by NICE as options	Cetuximab (*Erbitux*®) and panitumumab (*Vectibix*®)	For previously untreated epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer in adults: Cetuximab is recommended as an option in combination with: • 5 fluorouracil, folinic acid and oxaliplatin (FOLFOX) or • 5 fluorouracil, folinic acid and irinotecan (FOLFIRI) Panitumumab is recommended as an option in combination with: • FOLFOX or • FOLFIRI	The TAG acknowledged **NICE TA 439 (March 2017)** and recommended traffic light classifications of Red (Hospital/Specialist only) for these treatments.	SCG-commissioning responsibility *Noted by the D&TCG*
May 2017	**NICE TA 440 (April 2017)**	Pegylated liposomal irinotecan	For treating metastatic adenocarcinoma of the pancreas in adults whose	The TAG acknowledged **NICE TA 440 (April 2017)** and recommended a traffic light classification of **Double Red (Not**	SCG-commissioning responsibility

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	Not recommended by NICE	(*Onivyde*®)	disease has progressed after gemcitabine-based therapy	**recommended for routine use)** for this treatment.	*Noted by the D&TCG*
May 2017	**NICE TA 441 (April 2017)** Recommended by NICE as an option, if the company provides it with discount agreed under PAS. *N.B.* serum transaminase levels should be monitored monthly during treatment and up to 4 months after the last dose of *Zinbryta*®.	Daclizumab (*Zinbryta*®) for treating relapsing-remitting multiple sclerosis in adults	For treating multiple sclerosis in adults, only if: • the person has active relapsing–remitting multiple sclerosis previously treated with disease-modifying therapy, or rapidly evolving severe relapsing–remitting multiple sclerosis (that is, at least 2 relapses in the previous year and at least 1 gadolinium-enhancing lesion at baseline MRI) and • alemtuzumab is contraindicated or otherwise unsuitable	The TAG acknowledged **NICE TA 441 (April 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this treatment.	SCG-commissioning responsibility *Noted by the D&TCG*
May 2017	**NICE TA 442 (April 2017)** Recommended by NICE as an option for treating plaque psoriasis in adults, only the company provides it with discount agreed under PAS. Stop ixekizumab treatment at 12 weeks if inadequate	Ixekizumab (*Taltz*®)	For treating moderate to severe plaque psoriasis only if: • the disease is severe, as defined by a total PASI of 10 or more and a DLQI > 10 • the disease has not responded to standard systemic therapies, e.g. ciclosporin, methotrexate and PUVA • or these treatments are	The TAG acknowledged **NICE TA 442 (April 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** until a treatment pathway has been agreed locally for this CCG-commissioning responsibility treatment, and a related business application supported.	*The D&TCG noted and supported the TAG's recommendations and decided that* Ixekizumab (Taltz®) for treating moderate to severe plaque psoriasis *as per* **NICE TA 442 (April 2017)** *is* ***Not commissioned*** *until a treatment pathway for psoriasis has been agreed locally, and a related business application supported.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	response. Adequate response is defined as: • a 75% reduction in 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.		contraindicated or the person cannot tolerate them		
May 2017	**NICE TA 443 (April 2017)** Recommended by NICE as an option only if the company provides it with discount agreed under PAS. Assess the response to obeticholic acid after 12 months. Only continue if there is evidence of clinical benefit.	Obeticholic acid (*Ocaliva*®)	For treating primary biliary cholangitis • in combination with ursodeoxycholic acid for people whose disease has responded inadequately to ursodeoxycholic acid or • as monotherapy for people who cannot tolerate ursodeoxycholic acid	The TAG acknowledged **NICE TA 443 (April 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
May 2017	**NG 65 (February 2017)** This guideline aims to raise awareness of the features of	Spondyloarthritis in over 16s: diagnosis and management	Includes recommendations on: 1.1 Recognition and referral in non-specialist care settings 1.2 Diagnosing	The TAG noted the importance of timely recognition and referral for suspected spondyloarthritis under the section 1.1. of NG 65 and considered how this might be promoted to local practitioners in addition	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	spondyloarthritis and provide clear advice on what action to take when people with signs and symptoms first present in healthcare settings. It also provides advice on the range of treatments available.		spondyloarthritis in specialist care settings 1.3 Information and support 1.4 Pharmacological management of spondyloarthritis 1.5 Non-pharmacological management of spondyloarthritis 1.6 Surgery for spondyloarthritis 1.7 Managing flares 1.8 Long-term complications 1.9 Organisation of care	to current clinical training programmes. The TAG otherwise acknowledged **NG 65 (February 2017)**	
May 2017	**NG 66 (March 2017)** This guideline covers assessing, diagnosing and managing mental health problems in adults (aged 18 and over) who are in contact with the criminal justice system. It aims to improve mental health and wellbeing in this population by establishing principles for assessment and management, and promoting more coordinated care planning and	Mental health of adults in contact with the criminal justice system	Includes recommendations on: • assessing and managing a person's mental health problems, including assessing risk to themselves and others • planning their care • psychological and pharmacological interventions • how services should be organised • staff training	The TAG acknowledged **NG 66 (March 2017)**	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	service organisation across the criminal justice system				
July 2017	**NICE TA 444 (May 2017)** ***Terminated appraisal*** - no evidence submission was received from Boehringer Ingelheim.	Afatinib (*Giotrif*®)	For treating advanced squamous non-small-cell lung cancer after platinum-based chemotherapy.	The TAG acknowledged **NICE TA 444 (May 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
July 2017	**NICE TA 445 (May 2017)** Recommended as options alone or in combination with methotrexate, and only if provided with discount under the patient access scheme	Certolizumab pegol (*Cimzia*®) and Secukinumab (*Consentyx*®)	For treating active psoriatic arthritis after inadequate response to DMARDs.	The TAG acknowledged **NICE TA 445 (May 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** pending approval of a treatment pathway (and thereafter Red (Hospital/Specialist only) for these CCG-commissioning responsibility treatments.	*A proposed treatment pathway for use of biologics in psoriatic arthritis from the NNUH (also on behalf of the JPUH and the QEH) was considered by the D&TCG and was supported, subject to being reworded in line with NICE guidance.* *The D&TCG otherwise agreed to commission* Certolizumab pegol (*Cimzia*®) *and* Secukinumab (*Consentyx*®) *for treating active psoriatic arthritis after inadequate response to DMARDs as* Red (Hospital/Specialist only). *The D&TCG also agreed to revise the current* **Double Red (Not recommended for routine use)** *classification for apremilast (Otezla®) for active psoriatic arthritis in adults to* Red (Hospital/Specialist only)

