Therapeutics Advisory Group

Improving lives together
Norfolk and Waveney Integrated Care System

A Policy and Procedure for Commissioning New Medicines and Devices across Norfolk and Waveney NHS

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Version 2	August 13
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Page

1. Introduction

Medicines optimisation ensures people obtain the best possible outcomes from their medicines while minimising the risk of harm.

Medicines optimisation requires evidence-informed shared decision making between the patient and the professional(s) providing an individualised, person-centred approach to medicines use, within the available resources.

Medicines management considers the systems of processes and behaviours determining how medicines are used by patients and the NHS, whereas medicines optimisation focuses on outcomes for patients obtained from their medicines. Medicines management is an important enabler of medicines optimisation and is a term that has been used historically in the NHS for managing people's medicines

A new medicine or device, or a new indication for an existing medicine or device, can be a welcome addition to the formulary, providing a significant advance over current treatment in terms of its increased effectiveness or an improved side-effect profile. However, many new medicines or formulations offer little of clinical advantage over existing treatments. Furthermore, new medicines are often more expensive than existing treatments.

Having made provision for the cost of medicines within fixed budgets, the unexpected introduction of an expensive new medicine or indication upsets carefully laid plans. Budgets become overspent and resources may be diverted from other areas of patient care to fund the new medicine - perhaps to the detriment of the overall well-being of patients.

When making decisions, NICE strive to balance the need to achieve the most overall benefit for the greatest number of people, with the need to ensure fairness and respect for individual choice.
We need to

- know how additional benefit offered by any new medicine or indication applies to our local population and whether hardship may be imposed on other patients when resources are diverted from their care.
- incorporate guidance from the National Institute for Health and Care Excellence (NICE) and consider how best to implement it within local circumstances.
- estimate the financial and human resources necessary for implementation and secure appropriate funding, workforce and service development.

With these ethical, legal and financial implications, the introduction of new medicines must be undertaken in a considered fashion. This document describes the method used for the introduction of new medicines across the Norfolk and Waveney ICS area.

In line with NICE principles, NICE guidance and standards we need to be up to date to ensure people receive the best care and advice and as such will review and revise as necessary. Norfolk and Waveney ICB will review local decisions where NICE guidance changes to ensure best value evidence-based care.

2. Key features of the policy

- NICE Technology Appraisals (TA) will be funded via the statutory responsibility to make funding available for a drug or treatment recommended by a NICE TA and to begin doing so no later than 90 calendar days (30 calendar days for EAMS products or

for products appraised via the Fast Track Appraisal process) after the guidance is published, unless otherwise specified in the guidance.

- The introduction of new medicines without a NICE TA or indications should consider the cost pressures in all healthcare sectors. Affordability and cost-effectiveness are important wherever the medicine is prescribed.

- The default position for new medicines and indications is that they are not routinely available until they have been assessed, prioritised and commissioned. Thus, as the financial year progresses, there will be a growing list of new medicines and indications awaiting prioritisation and possible commissioning in the next financial year.

- The assessment of medicines will be an **on-going continuous process** throughout the financial year, but prioritisation for additional funding will only take place on an **annual basis** as part of the commissioning cycle. Medicines will be considered alongside all other proposals for development.

- The assessment of new medicines should prompt a comparison of existing medicines or treatments for the same or other conditions to determine their relative cost-effectiveness and, where appropriate, their place in the treatment pathway. Some introductions will only take place if resources are transferred from other, less valuable, activities.

- The Therapeutics Advisory Group (TAG) will act as the professional advisory group for the Norfolk Waveney ICS health economies. It will consider medicines, devices or indications for which extra funding or guidance is sought that the Integrated Commissioning Board (ICB) will want to ensure equity of provision across the Norfolk and Waveney ICS area. It will consider all guidance on medicines from the National Institute for Health and Care Excellence (NICE), NHS England and other national guidance (e.g., QIPP (Quality, Innovation, Productivity and Prevention)).

- The recommendation on the suitability of prescribing a medicine in primary care, as opposed to secondary care, should be made on grounds of clinical appropriateness and patient safety and will take account of guidance from NICE and other national bodies. It should not be influenced by the likely source of funding for the medicine.

- Provider Trust-based Drug and Therapeutics Committees (DTCs) will play a gatekeeper role for the introduction of new medicines for indications within the Trust. This includes medicines for clinical trials, which should be introduced in conjunction with R&D Governance Committees.

- In the case of medicines which are excluded from the tariffs, Providers may shortlist new medicines and indications identified through the annual Horizon Scanning process for consideration for commissioning by the Integrated Care Boards. This includes estimates of the likely impact of expected guidance from the National Institute for Health and Care Excellence.

