North of Tyne, Gateshead and North Cumbria Area Prescribing Committee
Terms of Reference
July 2021

The Terms of Reference will be formally reviewed every 2 years.

Purpose of Committee

To facilitate cross-organisational, rational clinical decision making, following a proper consideration of the evidence[1] and to act as a forum to address medicines optimisation issues which affect primary care, acute hospitals, mental health, local authority, learning disabilities and social care.
The Area Prescribing Committee (APC) will serve the following participating organisations:

Gateshead Health NHS Foundation Trust
Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH)
NHS Newcastle Gateshead Clinical Commissioning Group (NHS NGCCG)
NHS North Tyneside Clinical Commissioning Group (NHS NTCCG)
NHS Northumberland Clinical Commissioning Group (NHS NCCG)
Cumbria, Northumberland Tyne and Wear NHS Foundation Trust (CNTW)
Northumbria Healthcare NHS Foundation Trust (NHCT)
North Cumbria CCG
North Cumbria Integrated Care NHS Foundation Trust

Membership

The Committee shall comprise as a minimum:

- Medical, nursing, pharmacy, commissioning and other staff from participating organisations to ensure a 'good mix' of viewpoints reflecting different professional, clinical, educational, management, commissioning and organisational backgrounds (as deemed appropriate by the Committee and the Chief Executives of the participating organisations). Each participating organisation is responsible for ensuring that it is well represented.
- Those staff with responsibility for developing/managing the shared formulary
- At least one representative from each provider organisation
- At least one representative from each CCG
- Representatives from commissioning support organisations as required by CCGs
- Chairs of sub-groups of the APC
- Paediatric representation
- A community pharmacist nominated by the Local Pharmaceutical Committees.
- A GP nominated by the Local Medical Committee
- A lay person as a patient representative.
- Other individuals will be co-opted as required e.g. Local Authority, NHS England, AHSN, Strategic Clinical Networks

[1] NHS constitution

No member may fulfill two of the above roles at the same meeting.
A Chair should be elected by the Committee. The period of chairmanship should be 3 years.
The committee should also elect a Vice Chair. The tenure for a Vice Chair is 3 years.
The Chair and Vice Chair positions should be elected from different organisations and represent both provider and commissioner organisations (i.e. if the Chair is a commissioner member then the Vice Chair should be a provider member, or vice versa).
The committee should elect a professional secretary. The tenure for the professional secretary is 3 years.
Officers may stand for re-election.
To be in quorum, the Chair or Vice Chair has to be present and at least 6 other members with a minimum of 2 CCGs represented. It is the responsibility of participating organisations to ensure that they are adequately represented, with deputies attending meetings where appropriate. The professional secretary must be present or a suitable deputy identified.
If a meeting is not quorate all decisions/recommendations taken at that meeting must be ratified by the absent members prior to implementation via email.

Conditions of Membership

Members must endeavour to send a representative or a deputy if they cannot attend.

Members will be expected to have complied with their organisational declarations of interest procedures. Current interests that might affect specific recommendations and/or decisions of the committee must also be declared at the start of each meeting. This will be noted in the minutes. If an individual is in any doubt whatsoever about whether there is a conflict of interest, or one that might be perceived as such by others, then he/she should state this. The principles outlined by NICE[2] relating to such declarations must be adhered to. Members declaring a conflict of interest may be excluded from discussions/decision making as deemed appropriate by the Chair. As members will be truly representative, membership carries with it a burden of dissemination/ communication/implementation within their different organisations. Members may resign from the committee at any time by communicating this to the Chair or professional secretary.

Objectives and Functions

Adherence to the recommendations made by the APC, and the consequences of implementation, are the responsibility of member organisations.

The Area Prescribing Committee provides a forum to undertake (either collectively as a group or individually through its members) the following:

- To secure the commitment of member organisations and staff to the use of a rational, cost effective and safe system of drug usage.

[2] https://www.nice.org.uk/media/default/about/who-we-are/policies-and-procedures/code-of-practice-for-declaring-and-managing-conflicts-of-interest.pdf

- To develop/manage a shared formulary for use across participating organisations. The APC retains the overarching responsibility for the North of Tyne, Gateshead and North Cumbria formulary. The formulary comprises a list of drugs that are recommended for initiation by prescribers. The APC ensures that a system operates effectively to manage the introduction (or otherwise) of novel drugs, formulations and materials (whether by consultant request or otherwise).
- To undertake ongoing review of the formulary in a planned and timely manner.
- To recommend, based on the available evidence, the place in treatment locally of new drugs/formulations, or of new indications for existing drugs.
- To be the mechanism for ensuring that the medicines related aspects of national guidelines and NICE are considered as part of local implementation processes and are incorporated in the development of prescribing guidelines.
- To ensure that medicines with a positive NICE TAG, or EAMS approval, recommendation are available for patients, when deemed the appropriate clinical choice for them, no later than 90 days post NICE publication for TAGs, unless the publication specifically notes a shorter period, and as defined in the EAMS scheme.
- To ensure NHS England and NTAG recommendations relating to medicines are reflected in the North of Tyne, Gateshead & North Cumbria formulary. Note: The committee will not consider products which are due to have decisions made about them by either of the above organisations within 6 months.
- To consider recommendations made by the Regional Medicines Optimisation Committees (RMOCs)
- To promote compliance to the formulary by the participating organisations.
- To instruct the audit/review of formulary decisions as appropriate to ensure that any conditions stipulated as part of the formulary approval have been adhered to.
- To promote evidence-based decision making particularly with relevance to the managed entry of new drugs.
- To facilitate communication, joint decision making and effective working between the participating organisations.
- To identify and alert all stakeholders to financial pressures associated with drug use.
- To develop and promote the use of shared care guidelines. To clarify who should undertake the prescribing of different categories of medicines and to maintain/promote the ‘traffic light system’ currently in use.
- To request the development and review of guidelines where they have a substantial impact on items prescribable on FP10.
- To identify issues and recommend change in policy to improve safety, quality, effectiveness and economy throughout the medicines optimisation process, especially that occurring across the primary/secondary care interface. To monitor implementation.
- To liaise with other groups/committees in participating organisations, as necessary, including those responsible for finance, clinical governance, clinical effectiveness, clinical audit, clinical risk and education and training.
- To give advice and/or make recommendations on the drug related aspects of NICE or other national guidance.