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
					as per **NICE TA 433** and in line with the treatment pathway.
July 2017	**NICE TA 446 (June 2017)** Recommended by NICE as an option only if provided with discount under the patient access scheme, and also under the Cancer Drugs Fund.	Brentuximab vedotin (*Adcetris*®)	For treating CD30-positive Hodgkin lymphoma.	The TAG acknowledged **NICE TA 446 (June 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
July 2017	**NICE TA 447 (June 2017)** Recommended for use within the Cancer Drugs Fund as an option under specified conditions	Pembrolizumab (*Keytruda*®)	For untreated PD-L1-positive metastatic non-small-cell lung cancer	The TAG acknowledged **NICE TA 447 (June 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
July 2017	**NICE TA 448 (June 2017)** Recommended by NICE as an option only if provided with discount under the patient access scheme	Etelcalcetide (*Parsabiv*®)	For treating secondary hyperparathyroidism in adults with chronic kidney disease on haemodialysis.	The TAG acknowledged **NICE TA 448 (June 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
July 2017	**NICE TA 449 (June 2017)** Recommended by NICE under specified criteria as options, and only if	Everolimus (*Afinitor*®) and sunitinib (*Sutent*®)	For treating unresectable or metastatic neuroendocrine tumours in people with progressive disease in adults	The TAG acknowledged **NICE TA 449 (June 2017)** and recommended traffic light classifications of Red (Hospital/Specialist only) for these SCG-commissioning responsibility treatments.	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	provided with discount under the patient access scheme				
July 2017	**NICE TA 450 (June 2017)** Recommended within its marketing authorisation as an option, only if the company provides it with the discount agreed in the patient access scheme.	Blinatumomab (*Blincyto*®)	For treating Philadelphia-chromosome-negative relapsed or refractory precursor B-cell acute lymphoblastic leukaemia in adults	The TAG acknowledged **NICE TA 450 (June 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
July 2017	**NICE TA 451 (June 2017)** Recommended by NICE as an option under specified criteria, if the company provides it with discount agreed under PAS.	Ponatinib (*Iclusig*®)	For treating chronic myeloid leukaemia and acute lymphoblastic leukaemia in adults	The TAG acknowledged **NICE TA 451 (June 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
July 2017	**NICE FAD (April 2017):** Recommended as an option for adults who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-alpha inhibitor or	Ustekinumab (*Stelara*®)	For moderately to severely active Crohn's disease after previous treatment	The TAG acknowledged **NICE FAD (April 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this CCG-commissioning responsibility treatment when considering it alongside a local application for use and proposed treatment pathway for use of anti-TNFs in moderate to severe Crohn's disease.	*The D&TCG noted the TAG's recommendation and decided to classify this treatment as* **Double Red (Not recommended for routine use)** *in the interim, until the NICE TA has been published and the draft treatment pathway clarified.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	have medical contraindications to such therapies				
July 2017	**NICE FAD (June/July 2017):** *Review* of NICE TA 244 (Jan 2012) Currently classified as **Double Red (Not recommended for routine use)** (March 2012)	Roflumilast (*Daxas*®)	For treating chronic obstructive pulmonary disease as follows: 1.1 Recommended by NICE as an add-on to bronchodilator therapy, as an option for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis, only if: • the disease is severe, defined as a forced expiratory volume in 1 second (FEV1) after a bronchodilator of less than 50% of predicted normal, and • the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid. 1.2 Treatment with roflumilast should be started by a specialist in respiratory medicine.	The TAG acknowledged **NICE FAD (June/July 2017)** and recommended maintaining the current traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment until the NICE TA guidance is published.	*The D&TCG noted and supported the TAG's recommendation* - **Double Red (Not recommended for routine use) / Not Commissioned** *until the NICE TA has been published and the treatment's place in the COPD treatment pathway agreed. The D&TCG also recommended that there should be agreement on the definition of* "a specialist in respiratory medicine" *under NICE recommendation 1.2.*
July 2017	**NICE Highly Specialised**	Eliglustat (*Cerdelga*®)	For treating type 1 Gaucher disease	The TAG acknowledged **NICE FAD (June/July 2017)** and recommended a	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	Technology Guidance HST 5 (June 2017): Recommended by NICE if provided with discount under PAS			traffic light classification of Red (Specialist Centre only) for this SCG-commissioning responsibility treatment.	
July 2017	**NICE Highly Specialised Technology Guidance HST 5 (June 2017):** Recommended by NICE if provided with discount under PAS	Eliglustat (*Cerdelga*®)	For treating type 1 Gaucher disease	The TAG acknowledged **NICE FAD (June/July 2017)** and recommended a traffic light classification of Red (Specialist Centre only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
July 2017	**NG 67 (March 2017)** This guideline covers medicines support for adults (aged 18 and over) who are receiving social care in the community. It aims to ensure that people who receive social care are supported to take and look after their medicines effectively and safely at home. It gives advice on assessing if people need help with managing their	Managing medicines for adults receiving social care in the community	Includes recommendations on: • governance arrangements and joint working between health and social care • assessing medicines support needs • supporting people to take their medicines, including covert administration and managing concerns • staff training and competency • sharing medicines information and record keeping • safely ordering and supplying medicines	The TAG acknowledged **NG 67 (March 2017)** and considered that there was some information which may be useful to summarise in the Norfolk & Waveney Prescriber newsletter.	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	medicines, who should provide medicines support and how health and social care staff should work together.		and transporting, storing and disposing of medicines		
Sept 2017	**NICE TA 452 (July 2017)** ***Terminated appraisal*** - no evidence submission was received from Janssen–Cilag	Ibrutinib (*Imbruvica*®)	For untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation	The TAG acknowledged **NICE TA 452 (July 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Sept 2017	**NICE TA 453 (July 2017)** ***Terminated appraisal*** - no evidence submission was received from Janssen–Cilag	Bortezomib (*Velcade*®)	For treating multiple myeloma after second or subsequent relapse	The TAG acknowledged **NICE TA 453 (July 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Sept 2017	**NICE TA 454 (July 2017)** ***Terminated appraisal*** - no evidence submission was received from Janssen–Cilag	Daratumumab (*Darzalex*®) with lenalidomide & dexamethasone	For treating relapsed or refractory multiple myeloma	The TAG acknowledged **NICE TA 454 (July 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Sept 2017	**NICE TA 455 (July 2017)**	Adalimumab (*Humira*®), etanercept (*Enbrel*®, *Benepali*®) and ustekinumab (*Stelara*®) are		The TAG acknowledged **NICE TA 455 (July 2017)** and recommended traffic	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	Recommended as options by NICE under specified circumstances	recommended for plaque psoriasis in children and young people as follows: NICE recommends **adalimumab** as an option for those aged 4 years or older, only if the disease: • is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and • has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated. NICE recommends **etanercept** as an option for those aged 6 years or older, only if the disease: • is severe, as defined by a total PASI of 10 or more and • has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated. NICE recommends **ustekinumab** as an option for those aged 12 years or older, only if the disease: • is severe, as defined by a total PASI of 10 or more • has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated. **Stop etanercept** at **12 weeks**, and **adalimumab** and **ustekinumab** at **16 weeks**, if the psoriasis has not responded adequately i.e. if a 75% reduction in the baseline PASI score has not been achieved.	light classifications of Red (Hospital/Specialist only) for these SCG-commissioning responsibility treatments.	
Sept 2017	**NICE TA 456 (July 2017)** Recommended as an option by NICE under specified	Ustekinumab (*Stelara*®) for moderately to severely active Crohn's disease in adults after previous treatment, is recommended as follows: **1.1** Recommended by NICE as an option for those who have had an inadequate response with, lost response to, or were intolerant to either	The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in Crohn's disease. The TAG agreed to support the pathway which recommended use of ustekinumab	*Noted and supported by the D&TCG.* *Use of ustekinumab as a second line option for treating moderately to severely active Crohn's disease in adults is*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	circumstances	conventional therapy or a TNF-alpha inhibitor or have medical contraindications to such therapies. **1.2** The choice between ustekinumab or another biological therapy should be made on an individual basis after discussion between the patient and their clinician about the advantages and disadvantages of the treatments available. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose). **1.3** Ustekinumab should be given until treatment failure (including the need for surgery) or until 12 months after the start of treatment, *whichever is shorter*. People should then have their disease reassessed in accordance with NICE's recommendations for infliximab and adalimumab for the treatment of Crohn's disease to see whether treatment should continue.		as a second line option for treating moderately to severely active Crohn's disease in adults. The TAG therefore affirmed the previously recommended traffic light classification of Red (Hospital/Specialist only) for this CCG-commissioning responsibility treatment in line with **NICE TA 456 (July 2017)** and the local treatment pathway.	*commissioned as* Red (Hospital/Specialist only) *in line with* **NICE TA 456 (July 2017)** *and as specified in the local treatment pathway.*
Sept 2017	**NICE TA 457 (July 2017)** Recommended as an option by NICE under specified criteria.	Carfilzomib (*Kyprolis*®) (with dexamethasone)	For previously treated multiple myeloma where the patient has had only 1 previous therapy, which did not include bortezomib	The TAG acknowledged **NICE TA 457 (July 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Sept 2017	**NICE TA 458 (July 2017)** This guidance is a **Cancer Drugs Fund** reconsideration of (TA371), which it replaces.	Trastuzumab emtansine (*Kadycla*®)	For treating HER2-positive advanced breast cancer after trastuzumab and a taxane	The TAG acknowledged **NICE TA 458 (July 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Sept 2017	**NICE TA 459 (July 2017)** NICE recommends	Collagenase clostridium histolyticum (*Xiapex*®) for treating Dupuytren's contracture with a palpable cord in adults. For people not taking part		The TAG acknowledged **NICE TA 459 (July 2017)** and recommended a traffic light classification of **Double Red (Not**	*Noted and supported by the D&TCG.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	that people who meet the inclusion criteria for the ongoing clinical trial (HTA-15/102/04), comparing collagenase clostridium histolyticum (CCH) with limited fasciectomy, are encouraged to participate in the study.	in the ongoing clinical trial, CCH is recommended as an option only if *all* of the following apply: • There is evidence of moderate disease (functional problems and metacarpophalangeal joint contracture of 30° to 60° and proximal interphalangeal joint contracture of less than 30° or first web contracture) plus up to 2 affected joints. • Percutaneous needle fasciotomy (PNF) is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon. • The choice of treatment (CCH or limited fasciectomy) is made on an individual basis after discussion between the responsible hand surgeon and the patient about the risks and benefits of the treatments available. • One injection is given per treatment session by a hand surgeon in an outpatient setting.		**recommended for routine use)** for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use.	
Sept 2017	**NICE TA 460 (July 2017)** Recommended as options by NICE under specified circumstances. Adalimumab is SCG-commissioning responsibility and dexamethasone intravitreal implant is CCG-commissioning responsibility	Adalimumab and dexamethasone intravitreal implant for treating non-infectious uveitis in the posterior segment of the eye in adults as follows: **1.1 Adalimumab** is recommended as an option in adults with inadequate response to corticosteroids, only if there is: • active disease (that is, current inflammation in the eye) and • inadequate response or intolerance to immunosuppressants and • systemic disease or both eyes are affected (or 1 eye is affected if the second eye has poor visual acuity) and • worsening vision with a high risk of blindness (for example, risk of blindness that is similar to that seen in people with macular oedema). **1.2** *Stop* in adults with inadequate response to corticosteroids if there is 1 of the following:		The TAG noted the difference in responsible commissioner for each treatment option and acknowledged that local use would be determined by designation of a specialist centre status in any of the local provider trusts. The TAG acknowledged **NICE TA 460 (July 2017)** and recommended traffic light classifications of **Double Red (Not recommended for routine use)** for these SCG-commissioning responsibility and CCG-commissioning responsibility treatments pending the submission and approval of a business application for their use.	*Noted and supported by the D&TCG.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
		• new active inflammatory chorioretinal or inflammatory retinal vascular lesions, or both or • a 2-step increase in vitreous haze or anterior chamber cell grade or • worsening of best corrected visual acuity by 3 or more lines or 15 letters. **1.3 Dexamethasone intravitreal implant** is recommended as an option only if there is: • active disease (that is, current inflammation in the eye) and • worsening vision with a risk of blindness. •			
Sept 2017	**NICE TA 461 (July 2017)** Recommended as an option by NICE under specified criteria. Currently classified as **Double Red (Not recommended for routine use)** (March 2012 & July 2017). The TAG considered NICE FAD June 2017 which supported use, and recommended maintaining the Double Red classification until a positive NCE TA was published and the treatment's	Roflumilast (*Daxas*®) for treating chronic obstructive pulmonary disease as follows: **1.1** Roflumilast, as an add-on to bronchodilator therapy, is recommended as an option for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis, only if: • the disease is severe, defined as a forced expiratory volume in 1 second (FEV_1) after a bronchodilator of less than 50% of predicted normal, and • the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid. **1.2** Treatment with roflumilast should be started by a specialist in respiratory medicine.		The TAG acknowledged **NICE TA 461 (July 2017)** and recommended maintaining the **Double Red (Not recommended for routine use)** classification for this CCG-commissioning responsibility treatment pending the submission and approval of a business application for its use. The TAG felt that this was an expensive add-on option with limited supporting evidence of benefit which should be reviewed for assessment of effectiveness / benefit after an agreed time period e.g.one year's use. The TAG also recognised the need to clarify which local clinicians would be designated as a specialist in respiratory medicine and recommended that initiation of roflumilast should be limited to consultants in respiratory medicine.	*The D&TCG noted that the SMC (August 2017) had recommended **against use** of roflumilast following a resubmission from the manufacturer.* *The TAG's recommendation was noted and supported by the D&TCG, with reiteration that any future use of roflumilast would be limited to initiation by consultants in respiratory medicine only.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	place in the Norfolk CCGs COPD pathway and the GYW pathway agreed.				
Sept 2017	**NICE TA 462 (July 2017)** Recommended by NICE as an option, only when the company provides nivolumab with the discount agreed in the patient access scheme.	Nivolumab (*Opdivo*®)	For treating relapsed or refractory classical Hodgkin lymphoma in adults after autologous stem cell transplant and treatment with brentuximab vedotin	The TAG acknowledged **NICE TA 462 (July 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Sept 2017	**NICE TA 463 (August 2017)** Recommended by NICE as an option, and only if the company provides cabozantinib with the discount agreed in the patient access scheme.	Cabozantinib (*Cabometyx*®)	For previously treated advanced renal cell carcinoma in adults after vascular endothelial growth factor (VEGF)-targeted therapy.	The TAG acknowledged **NICE TA 463 (August 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Sept 2017	**NICE TA 464 (August 2017)** This guidance: • aligns NICE technology appraisal guidance on the use of bisphosphonates	Bisphosphonates (alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid) For treating osteoporosis in adults, as follows: **1.1** Oral bisphosphonates (alendronic acid, ibandronic acid and risedronate sodium) are recommended as options for treating osteoporosis in adults only if: • the person is eligible for risk assessment as defined in NICE's guideline on osteoporosis		The TAG acknowledged **NICE TA 464 (August 2017)** and recommended that the Prescribing Reference Group be requested to consider the implications of this guidance which recommends a lower treatment threshold, for a wider patient group than previously recommended. The TAG also considered that there should be no case-finding or screening to	*Noted and supported by the D&TCG.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	for preventing osteoporotic fragility fractures with NICE's guideline on osteoporosis: assessing the risk of fragility fracture • The previous NICE technology appraisal guidance TA160 and TA161 did not: ○ include recommendations for men ○ cover bisphosphonate treatments available, such as ibandronic acid and zoledronic acid.		(recommendations **1.1** and **1.2**) ***and*** • the 10-year probability of osteoporotic fragility fracture is at least 1%. **1.2** Intravenous bisphosphonates (ibandronic acid and zoledronic acid) are recommended as options for treating osteoporosis in adults only if: • the person is eligible for risk assessment as defined in NICE's guideline on osteoporosis (recommendations 1.1 and 1.2) ***and*** • the 10-year probability of osteoporotic fragility fracture is at least 10% ***or*** • the 10-year probability of osteoporotic fragility fracture is at least 1% and the person has difficulty taking oral bisphosphonates (alendronic acid, ibandronic acid or risedronate sodium) or these drugs are contraindicated or not tolerated. **1.3** Estimate the 10-year probability of osteoporotic fragility fracture using the FRAX or QFracture risk tools, in line with NICE's guideline on osteoporosis. **1.4** The choice of treatment should be made on an individual basis after discussion between the responsible clinician and the patient, or their carers, about the advantages and disadvantages of the treatments available. If generic products are available, start treatment with the least expensive formulation, taking into account administration costs, the dose needed and the cost per dose.	identify suitable patients outside the terms of the guidance.	
Sept 2017	**NICE TA 465 (August 2017)** Recommended by NICE for use within the Cancer Drugs Fund as an option	Olaratumab (*Lartruvo*®) in combination with doxorubicin	For treating advanced soft tissue sarcoma in adults only if: • they have not had any previous systemic chemotherapy for this	The TAG acknowledged **NICE TA 465 (August 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	only if: • the conditions in the managed access agreement for olaratumab are followed.		indication • they cannot have curative treatment with surgery, or their disease does not respond to radiotherapy		
Sept 2017	**NICE TA 466 (August 2017)** Recommended as option by NICE	Baricitinib (*Olumiant*®) (with methotrexate) for active moderate to severe rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying anti-rheumatic drugs (DMARDs), only if: • disease is severe (a disease activity score [DAS28] of more than 5.1) and • the company provides baricitinib with the discount agreed in the patient access scheme. **1.2** Baricitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if: • disease is severe (a DAS28 of more than 5.1) and • they cannot have rituximab and • the company provides baricitinib with the discount agreed in the patient access scheme. **1.3** Baricitinib can be used as monotherapy for people who cannot take methotrexate because it is contraindicated, or because of intolerance, when the criteria in sections 1.1 and 1.2 are met. **1.4** Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After an initial	The TAG acknowledged **NICE TA 466 (August 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use, and its place in the local treatment pathway clarified.	*Noted and supported by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
		response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained.			
Sept 2017	**NICE TA 467 (August 2017)** Recommended by NICE as an option under specified criteria and only if the company provides it with discount agreed under the patient access scheme	Holoclar (*ex vivo expanded autologous human corneal epithelial cells containing stem cells*)	For treating limbal stem cell deficiency after eye burns	The TAG acknowledged **NICE TA 467 (August 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Sept 2017	**NICE TA 468 (August 2017)** ***Terminated appraisal*** - no evidence submission was received from Swedish Orphan Biovitrum Ltd *Current TAG classification is* **Double Red (Not recommended for routine use) / Not commissioned** *for opioid-induced constipation in palliative care (as per* ***NICE TA 277*** *(March 2013)).*		Methylnaltrexone bromide (*Relistor*®) for treating opioid-induced constipation	The TAG acknowledged **NICE TA 468 (August 2017)** and re-affirmed a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment.	*Noted and supported by the D&TCG*
Sept 2017	**NICE TA 469 (August 2017)** ***Terminated appraisal*** – no evidence submission was received from Gilead Sciences	Idelalisib (*Zydelig*®) with ofatumumab (*Arzerra*®)	For treating chronic lymphocytic leukaemia	The TAG acknowledged **NICE TA 469 (August 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Sept 2017	**NICE TA 470 (August 2017)** ***Terminated***	Ofatumumab (*Arzerra*®) with chemotherapy	For treating chronic lymphocytic leukaemia	The TAG acknowledged **NICE TA 470 (August 2017)** and recommended a traffic light classification of **Double Red**	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	appraisal– no evidence submission was received from Novartis Pharmaceuticals UK			**(Not recommended for routine use)** for this SCG-commissioning responsibility treatment.	
Sept 2017	**NICE TA 471 (August 2017)** Recommended by NICE as an option	Eluxadoline (*Truberzi*®)	For treating irritable bowel syndrome with diarrhoea in adults, only if: • the condition has *not* responded to other pharmacological treatments (for example, anti-motility agents, antispasmodics, tricyclic antidepressants) or • pharmacological treatments are contraindicated or not tolerated, and • it is started in secondary care. Stop eluxadoline at 4 weeks if there is inadequate relief of the symptoms of irritable bowel syndrome with diarrhoea.	The TAG acknowledged **NICE TA 471 (August 2017)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use, and its place in the local treatment pathway clarified.	*Noted and supported by the D&TCG*
Sept 2017	**NICE TA 472 (August 2017)** NICE recommends use as an option within the **Cancer Drugs Fund** as an	Obinutuzumab (*Gazyvaro*®) with bendamustine, then obinutuzumab as maintenance	For treating follicular lymphoma in adults that did not respond or progressed during or up to 6 months after treatment with rituximab or a	The TAG acknowledged **NICE TA 472 (August 2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	option for treating adults with follicular lymphoma, only if the conditions in the managed access agreement for obinutuzumab are followed.		rituximab-containing regimen		
Sept 2017	**NG 68 (April 2017)** Sexually transmitted infections: Condom distribution schemes This guideline is a review of NICE guideline PH3 (February 2007) The aim is to reduce the risk of sexually transmitted infections (STIs) and provide a good introduction to broader sexual and reproductive health services, for younger people, and help prevent unplanned pregnancies.		Includes recommendations on: • 1.1 Targeting services • 1.2 Multicomponent schemes for young people in health, education, youth and outreach settings • 1.3 Single component schemes	The TAG acknowledged **NG 68 (April 2017)**	*Noted by the D&TCG*
Sept 2017	**NG 69 (May 2017)** This guideline covers assessment, treatment, monitoring and inpatient care for children, young people and adults with eating disorders. It aims to improve the care people receive by detailing the most effective treatments for anorexia nervosa, binge eating disorder and	Eating disorders: recognition and treatment	This guideline includes recommendations on: • identifying eating disorders • treating anorexia nervosa • treating binge eating disorder • treating bulimia nervosa • physical and mental health comorbidities • assessing, monitoring and managing physical health • inpatient and day	The TAG acknowledged **NG 69 (May 2017)**	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	bulimia nervosa.		patient care		
Sept 2017	**NG 71 (July 2017) - Parkinson's disease in adults** This guideline covers diagnosing and managing Parkinson's disease in people aged 18 and over. It aims to improve care from the time of diagnosis, including monitoring and managing symptoms, providing information and support, and palliative care. There are several new recommendations for 2017 regarding pharmacological treatment of Parkinson's disease. Includes recommendations on: • information and support • diagnosing Parkinson's disease	Includes several new recommendations regarding pharmacological treatment of Parkinson's disease: ▪ Ergot-derived dopamine agonists – **not recommended first line (1.3.11-12)** ▪ Amantadine for dyskinesia not managed by other options **(1.3.13)** ▪ ***"Do not do"*** – anticholinergics for Parkinson's dyskinesia and/or motor fluctuations **(1.3.14)** ▪ Modafinil for excessive daytime sleepiness **(1.5.2-3)** – currently **Double Red** (Sept 2010) ▪ Clonazepam or melatonin for RBD **(1.5.5)** ▪ Treatment of nocturnal akinesia **(1.5.6-7)** ▪ Midodrine, then fludrocortisone, for orthostatic hypotension in Parkinson's disease (currently Green for severe cases due to autonomic dysfunction (Nov 2015)) **(1.5.8-10)** ▪ Quetiapine, then clozapine, **but not olanzapine** for hallucinations and delusions in Parkinson's disease, where no cognitive impairment **(1.5.16-18)** ▪ Hallucinations and delusions in Parkinson's disease **"*Do not Do*"- olanzapine not recommended (1.5.19)** ▪ "***Do not Do*" – Phenothiazines or butyrophenones** not recommended in Parkinson's disease since worsen motor features of the condition **(1.5.20)** ▪ Anticholinesterase inhibitors and memantine Parkinson's disease dementia **(1.5.22-24)** ▪ Topical atropine, glycopyrronium bromide and botulinum toxin A for drooling of saliva where non-pharmacological management is not available or not effective **(1.5.26-29)** ▪ Pharmacological neuroprotective therapy – **"*Do not Dos*" for vitamin E, co-enzyme**	The TAG acknowledged **NG 71 (July 2017)** and agreed that the NICE recommendations that *advise against* use of certain treatments should be classified as **Double Red (Not recommended for routine use)**. The TAG also recommended that the Prescribing Reference Group be requested to consider the other recommendations within **NG 71** for use of drug treatments with a view to incorporating in local formularies and prescribing guidance for Parkinson's disease.	*The D&TCG noted and supported the TAG's recommendations and agreed that the following treatments are classified as* **Double Red (Not recommended for routine use) / Not commissioned**: 1. First-line use of ergot-derived dopamine agonists in Parkinson's disease. 2. Use of anticholinergics for Parkinson's dyskinesia and/or motor fluctuations. 3. Olanzapine for hallucinations and delusions in Parkinson's disease, where no cognitive impairment. 4. Use of either phenothiazines or butyrophenones in Parkinson's disease (worsen motor features of the condition). 5. Vitamin E, co-enzyme Q10, dopamine agonists and MAO-B inhibitors as pharmacological neuroprotective therapy. The D&TCG also noted the NICE recommendation for second-line use of clozapine after quetiapine, for hallucinations and delusions in Parkinson's disease, where no cognitive impairment. The D&TCG agreed that, in common with other indications for use, clozapine is classified