- ICBs will consider the more immediate use and funding of a medicine in individual patients on grounds of exceptionality – or, more widely, if there is national guidance or direction about a new medicine.

- The budget-setting process for prescribing will take account of the likely impact of expected new drugs and recommendations from NICE.

3. A series of decisions

All NICE-approved treatments must be included in local formularies for use in line with the guidance. If there is more than one NICE-approved medicine for the same indication, local NHS organisations may indicate that a particular medicine is preferred locally if one of the medicines offers better value than the other(s), or there is a clear local clinical consensus, or to achieve optimal stock control. However, clinicians and their patients must remain able choose any NICE-recommended treatment if, after an informed discussion, they consider it appropriate to do so. Frequently-asked-questions-on-NICE-compliance.pdf

When making decisions regarding whether any other new medicine should be recommended for commissioning, a series of questions are asked to determine the treatment's worth against other medicines. Please see Appendix 1 for Decision-Making Framework for Recommendations on New Medicines and Indications.

In the light of the above, where available, we refer to the evaluations produced by the National Institute for Health and Care Excellence (NICE) and its guidance for the NHS. Providers and commissioners must not restrict access to NICE-approved medicines by adding to or modifying the clinical eligibility criteria stated in the NICE technology appraisal (TA) or highly specialised technology evaluation (HST).

4. Funding aims

ICBs are committed to ensuring that medicines recommended for use by NICE are properly implemented and appropriately funded – including considering the funding of any consequential service developments.

Where there is no guidance from NICE, ICBs **aim to ensure** that medicines or indications which are funded meet the following criteria. These are adapted from NICE's ambition to deliver patient access to proven, affordable and transformative medicines in a financially sustainable way and the three central issues identified in the NHS Commercial Framework for new Medicines (accessed 7/3/2025)

- ensuring treatments are clinically- and cost-effective and represents the best use of NHS resources
- ensuring the NHS can afford to introduce clinically- and cost-effective treatments now and in the future
- ensuring any commercial arrangements are transactable within the NHS so that their value is realised and the burden on the NHS is minimised.

These medicines will **still have to be assessed alongside other priorities** in the ICBs' commissioning plans before a decision is made on a medicine's priority and affordability.

4.1 Criteria

1. The medicine is used for a medical condition.

2. There is sufficient evidence to draw conclusions about the medicine's effects on health outcomes.

3. The evidence demonstrates that the medicine can be expected to produce its intended effects on health outcomes.

4. The medicine's expected beneficial effects on health outcomes outweigh its expected harmful effects.

5. The medicine is a cost-effective method to address the medical condition and that we have clarified the financial impact of its introduction.

4.2 Definitions

- **Medical condition:** a medical condition is a disease, an illness, or an injury. A biological or psychological condition that lies within the range of normal human variation is not considered a disease, illness or injury.

- **Health outcomes:** health outcomes are outcomes of medical conditions that directly affect the length or quality of a person's life. (For example: evidence of lowered mortality, not just lowered cholesterol.)

- **Sufficient evidence:** evidence is sufficient to draw conclusions if it is peer reviewed, is well controlled, directly or indirectly relates the intervention to health outcomes, and is reproducible both within and outside of research settings. (For example: for a medicine to be used in primary care: - a randomised controlled trial of a medicine used in a typical primary care setting of sufficient duration to measure a number of health as opposed to intermediate outcomes.)

- **Cost-effective:** a medicine is considered cost-effective if there is no other available intervention that offers a clinically appropriate benefit at a lower cost.

- **Indication:** the condition which is treated by the medicine.

5. The introductory sequence

5.1 Effectiveness

The starting point for the introduction of a medicine or indication is to consider the research-based evidence of its effectiveness. We will take into consideration the quality and "maturity" of the evidence, the choice of outcome measures evaluated and the setting in which the trial took place.

5.2 Guideline for use

Drawing on the evidence of effectiveness, clinicians should collaborate to develop treatment pathway and guideline for the proposed use of a medicine. The guideline will be considered alongside the evidence. Where a medicine is likely to be started, modified, monitored and stopped by specialists, prescribing responsibility for the patient rests with the specialist. However, if it is considered that patient care would be improved through sharing clinical and prescribing responsibility with GPs, a shared-care protocol should be developed for consideration by the Therapeutics Advisory Group. Shared care guidelines should follow the recommendations made by the GMC - Shared care - professional standards - GMC (accessed 7/3/2025)

5.3 Clinical responsibility

A key decision when introducing medicines within Norfolk and Waveney ICS is the assessment of whether a medicine is **appropriate for prescribing in primary care.** This is formally determined and advised by the Therapeutics Advisory Group (TAG). Furthermore, hospital clinicians should only ask GPs to prescribe those medicines which have been approved for use by the local Trusts.

