# Norfolk and Waveney Therapeutics Advisory Group (TAG)

# Terms of reference

### Version 2.1 – March 2025

## Purpose of the TAG

The TAG is the professional advisory group working on behalf of Norfolk and Waveney ICB and is accountable to them. TAG has a responsibility to promote rational, evidence-based, high quality, best-value medicines optimisation across Norfolk and Waveney in order to ensure equity of access to medicines for all residents.

The TAG will make recommendations in ways that are clear, consistent, defensible and take account of regional and national guidance, using the NHS 'Ethical & Commissioning Principles' Framework and local decision-making criteria (Appendix 1)

There will be a systematic approach to whole therapeutic areas, rather looking solely at single drugs in isolation from the care pathway. There will be consideration of other health-system costs to support and facilitate service redesign.

## Key functions of the TAG

- Advise Norfolk and Waveney Integrated Care Board (ICB) and local NHS Trusts on the commissioning and provision of new medicines and new indications for medicines, including financial implications.
- Provide prescribing advice to clinicians across primary and secondary care
- Inform the development of and ratify local medicine-related clinical guidelines or pathways and shared care guidelines, coordinating care across primary and secondary care.
- Approve changes to the Norfolk and Waveney Formulary for medicines (including medical devices listed in the drug tariff) that are prescribed only in primary care or both primary and secondary care, as well as those high-cost drugs which are prescribed solely in secondary care in accordance with NICE Technology Appraisals.
- Maintain the traffic light classifications for prescribing responsibility (Appendix 2).
- Review and ratify Patient Group Directions.
- Work with local Provider Committees across Norfolk and Waveney
- Work with providers to develop prescribing policies/agreed care pathways linked to formulary changes that take account of the secondary/primary care interface and the overall cost implications of both primary and secondary care prescribing.
- Support and assist in the resolution of problems relating to medicine provision at the interfaces of care.
- Advise on the adoption of NICE Technology Appraisals (TAs). Where appropriate, advise on their implementation and suitable pathways of care. (NICE TAs may be added to the formulary prior to ratification in certain circumstances, for example TAs with 30-day implementation requirements. Funding of positive TAs is mandatory within specified timescales).
- Note and advise on the implementation of medicine-related NICE Clinical Guidelines.
- Note and advise on the implementation of NICE Highly Specialised Technologies Guidance.
- Approve and adapt for local use medicine-related national Clinical Commissioning Policies, including interim policies (the policy may be adopted where appropriate, and any necessary medicines added to the formulary prior to ratification as dictated by the timescale for implementation of the national policy).
- Review and critically appraise the evidence and place in therapy for the commissioning of new medicines which are not being considered by NICE.

- Support the East of England Priorities Advisory Committee (PAC) and work with other NHS organisations contributing to development, ratification and implementation of policies as appropriate. The TAG would usually expect to adopt the PAC recommendations with local amendment when required.
- Respond to and prioritise NHS policy developments impacting on prescribing and medicines use, including medicines safety issues.
- Define and ensure the completion, analysis and reporting of audits of use across the health system of formulary additions, against anticipated place in therapy.
- Promote information sharing and good practice to ensure that medicines are being used safely.
- Discuss and ratify recommendations from relevant sub committees such as the Prescribing Formulary Group.
- Communicate recommendations and outputs effectively to all relevant member and stakeholder organisations. Encourage and support implementation**.**
- **Note** - The TAG does not make recommendations on individual cases, nor will it consider the application of TAG advice in individual circumstances.

## Membership

Members are nominated by their organisations to provide informed, professional opinion.

NHS provider organisations are represented by a Pharmacist and a Senior Clinician with responsibilities in medicines optimisation – typically the Chair of the acute trust's Drug and Therapeutics Committee. These organisations are encouraged to nominate deputies to attend in their absence to ensure appropriate input and balance.

**Core membership**

- **TAG Chair** – GP and Speciality Advisor for Prescribing and Elective Recovery (NWICB)
- **Chief Pharmacist** or nominated deputy from acute trusts, mental health and community services:
  - Norfolk and Norwich University Hospital (NNUH)
  - James Paget University Hospital (JPUH)
  - Queen Elizabeth Hospital (QEH)
  - Norfolk and Suffolk NHS Foundation Trust (NSFT)
  - East Coast Community Healthcare (ECCH)
  - Norfolk Community Health and Care (NCHC)
- **Drug and Therapeutics Committee Chair** or nominated deputy from each of the local acute trusts listed above
- **Place-based GPs**
- **Consultant/Specialist in Public Health Medicine**
- **Associate Director of Pharmacy and Medicines Optimisation** (NWICB)
- **Head of Pharmacy and Medicines Optimisation – Quality and Safety (Deputy Chief Pharmacist)** (NWICB)
- **Head of Interface and Formulary** (NWICB)
- **Head of Population Health and Data Analysis** (NWICB)
- **Head of Clinical Experience & Delivery** (NWICB)