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	• pharmacological management of motor symptoms • pharmacological management of non-motor symptoms • non-pharmacological management of symptoms • impulse control disorders • palliative care	**Q10, dopamine agonists and MAO-B inhibitors (1.6.1-4)** ▪ Deep brain stimulation, only where best medical therapy, including apomorphine, is inadequate **(1.8.1-3)** ▪ Levodopa-carbidopa intestinal gel (*Duodopa*®) – recommendation to review the NHSE policy which currently provides it on the NHS **(1.8.4)**			as Red (Hospital / Specialist use only) where the specialist wishing to use the treatment is also responsible for providing blood monitoring for the treatment in line with manufacturer's SPC and national safety guidance. Local commissioners to be advised of this issue when planning Parkinson's services with local providers.
Sept 2017	**NG 72 (July 2017)**	Developmental follow-up of children and young people born preterm	Includes recommendations on: • information and support for parents and carers • risk and prevalence of developmental problems and disorders • how to conduct enhanced developmental support and surveillance, who should have it, and who should provide it • neonatal audit	The TAG acknowledged **NG 72 (July 2017)**	*Noted by the D&TCG.*
Sept 2017	**NICE Highly Specialised Technology Guidance HST 6 (August 2017):** Recommended by	Asfotase alfa (*Strensiq*®)	For treating paediatric-onset hypophosphatasia only: • for people who meet the criteria for treatment within the managed	The TAG acknowledged **NICE Highly Specialised Technology Guidance HST 6 (August 2017)** and recommended a traffic light classification of Red (Specialist Centre only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	NICE if the company provides asfotase alfa with the confidential commercial terms agreed with NHS England.		access arrangement (see section 4.18), and • for the duration of this arrangement and in line with the other conditions it specifies		
Sept 2017	**NICE Evidence Summaries June 2017:**	**ES15 Early breast cancer (preventing recurrence and improving survival): adjuvant bisphosphonates**		The TAG noted the NICE evidence summary.	*Noted by the D&TCG.*
Nov 2017	**NICE TA 357 (Sept 17)** *Update* - amended after a change to the commercial arrangements in August 2017. Recommended as an option by NICE.	Pembrolizumab (*Keytruda*®)	For treating advanced (unresectable or metastatic) melanoma in adults after disease progression with ipilimumab, and, for BRAF V600 mutation positive disease, a BRAF or MEK inhibitor	The TAG acknowledged **NICE TA 357 (Sept 17)** and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Nov 2017	**NICE TA 366 (Sept 17)** *Update* - amended after a change to the commercial arrangements in August 2017. Recommended as an option by NICE.	Pembrolizumab (*Keytruda*®)	For advanced (unresectable or metastatic) melanoma in adults not previously treated with ipilimumab	The TAG acknowledged **NICE TA 366 (Sept 17)** and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Nov 2017	**NICE TA 428 (Sept 17)** *Update* - amended after a change to	Pembrolizumab (*Keytruda*®)	For treating PD-L1-positive non-small-cell lung cancer in adults after chemotherapy	The TAG acknowledged **NICE TA 428 (Sept 17)** and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	the commercial arrangements in August 2017) Recommended as an option by NICE.			responsibility treatment.	
Nov 2017	**NICE TA 473 (Aug 17)** This guidance is a Cancer Drugs Fund reconsideration which replaces TA172.	Cetuximab (*Erbitux*®)	For treating recurrent or metastatic squamous cell cancer of the head and neck in adults, only if the cancer started in the oral cavity	The TAG acknowledged **NICE TA 473 (Aug 17)** and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Nov 2017	**NICE TA 474 (Sept 17)** This guidance is a Cancer Drugs Fund reconsideration of sorafenib which replaces TA189. Recommended as an option by NICE.	Sorafenib (*Nexavar*®)	For treating advanced hepatocellular carcinoma only for people with Child-Pugh grade A liver impairment	The TAG acknowledged **NICE TA 474 (Sept 17)** and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Nov 2017	**NICE TA 475 (Sept 17)** Recommended as an option by NICE.	Dimethyl fumarate (*Skilarence*®)	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 of 10 or more and a Dermatology Life Quality Index of more than 10 and • has not responded to other systemic therapies, including, ciclosporin,	The TAG acknowledged **NICE TA 475 (Sept 17)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use and confirmation of its place in the local treatment pathway.	*Noted and supported by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
			methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated.		
Nov 2017	**NICE TA 476 (Sept 17)** This guidance replaces NICE TA 360 which previously recommended *against* use. Recommended as an option by NICE.	Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel; *Abraxane*®)	(with gemcitabine) for untreated metastatic pancreatic cancer	The TAG acknowledged **NICE TA 476 (Sept 17)** and recommended a revised traffic light classification - currently **Double Red** (Nov 2015) – of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Nov 2017	**NICE TA 477 (Oct 17)** Providers are NHS tertiary referral centres. Recommended as an option by NICE.	Autologous chondrocyte implantation	For treating symptomatic articular cartilage defects of the knee	The TAG acknowledged **NICE TA 477 (Oct 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Nov 2017	**NICE TA 478 (Oct 17)** Recommended as an option by NICE.	Brentuximab vedotin (*Adcetris*®)	For treating relapsed or refractory systemic anaplastic large cell lymphoma in adults, only if they have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1	The TAG acknowledged **NICE TA 478 (Oct 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
Nov 2017	**NICE TA 479 (Oct 17)** Recommended as an option by NICE.	Reslizumab (*Cinqaero*®)	For treating severe eosinophilic asthma that is inadequately controlled in adults despite maintenance therapy with high-dose inhaled corticosteroids plus another drug, only if: • the blood eosinophil count has been recorded as 400 cells per microlitre or more • the person has had 3 or more severe asthma exacerbations needing systemic corticosteroids in the past 12 months	The TAG acknowledged **NICE TA 479 (Oct 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Nov 2017	**NICE TA 480 (Oct 17)** Recommended as an option by NICE.	Tofacitinib (*Xeljanz*®)	(with and without methotrexate) for moderate to severe active rheumatoid arthritis in adults	The TAG acknowledged **NICE TA 480 (Oct 17)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use and confirmation of its place in the local treatment pathway.	*Noted and supported by the D&TCG*
Nov 2017	**NICE TA 481 (Oct 17)** Recommended as initial options for use, by NICE. (Basiliximab – currently Red.	Immunosuppressive therapy: Basiliximab (*Simulect*®) Immediate-release tacrolimus Mycophenolate mofetil	To prevent organ rejection in kidney transplant in adults	The TAG acknowledged **NICE TA 481 (Oct 17)** and re-affirmed a traffic light classification of Red (Hospital/Specialist only) for basiliximab, and of Amber (Option for GP prescribing under an approved shared care agreement) for immediate-release tacrolimus, myciphenolate mofetil / mycophenolic acid, and sirolimus which are SCG-	*Noted and supported by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	Tacrolimus – currently Amber. Mycophenolate mofetil / Mycophenolic acid – currently Amber. Sirolimus – currently Amber.)			commissioning responsibility treatments, the costs of which are currently being recouped by the CCGs from NHS England to cover any prescribing by GPs. The use of the current shared care agreements to be extended until the end of March 2018. Rabbit anti-human thymocyte immunoglobulin, prolonged-release tacrolimus, mycophenolate sodium, sirolimus, everolimus and belatacept are *not* recommended by NICE as initial treatments to prevent organ rejection in adults having a kidney transplant. The TAG therefore also recommended a traffic light classification of **Double Red (Not recommended for routine use)** for these treatments for this indication.	
Nov 2017	**NICE TA 482 (Oct 17)** Recommended as initial options for use, by NICE. ***NB** current local **Shared Care Agreements** for tacrolimus, mycophenolate mofetil / mycophenolic acid and sirolimus apply only to use in **adults***	Immunosuppressive therapy: Basiliximab (*Simulect*®) Immediate-release tacrolimus Mycophenolate mofetil	To prevent organ rejection in kidney transplant in children and young people	The TAG acknowledged **NICE TA 482 (Oct 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for these SCG-commissioning responsibility treatments. Rabbit anti-human thymocyte immunoglobulin, prolonged-release tacrolimus, mycophenolate sodium, sirolimus, everolimus and belatacept are *not recommended* as initial treatments to prevent organ rejection in children and young people having a kidney transplant. The TAG therefore also recommended a traffic light classification of **Double Red (Not recommended for routine use)** for these treatments for this indication.	*Noted by the D&TCG*
Nov 2017	**NICE TA 483 (Nov**	Nivolumab	For previously treated local advanced or	The TAG acknowledged **NICE TA 483 (Nov 17)** and recommended a traffic light	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	17) Nivolumab will continue to be available through the Cancer Drug Fund while the guidance is being updated, as part of the managed access agreement.	(*Opdivo*®)	metastatic squamous non-small-cell lung cancer in adults after chemotherapy only if nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease progression	classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	
Nov 2017	**NICE TA 484 (Nov 17)** Nivolumab will continue to be available through the Cancer Drug Fund while the guidance is being updated, as part of the managed access agreement	Nivolumab (*Opdivo*®)	For previously treated locally advanced or metastatic non-squamous non-small-cell lung cancer in adults after chemotherapy, only if their tumours are PD-L1 positive and nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease progression	The TAG acknowledged **NICE TA 484 (Nov 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG*
Nov 2017	**NICE TA 485 (Nov 17)** Recommended as an option by NICE.	Sarilumab (*Kevzara*®)	(with and without methotrexate) for moderate to severe active rheumatoid arthritis in adults	The TAG acknowledged **NICE TA 485 (Nov 17)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use and confirmation of its place in the local treatment pathway.	*Noted and supported by the D&TCG*
Nov 2017	**NICE TA 486 (Nov 17)** CCG-commissioning responsibility Recommended as an option by NICE. Ranibizumab is already recommended by		Aflibercept (*Eylea*®) for treating visual impairment because of myopic choroidal neovascularisation in	The TAG acknowledged **NICE TA 486 (Nov 17)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this CCG-commissioning responsibility	*Noted and supported by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	NICE for this indication. 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 ranibizumab. If both aflibercept and ranibizumab are considered to be suitable treatments, the least costly should be used, taking into account anticipated administration costs, dosage and price per dose.		adults	treatment pending the submission and approval of a locally developed business application for its use and confirmation of its place in the local treatment pathway.	
Nov 2017	**NICE CG 28 (updated September 2017)** NICE has updated recommendation 1.1.5.4 to clarify the training needed for therapists. They also updated recommendation 1.4.1.1 to delete reference to a questionnaire which is no longer relevant.	Depression in children and young people: identification and management	Includes recommendations on: • care of all children and young people with depression • stepped care • step 1: detection, risk profiling and referral • step 2: recognition • step 3: mild depression • steps 4 and 5: moderate to severe depression • transfer to adult services	The TAG acknowledged **NICE CG 28 (updated September 2017)**	*Noted by the D&TCG*
Nov 2017	**NICE CG 153 (updated September 2017)** NICE has revised the guideline throughout to link to other NICE	Psoriasis: assessment and management	Includes recommendations on: • principles of care • assessment and referral • topical therapy	The TAG acknowledged **NICE CG 153 (updated September 2017)**	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	guidance (TAs) and some relevant non-NICE guidelines, as well as including new MHRA safety advice and updated licensing information.		• phototherapy (broad- or narrow-band narrowband ultraviolet B light & psoralen with local ultraviolet A) • systemic therapy		
Nov 2017	**NICE NG 51 (updated September 2017)** NICE has updated recommendation 1.4.3 to properly divide 2 bullet points. Table 3 and recommendations 1.4.9 and 1.9.2 were corrected to give oxygen saturation as less than 92% in air. Table 2 was amended to include tympanic temperature as a moderate risk factor. Table 3 was amended to add pallor of skin, lips or tongue as an intermediate to high risk factor, and recommendation 1.4.9 was amended to remove pale or flushed as an intermediate risk factor.		Sepsis: recognition, diagnosis and early management Includes recommendations on: • Identifying and assessing people with suspected sepsis • Risk factors and risk stratification for sepsis • Managing suspected sepsis in acute hospital settings and out of hospital	The TAG acknowledged **NICE NG 51 (updated September 2017)**	*Noted by the D&TCG*
Nov 2017	**NICE NG 73 (September 2017)** This guideline updates and replaces the recommendations on endometriosis in NICE's fertility problems guideline (CG 156), which includes recommendations on fertility tests and	Endometriosis: diagnosis and management	Includes recommendations on: • organisation of care • information and support • endometriosis symptoms and signs • when to refer • diagnosing endometriosis • pharmacological	The TAG acknowledged **NICE NG 73 (September 2017)**	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	treatments such as assisted reproduction.		• management • surgical management		
Nov 2017	**NICE NG 74 (September 2017)**	Intermediate care including reablement	Includes recommendations on: • core principles of intermediate care, including reablement • supporting infrastructure • assessment of need for intermediate care • referral into intermediate care and entering the service • delivering intermediate care • transition from intermediate care • training and development	The TAG acknowledged **NICE NG 74 (September 2017)**	*Noted by the D&TCG*
Nov 2017	**NICE NG 75 (September 2017)**	Faltering growth: recognition and management of faltering growth in children	Includes recommendations on: • weight loss in the early days of life • faltering growth after the early days of life • organisation of care • information and support for parents and carers	The TAG acknowledged **NICE NG 75 (September 2017)**	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
Nov 2017	**NICE NG 76 (October 2017)** Clinical features of abuse and neglect (including physical injury) are covered in NICE's guideline on child maltreatment. Recommendations relevant to both health and social care practitioners appear in both guidelines. NICE has also produced guidelines on children's attachment, harmful sexual behaviour and domestic violence and abuse.	Child abuse and neglect	Includes recommendations on: • principles for working with children, young people, parents and carers • factors that increase vulnerability to child abuse and neglect • recognising child abuse and neglect • assessing risk and need • early help for families showing possible signs of child abuse or neglect • multi-agency response to child abuse and neglect • therapeutic interventions for children, young people and families after child abuse and neglect • planning and delivering services	The TAG acknowledged **NICE NG 76 (October 2017)**	*Noted by the D&TCG*
Nov 2017	**NICE NG 77 (October 2017)**	Cataracts in adults: management Includes recommendations on: • patient information • referral for cataract surgery • preoperative assessment and biometry • preventing wrong lens implant errors • surgical timing and technique		The TAG acknowledged **NICE NG 77 (October 2017)**	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
		• preventing and managing complications • postoperative assessment			
Nov 2017	**NICE NG 78 (October 2017)**	Cystic fibrosis: diagnosis and management Includes recommendations on: • diagnosis • service delivery, including how to organise services and multidisciplinary teams • annual and routine reviews • monitoring, assessment and management, including for lung disease, pulmonary infection, distal intestinal obstruction syndrome, liver disease and cystic-fibrosis-related diabetes • preventing cross-infection		The TAG acknowledged **NICE NG 78 (October 2017)**	*Noted by the D&TCG*
Nov 2017	**NICE NG 79 (October 2017)**	Sinusitis (acute): antimicrobial prescribing	Includes recommendations on: • managing symptoms, including advice when an antibiotic is not needed and the use of corticosteroids and nasal sprays • choice of antibiotic when a back-up or immediate prescription is needed • self-care	The TAG noted the differences in recommended antibiotic choices for acute sinusitis compared with the locally agreed antibiotic formularies, and was advised that NG 79 would be taken into consideration as part of the on-going review of the formularies. The TAG otherwise acknowledged **NICE NG 79 (October 2017)**	*Noted by the D&TCG*
Nov 2017	**NICE NG 81 (October 2017)**	Glaucoma: diagnosis and management	Includes recommendations: • case-finding • diagnosis • standard practice for all assessments	The TAG noted that NG 81 now states that generic eye drop options should be used first-line in the treatment of glaucoma and that preservative-free products should be reserved for use where there is known allergy or high risk of conversion to chronic open angle	*Noted by the D&TCG*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
			• reassessment • treatment • organisation of care • providing information	glaucoma (COAG). The TAG otherwise acknowledged **NICE NG 81 (October 2017)**	
Nov 2017	**NICE CG 71 (updated Nov 2017)** NICE reviewed the evidence for case finding and diagnosis, identification using cascade testing, and management using statins and added, updated and deleted recommendations in 1.1, 1.2 and 1.3. They also removed nicotinic acid from 1.3 because it no longer has a UK licence.	Familial hypercholesterolaemia: identification and management	Includes recommendations on: • diagnosis • identifying people with FH using cascade testing • drug treatment, lifestyle interventions and specialist treatment • information and support on contraception for women with FH and for pregnant women with FH • review and referral for evaluation of coronary heart disease	The TAG acknowledged **NICE CG 71 (updated Nov 2017)**	*Noted by the D&TCG*
Jan 2018	**NICE TA 487 (Nov 17)** **Next review**: The guidance will be updated when the data collection period has ended (Dec 2020). Venetoclax will continue to be available through the Cancer Drugs	Venetoclax (*Venclyxto*®)	For treating chronic lymphocytic leukaemia	The TAG acknowledged **NICE TA 487 (Nov 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.* *The D&TCG also recommended monitoring for any inappropriate prescribing of this oral treatment in primary care.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	Fund in the interim, via the managed access agreement.				
Jan 2018	**NICE TA 488 (Nov 17)** Recommended as an option by NICE.	Regorafenib (*Stivarga*®)	For previously treated unresectable or metastatic gastrointestinal stromal tumours	The TAG acknowledged **NICE TA 488 (Nov 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.* *The D&TCG also recommended monitoring for any inappropriate prescribing of this oral treatment in primary care.*
Jan 2018	**NICE TA 489 (Nov 17)** *Not recommended by NICE*	Vismodegib (*Erivedge*®)	For treating basal cell carcinoma	The TAG acknowledged **NICE TA 489 (Nov 17)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*
Jan 2018	**NICE TA 490 (Nov 17)** **Next review:** The guidance will be updated when data collection ends (circa Sept19 when 4-year follow-up data from CheckMate-141 are available). Nivolumab will continue to be available through the CDF in the interim, as part of the managed access agreement.	Nivolumab (*Opdivo*®)	For treating squamous cell carcinoma of the head and neck after platinum-based chemotherapy	The TAG acknowledged **NICE TA 490 (Nov 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
Jan 2018	**NICE TA 491 (Nov 17)** NICE recommends as an option. **Next review**: will be updated when data collection ends (circa Sept 2020). Ibrutinib will continue to be available in the CDF in the interim, as part of managed access agreement.	Ibrutinib (*Imbruvica*®)	For treating Waldenstrom's macroglobulinaemia	The TAG acknowledged **NICE TA 491 (Nov 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.* *The D&TCG also recommended monitoring for any inappropriate prescribing of this oral treatment in primary care.*
Jan 2018	**NICE TA 492 (Dec 17)** NICE recommends as an option. **Next review**: The guidance will be updated when data collection ends (circa Dec 2020), when final analyses of IMvigor 130 are available). Atezolizumab will be available in the CDF in the interim, via the managed access agreement.	Atezolizumab (*Tecentriq*®)	For untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable	The TAG acknowledged **NICE TA 492 (Dec 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*
Jan 2018	**NICE TA 493 (Dec 17)** Recommended as an option by NICE.	Cladribine (*Mavenclad*®) tablets	For treating relapsing-remitting multiple sclerosis	The TAG acknowledged **NICE TA 493 (Dec 17)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning	*Noted by the D&TCG.* *The D&TCG also supported the TAG's recommendation to monitor for any inappropriate*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
				responsibility treatment. The TAG also agreed that it would be prudent to monitor for any inappropriate prescribing of this oral treatment in primary care.	*prescribing of this oral treatment in primary care*
Jan 2018	**NICE TA 494 (Dec 17)** CCG-commissioning responsibility Currently classified in Norfolk and Waveney as **Double Red (Not recommended for routine use)** (Sep 2016) Naltrexone–bupropion (*Mysimba*®) is **not recommended** for managing overweight and obesity in adults alongside a reduced-calorie diet and increased physical activity.		Naltrexone–bupropion (*Mysimba*®) for managing overweight and obesity	The TAG acknowledged **NICE TA 494 (Dec 17)** 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&TCG.*
Jan 2018	**NICE TA 495 (2017)** Recommended as an option by NICE as initial endocrine-based therapy in adults.	Palbociclib (*Ibrance*®) (with an aromatase inhibitor)	For previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer	The TAG acknowledged **NICE TA 495 (2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.* *The D&TCG also recommended monitoring for any inappropriate prescribing of this oral treatment in primary care.*
Jan 2018	**NICE TA 496 (2017)** Recommended as an option by NICE as initial endocrine-based therapy in adults.	Ribociclib (*Kisqali*®) (with an aromatase inhibitor)	For previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer	The TAG acknowledged **NICE TA 496 (2017)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.* *The D&TCG also recommended monitoring for any inappropriate prescribing of this oral treatment in primary care.*
Jan 2018	**NICE NG 80 (November 2017)** NICE notes that:	Asthma: diagnosis, monitoring and chronic asthma	Includes recommendations on: • Initial clinical	The TAG noted the differences between NG 80 and current BTS/SIGN guidance for asthma regarding earlier use of leukotriene receptor antagonists (LTAs)	*The D&TCG the differences from other national guidance highlighted by the TAG.* *It was noted that earlier use of*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	The investment and training required to implement the guideline will take time. In the meantime, primary care services should implement what they can of the recommendations, using currently available approaches to diagnosis until the infrastructure for objective testing is in place	management	assessment • Diagnosing asthma in young children • Objective tests for diagnosing asthma (including diagnostic algorithms) • Pharmacological treatment • Adherence, self-management and decreasing treatment • Monitoring asthma control	after ICS and ahead of inhaled LABA, and use of objective diagnostic testing including spirometry, fractional exhaled nitric oxide (FeNO), and peak flow management. BTS has published a clinical response to the NICE guidelines. The TAG otherwise acknowledged **NICE NG 80 (November 2017).**	*LTAs might benefit people with allergic aspects to their asthma.* *FeNO testing costs ~£5 per test. To be flagged to Business Intelligence for possible monitoring.* *To be flagged to local Pathology Services Group via Dr Mark Lim, Programme Director, Acute Services, GY&W CCG. GY&W CCG have advised their practices to continue to follow BTS/SIGN guidance.*
Mar 2018	**NICE TA 497 (January 2018)** Recommended as an option by NICE.	Golimumab (*Simponi*®)	For treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, nonsteroidal anti-inflammatory drugs.	The TAG acknowledged **NICE TA 497 (January 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.*
Mar 2018	**NICE TA 498 (January 2018)** Recommended as an option by NICE.	Lenvatinib (*Kisplyx*®) (with everolimus) *NB oral formulation*	For previously treated advanced renal cell carcinoma in adults who have had 1 previous vascular endothelial growth factor (VEGF)-targeted therapy	The TAG acknowledged **NICE TA 498 (January 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment	*Noted by the D&TC.*
Mar 2018	**NICE TA 499 (January 2018)** Recommended as	Glecaprevir–pibrentasvir	For treating chronic hepatitis C	The TAG acknowledged **NICE TA 499 (January 2018)** and recommended a traffic light classification of Red	*Noted by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	an option by NICE.	(*Maviret*®) *NB oral formulation*		(Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.	
Mar 2018	**NICE TA 500 (January 2018)** Recommended as an option by NICE.	Ceritinib (*Zykadia*®) *NB oral formulation*	For untreated ALK-positive non-small-cell lung cancer in adults	The TAG acknowledged **NICE TA 500 (January 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.	*Noted by the D&TC.*
Mar 2018	**NICE TA 501 (January 2018)** Not recommended by NICE.	Intrabeam radiotherapy system	For adjuvant treatment of early breast cancer	The TAG acknowledged **NICE TA 501 (January 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this NHSE--commissioning responsibility treatment.	*Noted by the D&TC.*
Mar 2018	**NICE TA 502 (January 2018)** Recommended as an option by NICE.	Ibrutinib (*Imbruvica*®)	For treating relapsed or refractory mantle cell lymphoma	The TAG acknowledged **NICE TA 502 (January 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.	*Noted by the D&TC.*
Mar 2018	**NICE TA 503 (January 2018)** Not recommended by NICE (NB: previously classified as **Double Red** as per **NICE TA 239** (Dec 2011) which recommends against use as an alternative to aromatase inhibitors for the treatment of oestrogen-receptor-positive, locally advanced or metastatic breast cancer in postmenopausal women whose cancer has relapsed on or after adjuvant anti-oestrogen therapy, or who have disease progression on anti-oestrogen therapy)		Fulvestrant (*Faslodex*®) for *untreated* locally advanced or metastatic oestrogen-receptor positive breast cancer in postmenopausal women	The TAG acknowledged **NICE TA 503 (January 2018)** and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for this NHSE--commissioning responsibility treatment.	*Noted by the D&TC.*
Mar 2018	**NICE TA 504**	Pirfenidone	For treating idiopathic	The TAG acknowledged **NICE TA 504**	*Noted by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	(February 2018) Recommended as an option by NICE.	(*Esbriet*®)	pulmonary fibrosis in adults	**(February 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.	
Mar 2018	**NICE TA 505 (February 2018)** Recommended by NICE as an option for use within the Cancer Drugs Fund	Ixazomib (*Ninlaro*®) with lenalidomide and dexamethasone	For treating relapsed or refractory multiple myeloma	The TAG acknowledged **NICE TA 505 (February 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.	*Noted by the D&TC.*
Mar 2018	**NICE TA 506 (February 2018)** Not recommended by NICE	Lesinurad (*Zurampic*®) with a xanthine oxidase inhibitor	For treating chronic hyperuricaemia in people with gout whose serum uric acid is above the target level despite an adequate dose of a xanthine oxidase inhibitor alone.	The TAG acknowledged **NICE TA 503 (January 2018)** and recommended 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.*
Mar 2018	**NICE TA 507 (February 2018)** Recommended by NICE as an option	Sofosbuvir–velpatasvir–voxilaprevir (*Vosevi*®)	For treating chronic hepatitis C in adults	The TAG acknowledged **NICE TA 507 (February 2018)** and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.	*Noted by the D&TC.*
Mar 2018	**NG 82 (January 2018)** • NICE resource impact report • NHS Clinical Commissioners comment on NG82 • GMC statement	Age-related macular degeneration (Various treatment options)	Includes recommendations on: • classifying AMD • providing information and support • risk factors • diagnosis and referral • pharmacological and non-pharmacological management	The TAG acknowledged **NG 82 (January 2018)** and noted that it included recommendations regarding treatment thresholds which deviated from the previously commissioned NICE TAs. The TAG also noted the recommendations that suspected cases should be referred to the local service within 1 working day, and that appropriate treatment should started within 2 weeks of confirmed diagnosis of	*The D&TC noted the TAG's comments regarding* **NG 82 (January 2018)** *and confirmed that the previously agreed commissioning position and treatment pathway for wet AMD are maintained for the time being.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	re NG82 European court ruling that off-label drugs can compete directly with licensed drugs for the same indication CCG-commissioning responsibility		• monitoring	wet AMD, which will have service implications for addressing by CCGs. References to use of bevacizumab as a treatment option were noted and would be further considered as appropriate following to the outcome of the judicial review.	
Mar 2018	**NG 83 (January 2018)**	Oesophago-gastric cancer: assessment and management in adults	Includes recommendations on: • radical and palliative treatment • nutritional support • follow-up and support • service organisation	The TAG acknowledged **NG 83 (January 2018)**	*Noted by the D&TC.*
Mar 2018	**NG 84 (January 2018)**	Sore throat (acute): antimicrobial prescribing	Includes recommendations on: • managing acute sore throat, including advice when an antibiotic is not needed • choice of antibiotic when a back-up or immediate prescription is needed • self-care • 2-page summary of recommendations	The TAG acknowledged **NG 84 (January 2018)** and noted that local use of antibiotics is under scrutiny by NHS England. Antibiotic usage will be covered under the Norwich, South Norfolk and West Norfolk CCGs' prescribing incentive schemes for 2018. The TAG recommended that a coordinated approach to promoting this guidance would have more impact if taken forward by the CCGs' communications teams.	*Noted and supported by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
Mar 2018	**NG 85 (February 2018)**	Pancreatic cancer in adults: diagnosis and management	Includes recommendations on: • diagnosis • monitoring for people with an inherited high risk of pancreatic cancer • staging • psychological support • pain and nutrition management • management for resectable, borderline resectable and unresectable cancer	The TAG acknowledged **NG 85 (February 2018)**	*Noted by the D&TC.*
Mar 2018	**NG 86 (February 2018)**	People's experience in adult social care services: improving the experience of care and support for people using adult social care services	Includes recommendations on: • providing information • assessing care and support needs and care planning • providing care and support • staff skills and experience • involving people who use services in service design and improvement	The TAG acknowledged **NG 86 (February 2018)**	*Noted by the D&TC.*
Mar 2018	**NICE CG 147 (*update* Feb 2018)** NICE has reviewed the evidence for	Peripheral arterial disease: diagnosis and management	Includes recommendations on: • assessing for PAD • imaging for	The TAG acknowledged **NICE CG 147 (*update* Feb 2018)**	*Noted by the D&TC.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
	diagnosing peripheral arterial disease in people with diabetes and added 2 recommendations.		revascularisation • managing intermittent claudication • managing critical limb ischaemia • preventing cardiovascular disease in people with PAD		
Mar 2018	**NICE Medical Technologies Guidance (MTG) 36 (Feb 2018)** Transanal irrigation / Rectal irrigation appliances are currently **Double Red (Not commissioned)**	*Peristeen* transanal irrigation system for managing bowel dysfunction	NICE recommendations: **1.1** The case for adopting *Peristeen* for transanal irrigation in people with bowel dysfunction is supported by the evidence. *Peristeen* can reduce the severity of constipation and incontinence, improve quality of life and promote dignity and independence. **1.2** *Peristeen* may not be suitable for all people with bowel dysfunction. It may take several weeks before a person is comfortable with using *Peristeen*, and some people may choose to stop using it. It is therefore most effective when offered with specialist training for users, carers and NHS staff, and structured patient support. **1.3** Cost modelling for	The TAG was advised that some prescribing of this product persisted beyond the decision to classify its (and similar TAI products') use as not commissioned. Liaison with local specialist services is in progress and a local formulary and guidelines are under development. No change to the current classification recommended in the interim. The TAG otherwise acknowledged **NICE Medical Technologies Guidance (MTG) 36 (Feb 2018)**	*Noted and supported by the D&TC.* *Still recommended as not commissioned, as per previous decision.*