5.4 Financial impact

The total cost of the proposed introduction of the treatment is estimated for the population of the local health economy For NICE TA's this is supported by NICE costing templates. This cost can then be apportioned to the primary and secondary sectors depending on where clinical responsibility rests. This allows for an assessment of the medicine's financial impact on existing agreements and prescribing budgets and to fit with the values of the ICS.

5.5 Economic appraisal

An assessment of the cost-effectiveness of the proposed medicine or indication will be made which should consider the additional costs needed for the introduction of the medicine in the setting in which it is proposed to be used - that is, to consider any extra staff, equipment, activity or monitoring needed.

5.6 Prioritising medicines for commissioning

The ICBs are legally required to fund the medicines and indications recommended by the technology appraisals from NICE. The Therapeutics Advisory Group (TAG) will estimate the financial impact of upcoming appraisals to inform the commissioning process.

Otherwise, the TAG will identify those medicines which are of highest priority for introduction. These are likely to be the medicines or indications with the greatest **cost-effectiveness**. TAG will consider - and may need to **review - previous decisions** to ensure consistency and to ensure that medicines and indications of greatest value are used.

Technical factors which will influence the priority status of a medicine or indication include the quantity, quality and strength of evidence of effectiveness and cost-effectiveness, the availability of alternative treatments, safety, etc.

In prioritising medicines for commissioning recommendations, the TAG considers the Department of Health publications 'Innovation, Health & Wealth: Accelerating Adoption and Diffusion in the NHS' (accessed 7/3/2025), 'NICE - Good Practice Guidance on developing and updating local formularies' (accessed 7/3/2025) and the NHSE Medicines Value and Access Programme (accessed 7/3/2025)

In order to meet the requirements for NICE TAs to be funded and in formularies within the specified time 90 days or 30 days for fast-track appraisals, the TAG will make recommendations to the ICB Drugs and Therapeutics Commissioning Group based on the NICE Final Appraisal Document (FAD), facilitating the timely adoption of a NICE TA. The TAG will consider NICE FADs where the drug is supported as an "option" in treatment. The TAG will **provide clinical input as to where the drug sits in a treatment pathway** and the views of local Trust clinicians will be sought.

5.7 Commissioning process

The Therapeutics Advisory Group recommendations are submitted to the ICB, via the Medicines Optimisation Programme Board for a commissioning recommendation to be made to the ICB Board.

5.8 The final decision

When commissioned, the treatment (and any related service developments) will be made available and a traffic light classification will be assigned (Appendix 2).

6. Introducing medicines in Primary Care

With few exceptions, all medicines licensed in the UK can be prescribed by GPs. Even unlicensed medicines can be prescribed, although GPs are discouraged to do this where an alternative licensed product is available.

ICS prescribing leads, the ICB Medicines Optimisation team and Trust-based Drug and Therapeutics Committees are working together to harmonise formularies for medicines which are widely used in primary care. This activity is conducted through working groups such as the Prescribing Reference & Formulary Group.

The ICB considers both clinical appropriateness and affordability when using a medicine. The introduction of medicines within Norfolk and Waveney should consider cost-pressures in the primary care sector as well as the secondary sector. Cost-effectiveness and best value is important whoever prescribes the medicine.

The process for assessing medicines which are licensed and likely to be prescribed by GPs is as follows:

- Medicines are proposed for assessment by the Therapeutics Advisory Group (TAG) via the local
    - Prescribing Formulary Group.
    - Medicines Optimisation groups aligned to N&W provider trusts.

- Recommendations made by the TAG are forwarded to the ICB for commissioning consideration via the Norfolk & Waveney ICB Drugs and Therapeutics Commissioning Group (D&TCG)

- The TAG will make recommendations on whether the medicine is suitable for prescribing by GPs, by specialists or whether a shared-care arrangement is appropriate. NWICB “Shared Care Principles” document is in development.

- Commissioning decisions regarding medicines and indications are formally communicated to NHS provider Trusts by the ICB and are also disseminated to all prescribers and pharmacists in Norfolk & Waveney, usually via the TAG Newsletter, available on Netformulary platform and disseminated via GP News. They are also added to the Knowledge NoW website

- Drugs less suitable for prescribing are listed.

7. Introducing medicines within NHS Provider Trusts

Most new medicines or formulations have modest cost-impact and/or will join medicines of comparable clinical impact. Most decisions on the introduction of new medicines are appropriately made within an NHS Provider Trust. This will allow the Trust to take account of its specialty mix, clinical experience and expertise, work settings and financial status.