**Also in attendance**

- Medicines Optimisation Senior Technician – Interface and Formulary (TAG Lead)
- TAG note taker
- Healthwatch / patient representative

**Optional meeting attendance**

- Local Medical Committee representative
- Local Pharmaceutical Committee representative
- Representative from Academia

Where appropriate, the committee may invite and actively seek the views of appropriate Consultant and / or service leads for specific issues in order that decisions are made with full acknowledgement of specialist expertise and reflect the need of the local health economy.

Other healthcare professionals may attend the meetings on an ad-hoc basis to observe at the discretion of the Chair.

In the absence of the nominated Chair, another core member of the committee will deputise.

## Quoracy

The Committee will be quorate to make decisions if the following members are present:

- Seven members or their deputies, to include the **Chair** (or nominated deputy) and **three each from primary and secondary care** organisations.
- Of the primary and secondary care representation, **one from each** must be **clinical / medically trained.**

In the light of non-attendance by members / organisations resulting in the meeting not being quorate, the Chair may determine that there are appropriate people present to make decisions and allow the meeting to proceed. Some agenda items may be rescheduled if necessary. **All recommendations made when the meeting is not quorate must be circulated by email and approved by enough members to achieve quoracy.**

Some papers may receive virtual consideration by the committee. Recommendations agreed by this process will need to be ratified at a full committee meeting before they are issued.

The same minimum quoracy is required to make virtual decisions.

**'Chair's action'** may be used to review and approve any urgent business, or where minor changes to previously agreed papers are required between meetings. Any such business agreed by a Chair's action will be documented and either circulated for virtual approval or shared at the following meeting for ratification by the committee.

## Meetings and Agenda-Setting

- The TAG will be supported by the Medicines Optimisation Senior Technician – Interface and Formulary (TAG Lead), employed by NWICB.
- All of the organisations represented on the committee will be able to request agenda items for discussion at the meeting. Submission deadlines will be provided by the TAG Lead.
- Agenda and supporting documents will be confirmed by the Chair and sent to members on the Wednesday before the TAG meeting.
- The TAG meetings are held on the first Wednesday of the month virtually via Microsoft Teams.
- The ICB reserves the right to cancel or postpone a meeting at short notice due to additional work pressures or lack of agenda items.
- The ICB commit to hosting at least 6 meetings per year (April – March)
- There will be no meeting in August due to summer annual leave
- In between meetings, essential items may be emailed to committee members for comment.

## Duties and Responsibilities

### Chair

- The Chair should consider any known interests of members in advance and begin each meeting by asking for declaration of relevant interests. The Chair should take appropriate action in relation to declarations of interest.

- Ensure the smooth and timely running of meetings.
- Ensure that the case supporting recommendations is consistent with the critical appraisal of the evidence and that the rationale for the recommendations are clearly captured for the record of the meeting.
- Clarify and ensure that the rationale for each recommendation is documented and followed up.

**Members**

- Commit to regular attendance of TAG meetings. Their attendance to be regularly informed by the considered views of their service area / organisation and their peers.
- Gather their service area / organisation's view on the evidence for clinical and best-value in the papers circulated to the group in advance of the meeting.
- Critically appraise the evidence and test the rationale in the case for change, using their clinical and / or management knowledge to consider the impact on patient care.
- Promote two-way communication between TAG meetings and relevant service area / organisation.
- Communicate and champion decisions from TAG to these organisations for implementation.
- Read relevant papers / discussion documents as supplied for the meeting prior to attendance at the TAG meeting so that discussions can be informed and as concise as possible, and agreement can be reached
- Undertake work as necessary between meetings.
- Have the authority to make clinical and commissioning (where appropriate) recommendations on behalf of their constituent organisations or professional groups
- Complete an annual declaration of interests. The Chair will request any additional declarations at the beginning of each meeting which might have a bearing on their actions, views and involvement in discussions within the TAG.

## Commissioning Process for TAG recommendations

- The TAG will consult with relevant parties when developing policies and advice.
- The TAG can solicit advice from external experts and local networks
- 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. If this cannot be met, the Chair will use their discretion to take the recommendation forward. A small number of objections may be accepted - these will be recorded in the meeting notes.
- TAG members should be mindful to represent a body of opinion, not merely their own.
- Following the TAG meeting, recommendations will be forwarded to the NWICB Medicines Optimisation Programme Board for further discussion and ratification.