Date	NICE Guidance	Drug / Treatment	Indication for use	TAG Recommendation	Related D&TCG Commissioning Decision
			Peristeen is *uncertain*, but it is likely that it provides additional clinical benefits without costing more than standard bowel care.		

1. TAG Recommendations 2017/18

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 2017	**Therapeutics Advisory Group:** **NNUH & QEH Joint Guideline: Antibiotic Management of Diabetes Related Foot Infections in Adults**	Various antibiotics	Management of Diabetes Related Foot Infections in Adults	The TAG was advised that feedback had been sent to the authors recommending that additional text regarding the need to monitor LFTs in patients on long-term fusidic acid for osteomyelitis. The guideline is already hyperlinked from the Primary Care Antibiotic Formulary in Norfolk. The TAG otherwise supported the guidance.	*Noted by the D&TCG*
May 2017	**Therapeutics Advisory Group:** **N&W GP Prescribing Information:**	Sodium oxybate	For treatment of adult narcoleptic patients with cataplexy who were already on treatment prior to July 2013	Guidance last reviewed July 2013. Three patients remain on treatment in Norfolk (North Norfolk, West Norfolk & Norwich CCGs). The TAG recommended that the prescribing information could be withdrawn from use on Knowledge Anglia.	*Noted and supported by the D&TCG*
May 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due May 2016***	Atomoxetine (*Strattera*®)	For ADHD and related disorders in Children & Adolescents	**March 2017:** No recommendations for changes from local specialists. Concern was expressed that GPs are required to be responsible for annual assessment of monitoring results such as weight, height	**March 2017:** *Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
				and BP. The TAG agreed to support continued use of the document as Amber (Option for GP prescribing under an approved shared care agreement) in the interim and would revisit this item at the next meeting to obtain other TAG GPs' views regarding monitoring responsibility. **May 2017:** One other TAG GP's views were available. The issues expressed in March 2017 were reiterated to the committee. However the TAG decided to maintain use of the previously agreed version of the agreement.	**May 2017:** *Noted by the D&TCG.*
May 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due January 2016***	Dronedarone (*Multaq*®)	For non-permanent atrial fibrillation	The TAG supported the minor changes recommended by the authors and agreed to recommend continued use of the revised document as Amber (Option for GP prescribing under an approved shared care agreement).	*Noted and supported by the D&TCG.*
May 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due September 2016***	Azathioprine	For use in Ulcerative Colitis & Crohn's Disease	The TAG supported the minor changes recommended by the author / editor and agreed to recommend continued use of the revised document as Amber (Option for GP prescribing under an	*Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
				approved shared care agreement). The TAG also clarified that the agreement applies to use in adults.	
May 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due September 2016***	Mercaptopurine	For use in Ulcerative Colitis & Crohn's Disease	The TAG supported the minor changes recommended by the author / editor and agreed to recommend continued use of the revised document as Amber (Option for GP prescribing under an approved shared care agreement). The TAG also clarified that the agreement applies to use in adults.	*Noted and supported by the D&TCG.*
May 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due July 2016***	Modified-Release Tapentadol	For severe chronic pain in patients who are intolerant of Modified-Release Morphine	In the absence of any recommendations for change received from the authors, the TAG agreed to support use of the shared care agreement, which had been updated in line with the manufacturer's SPC, in the interim as Amber (Option for GP prescribing under an approved shared care agreement). In view of concerns regarding safe and appropriate use of tapentadol, the TAG also recommended that the views of local palliative care specialists regarding the need for its continued use be sought and returned to the committee, along with ePACT data on recent usage and any available	*Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
				evidence regarding its efficacy and safety.	
May 2017	**Therapeutics Advisory Group:** ***Revised* BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs 2017 - *Link*** **Changes to national NHS Provider Contract 2017-19 which affect the provider and GP interface**	Various - DMARDs	Rheumatoid, Inflammatory Bowel Disease, and Dermatology – monitoring requirements	The TAG noted the key changes in the revised BSR / BHPR guidelines and considered the implications for shared care guidance previously supported by the TAG. The TAG also noted the changes to the national NHS Provider Contract 2017-19 which affect the provider and GP interface. The TAG acknowledged these issues and would consider any proposals for revising the shared care agreements in due course.	*Noted by the D&TCG.*
	Prescribing Reference Group:	Pramipexole Prolonged Release	For idiopathic Parkinson's disease	Recommended by TAG in March 2011 as **Double Red (Not recommended for routine use)** and not commissioned for new patients, due to not being a cost-effective treatment option. However still being used (for established and possibly for new patients). A 50% cheaper branded product, *Pipexus®,* has recently become available which may offer an option for switching from *Mirapexin P-R.* The TAG confirmed that use of the more expensive	*Noted and supported by the D&TCG.* *The D&TCG also queried whether local MFE specialists should be contacted regarding possible use of pramipexole PR for movement disorders.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
				prolonged-release pramipexole preparations is not supported and reaffirmed the traffic light classification of **Double Red (Not recommended for routine use)** for this formulation. The TAG would also await feedback from local neurology specialists regarding their acknowledgement of this position.	
May 2017	**Prescribing Reference Group: Formulary Updates:**	Various	**Eye Formulary** **Dry Eye Treatment Pathway**	The updated Formularies were noted by the TAG.	*Noted by the D&TCG.*
May 2017	**Prescribing Reference Group:**	**Key Message Bulletins – *New*** **Bulletin 38: Anticipatory Prescribing in End of Life (Adults)** **Bulletin 39: Prescribing Considerations at End of Life (EOL)** **Bulletin 40: Initiation and Management of Opioids in Palliative Care** **Key Message Bulletins – *Updates*** Bulletin 10: **Asthma - adults** Bulletin 11: **Asthma – adolescents** Bulletin 12: **Asthma – children** Bulletin 13: **Acute asthma**		The ***New*** and ***Updated*** Key Message Bulletins were noted and supported by the TAG	*Noted by the D&TCG.*
July 2017	**Therapeutics Advisory Group:** **Early review of established shared care agreements and one new shared care proposal for DMARDs following the publication of the revised BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs 2017 - *Link***				

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
July 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due July 2018***	Oral and Subcutaneous Methotrexate	For the Treatment of Rheumatoid Arthritis, Juvenile Arthritis, Connective Tissue Disease, Felty's Syndrome, Psoriasis and Inflammatory Bowel Disease	The TAG recommended that the shared care agreement be ratified for continued use with the recommended changes, including confirmation that the shingles vaccine may be given to JCVI-recommended patients taking standard DMARD doses of methotrexate.	*The D&TCG was advised that work on up-dating and finalising the shared care agreement was still in progress.*
July 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due July 2017***	Leflunomide	For treatment of rheumatoid or psoriatic arthritis	The TAG recommended that the shared care agreement be ratified for continued use with the recommended changes, including confirmation that the shingles vaccine may be given to JCVI-recommended patients taking standard DMARD doses of leflunomide, and confirmation that GP monitoring responsibilities would be monthly at most.	*The D&TCG was advised that work on up-dating and finalising the shared care agreement was still in progress.*
July 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due January 2016***	Ciclosporin	For use in the treatment of Rheumatic and Dermatological diseases	The TAG recommended that the shared care agreement be ratified for continued use with the recommended changes, including confirmation that the shingles vaccine may be given to JCVI-recommended patients taking standard DMARD doses of ciclosporin.	*The D&TCG was advised that work on up-dating and finalising the shared care agreement was still in progress.*
July 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:**	Mycophenolate Mofetil	For use in the treatment of autoimmune conditions	The TAG recommended that the shared care agreement be ratified for continued use	*The D&TCG was advised that work on up-dating and finalising the shared care agreement was*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
	Review due January 2019			with the recommended changes, including confirmation that the shingles vaccine may be given to JCVI-recommended patients taking doses of mycophenolate mofetil described under the shared care document.	*still in progress.*
July 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due May 2018***	Azathioprine	For use in Autoimmune Diseases	The TAG recommended that the shared care agreement be ratified for continued use with the recommended changes, including confirmation that the shingles vaccine may be given to JCVI-recommended patients taking doses of azathioprine described under the shared care document.	*The D&TCG was advised that work on up-dating and finalising the shared care agreement was still in progress.*
July 2017	**Therapeutics Advisory Group:** **Shared Care *Proposal (New)*:**	Sulfasalazine	For the Treatment of Inflammatory Arthritis and Inflammatory Bowel Disease	The TAG agreed to support use of this shared care proposal and recommended a traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement).	*The D&TCG was advised that work on finalising the shared care agreement was still in progress.*
July 2017	**Prescribing Reference Group:**	Pramipexole Prolonged Release for idiopathic Parkinson's disease	**May 2017:** Recommended by TAG in March 2011 as **Double Red (Not recommended for routine use)** and not commissioned for new patients, due to not being a cost-effective treatment option. However still being used (for established and possibly for new patients). A 50% cheaper branded product, *Pipexus®,* has recently become available which may offer an option for switching from *Mirapexin P-R.*		**May 2017:** *Noted and supported by the D&TCG.* *The D&TCG also queried whether local MFE specialists should be contacted regarding possible use of pramipexole PR for movement disorders.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
			The TAG confirmed that use of the more expensive prolonged-release pramipexole preparations is not supported and reaffirmed the traffic light classification of **Double Red (Not recommended for routine use)** for this formulation. The TAG would also await feedback from local neurology specialists regarding their acknowledgement of this position. **PRG June 2017:** Feedback from the NNUH welcomed and noted. NNUH Formulary Pharmacist to ensure that specialists are kept abreast trust and primary care formulary decisions. In-trust switching policy to be developed. **TAG July 2017:** NNUH D&TC Chair has reminded specialists that prolonged-release pramipexole is not commissioned and should not be used routinely.		**July 2017:** *The D&TCG was advised that the CCGs are liaising with the Trusts regarding such interface issues where clinical practice has been in contravention of the commissioned position.*
July 2017	**Prescribing Reference Group:** The appliances and sundries are expensive and imposing additional and unplanned burden on Primary Care budgets. The PRG has recommended that no new patients should be started on anal irrigation systems. Existing patients should be slotted into a locally devised treatment pathway once available.	Anal Irrigation appliances e.g. Peristeen Anal Irrigation System (Coloplast)	Continence care	The TAG recommended applying a classification of **Double Red indication (Not recommended for routine use)** until such time as a business application and proposed treatment pathway for use of any these products is submitted. The TAG agreed that such applications should be written and submitted by the interested Trust (not by the product manufacturer).	*Noted and supported by the D&TCG – **Not commissioned***
July 2017	**Prescribing Reference Group:** **Norfolk & Waveney "Drugs of Low Priority" DROP List Recommendations:**				
July 2017	**Prescribing Reference Group:** **28 days' supply** (56) costs **£47.60** compared with ferrous fumarate or sulphate preparations costing £1 to £3	***Feraccru*® -** capsules containing 231.5mg ferric maltol (equivalent	Licensed to treat iron deficiency anaemia in inflammatory bowel disease (IBD). Currently used in-Trust at the NNUH but requests have also	The TAG recommended applying a classification of **Double Red indication (Not recommended for routine use)** until such time as a business application for use	*Noted and supported by the D&TCG – **Not commissioned***