Trusts have developed mechanisms for the assessment of new medicines and indications. Such mechanisms build upon the functions of existing Drug and Therapeutics Committees.

A typical mechanism involves Clinical Directors/ Service Leads who make submissions to their D&T Committee or equivalent professional advisory body. Submissions address the issue of the medicine's clinical effectiveness and its cost-effectiveness when compared to other treatments for the same condition.

D&T Committees validate these submissions according to their organisation's Ethical Framework.

7.1 Responsibilities of NHS Provider Trust D&T Committees[1]

In respect to the introduction of new medicines or indications, this policy endorses the following responsibilities:

- the sole gateway advising on the introduction of new medicines or indications within the Trust.
- evaluating the effectiveness and assessing the cost implications of new medicines or indications.
- horizon scanning for new medicines or new indications.
- consideration of guidance developed by the Therapeutics Advisory Group.
- collection and preparation of business cases for consideration by the Therapeutics Advisory Group.
- where a NICE technology appraisal is awaited for a new medicine or indication, a plan for introduction should be prepared sufficiently in advance, including the proposed place in the pathway. If such a medicine or indication is recommended for use by NICE, funding can subsequently be made available no later than three months after publication of the guidance. The ICB will facilitate the planned addition to improve NICE implementation across all Trusts.
- agreeing protocols for the use of a medicine or indication within the Trust.
- monitoring medicine use within the Trust.
- considering and endorsing requests for exceptional funding in individual patients.

8. Therapeutics Advisory Group (TAG)

1 Or equivalent professional advisory body.

Whilst it is expected that most decisions on the introduction of new medicines, formulations or new indications will be made by Trust D&TC, where a D&TC decision might affect other organisations there is an important role for submission to the TAG for guidance across the local health economy. It should be noted that submissions from a Trust should be made and have been considered by the Trust D&T Committee.

8.1 Tasks

The role of the Therapeutics Advisory Group is **to provide informed professional advice across Norfolk and Waveney** on the clinical use of medicines, dressings and other prescribable items such as those evaluated by the Advisory Committee on Borderline Substances (ACBS), herbal remedies etc **that are commissioned by ICBs.** This includes:

- **advice** on the managed introduction and implementation of new medicines and indications into practice – including on the most appropriate method of introducing medicines recommended by NICE.
- **advice** on the prescribing responsibility across the Primary / Secondary care interface.
- **advice** on non-medical prescribing issues and PGDs where appropriate.
- to take note of commissioning decisions made by other commissioners e.g., NHS England, neighbouring ICBs.

8.2 Terms of Reference

The TAG Terms of Reference are published separately here

8.3 Which medicines and prescribable devices are considered by TAG?

1. All medicines for which NICE has published Technology Appraisals where the medicine is an option for treatment. This includes an updated and publication of a replacement TA where a treatment has been granted a license extension.
2. Medicines for which guidance is needed on ***use in the primary care setting***, including the approval of ***shared-care guidelines***.
3. Medicines for which there is uncertainty over ***clinical and prescribing responsibility*** across the primary secondary care interface.
4. Medicines which are ***excluded from the tariffs*** of "Payment by Results" or are used in Healthcare Resource Groups which are ***excluded from tariff***.
5. Medicines or new indications for which a Trust is seeking ***additional funding*** e.g., as a "pass-through" payment/IFR - or ***guidance*** e.g., because of impact in primary care.
6. Medicines for which we need an assessment of their ***therapeutic value*** or ***cost-effectiveness***, including:
    - Medicines which open ***new therapeutic avenues***, e.g., the "first medicine for a condition".
    - Medicines which operate through ***new mechanisms***, e.g., the first of a new class of medicine.

- Medicines with a ***high*** impact on patient benefit or cost across primary and secondary care

7. Medicines which are subject to investigation in trials and which may require significant investment in excess treatment costs where the ICBs require additional clinical guidance in addition to information considered by the D&TCG.

8. **All devices** that are prescribable in primary care – ones with significant financial impact and ones that are mandated

Other points

- It is important not to overburden the process, so ***medicines with a high-cost impact will be evaluated preferentially***.

- Submissions from a Trust should be made and have been considered by the Trust D&T Committee.

- Submissions should justify the requirement for ***additional*** expenditure on the treatment.

8.4 Taking forward TAG Recommendations

The Therapeutics Advisory Group is a **professional clinical advisory group**. It gives advice and makes recommendations.

Most recommendations made through the Therapeutics Advisory Group can be implemented through small changes in clinical and administrative practice.