Recommendations made by the TAG are arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, TAG guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and / or guardian or carer.

## Output and Communication

Recommendations from the Norfolk and Waveney TAG are presented in a variety of formats including bulletins, updates to Netformulary, clinical pathways and Shared Care Agreements.

- The TAG recommendations and related commissioning decisions are made publicly available through local websites such as Knowledge NoW.
- An annual report on TAG recommendations and activities is provided to the ICS.
- Meeting notes are provided to members of the TAG and to local stakeholders.

- Commissioning decision summaries are circulated to local NHS Provider Trusts
- "TAG Update" newsletter is published and distributed through communication channels.
- Netformulary, the online formulary, is updated following ratification of recommendations.
- ICB and NHS Provider Trust intranets disseminate the TAG information.
- Reports are sent to relevant groups involved in service development.
- Through contributions to guidelines produced by others.
- ICB / ICS strategic delivery plans are updated when appropriate.
- Recommendations are reflected in the work of the ICB Medicines Optimisation Team and their responses to medicines-related queries.
- Through processes internal to the ICB and NHS Provider Trusts (e.g. Trust-based Drug and Therapeutics Committees, ICB-prescribing committees, clinical governance processes, audits etc)

It is the responsibility of all Committee members to ensure that they communicate the TAG recommendations in an appropriate manner to the organisation that they represent.

## Appeals Process

The TAG is willing to reconsider recommendations made if new significant drug information on efficacy, safety or cost is provided to the committee. If an appeal against a recommendation is made on the basis that due process has not been followed, this will be referred to the ICB Medicines Optimisation Team for consideration. The team will not re-review the evidence presented but will consider if due process has been followed. It will be for the TAG to reconsider its recommendations (or otherwise) in the light of any feedback regarding the process followed.

## Sponsorship

Members of TAG and its sub-committees are barred from accepting sponsorship from the pharmaceutical industry, either as an individual or to support an event unless the funding has been approved by the ICB sponsorship committee.

## Declarations of Interest

All interests must be declared as per **Managing Conflicts of Interest in the NHS: Guidance for staff and organisations** which states:

- **For members of advisory groups which contribute to direct or delegated decision making on the commissioning or provision of taxpayer funded services, i**ndividuals MUST declare interest and exclude themselves from any discussion / receipt of papers for any related agenda item.

- If a member has an actual or potential interest the chair should consider the following approaches and ensure that the reason for the chosen action is documented in minutes or records:

    - Requiring the member to not attend the meeting
    - Ensuring that the member does not receive meeting papers relating to the nature of their interest
    - Requiring the member to not attend all or part of the discussion and decision on the related matter
    - Noting the nature and extent of the interest, but judging it appropriate to allow the member to remain and participate
    - Removing the member from the group or process altogether

# 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**<br>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.**<br>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.**<br>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**<br>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**<br>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.**<br>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**<br>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**<br>This covers most drugs on the primary care formulary |
| SWITCH | **Not recommended for prescribing. Switch to cost-effective alternative**<br>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**<br>Drugs in this category will be available to buy over the counter. |
| DM | **Discontinued Medicines**<br>This category will be under constant review and updated regularly |

**Therapeutics Advisory Group**

Improving lives together
Norfolk and Waveney Integrated Care System

| | |
|---|---|
| **Title** | TAG Terms of Reference |
| **Description of policy** | To inform healthcare professionals |
| **Scope** | |
| **Prepared by** | Therapeutics Advisory Group |
| **Evidence base / Legislation** | Level of Evidence:<br>*A. based on national research-based evidence and is considered best evidence*<br>***B. mix of national and local consensus***<br>*C. based on local good practice and consensus in the absence of national research based information.* |
| **Dissemination** | Is there any reason why any part of this document should not be available on the public website? ☐ Yes / No ☒ |
| **Approved by** | *TAG* |
| **Authorised by** | *MOPB* |
| **Review date and by whom** | TAG – April 2027 |
| **Date of issue** | April 2025 |

| Version | Date | Author | Status | Comment |
|---|---|---|---|---|
| 1.0 | Oct 2023 | TAG Lead Technician, NWICB | Draft | New Terms of Reference developed following changes to TAG and comments received at earlier meetings |
| 2.0 | Dec 2023 | TAG Lead Technician, NWICB | Draft | Updated following comments received from TAG in Nov 2023. Acknowledgement to Terms of Reference document developed by Bedford, Luton and Milton Keynes APC |
| 2.1 | March 2025 | Senior Technician, Interface and Formulary, NWICB | Final | Document reviewed and supported by TAG |
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