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
	(***Link*** to MIMS cost comparison table). Recommended to be added to the DROP List.	to 30mg ferrous iron)	been made to GPs.	of *Feraccru*® is submitted.	
July 2017	**Prescribing Reference Group:** Limited evidence for benefit available other than from the company and not licensed in the UK. Other similar products also not supported. Recommended to be added to the DROP List.	**Combination topical products for Melasma / Chloasma containing tretinoin, hydroquinone and a corticosteroid** e.g. *Tri-Luma*® cream containing tretinoin 0.05%, hydroquinone 4% and fluocinolone acetonide 0.01% e.g. *Melanorm-HC* Cream containing tretinoin 0.05%, hydroquinone 2% and hydrocortisone 1% e.g. *Pigmanorm*® Cream contains tretinoin 0.1%, hydroquinone 5%, hydrocortisone 1%	The TAG recommended applying a classification of **Double Red indication (Not recommended for routine use)** until such time as a business application for use of any these products is submitted.	*Noted and supported by the D&TCG – **Not commissioned***
July 2017	**Prescribing Reference Group:** Should be provided through a specialist service and not on prescription, only after specialist assessment. Recommended to be added to the DROP List.	**Bamboo bedding:** e.g. Symmetrikit bamboo sheet and cushion covers Requested in other parts of the eastern region related to the care of very disabled patients with severe needs.	The TAG recommended applying a classification of **Double Red indication (Not recommended for routine use)** until such time as a business application for use of any these products is submitted.	*Noted and supported by the D&TCG – **Not commissioned***
July 2017	**Prescribing Reference Group:** Patient requests to GPs reported. Recommended to be added to the DROP List.	**"Bio-identical" Hormone Replacement Therapy for use in menopause:** No evidence of additional benefit and not recommended by NICE NG 23 (November 2013) Menopause: diagnosis and management	The TAG recommended applying a classification of **Double Red indication (Not recommended for routine use)** for these products.	*Noted and supported by the D&TCG – **Not commissioned***
July 2017	**Prescribing Reference Group:** Prescribable under ACBS criteria only for hypoproteinaemia. The PRG noted that dietitians are requesting GP to prescribe	Recommended to be added to the DROP List: **ProSource Jelly –** protein-containing food supplement for use in patients with protein energy malnutrition	The TAG recommended applying a classification of **Double Red indication (Not recommended for routine use)** until such time as a business application for use	*Noted and supported by the D&TCG – **Not commissioned***

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
	for malnutrition. Business case needed describing how hypoproteinaemia will be measured. Not to be used for patients with venous leg ulcers.			of this product is submitted.	
Sept 2017	**Early review of established shared care agreements and one new shared care proposal for DMARDs following the publication of the revised BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs 2017 - *Link***				
Sept 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:**	Oral and Subcutaneous Methotrexate	Treatment of Rheumatoid Arthritis, Juvenile Arthritis, Connective Tissue Disease, Felty's Syndrome, Psoriasis and Inflammatory Bowel Disease	The TAG noted and supported the final versions of the shared care agreements and the summary of changes made in line with the revised BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs 2017 - *Link*.	*Noted and supported by the D&TCG.*
Sept 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:**	Leflunomide	Treatment of rheumatoid or psoriatic arthritis		
Sept 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:**	Ciclosporin	Treatment of Rheumatic and Dermatological diseases		
Sept 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:**	Mycophenolate Mofetil	Treatment of autoimmune conditions		
Sept 2017	**Therapeutics Advisory Group:** **Shared Care Agreement**	Azathioprine	For use in Autoimmune Diseases		
Sept 2017	**Therapeutics Advisory Group:** **Shared Care *Proposal* (*New*):**	Sulfasalazine	Treatment of Inflammatory Arthritis and Inflammatory Bowel Disease	The TAG noted and support the final version of this new shared care agreement which was written in line with the revised BSR and BHPR guidelines 2017 - *Link*, and confirmed a traffic light classification of Amber	*Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
				(Option for GP prescribing under an approved shared care agreement).	
Sept 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due Sept 2016***	Duloxetine	Treatment of moderate to severe Stress Urinary Incontinence (SUI)	The TAG noted the revised draft this shared care agreement which had been reviewed and updated in line with the manufacturer's SPC. No further recommendations for changes had been received from the authors / local specialists. The TAG supported continued use of the document and confirmed a traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement).	*Noted and supported by the D&TCG.*
Sept 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due Sept 2016***	LHRH Agonists	Treatment in Gynaecology	The TAG noted the revised draft this shared care agreement which had been reviewed and updated in line with the manufacturer's SPCs. No further recommendations for changes had been received from the authors / local specialists. The TAG supported continued use of the document and confirmed a traffic light classification of Amber (Option for GP prescribing under an	*Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
				approved shared care agreement).	
Sept 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due Sept 2016***	Low Molecular Weight Heparins (LMWH): Dalteparin sodium (*Fragmin*®) Enoxaparin (*Clexane*®) Tinzaparin (*Innohep*®)	Indications where oral anticoagulants are not indicated	The revised draft this shared care agreement had been reviewed and updated in line with the manufacturer's SPCs. No further recommendations for changes had been received from the authors / local specialists. The TAG supported its continued use and confirmed a classification of Amber (Option for GP prescribing under an approved shared care agreement).	*Noted and supported by the D&TCG.*
Sept 2017	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due November 2016***	Anagrelide (*Xagrid*®)	For adults with essential thrombocythaemia	The revised draft this shared care agreement had been reviewed and updated in line with the manufacturer's SPCs. No further recommendations for changes had been received from the authors / local specialists. The TAG supported its continued use and confirmed a classification of Amber (Option for GP prescribing under an approved shared care agreement).	*Noted and supported by the D&TCG.*
Sept 2017	**Therapeutics Advisory Group:**	Hydroxycarbamide 500mg capsules	For adults with myeloproliferative disorders needing cytoreduction	The revised draft this shared care agreement had been reviewed and updated in line	*Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for Use	TAG Recommendation	D&TCG Commissioning Decision
	Shared Care Agreement: ***Review due November 2016***	(*Hydrea*®)		with the manufacturer's SPCs. No further recommendations for changes had been received from the authors / local specialists. The TAG supported its continued use and confirmed a classification of Amber (Option for GP prescribing under an approved shared care agreement).	

Sept 2017	Drug Tariff Group / Product	Indication for use	PRG-recommended classification to the TAG	TAG Recommendation for the D&TCG	*D&TCG decision*
	Lymphoedema garments	Compression in management of lymphoedema	Red (Specialist use only) for patients with lymphoedema assessed by the specialist service; **Double Red/ Not recommended for routine use)** for all other uses	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Anal irrigation systems	Anal irrigation (also known as rectal irrigation or trans-anal irrigation)	Work on developing local criteria for use within an approved treatment pathway following liaison with local service providers in progress.	Current TAG / D&TCG status - **Double Red (Not commissioned)** for any new patients - July 2017	*Noted and supported by the D&TCG.*
	Deodorants (stoma)	Odour management related to stoma	**Double Red (Not recommended for routine use)**	No status - current advice not to issue in Key Message Bulletin Number 21. Supported by the TAG	*Noted and supported by the D&TCG.*
	Dry mouth products - artificial saliva or salivary	Dry mouth where simple measures alone have been inadequate	Maintain current **Double Green** recommendation, for use where other measures such as those listed in the PAC guidance had failed. The	Currently **Double Green** for Xerotin artificial saliva spray (NNUH business application Sept13 supporting a preferred cost-effective product).	*Noted and supported by the D&TCG.*

	stimulants		recommendation to be expanded to "*Xerotin*, or other cost-effective product"	Recommendation to be expanded to "… or other cost-effective product". PRG recommendation supported by the TAG.	
	Silk garments	Dermatology	Liaison with NCH&C necessary to determine the terms of the contracted service. The PRG recommended a classification of Green (GP prescribable following specialist recommendation) for use only following specialist assessment within agreed criteria for use.	PRG recommendation supported by the TAG.	*The D&TCG was advised of a recent review of silk garments in children with moderate to severe eczema which questioned the clinical and economic benefit of providing silk garments in addition to standard care. The D&TCG therefore decided not to support the TAG's recommendation for the time being.* *Classified as* **Double Red/ Not recommended for routine use)** *in line with the EoE PAC recommendations - insufficient evidence to support routine use.*
	Ostomy underwear	Support following stoma surgery	Green (GP prescribable following specialist recommendation) for parastomal hernia. Otherwise **Double Red (Not for routine use)**	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Inhalation solutions - hypertonic sodium chloride solutions for	Clearance of mucosal secretions in cystic fibrosis and non-CF bronchiectasis	Current primary care use may be historical, initiated prior to commissioning responsibility transferring to NHS England in 2013. ScriptSwitch message to be	Current TAG / D&TCG status - Red (Hospital only) - May 2013. A project is needed to repatriate this treatment and recharge such use back to NHS England.	*Noted and supported by the D&TCG.*

	nebulisation E.g. MucoClear®, Nebusal®		reinforced that it is the Hospital's responsibility to prescribe and supply.	PRG recommendation supported by TAG.	
	Plantar pressure offloading devices	Prevention and management of diabetic foot problems	Green (GP prescribable following specialist recommendation) in line with an agreed treatment pathway for diabetic foot care.	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Nasal products – such as saline nasal sprays, e.g. Sterimar®, Aqua maris®.	Nasal congestion and sinusitis	TAG's current recommendation should be maintained i.e. **Double Red (Not commissioned)**	Current TAG / D&TCG status - **Double Red (Not commissioned)** - Nov 2015	*Noted and supported by the D&TCG.*
	Ear wax softening products - simple remedies such as olive oil, almond oil and sodium bicarbonate; proprietary products containing ingredients such as docusate sodium and urea-hydrogen peroxide		**Double Red (Not recommended for routine use)**. Self-care should be encouraged and used by patients prior to mechanical removal of ear wax.	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Oscillating positive expiratory pressure (OPEP) device- Acapella®, Flutter®, Lungflute®, Pari O-PEP®, RC-Cornet®	Airway clearance in those with CF and non-CF bronchiectasis	Current TAG classification of **Double Red (Not commissioned)** to be maintained pending any local interest in use and the development of business applications	Current TAG / D&TCG status - **Double Red (Not commissioned)** - Nov 2015 (Flutter Device). Update recommendation with listed category name and products, pending local business application.	*Noted and supported by the D&TCG.*
	Belladonna adhesive plaster	Pain relief	**Double Red (Not recommended for routine use)**	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Potassium hydroxide solution e.g. Molludab, Mollutrex	Treatment of molluscum contagiosum	**Double Red (Not recommended for routine use)**	Current TAG / D&TCG status - **Double Red (Not commissioned)** - Nov 2015	*Noted and supported by the D&TCG.*

	Insert for female stress incontinence e.g. Contiform	Female stress urinary incontinence	The PRG noted that use of these products are listed by NICE under "Do not do" and recommended a classification of **Double Red (Not for routine use)**.	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Auto inflation device e.g. Otovent®	Equalisation of pressure in the middle ear: in otitis media with effusion (glue ear); air travel	*Consider* **Double Green (GP prescribable)** *in line with agreed guidance for use*, with a view to saving ENT referrals in children	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Cycloidal vibration accessories e.g. Vibro-pulse® accessories	Therapy for cellulitis, venous leg ulcers and lower limb oedema	**Double Red (Not recommended for routine use)**	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Head lice devices and products	Head lice treatment	Self-care to be encouraged – not for GP prescribing. Maintain the current TAG classification of Double Red (Not recommended for routine use)	Current TAG / D&TCG status - **Double Red (Not commissioned)** - Nov 2015	*Noted and supported by the D&TCG.*
	Pelvic toning devices - Several pelvic toning devices are available, but only three are listed in the Drug Tariff: • PelvicToner® • Kegel8® • Aquaflex®	Pelvic floor muscle training	No evidence of these products offering any advantage over pelvic floor exercises alone. Recommended as **Double Red (Not recommended for routine use)**.	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Eye conditions including dry-eye syndrome, meibomian cysts, styes and blepharitis Eye compress - 3 are listed in the DT: • Hot Eye Compress® • Meibopatch® • MGDRx Eye Bag®		**Double Red (Not recommended for routine use)**; self-care to be encouraged as per NHS Choices advice	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*

	Needle-free insulin delivery system e.g. Injex®, Insujet®	Needle phobia	Current TAG classification to be maintained. Any requests for use should be managed via the IFR process.	Current TAG / D&TCG status - **Double Red (Not commissioned)** - Nov 2015	*Noted and supported by the D&TCG.*
	Bacterial decolonisation products, specifically Prontoderm® foam and Prontoderm® nasal gel	Topical decolonisation of MRSA carriers	**Double Red (Not recommended for routine use)**	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Acne treatment – specifically Aknicare® cream and lotion, Aknicare® sr skin roller	Acne	Those who wish to try Aknicare® products should be directed to purchase them for self-care but should be advised that benzoyl peroxide-containing OTC products are generally preferred because of the substantial clinical trial evidence to support their use. Not for GP prescribing - **Double Red (Not recommended for routine use)**	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*
	Inspiratory muscle training devices - 3 inspiratory muscle training devices are listed in the Drug Tariff: • POWER breathe® Medic • Threshold IMT® • Ultrabreathe®	COPD, non-CF bronchiectasis, upper spinal cord injuries. Cystic fibrosis, asthma.	**Double Red (Not recommended for routine use)** pending any local interest in use and the development of business applications	PRG recommendation supported by the TAG.	*Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for use	TAG Recommendation	D&TCG Commissioning Decision
Sept 2017	**Prescribing Reference Group:** **Annual NHS cost per patient:** £7k to £15k at licensed doses. Other more cost-effective options are available. Recommended to be added to the DROP List.	Trimipramine	For treatment of depressive illness, especially where sleep disturbance, anxiety or agitation are presenting symptoms	The TAG recommended applying a classification of **Double Red indication (Not recommended for routine use)** for all uses of trimipramine to prevent use in any new cases and also to encourage the review of current long-standing cases.	*Noted and supported by the D&TCG.*
Sept 2017	**Prescribing Reference Group:** **Annual NHS cost per patient:** £2k to £8k. Other more cost-effective options are available.	Dicycloverine	Smooth muscle antispasmodic for GI indications	The TAG recommended applying a classification of **Double Red indication (Not recommended for routine use)** for all uses of dicycloverine to prevent use in any new cases and also to encourage the review of current long-standing cases.	*Noted and supported by the D&TCG.*
Sept 2017	**Prescribing Reference Group:**	Various	Respiratory Disease	**Formulary Updates:** **COPD Formulary** – *updated in line with GOLD 2017 guidelines* **Respiratory Resources:** • **Inhalers used in Asthma** • **Inhalers used in COPD** • **COPD Primary Care Guideline** • **COPD Self management plan** Noted by the TAG	*Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for use	TAG Recommendation	D&TCG Commissioning Decision
Sept 2017	**Prescribing Reference Group:**	Various	Nutritional supplementation	**Nutrition Formulary** – *updated with information on licensed magnesium glycerophosphate product* Noted by the TAG	*Noted and supported by the D&TCG.*
Nov 2017	**Therapeutics Advisory Group:** **Shared Care Agreement: *Review due May 2017***	Tacrolimus	For Adult Renal Transplant Patients	Following publication of **NICE TA 481 (Oct 17)** - Immunosuppressive therapy, the TAG supported continued use of these shared care documents with an extended review date to cover use until the end of March 2018 and confirmed a traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement).	**November 2017:** *The TAG's recommendation to extend use of the shared care agreements was noted and supported by the D&TCG.*
Nov 2017	**Therapeutics Advisory Group:** **Shared Care Agreement: *Review due May 2017***	Mycophenolate mofetil / Mycophenolic acid	For Adult Renal Transplant Patients		
Nov 2017	**Therapeutics Advisory Group:** **Shared Care Agreement: *Review due Sept 2016***	Sirolimus	For Adult Renal Transplant Patients		
Nov 2017	**Therapeutics Advisory Group:** **Current shared care agreement for use in children and adolescents - *Link***	melatonin / Circadin®	For adolescent patients once they reach 18 years	The TAG noted the concerns raised by a GP regarding how to manage patients taking melatonin once they leave the care of the commissioned service because of their age, and agreed to seek advice from local specialists on how GPs might review these patients.	*Noted by the D&TCG.*
Nov 2017	**Therapeutics Advisory Group:**	Various	Monitoring Drugs in Primary Care	The TAG considered the guidance which had been	*Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for use	TAG Recommendation	D&TCG Commissioning Decision
	***Suggested* Guidance on Monitoring of Drugs in Primary Care –** *update* November 2017			updated in line with revised shared care agreements for DMARDs and supported use of the revised document.	
Nov 2017	**Prescribing Reference Group:** **Annual NHS cost per patient:** £7k *Fiasp*® is insulin aspart in a new formulation with a faster onset of action than NovoRapid®. There are currently no alternative formulations of insulin aspart available or in development. The PRG considered the available NHS review of this new insulin formulation, and noted the lack of superiority of other available treatments. The PRG recommended that the TAG considers applying a **Double Red (Not recommended for routine use)** classification, pending local agreement on a patient group and the product's place in the diabetes treatment pathway.	Insulin Aspart (*Fiasp*®)	For diabetes mellitus in adults	The TAG noted that local specialists had already been recommending use of *Fiasp*® to GPs, outside of any local business application and formal consideration for local funding. Anecdotal reports of patients using more units of *Fiasp*® compared with previous requirements for *NovoRapid*® were noted with concern regarding potential increased costs for no know benefit. The TAG agreed to support the PRG's advice and to recommend a traffic light classification of **Double Red (Not recommended for routine use)** to use of Insulin Aspart (*Fiasp*®) for any new patients pending local agreement on a patient group and the product's place in the diabetes treatment pathway.	**November 2017:** *The PRG and TAG's recommendations were noted and supported by the D&TCG and commissioning position of* **Double Red (Not recommended for routine use) / Not commissioned** applied. *The D&TCG was also advised that use of Fiasp® would be part of regional level discussions between CCGs and diabetes specialists in December 2017.*
Nov 2017	**Prescribing Reference Group:**	**Preparations for the care**	Blepharitis	The TAG noted and supported the PRG's advice and recommended	**November 2017:** *The PRG and TAG's recommendations*