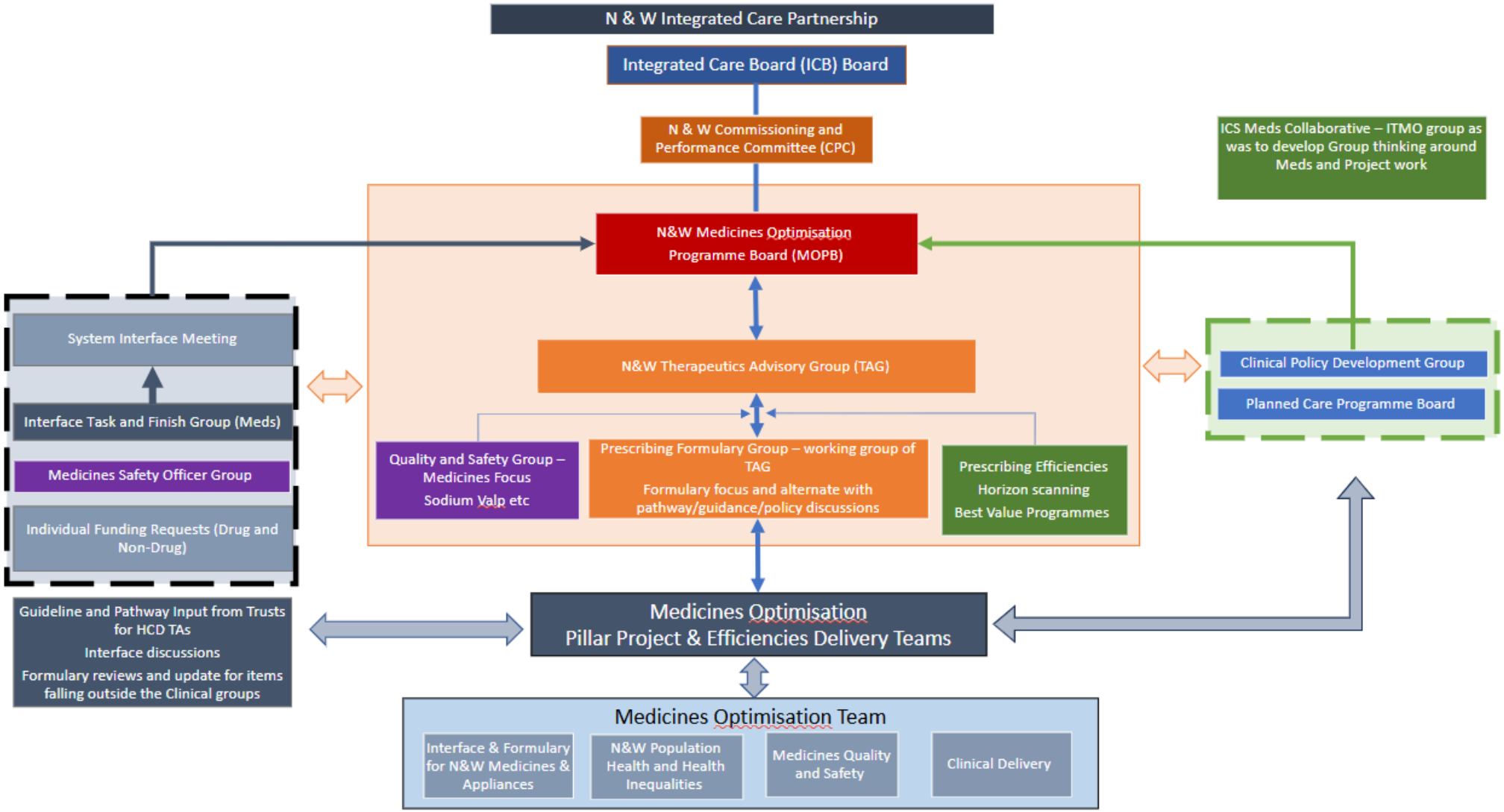
Recommendations for GPs are disseminated and supported by the ICB Medicines Optimisation Team. Clinical recommendations affecting hospital Trust staff can usually be taken forward by Trust-based Drug and Therapeutics Committees and considered by usual internal mechanisms.

However, some recommendations will need to be handled through more complex commissioning arrangements - particularly those medicines which are excluded from Tariff where service developments are required. It is possible that some recommendations may not be implemented due to competing priorities.

The outcome of TAG recommendations is determined by commissioning decisions ultimately made by the ICB Board, via the Medicines Optimisation Programme Board (MOPB).

The TAG will receive reports on the implementation and prescribing outcomes of its recommendations for consideration, and report to the MOPB where practice continues to differ from recommendations.

See next page for current committee structure.


N & W Integrated Care Partnership
Integrated Care Board (ICB) Board
N & W Commissioning and Performance Committee (CPC)
ICS Meds Collaborative – ITMO group as was to develop Group thinking around Meds and Project work
N&W Medicines Optimisation Programme Board (MOPB)
System Interface Meeting
Interface Task and Finish Group (Meds)
Medicines Safety Officer Group
Individual Funding Requests (Drug and Non-Drug)
N&W Therapeutics Advisory Group (TAG)
Quality and Safety Group – Medicines Focus
Sodium Valp etc
Prescribing Formulary Group – working group of TAG
Formulary focus and alternate with pathway/guidance/policy discussions
Prescribing Efficiencies
Horizon scanning
Best Value Programmes
Clinical Policy Development Group
Planned Care Programme Board
Guideline and Pathway Input from Trusts for HCD TAs
Interface discussions
Formulary reviews and update for items falling outside the Clinical groups
Medicines Optimisation Pillar Project & Efficiencies Delivery Teams
Medicines Optimisation Team
Interface & Formulary for N&W Medicines & Appliances
N&W Population Health and Health Inequalities
Medicines Quality and Safety
Clinical Delivery

9. Commissioning new medicines

9.1 The annual commissioning cycle

As part of the annual commissioning cycle, the Horizon Scanning list of new medicines and indications for the coming financial year will be produced in collaboration with all Trusts and the ICB.

Trusts will need to facilitate in the preparation of plans to support the introduction of a new medicine or indication and where this involves a medicine under appraisal by NICE, the plan will be developed before NICE publication to expedite timely service development where needed.

The TAG will review the medicines highlighted in Horizon Scanning alongside other sources of evidence and will attempt a prioritisation based largely on the ***technical aspects*** of a medicine – such as effectiveness and cost-effectiveness and will also estimate funding requirements and where a NICE TA is expected, the likely financial impact for the Commissioners and Providers.

The ICB commissioning process undertakes a further level of prioritisation to take account of the affordability of the recommendations when set alongside competing proposals for development in accordance with the Ethical Framework.

Additional funding for new medicines or indications may only become available for the following April - a period of up to 14 months. Medicines will not ordinarily be funded “out-of-cycle”.

The Therapeutics Advisory Group and NHS Provider Trust D&T committees will continue to evaluate medicines throughout the year. This will result in a prioritised list of medicines which are deemed of value but are not yet funded. The Therapeutics Advisory Group will periodically review the list to take account of:

- new guidance prepared for the NHS by NICE.
- newly introduced medicines or indications.
- new research information on existing or new medicines.
- new information on pricing or licensed indications.
- new information on medicine safety.

9.2 Non-tariff medicines commissioned by ICB (Not applicable whilst in Block funding arrangements)

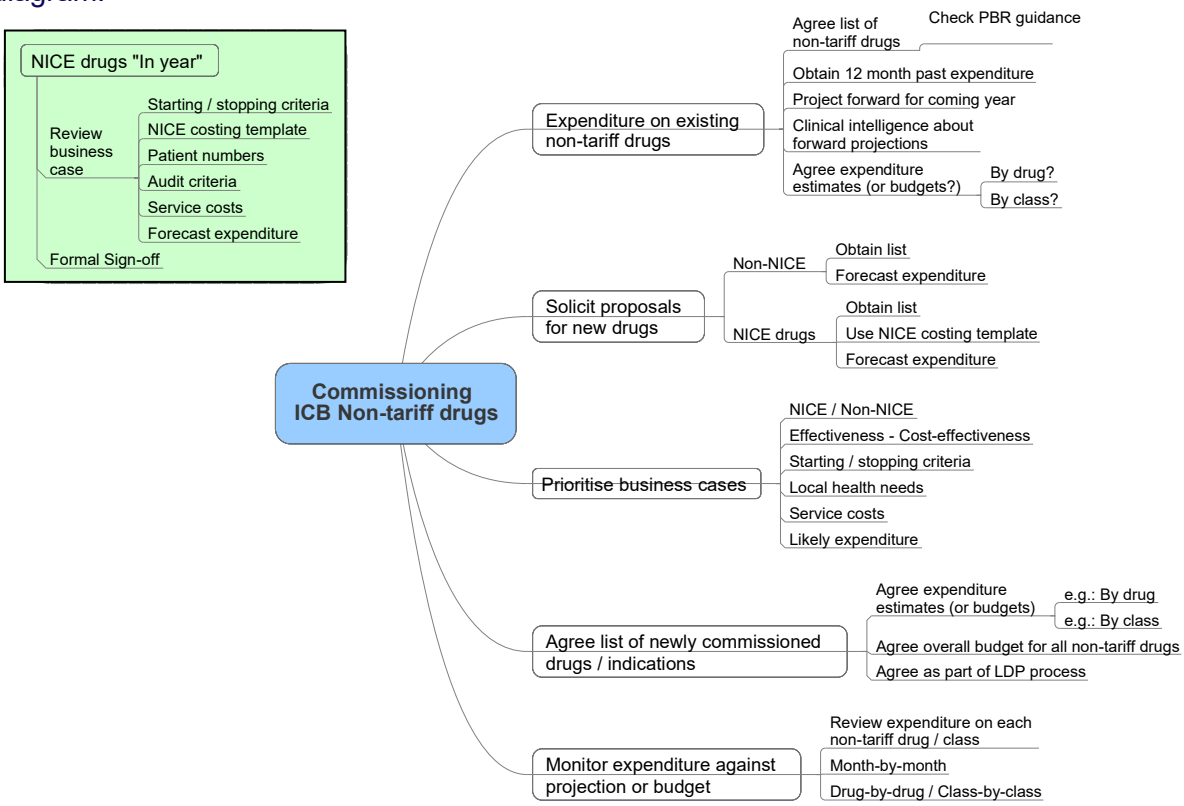
The list of "non-tariff medicines" may vary from year to year. Expenditure on this list of medicines and devices is subject to the local commissioning process.