Date	Reason for review by the TAG	Drug	Indication for use	TAG Recommendation	D&TCG Commissioning Decision
	No formal recommendation currently applied to these products which are considered suitable for patients to purchase and follow self-care; not for NHS prescribing. PRG members requested that the TAG considered applying a traffic light classification of **Double Red (Not recommended for routine use)**.	**of eyelids:** e.g. *Blephasol*, *Blephaclean*, *Systane* for blepharitis	CKS advice on first-line management of blepharitis - ***Link***	a traffic light recommendation of **Double Red (Not recommended for routine use)** for use of these products.	*were noted and supported by the D&TCG and commissioning position of* **Double Red (Not recommended for routine use) / Not commissioned** applied.
Nov 2017	**Prescribing Reference Group:** Previously recommended **(August 2017)** for limited use when considered as part of the EoE Medical Devices DROP List. **October 2017:** The PRG noted a new RCT of silk garments for children with moderate to severe eczema versus best care, with the conclusion that silk garments gave no additional benefits to standard care. **Link to key reference -** http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002280 The PRG therefore made a revised recommendation to the TAG to apply a classification of **Double Red (Not recommended for routine use)**.		Silk garments for use in dermatology - eczema:	The TAG noted and supported the PRG's recommendations and confirmed the revised traffic light recommendation of **Double Red (Not recommended for routine use)**.	*Noted by the D&TCG in September 2017 and listed as* **Not commissioned**.
Nov 2017	**Prescribing Reference Group:** **Guidance for Primary Care in Norfolk & Waveney:**	Vitamin D (Colecalciferol)	Diagnosis and Management of Vitamin D Deficiency in Paediatric patients (<18 years), with eGFR >30ml/min	The TAG noted and supported the guidance for use of vitamin D in children and adolescents.	*Noted and supported by the D&TCG.*

Date	Reason for review by the TAG	Drug	Indication for use	TAG Recommendation	D&TCG Commissioning Decision
	- ***Link***				
Nov 2017	**Prescribing Reference Group:** ***Key Message Bulletins***	Bisphosphonates	Osteoporosis	Noted and supported by the TAG as part of implementation of NICE TA 464 - Bisphosphonates for treating osteoporosis (Aug 17)	*Noted and supported by the D&TCG.*
Jan 2018	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due Sept 2017***	Riluzole	For treatment of the amyotrophic lateral sclerosis form of Motor Neurone Disease	Updated in line with current BNF and SPC regarding side effects, cautions and interactions. Licensed oral suspension now available. NNUH specialists contact information updated. The TAG agreed to support continued use of the revised shared care agreement for this treatment.	*Noted and supported by the D&TCG.*
Jan 2018	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Review due Feb 2017***	Perampanel	For adjunctive treatment in epilepsy	Updated in line with current SPC and NICE CG 137 – proposed updated text highlighted in Amber font. Treatment pathway confirmed as still valid by NNUH Consultant Neurologist The TAG agreed that this treatment could be re-classified as Green (GP prescribable following specialist recommendation) and used as per the	*Noted and supported by the D&TCG.* *Commissioned as* Green (Suitable for GP prescribing following specialist recommendation) *The D&TCG also advised that the first supply should continue to be provided by the specialist to cover initial titration of treatment.*

Date	Reason for review by the TAG	Drug	Indication for use	TAG Recommendation	D&TCG Commissioning Decision
				previously agreed treatment pathway.	
Jan 2018	**Therapeutics Advisory Group:** **UKMi In Use Product Safety Assessment Report:**	Methotrexate pre-filled devices	Rheumatoid arthritis	The TAG noted this information.	*Noted by the D&TCG*
Jan 2018	**Prescribing Reference Group:**	*Budenofalk*®	For use in Crohn's disease in adults	PRG recommendation that the TAG considers applying a Green (Suitable for GP prescribing following specialist recommendation) classification to this treatment and that it is supported for possible future addition to the local G-I Formulary: The TAG agreed to support the PRG's recommendation.	*Noted and supported by the D&TCG.* *Commissioned as* Green (Suitable for GP prescribing following specialist recommendation)
Jan 2018	**Prescribing Reference Group:**	Potassium aminobenzoate (*Potaba*®) (capsules and powder)	For treatment of Peyronie's disease, Scleroderma	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification to this treatment: The TAG agreed to support the PRG's recommendation.	*Noted and supported by the D&TCG as* **Double Red (Not recommended for routine use)** - *Not commissioned*
Jan 2018	**Prescribing Reference Group:**	Treatment Pathway: *Review*	Overactive Bladder	Reviewed (no changes) and supported for continued use by the PRG – to be revisited when the Urology Formulary is	*Noted and supported by the D&TCG*

Date	Reason for review by the TAG	Drug	Indication for use	TAG Recommendation	D&TCG Commissioning Decision
				reviewed during 2018: The TAG agreed to support the PRG's recommendation subject to recommended minor changes to the flowchart.	
Jan 2018	**Prescribing Reference Group:**	Dulaglutide (*Trulicity*®)	For Type 2 diabetes mellitus – third line option	PRG recommendation that the TAG considers applying a Green (Suitable for GP prescribing following specialist recommendation) classification to this treatment and that it is supported for addition to the local Diabetes Formulary as third line option: The TAG agreed to support the PRG's recommendation.	*Noted and supported by the D&TCG. Commissioned as* Green (Suitable for GP prescribing following specialist recommendation) with a view to being added to the local Diabetes Formulary.
Jan 2018	**Prescribing Reference Group:**	Prescribing Guidance for Primary Care:	Phenylketonuria (PKU) foods	The PRG supported use of guidance for GPs on the recommended number of food units that may be issued per month for PKU foods. The TAG agreed to support the PRG's recommendation to adopt the guidance.	*Noted and supported by the D&TCG.*
Jan 2018	**Prescribing Reference Group:**	DROP List Additions:	• *Regaine*® products • Combination analgesics with caffeine	PRG request (April 2017) that the TAG considers applying a **Double Red (Not recommended for routine use use)**	*Noted and supported by the D&TCG as* **Double Red (Not recommended for routine use)** - *Not commissioned*

Date	Reason for review by the TAG	Drug	Indication for use	TAG Recommendation	D&TCG Commissioning Decision
				classification to these products to formalise their classification. The TAG agreed to support the PRG's recommendations.	
Jan 2018	**Prescribing Reference Group:**	***Key Message Bulletins*** – *Updates*	**No. 1:** Reviewing ACE inhibitors and A2RAs **No. 4:** Erectile dysfunction drugs **No. 5:** 7-day prescriptions **No. 6:** MCA supply **No. 7:** Neuropathic pain	Noted and supported by the TAG	*Noted by the D&TCG.*
Mar 2018	**Therapeutics Advisory Group:** **Shared Care Agreement:** ***Last reviewed November 2017***	Mycophenolate mofetil / Mycophenolic acid	For immunosuppression in Adult Renal Transplant Patients	Updated in line with other SCA for use in autoimmune disease regarding guidance added regarding the need for effective contraception in patients taking MMF and their partners as per MHRA drug safety warning (Feb 2018). The TAG noted the recommended changes and agreed to support the revised shared care agreement.	*Noted and supported by the D&TC.*
Mar 2018	**Therapeutics Advisory Group:** **GP Prescribing Guidance:** ***Review*** – updated with MHRA safety information regarding hepatic adverse effects revised monitoring	Ulipristal acetate (*Esmya*®)	For intermittent treatment of moderate to severe symptoms of uterine fibroids	MHRA safety notice advises against initiating treatment courses in new or previous patients. Currently classified as Green – the TAG agreed to revise to **Double Red (Not recommended for routine**	*Noted and supported by the D&TC.* *Not commissioned in the interim period. To be revisited when the EU-wide safety review is completed and results published.* *The D&TC noted that this restriction does not apply to the other ulipristal-*

Date	Reason for review by the TAG	Drug	Indication for use	TAG Recommendation	D&TCG Commissioning Decision
	requirements. Revised GP Prescribing Guidance already published on Knowledge Management and shared with local specialists. Safety warning added to Scriptswitch.			**use)** with no new patients or courses of treatment to be initiated, pending results of EU-wide evidence review.	*containing product, ellaOne®.*
Mar 2018	**Therapeutics Advisory Group:** **Shared Care Agreement: *Review*** • Update required regarding giving varicella vaccination prior to starting methotrexate • Issues regarding patients being switched to a different product in Primary Care from that initiated by the hospital, and clarification of responsibility for training patients to use the alternative device *UKMi Safety Assessment of MTX pre-filled devices provided for information.* ***Link*** to current version	Methotrexate	For the treatment of Rheumatoid Arthritis, Juvenile Arthritis, Connective Tissue Disease, Felty's Syndrome, Psoriasis and Inflammatory Bowel Disease	The NNUH Rheumatology Service has 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. Regarding reported switches to alternative injection devices, the NNUH was asked to share which practices were involved for further investigation. The TAG also considered whether to add a newly available liquid formulation of methotrexate to the shared care agreement, but decided that since the need for its use would be rare, requests for its use could be decided on an individual basis as identified by the trust. The TAG was also advised to update the agreement to specify: • use in Crohn's disease rather than in inflammatory bowel disease, • that hospital letters to GPs will state the recommended frequency of monitoring, • that dose changes will be made by the specialist (not GPs). These changes were agreed to be made to the 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
Mar 2018	**Prescribing Reference Group:** NICE Medtech innovation briefing mib139 (January 2018) provided	*Epifix*® for chronic wounds	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification to this treatment on the basis of a lack of sufficient evidence to justify the significant cost of this product: 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*
Mar 2018	**Prescribing Reference Group:**	Alimemazine for use as a sedative in children / general antihistamine	PRG recommendation that the TAG considers applying a **Double Red (Not recommended for routine use)** classification to this treatment on the basis of a lack of sufficient evidence to justify the significant cost of this product over other available alternatives. 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*
Mar 2018	**Prescribing Reference Group:** **Prescribing Advice**	Prescribing prednisolone for patients requiring soluble tablets / liquid formulation		The TAG noted and agreed to support the PRG's prescribing guidance document. The NNUH agreed to share information on the patient groups who should not have plain tablets (small numbers).	*Noted and supported by the D&TC.*
Mar 2018	**Prescribing Reference Group:**	***Key Message Bulletins*** *– Updates* • **Bulletin 8: Medicines Optimisation of Hypoglycaemic Agents** • **Bulletin 17: Insulin (Type 2 Diabetes)** • **Bulletin 22: Blood Glucose Test Strips** • **Bulletin 23: Cost Effective Lancets for patient self-use** • **Lancets Cost Comparison** • **Needles for Pre-filled and Reusable Pen Injectors**		Noted and supported by the TAG	*Noted by the D&TC.*

1. TAG Recommendations 2017/18

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 2017	**East of England Priorities Advisory Committee (PAC):** ***Draft* position statement regarding** **NHS England Early Access to Medicines Scheme (EAMS):** - ***Link*** "*CCGs will not automatically continue to fund treatment for patients initiated under the EAMS scheme upon the product becoming licensed unless a positive NICE TA is in place. It is the responsibility of initiating Trusts to ensure funding is available for the continuation of treatment once a product licence is granted until a positive NICE TA is published*"	Dupilumab	For adults with severe atopic dermatitis who have failed to respond, or who are intolerant of or ineligible for all approved therapies	The TAG noted the EAMS decision regarding dupilumab and agreed to recommend support for the PAC's proposed position statement regarding this treatment. The TAG also recommended an *interim* traffic light classification of **Double Red (Not recommended for routine use)** until a local business application for its use is supported following a positive NICE TA related to this treatment.	*The D&TCG noted and supported the TAG's recommendations and decided that Dupilumab for adults with severe atopic dermatitis who have failed to respond, or who are intolerant of or ineligible for all approved therapies is* **Double Red (Not recommended for routine use) / Not commissioned** *until a local business application for its use is supported following a positive NICE TA related to this*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
					treatment.
May 2017	**East of England Priorities Advisory Committee (PAC):** ***Draft* Recommendations (March 2017):** *Not recommended by the PAC for routine commissioning.* Deferasirox, Deferiprone, Desferrioxamine for iron chelation in thalassaemia, sickle cell disease are chronic iron overload are listed as NHSE SCG-commissioning responsibility	Iron Chelators - Deferasirox (*Exjade*®), Deferiprone (*Ferriprox*®), Desferrioxamine (*Desferal*®)	For blood transfusion related iron overload in patients with myelodysplastic syndrome (MDS).	Previous TAG recommendations (January 2013) relating to use in "*anaemia related to iron overload*" and to "*treatment of chronic iron overload due to frequent blood transfusions*" are classified as Red (Hospital use only) / NHSE SCG-commissioning responsibility. The PAC has identified that use of iron chelators in MDS is CCG-commissioning responsibility and recommends against routine commissioning for this indication. The TAG agreed to support the PAC's recommendations and recommended a traffic light classification of **Double Red (Not recommended for routine use)** for	*The D&TCG noted and supported the TAG's recommendations to adopt PAC guidance, and decided that use of iron chelators Deferasirox, Deferiprone, and Desferrioxamine for blood transfusion-related iron overload in patients with myelodysplastic syndrome (MDS) is* **Double Red (Not recommended for routine use) / Not commissioned**

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
				use of the iron chelators for blood transfusion-related iron overload in patients with myelodysplastic syndrome.	
May 2017	**East of England Priorities Advisory Committee (PAC):** ***Draft* Recommendations (April 2017) - revisit:** *Not recommended by the PAC for routine commissioning.* In 2013, PAC issued negative recommendations on routine funding of sodium oxybate for narcolepsy with cataplexy in adults due to a lack of evidence of cost effectiveness. Historically, NHS England did not routinely fund for use in children (≤18 years old). However, in Dec16, it issued a positive policy for use in children from puberty until 19 years of age, where they have not responded to or cannot have current treatments	Sodium oxybate (*Xyrem*®)	Management of narcolepsy with cataplexy in adults aged ≥19 years NB: Use in children < 19 years old is NHSE SCG-commissioning responsibility. Use in adults aged ≥19 years old is CCG-commissioning responsibility	The TAG acknowledged the PAC's following recommendations: • Cost-effectiveness has not been demonstrated for the use of sodium oxybate for the management of narcolepsy with cataplexy in any patient group (children or adults). • There has been no new evidence of efficacy since the previous PAC policy was written in 2013. • The high cost of sodium oxybate and resulting Scottish Medicines Consortium	*The D&TCG noted and supported the TAG's recommendations to adopt the PAC's recommendations and reaffirmed that* Sodium oxybate (*Xyrem*®) for Management of narcolepsy with cataplexy in adults aged ≥19 years *is* **Double Red (Not recommended for routine use) / Not commissioned**. *The D&TCG also acknowledged that younger patients who had started sodium oxybate below 19 years of age would have to be considered on an individual basis once they reached*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
				(SMC) cost per QALY calculations remain unchanged and do not demonstrate cost effectiveness for use in adults. The TAG noted the PAC's updated recommendations and reaffirmed its previous recommended traffic light classification of **Double Red (Not recommended for routine use)**. The TAG acknowledged that any younger patients started on treatment below the age of 19 years of age would have to be considered on an individual basis once they reach adulthood and funding responsibility transfers from NHSE SCG to CCGs.	*adulthood if treatment was still required. The D&TCG considered that such patients should have undertaken a trial period without treatment (drug holiday), to ensure that it was still necessary, at a suitable opportunity leading up to their 19th birthday, and ahead of funding responsibility transferring from* NHSE SCG *to* CCGs. *The D&TCG also requested ePACT data is monitored regularly to check for any unplanned additional use in primary care in Norfolk & Waveney.*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
May 2017	**East of England Priorities Advisory Committee (PAC):** ***Draft* Recommendations:** *Not recommended for routine use and not recommended for funding in primary or secondary care*	*Freestyle Libre*® Glucose Recording System	Use in diabetes mellitus	The TAG noted the draft PAC recommendations and reaffirmed its previous recommended traffic light classification of **Double Red (Not recommended for routine use)** (May 2016).	*The D&TCG noted and supported the TAG's recommendation to support the PAC's recommendations and reaffirmed that use of the Freestyle Libre® Glucose Recording System is* **Double Red (Not recommended for routine use) / Not commissioned**.
May 2017	**East of England Priorities Advisory Committee (PAC):** ***Draft* Recommendations:**	Various (including use of oxygen)	Treatment of cluster headaches	Current local advice on the use of oxygen for cluster headaches is contained in Guidance and Supported Indications for Home Oxygen Use (supported by the TAG Jan17) which states: "*There should be a positive diagnosis of the condition. Oxygen is not a preventative therapy and is only*	*Noted and supported by the D&TCG.*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
				effective in aborting attacks. Ideally preventative therapy should also be considered." The TAG noted and supported the PAC's recommendations which were felt to be in line with local guidance.	
July 2017	**East of England Priorities Advisory Committee (PAC):** **<u>Recommendations (update July 2016)</u>:** *(recently noted on EoE PAC website*) Not recommended by the PAC for routine commissioning.	Rifaximin (*Targaxan*® / *Xifaxanta*®)	For the management of chronic diarrhoea associated with gastro-intestinal disorders (including Crohn's disease (CD), Ulcerative Colitis (UC), Diverticular disease (DD), Irritable bowel syndrome (IBS), recurrent Clostridium difficile infection and small intestinal bacterial overgrowth (SIBO)).	Currently **Double Red (Not recommended for routine use)** for travellers' diarrhoea, and Red (Hospital only) for treatment and prophylaxis of secondary hepatic encephalopathy. The TAG acknowledged the guidance from the PAC and agreed to recommend a classification of **Double Red (Not recommended for routine use)** for the management of chronic diarrhoea associated with gastro-intestinal	*The D&TCG noted and supported the PAC and the TAG recommendations and decided to classify this treatment as* **Double Red (Not recommended for routine use)** *for the additional specified indications.*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
				disorders (including Crohn's disease (CD), Ulcerative Colitis (UC), Diverticular disease (DD), Irritable bowel syndrome (IBS), recurrent Clostridium difficile infection and small intestinal bacterial overgrowth (SIBO)). The TAG also recommended a classification of **Double Red (Not recommended for routine use)** for use of rifaximin in ulcerative colitis patients with pouchitis where other treatments have failed, where failure to treat would otherwise require surgical intervention.	
July 2017	**East of England Priorities Advisory Committee (PAC):** **Recommendations (published May 2017) - revisit:** *Not recommended by the PAC for routine use in Type 1 diabetes or*	Insulin degludec (*Tresiba*®) for use in diabetes mellitus	**March 2017:** The TAG and the D&TCG agreed to adopt draft guidance (that had been agreed by the PAC membership) that recommended against commissioning routine use of insulin degludec in type 1 diabetes, and any use in type 2 diabetes – **Double Red (Not recommended for routine use)**.		