The ICB must agree clear implementation plans with the provider (as contained in a business case) for non-tariff medicines and they will need to be certain about the starting and stopping criteria before they commit resources. Alternative, extended or supplementary indications will not be funded without prior agreement.

They will also need to agree the appropriate associated service costs and HRGs.
They may also need assurance about the control mechanisms that NHS Provider Trusts establish to oversee the use of high-cost medicines or devices and they will periodically expect to review audits of their use, as for example, using those audits recommended by NICE.

Where ICBs and NHS Provider Trusts have agreed an expenditure estimate for the financial year for a medicine or device, the ICBs expect NHS Provider Trusts to review the forecast expenditure with them if there is a significant variance. They may need to establish different eligibility criteria before further expenditure is committed.

The commissioning process for ICB non-tariff medicines is summarised in the following diagram:



9.3 National Institute of Care Excellence

The National Institute for Health and Care Excellence (NICE) is an independent organisation producing guidance on drugs and treatments. 'Recommended for use by NICE Technology Appraisal Guidance' refers to a type of recommendation set out in legislation. The relevant health body is obliged to fund specified NICE Technology Appraisal Guidance recommendations from a date no longer than three months from the publication of the recommendation unless, in certain limited circumstances, a longer period is specified.

Making "informed decisions" in the absence of NICE guidance

Department of Health guidance expects PCTs, CCGs and henceforward ICS/ICBs, to take informed views about new technologies in the absence of NICE guidance:

> *"If a new intervention is not referred to NICE, this does not imply any judgement on whether the intervention(s) in question are clinically or cost effective. NHS bodies should continue to use existing arrangements to access the publicly available evidence and to determine local policies for the managed entry of the new intervention. The same principle should apply if an intervention has been referred to NICE but guidance is not yet available at the point at which the new intervention is first introduced."*[2]

> *"**Reiterating the Message of HSC 1999/176**: It is not acceptable to cite a lack of NICE guidance as a reason for not providing a treatment. A key role of the NHS is to make decisions about the use of new interventions, and this has always been the case, long before NICE was established. … NICE does not exist to "kite mark" all the interventions which are introduced for use in the NHS. … Not all new interventions will be referred to NICE for appraisal and for those interventions that are referred to NICE there may be a time lag. … Therefore, the NHS will have to continue to make informed decisions about the use of these interventions under either circumstance."*[3]

2 HSC 1999/176

3 Good practice guidance on managing the introduction of new healthcare interventions and links to NICE technology appraisal guidance. 14 Dec 2006. Gateway Ref: 7521

Appendix 1 - Decision-Making Framework for Recommendations on New Medicines and Indications

TAG Meeting Date: **Agenda Item:**

Medicine and Indication:

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

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 or specialist initiation)	Advice (Specialist recommendation)	Green (Suitable for initiation in Primary Care)
Skills of the Prescriber	Experience Of Condition	Specific	Specific	Specific	General
	Diagnosis	Specific	Specific	Specific	General
	Monitoring Progress Treatment	Difficult	Specific	General	General
Therapy	Patient Selection	Difficult	Specific	Specific	Easy
	Initiation Of Treatment	Difficult	Difficult/Complex	Easy	Easy
	Dose Titration	Difficult	Specific	Easy	Easy
	Monitoring Of Side Effects	Complex	Easy	Easy	Easy
	Method Of Administration	Complex	Standard	Standard	Standard
	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

Treatment assessed (Month and Year):

TAG Recommendation

TBC post meeting

1) Clinical Effectiveness

e.g. according to national guidelines…

2) Cost Effectiveness

e.g. most appropriate and cost- effective products have been recommended

3) Needs of the community

e.g. prevalence and incidence of disease being treated?

4) **Equity & Equality Impact Assessment** (see also embedded additional information including factsheet below to aid completion of this section)

Consider whether this decision of the TAG will have an impact for patients or staff in regard to Equality, Inclusion and Human Rights legislation.
Such impacts (negative) could include:

- Restriction of a drug which could benefit those with certain conditions[1,2]

Where the implementation of the decision of the TAG may impact on one or more equality group differently to others, a full equality impact assessment may need to be completed.

Protected Characteristics (under the Equality Act 2010):

Age; Disability; Gender reassignment; Marriage & Civil Partnership (in employment only); Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual orientation; carers; other identified groups.

Please state whether the decision will have an impact:

Yes ☐ *If **YES,** the proposal is likely to impact patients or staff. Please set out those impacts and any mitigations that have been identified in the section below. Examples include a process where the needs of exceptional cases can be met.*

No ☐ ***NO**, please state that the decision has been reviewed with regard to Equality, Inclusion and Human Rights and no issues have been identified in the section below.*

Provide rationale for impact assessment:

Should a significant impact be identified a full EQIA should be completed

5) Need for healthcare (incorporates patient choice and exceptional need)

e.g. are there alternative therapies available or is this a completely new treatment option?

6) Policy drivers:

e.g. relevant local or national guidance

7) Disinvestment:

- *How will this medicine help to address local health priorities?*
- *By using this medicine, what disinvestment in other medicines, interventions and services may be possible?*
- *How much would this save?*
- *Affordability considerations?*
- *Will this medicine help to address local health priorities?*

8) Environmental impact of decision (if applicable)

Appendix 2 – Current Traffic Light Classifications

BLACK	**Not commissioned. Not suitable for NHS prescribing in primary or secondary care** This covers medication and devices that are not commissioned for use in Norfolk and Waveney. It also includes NICE TAs where the treatment has not been recommended.
NICE approved	**NWICB are committed to fund positive NICE TAs. Awaiting clarification of place in pathway and commissioning arrangements. Further guidance to be issued when available.** This is a holding position which acknowledges NICE-approved TAs with ICB-commissioned responsibility which have not yet been allocated a traffic light classification.
BLUE	**Formulary application and discussion required prior to addition to formulary.** This includes new products on the Horizon Scanning list and those medications and devices in primary and secondary care which don't have a NICE TA or have not yet been considered for addition to formulary.
Double Red	**Not recommended for routine use. To be used only as a last resort in exceptional circumstances. Seek advice from Medicines Optimisation Team where appropriate** Includes situations such as transfer of care, patient moving from out of area, or where other treatment or pathway options have been exhausted. Some items may require formal approval via the IFR process.
RED	**Restricted Use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care** Includes acute and mental health trusts and other specialist commissioning services. Classification does not automatically signify that a drug will be available within secondary care.
FULL SCA	**Shared Care Agreement** These are drugs covered by a formal shared care agreement within the current LCS. Level will be highlighted in each individual document and in the Netformulary entry. Specialist will send a request to provider when it is deemed suitable to transfer prescribing to primary care. Agreement will be assumed unless the primary care provider states otherwise.
AI	**Amber Initiate - Specialist initiation. Prescribing will switch to primary care as per commissioning agreement or when clinically appropriate.** Specialist requirements will be noted in the drug's Netformulary entry and guidance document. Treatments listed under this classification are not included in the formal shared care LCS and there will be no additional payment for prescribing.
ADVICE	**Advice – Primary care initiation following specialist recommendation** Primary care initiation following receipt of verbal or written recommendation from primary or secondary care specialist clinician with relevant expertise.
Guidance documents will be developed to support prescribing of drugs within the AI and the ADVICE categories to support clinicians who may not have experience of prescribing or monitoring these drugs	
GREEN	**Formulary – Can be initiated and prescribed in primary or secondary care within licensed indications** This covers most drugs on the primary care formulary
SWITCH	**Not recommended for prescribing. Switch to cost-effective alternative** This category will act as a reminder of the cost-effective switches and will be reviewed monthly
OTC	**Available to buy over the counter. Consider self-care** Drugs in this category will be available to buy over the counter.
DM	**Discontinued Medicines** This category will be under constant review and updated regularly