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
	any use in type 2 diabetes. Restricted use in Type 1 diabetes under specified criteria supported. **July 2017:** *Current PAC recommendations state that insulin degludec could be considered in Type 1 diabetic patients with hyperosmolar hyperglycaemic state (HHS). However HHS is a condition that only occurs in Type 2 diabetes.* *The PAC will therefore consider whether to remove reference to HHS and have the guidance apply to Type 1 diabetes only, or to add a recommendation that it can be used in Type 2 diabetic patients with HHS.*		Restricted use of insulin degludec in type 1 diabetes under specified criteria, under specialist initiation - Green (GP prescribable following consultant initiation) was supported. **July 2017:** The TAG considered the use of insulin degludec in HHS and recommended that insulin degludec should remain as Green (GP prescribable following consultant initiation) for restricted use in Type 1 diabetes, with the reference to HHS being removed altogether, and that any use in type 2 diabetes would remain as **Double Red (Not recommended for routine use)**. The TAG database would be amended to reflect this amendment.		**July 2017:** *The D&CG was advised that the PAC had decided to amend their guidance by removing reference to use in HHS altogether, similarly to the TAG's recommendations.* *The D&TCG noted and supported the TAG's recommendations.*
Nov 2017	**East of England Priorities Advisory Committee (PAC):** **Interim Recommendations (Sept 2017):**	FreeStyle Libre® Glucose Monitoring System **The EoE PAC recommends:** **1.** The routine use of *FreeStyle Libre*® for all patients with type 1 and type 2 diabetes is *not* recommended. **2.** *FreeStyle Libre*® has not been demonstrated to be cost-effective and in the absence of a positive recommendation from a full technology appraisal (TA), produced and published by NICE, is not recommended for routine funding in primary care. **3.** This recommendation will be reviewed in the light of new evidence to support the cost effective use of *FreeStyle Libre*®.		The TAG noted and supported the EoE PAC's recommendations regarding the FreeStyle Libre® Glucose Monitoring System which supported the current local TAG and commissioning position of **Double Red (Not recommended for routine use / Not commissioned)**.	*Noted and supported by the D&TCG.* *The D&TCG was advised that an interface meeting between diabetes specialists and CCGs in the East Of England to discuss flash glucose monitoring, and other insulin products, had been arranged for mid Dec 2017.*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
Jan 2018	**East of England Priorities Advisory Committee (PAC):** **Interim Recommendations (Sept 2017):**	FreeStyle Libre® Glucose Monitoring System	**The EoE PAC recommends:** **1.** The routine use of *FreeStyle Libre*® for all patients with type 1 and type 2 diabetes is *not* recommended. **2.** *FreeStyle Libre*® has not been demonstrated to be cost-effective and in the absence of a positive recommendation from a full technology appraisal (TA), produced and published by NICE, is not recommended for routine funding in primary care. **3.** This recommendation will be reviewed in the light of new evidence to support the cost effective use of *FreeStyle Libre*®.	**November 2017:** The TAG noted and supported the EoE PAC's recommendations regarding the FreeStyle Libre® Glucose Monitoring System which supported the current local TAG and commissioning position of **Double Red (Not recommended for routine use / Not commissioned)**. **January 2018:** The TAG was advised that work on agreeing criteria for use and likely costs related to patient numbers was in progress, led by the PAC.	**November 2017:** *Noted and supported by the D&TCG.* *The D&TCG was also advised that an interface meeting between diabetes specialists and CCGs in the East Of England to discuss the place of flash glucose monitoring devices, and other insulin products, had been arranged via the PAC for mid December 2017.* **January 2018:** *Noted by the D&TCG – current commissioning position maintained in the interim.*
Jan 2018	**East of England Priorities Advisory Committee (PAC):**	Liothyronine	Maintenance treatment in hypothyroidism.	The TAG was advised that revised PAC guidance on liothyronine was being finalised and would be published soon.	*Noted by the D&TCG.* *Current commissioning position maintained in the interim.*

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
Jan 2018	**PrescQIPP Guidance -** http://www.prescqipp.info/headline-areas/priorities-advisory-committee-pac Bulletin 203 (December 2017) v2.0 Over-arching document to a number of bulletins providing further information on medicines that should be given a low priority for prescribing on the NHS, are poor value for money, suitable for self care or for which there are safer more suitable alternatives	Items which should not routinely be prescribed in primary care	This guidance will support CCGs in taking action on items that should not routinely be prescribed in primary care or on the NHS. The guidance supports the implementation of the NHS England guidance: https://www.england.nhs.uk/medicines/items-which-should-not-be-routinelyprescribed/	The TAG noted that almost all items recommended not be prescribed in primary care are either already classified as **Double Red (Not recommended for routine use) / Not commissioned** (17 out of 23), or as Red (Hospital only) for specified indications (3 out of 23). The current Green recommendation for restricted use of lidocaine patches in line with the local commissioned treatment pathway was maintained by the TAG. The TAG also recommended applying a **Double Red (Not recommended for routine use)** to Armour Thyroid for any indication related to hypothyroidism.	*The TAG's recommendations were noted and supported by the D&TCG, including the formal recommendation to classify use of* Armour Thyroid for any indication related to hypothyroidism *as* **Double Red (Not recommended for routine use**) – *confirmed as* ***not commissioned***.

Date of TAG meeting	Recommending body	Drug	Indication for Use	TAG Recommendation	N&W CCGs - D&TCG Decision
Jan 2018	**PrescQIPP Guidance -** http://www.prescqipp.info/headline-areas/priorities-advisory-committee-pac DROP-List Bulletin B200 (Nov 2017 v3.0) The PrescQIPP DROP List bulletin recommends restricting use of Lidocaine plasters to people diagnosed with post herpetic neuralgia in whom alternative treatments are contraindicated, not tolerated, or ineffective	Lidocaine Plasters for Neuropathic Pain	Currently commissioned in Norfolk & Waveney as Green (GP prescribable following specialist initiation) as monotherapy only for localised neuropathic pain when first line systemic therapies are ineffective or not tolerated as per the local Neuropathic Pain Pathway Previous decision was reviewed by the TAG in the light of this new guidance from PrescQIPP. The TAG agreed to maintain the wording of the current classification.		*Noted and supported by the D&TCG. Previous commissioning position maintained.*

1. TAG Recommendations 2017/18

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 2017/18 the TAG considered the following information:

Date of TAG Meeting	NHS England Item	Drug	Indication	TAG Recommendation / Action	N&W CCGs – D&TCG
July 2017	**NHS England Early Access to Medicines Scheme (EAMS):** **- *Link*** The positive scientific opinion has been issued to Dompe: • EAMS Public Assessment Report • Treatment protocols for patients and for healthcare professionals • EAMS Pharmacovigilance – oxervate	Oxervate	For the treatment of moderate or severe neurotrophic keratitis This is a potentially expensive agent which is not on the excluded drug list so may be assumed to be in tariff- potentially a secondary care treatment. The treatment is for 8 weeks only. The product must be stored in the freezer by both the supplying Pharmacy and the patient.	The TAG noted the EAMS decision regarding oxervate and agreed to recommend a position statement of: "*CCGs will not automatically continue to fund treatment for patients initiated under the EAMS scheme upon the product becoming licensed unless a positive NICE TA is in place. It is the responsibility of initiating Trusts to ensure funding is available for the continuation of treatment once a product licence is granted until a positive NICE TA is published*" The TAG also recommended an *interim* traffic light classification of **Double Red (Not recommended for routine use)** until national guidance recommending its use is published and a local business application is submitted and supported.	*The D&TCG noted and supported the TAG's recommendation and decided to classify this treatment as* **Double Red (Not recommended for routine use)** *in the interim, until national guidance recommending its use is published and a local business application is submitted and supported.*

1. TAG Recommendations 2017/18

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 2017/18 the TAG considered the following information:

Date of TAG Meeting	RMOC	Drug	Indication	TAG Recommendation / Action	N&W CCGs – D&TCG
Nov 2017	**Regional Medicines Optimisation Committees (RMOCs):** **RMOC (North) Position Statement:** - advice to local APCs published following *FreeStyle Libre*®'s inclusion in the November 2017 Drug Tariff **Current local commissioning position:** **Double Red (Not recommended for routine use / Not commissioned)** – May 2017	Flash Glucose Monitoring Systems – *FreeStyle Libre*® **RMOC recommendations:** Blood Glucose monitoring in Type 1 diabetes aged four and above, attending specialist Type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician and deemed to meet one or more of the following: **1.** Patients who undertake intensive monitoring >8 times daily **2.** Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycemia as described in NICE TA151) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy. **3.** Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose	The TAG was advised that Mid Essex CCG has revised its current policies to acknowledge the RMOC guidance by adapting the recommendations to require that two (rather than only one) of the patient criteria are met, and also, in line with current NICE guidance, that any recommended device should have an alarm to notify patients with impaired awareness that they are hypoglycaemic. The CCG has also separated their policies for use of Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring devices. The CCG's strategy is to consider use of an approved Flash Glucose Monitoring device ahead of CGM. The TAG noted this information. The TAG considered that the reference sources listed in the RMOC guidance were narrower than those used by the EoE PAC	*The TAG's recommendation to maintain the previous commissioning position regarding NHS provision of FreeStyle Libre® was noted and supported by the D&TCG, on the basis that no further evidence that would require a change in view had been considered and communicated by the RMOC.*

Date of TAG Meeting	RMOC	Drug	Indication	TAG Recommendation / Action	N&W CCGs – D&TCG
		monitoring with alarms and Freestyle Libre does not currently have that function. **4.** Frequent admissions (>2 per year) with DKA or hypoglycaemia. **5.** Those who require third parties to carry out monitoring and where conventional blood testing is not possible		in their interim guidance which supports the current local commissioning position for FreeStyle Libre® i.e. **Double Red (Not recommended for routine use / not commissioned**. The TAG therefore felt that the RMOC recommendations were not based on any further evidence that would persuade the TAG to change its previous view.	

1. TAG Recommendations 2017/18

G. MHRA *Drug Safety Update* Bulletins

The TAG noted Drug Safety Update Bulletins from March 2017 to January 2018 and revised previous TAG guidance where appropriate.

MHRA/CHM *Drug Safety Update* - March – April 2017:

- **Hyoscine butylbromide (Buscopan) injection:** risk of serious adverse effects in patients with underlying cardiac disease
- **SGLT2 inhibitors:** updated advice on increased risk of lower-limb amputation (mainly toes)
- **Valproate and developmental disorders:** new alert asking for patient review and further consideration of risk minimisation measures
- **Ponatinib (Iclusig▼):** risk of vascular occlusive events - updated advice on possible dose reduction
- **Multiple sclerosis therapies:** signal of rebound effect after stopping or switching therapy

MHRA/CHM *Drug Safety Update* - – May – June 2017:

- **Reminder of the withdrawal of retigabine (Trobalt):** patients must be withdrawn from treatment by the end of June 2017
- **Finasteride:** rare reports of depression and suicidal thoughts
- **Denosumab (Prolia®, Xgeva®▼):** reports of osteonecrosis of the external auditory canal
- **Brimonidine gel (Mirvaso®):** risk of systemic cardiovascular effects; not to be applied to damaged skin
- **Pseudoephedrine and ephedrine:** regular review of minimising risk of misuse in the UK
- **e-cigarettes and refill containers (e-liquids):** report suspected side effects and safety concerns

MHRA/CHM Drug Safety Update - July - August 2017:

- **Corticosteroids:** rare risk of central serous chorioretinopathy with local as well as systemic administration
- **Adrenaline auto-injectors:** updated advice after European review
- **Nivolumab (Opdivo▼), pembrolizumab (Keytruda▼):** reports of organ transplant rejection
- **Bendamustine (*Levact*®):** increased mortality observed in recent clinical studies in off-label use; monitor for opportunistic infections, hepatitis B reactivation
- **Daclizumab (*Zinbryta*®▼) and risk of severe liver injury:** initiation in multiple sclerosis now restricted, promptly review patients already on treatment
- **Ibrutinib (Imbruvica▼):** reports of ventricular tachyarrhythmia; risk of hepatitis B reactivation and of opportunistic infections

MHRA/CHM Drug Safety Update - September – October 2017:

- **Loperamide (*Imodium*®):** reports of serious cardiac adverse reactions with high doses of loperamide associated with abuse or misuse
- **Miconazole (*Daktarin*®):** over-the-counter oral gel contraindicated in patients taking warfarin
- **Clozapine:** reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus

- **Isotretinoin (Roaccutane):** rare reports of erectile dysfunction and decreased libido
- **Gabapentin (Neurontin):** risk of severe respiratory depression
- **Methylprednisolone injectable medicine containing lactose (Solu-Medrone 40 mg):** do not use in patients with cows' milk allergy

MHRA/CHM Drug Safety Update - November – December 2017:

- **Updates to Public Health England's Green Book chapter on live attenuated vaccines**
- **Antiepileptic drugs:** updated advice on switching between different manufacturers' products
- **Oral tacrolimus products:** reminder to prescribe and dispense by brand name in transplant patients
- **Quinine:** reminder of dose-dependent QT-prolonging effects; updated medicine interactions
- **Isotretinoin (Roaccutane):** *rare* reports of erectile dysfunction and decreased libido
- **Gadolinium-containing contrast agents:** removal of Omniscan and iv Magnevist, restrictions to the use of other linear agents
- **Cladribine (Litak, Leustat) for leukaemia:** reports of progressive multifocal encephalopathy (PML); stop treatment if PML suspected
- **Radium-223 dichloride (Xofigo▼):** do not use in combination with abiraterone and prednisone/prednisolone, following clinical trial signal of increased risk of death and fractures
- **Eluxadoline (Truberzi ▼):** risk of pancreatitis; do not use in patients who have undergone cholecystectomy or in those with biliary disorders
- **Fingolimod (Gilenya▼):** new contraindications in relation to cardiac risk
- **Fingolimod (Gilenya▼):** updated advice about risk of cancers and serious infections

MHRA/CHM Drug Safety Update - January – February 2018:

- **Drug-name confusion:** reminder to be vigilant for potential errors
- **Herbal medicines:** report suspected adverse reactions to the Yellow Card Scheme
- **Co-dydramol:** prescribe and dispense by strength to minimise risk of medication error
- **Mycophenolate mofetil, mycophenolic acid:** updated contraception advice for male patients
- **Misoprostol vaginal delivery system (Mysodelle):** reports of excessive uterine contractions (tachysystole) unresponsive to tocolytic treatment
- **Recombinant human erythropoietins:** very rare risk of severe cutaneous adverse reactions (SCARs)
- **Daclizumab (Zinbryta▼) and risk of severe liver injury:** new restrictions to use and strengthened liver monitoring

2. Horizon Scanning for 2017/2019

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 24 month period during 2017/2019.

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

The reports are also being used to form the TAG's **Work Programme for 2018/2019** 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 2018/19 include:

A. PRIMARY CARE IMPACT

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

- Alogliptin/ pioglitazone oral (Incresync®), alone or in combination with metformin, as an adjunct to diet and exercise - Type 2 diabetes mellitus
- Amoxicillin/ omeprazole/ rifabutin (Talicia®) - Fixed-dose combination of two antibiotics and a proton pump inhibitor in a single oral capsule for Helicobacter pylori infection
- Anacetrapib – oral cholesterol ester transfer protein inhibitor for hypercholesterolaemia (heterozygous familial and non-familial), 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
- Buprenorphine injection - Opioid-receptor partial agonist, given by once weekly or once monthly s.c. injection for opioid dependence
- Cebranopadol oral - Nociceptin (or opioid receptor like-1) receptor and opioid mu receptor agonist, first-in-class – for chronic cancer pain, moderate-to-severe, in adults.
- Crisaborole topical (Eucrisa®) - Non-steroidal phosphodiesterase (PDE-4) inhibitor, formulated as a topical cream or ointment - for atopic dermatitis, mild-to-moderate.
- Daclizumab for multiple sclerosis (secondary care prescribed treatment with long term monitoring requirements that may impact of primary care)
- Dapagliflozin oral (Forxiga®) - Type 1 diabetes mellitus in adults – in combination with insulin (licence extension).
- Deutetrabenazine oral - analogue of tetrabenazine, that acts as a vesicular monoamine transporter-2 (VMAT2) inhibitor. Initial dose 6mg twice daily, increased by 6mg weekly to 24mg twice daily – for Tardive dyskinesia (TD) in adults. A competitor to valbenzine. Current management of TD involves stopping the causative drug, if improvement occurs it can take up to 5 years.
- Doxylamine/ pyridoxine oral - Fixed-dose combination modified-release tablet containing a histamine H1 receptor antagonist (doxylamine 10mg) and vitamin B6 (pyridoxine 10mg). Initially two tablets taken at bedtime, may be increased to four tablets daily taken in three divided doses.
- Elobixibat oral - ileal bile acid transporter inhibitor 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, to improve glycaemic control when metformin and/or sulphonylurea and one of the monocomponents of Glyxambi do not provide adequate glycaemic control, or when already being treated with the free combination of empagliflozin and linagliptin.
- 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 - Inhibits nerve growth factor (NGF), a neurotrophin stimulated by pain-causing injury and inflammation. Pain due to osteoarthritis.
- Fluticasone/ umeclidinium/ vilanterol inhaler (Trelegy®) - Asthma or COPD in adult patients who are not adequately controlled by a combination of an ICS and a LABA

- Formoterol + Glycopyrrolate (Bevespi Aerosphere) for COPD
- Glycopyrrolate/ formoterol inhaler (Bevespi Aerosphere) - COPD, moderate-to-very severe
- Intepirdine oral - Serotonin 6 receptor (5-HT6) antagonist – for Lewy body dementia (no longer in development for Alzheimer's disease)
- Lesinurad - Uric acid transporter-1 inhibitor that increases uric acid excretion, first-in-class - for gout (2nd line) / Hyperuricaemia in gout, in combination with a xanthine oxidase inhibitor.
- Lubiprostone for constipation in children
- Lurasidone for bipolar depression
- Odanacatib (oral) for osteoporosis in postmenopausal women, primary or secondary prevention, when bisphosphonates are contra-indicated or not successful
- Omarigliptin for type 2 diabetes
- Paliperidone (Oral MR preparation) for schizophrenia in adolescents
- Patiromer oral (Veltassa®) - Potassium-binding polymer, non-absorbed – 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
- Romosozumab injection (Evenity®) - First-in-class humanised monoclonal antibody that inhibits sclerostin to decrease bone resorption and increase bone formation. Given by monthly s.c. injection – for osteoporosis in men and postmenopausal women.
- Safinamide oral (Alpha-aminoamide, MAO-B inhibitor (selective and reversible) / sodium and calcium channel antagonist/ dopamine uptake inhibitor/ glutamate release inhibitor, first-in-class) for Parkinson's disease (PD) early stage, adjunct to dopamine agonist therapy and for Parkinson's disease (PD), mid-late stage, adjunct therapy
- Sodium zirconium cyclosilicate (Lokelma®) - an insoluble and non-absorbed selective potassium binder - for (chronic) hyperkalaemia (oral preparation)
- Solithromycin for community acquired pneumonia
- Sotagliflozin oral - Dual sodium-glucose co-transporter 1 and 2 (SGLT1 and 2) inhibitor, first-in-class – for Type 1 diabetes mellitus in adults – in combination with insulin.
- Tasimelteon for insomnia
- Tecarfarin oral - Selective vitamin K epoxidase antagonist, eliminating CYP450-mediated drug interactions - Anticoagulation, in patients not suitable for DOAC therapy
- Tiotropium bromide for asthma in children
- Trientine oral (Cuprior®) - Copper chelating agent that forms a stable complex with copper that can be excreted renally - Treatment of Wilson's disease in adults, adolescents and children ≥ 5 years intolerant to D-penicillamine
- Valbenazine oral (Ingrezza®) - Vesicular monoamine transporter-2 (VMAT2) inhibitor - Tardive dyskinesia (TD) in adults
- Vorapaxar oral (Zontivity®) (Antiplatelet, thrombin receptor (PAR-1) antagonist, first-in-class) 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
- Atomoxetine for ADHD and related disorders in Children & Adolescents

- Azathioprine in Ulcerative Colitis and Crohn’s disease
- Colistin (nebulised) for bronchiectasis (non-Cystic Fibrosis)
- Dementia – drugs for Alzheimer’s disease and dementia with Lewy Bodies
- Denosumab (Prolia®) for treatment of osteoporosis in post-menopausal women at increased risk of fractures
- Mercaptopurine in Ulcerative Colitis and Crohn’s disease
- Mycophenolate mofetil / Mycophenolic acid for Adult Renal Transplant Patients
- Sirolimus for adult renal transplant patients
- Tacrolimus for adult renal transplant patients
- Tacrolimus use in Ulcerative Colitis

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:

- Filgotinib oral - Selective Janus Kinase (JAK) type 1 inhibitor; immunosuppressant. Active moderate-to-severe rheumatoid arthritis, after failed biological therapy.
- Netarsudil mesylate ophthalmic solution (Rhopressa®) - Rho kinase and norepinephrine transporter inhibitor and may have an anti-fibrate effect on trabecular meshwork cells - for open-angle glaucoma or ocular hypertension.
- Pitolisant for narcolepsy (in adults) – specialist initiation
- Roxadustat oral - Hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor, first-in-class. HIF transcription factors are involved in body defence mechanisms against low levels of oxygen – for anaemia in chronic kidney disease, first-line for dialysed and non-dialysed patients.
- Tofacitinib oral (Xeljanz®) - Janus kinase (JAK) 1, 2, and 3 inhibitor, functionally specific for JAK 1 and JAK3, immunosuppressant - Active psoriatic arthritis, second- or subsequent line (licence extension).
- Upadacitinib oral - Selective Janus Kinase (JAK) inhibitor – for Rheumatoid arthritis
- Vadadustat oral - Hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor. This blocks prolyl hydroxylase enzymes, leading to increased intracellular HIFα proteins which in turn increases erythropoietin secretion - Anaemia in chronic kidney disease, dialysed and non-dialysed patients – first-line

NICE DRUGS

Around **60 NICE-recommended treatments** are likely to come on line during 2018-19. 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 2018-19:

- Abatacept for treating active psoriatic arthritis after DMARDs
- Abemaciclib with an aromatase inhibitor for untreated advanced hormone-receptor positive, HER2-negative breast cancer
- Abiraterone for treating newly diagnosed high risk metastatic hormone-naive prostate cancer
- Alectinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer
- Arsenic trioxide for treating acute promyelocytic leukaemia
- Atezolizumab for NSCLC after platinum-based chemotherapy
- Atezolizumab for treating metastatic urothelial cancer after platinum-based chemotherapy
- Autologous chondrocyte implantation using chondrosphere for treating symptomatic articular cartilage defects of the knee

- Avelumab for merkel cell carcinoma
- Benralizumab for treating severe asthma
- Bezlotoxumab for preventing recurrent Clostridium difficile infection
- Blinatumomab for treating Philadelphia-chromosome-positive relapsed or refractory acute lymphoblastic leukaemia
- Brentuximab vedotin for treating CD30-positive Hodgkin's lymphoma
- Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma
- Brigatinib for treating ALK-positive non-small-cell lung cancer after crizotinib
- Brodalumab for treating moderate to severe plaque psoriasis
- Cabozantinib for untreated locally advanced or metastatic renal cell carcinoma
- Cenegermin for treating neurotrophic keratitis
- Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer
- Dabrafenib in combination with trametinib for adjuvant treatment of resected BRAF V600 positive malignant melanoma
- Daratumumab monotherapy for treating relapsed and refractory multiple myeloma
- Daratumumab with bortezomib for treating relapsed or refractory multiple myeloma
- Darvadstrocel for treating complex perianal fistula in Crohn's disease
- Dupilumab for treating moderate to severe atopic dermatitis after topical treatments
- Durvalumab with tremelimumab for untreated non-small-cell lung cancer with no EGFR- or ALK-positive mutations
- Eculizumab for treating refractory myasthenia gravis
- Erenumab for preventing migraine
- Eribulin for treating locally advanced or metastatic breast cancer after 1 chemotherapy regimen
- Gemtuzumab ozogamicin for untreated acute myeloid leukaemia
- Guselkumab for psoriasis (moderate, severe)
- Idelalisib for treating follicular lymphoma refractory to 2 treatments
- Ixekizumab for treating active psoriatic arthritis after DMARDs
- Lenvatinib for advanced, unresectable, untreated hepatocellular carcinoma
- Lenvatinib and sorafenib for treating differentiated thyroid cancer after radioactive iodine
- Letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant
- Liposomal cytarabine and daunorubicin for untreated acute myeloid leukaemia
- Midostaurin for untreated acute myeloid leukaemia
- Niraparib for ovarian cancer
- Nivolumab for treating metastatic or unresectable urothelial cancer after platinum-based chemotherapy
- Nivolumab with ipilimumab for untreated metastatic renal cell carcinoma
- Nusinersen for treating spinal muscular atrophy
- Ocrelizumab for treating primary progressive multiple sclerosis
- Ocrelizumab for treating relapsing multiple sclerosis

- Olaparib for maintenance treatment of recurrent, platinum-sensitive ovarian, fallopian tube and peritoneal cancer that has responded to platinum-based chemotherapy (including review of TA 381)
- Padeliporfin for prostate cancer (localised)
- Patiromer for treating hyperkalaemia
- Pembrolizumab for locally advanced or metastatic urothelial cancer where cisplatin is unsuitable
- Pembrolizumab for untreated PD-L1 positive metastatic non-small-cell lung cancer
- Pembrolizumab with pemetrexed and platinum-based chemotherapy for untreated non-small-cell lung cancer
- Pembrolizumab for untreated recurrent or metastatic squamous cell carcinoma of the head and neck
- Pembrolizumab for classical hodgkin lymphoma
- Pertuzumab with trastuzumab and docetaxel for treating HER2-positive breast cancer
- Sodium zirconium cyclosilicate for treating hyperkalaemia
- Tocilizumab for treating giant cell arteritis
- Tofacitinib for treating active psoriatic arthritis after DMARDs
- Venetoclax in combination with rituximab for treating relapsed or refractory chronic lymphocytic leukaemia

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 from 1 April 2016 with criteria for use can be accessed via:

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

B. SECONDARY CARE IMPACT

Non-NICE Drugs

- Actoxumab and bezlotoxumab for prevention of Clostridium difficile infection
- Aflibercept for diabetic retinopathy
- Andexanet alfa for anticoagulation reversal
- Anti-VEGF drugs for choroidal neovascularisation (CNV) secondary to conditions other than age-related macular degeneration (AMD) or pathological myopia (PM)
- Botulinum A toxin for limb spasticity post stroke
- Botulinum A toxin for limb spasticity in cerebral palsy
- Clevidipine injection (Cleviprex®) for perioperative hypertension
- Dalbavancin injection (Dalvance®) for complicated skin and skin structure infections (cSSSI), caused by gram-positive microorganisms
- Esketamine for tinnitus
- House dust mite allergen immunotherapy (sublingual tablet) (Mitizax®) for allergic rhinitis, allergic asthma and rhinoconjunctivitis
- Idarucizumab for reversal of the anticoagulant effect of dabigatran
- Nabiximols for cancer pain
- Netupitant/palonosetron for prevention of chemotherapy induced nausea and vomiting in adults
- Odanacatib for postmenopausal osteoporosis
- Oritavancin injection (Nuvocid®) for complicated skin and skin structure infections (cSSSI), caused by gram-positive microorganisms
- Propranolol oral (Hemangiol®) for proliferating Infantile haemangioma (IH), requiring systemic therapy
- Safinamide (oral) (an Alpha-aminoamide, MAO-B inhibitor (selective and reversible) / sodium and calcium channel antagonist / dopamine uptake inhibitor/ glutamate release inhibitor, first-in-class) for Parkinson’s disease (PD) early stage, adjunct to dopamine agonist therapy and for Parkinson’s disease (PD), mid-late stage, adjunct therapy
- Sufentanil sublingual tablet system for moderate to severe acute post--operative pain
- Tedizolid oral and injection (Sivextro®) for complicated skin and skin structure infections (cSSSI), caused by gram-positive microorganisms

APPENDIX 1

Terms of Reference for the TAG during 2017/18

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 NHS Anglia Commissioning Support Unit (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*): *Currently NICE applies a threshold of up to £30k per QALY, with higher limits applied to cancer treatments which may extend life.*	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&TCG 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*): Currently NICE applies a threshold of up to £30k per QALY, with higher limits applied to cancer treatments which may extend life.	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)

Annual Declaration of Actual & Potential Conflicts of Interest – April 2017

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 – March 2017 v5 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.

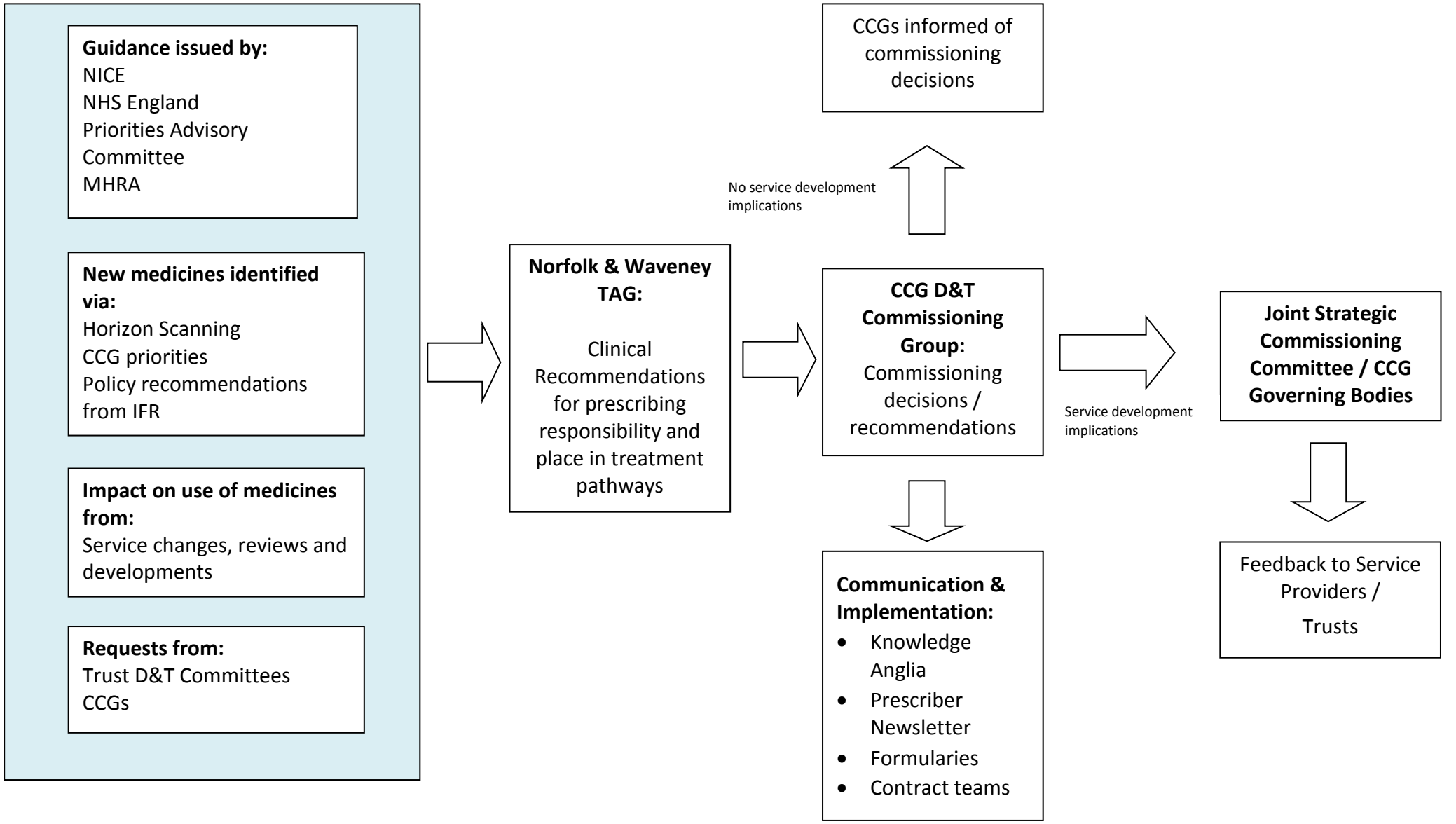
Examples of non-personal interests include fellowships, grants for the running of a unit or department, sponsorship of a post or member of staff, commissioned research or other work from staff in the unit and, sponsorship of attendance at scientific or similar meetings.

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
Priorities Advisory Committee
MHRA
New medicines identified via:
Horizon Scanning
CCG priorities
Policy recommendations from IFR
Impact on use of medicines from:
Service changes, reviews and developments
Requests from:
Trust D&T Committees
CCGs
Norfolk & Waveney TAG:
Clinical Recommendations for prescribing responsibility and place in treatment pathways
CCG D&T Commissioning Group:
Commissioning decisions / recommendations
No service development implications
CCGs informed of commissioning decisions
Service development implications
Joint Strategic Commissioning Committee / CCG Governing Bodies
Feedback to Service Providers / Trusts
Communication & Implementation:
Knowledge Anglia
Prescriber Newsletter
Formularies
Contract teams