- To engage with commissioning and financial managers at an appropriate level of seniority and align local formulary decisions within the framework of clinical commissioning.
- Identify where barriers lie that may delay the speed of adoption of medicines into the economy.
- The APC may be required to consider formulary requests for treatments which are the responsibility, or otherwise within the remit, of specialised commissioning, or which may span both specialised and non-specialised commissioning. The specialised commissioning team may require that a treatment for a specific indication satisfies all provider governance procedures and processes. In many cases, therefore, this means that a treatment for a specific indication must be accepted on the appropriate formulary. When such formulary requests are brought to the APC the position of the specialised commissioning team will be stated.

The remit of the committee includes all prescribable products, including related pharmaceutical products, that are used like medicines but are classified as medical devices, borderline substances and prescribable nutritional supplements.

The committee does not consider clinical trials and clinical trial products.

Reporting

Relevant committee and sub-committee documents, meeting agendas and minutes will be stored electronically for at least 3 years and accessible to all participating organisations on request.

Meetings

The Committee will normally meet every three months. However, additional meetings may be arranged should a need arise.
Documents for meetings will be circulated to members at least one week prior to the meeting. A shorter period can be accepted in exceptional circumstances and by prior agreement with the Chair.

Decision Making

Recommendations will take into consideration both clinical and cost-effectiveness relative to other interventions commissioned for the population, as well as affordability and consequences of implementation. Commercially agreed discounts or rebate schemes will only be considered once a decision based on clinical effectiveness is reached.
Participating organisations will need to ensure that they have appropriate corporate governance processes in place to ensure that the recommendations made by the APC are considered in the correct manner and endorsed as appropriate.
Recommendations are reached by consensus, taking into account declarations of interest. Any dissent against a recommendation will be noted.

Adoption of NICE Technology Appraised Drugs into the Formulary

If there is more than one NICE-approved medicine for a condition, the APC will not recommend that any one of them is used routinely in preference to the others (unless an order of preference is stated in the TAs or HSTs). Similarly, the APC will not recommend that a medicine that has not been assessed by NICE is used routinely in preference to a NICE-approved medicine.
The committee may however suggest to healthcare professionals that a particular medicine is preferred locally. Reasons for this could include cost, if a medicine is cheaper than other options, to reflect local clinical expert opinion or to achieve optimal stock control. Any such local recommendation must only be taken into account, however, after a patient and prescriber have discussed all treatment options and only if they have no preference about which medicine they want to use.[3]

Appeals

Applicants of new products/formulations can appeal against the recommendations by the committee. An intention to appeal should be made in writing to the professional secretary within 4 weeks of notification of the original recommendation.
Grounds for appeal are as follows:
 Significant new clinical evidence available to support application not considered as part of original application.
 Decision appears to be based on inaccurate or incomplete information.
 The process for the handling of new drug requests has not been followed.
Appeals that meet the criteria above will be heard at the next appropriate APC meeting where a total of twenty minutes will be allowed to hear the appeal. This would normally comprise a brief presentation by the appellant, of any new information not previously considered, or the reason the applicant feels the original decision making process was flawed, followed by questions by the committee. The appellant will be informed of the outcome of the appeal by the professional secretary within one week of the meeting.

Sub Committees

The following sub-committees/groups will carry out specific programs of work for the main committee:

- **Formulary Sub-Committee** – This group considers new product applications (for all prescribable products) and leads the development of the shared formulary. A recommendation to approve, defer or reject an application, with a summary of evidence, is presented to the APC. The approval of the APC is also sought for any proposed major change in policy.
- **Medicines Guideline and Use Group** – This group is responsible for:
  - The development and maintenance of a list that classifies locally approved medicines into the RED, AMBER, GREEN PLUS or GREEN categories.
  - Coordinating the development and review of guidelines where they have a substantial impact on items prescribable on FP10.
  - the development of medicines related Shared Care Guidelines

[3] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/Frequently-asked-questions-on-NICE-compliance.pdf

- recommendations regarding the content and format of information leaflets on drugs included in the GREEN PLUS classification where deemed appropriate
- Audit/review of formulary decisions to ensure that any conditions stipulated as part of formulary approval have been adhered to.

The group links, as required, with other committees and organisations to ensure that any changes are comprehensively considered and delivered and to ensure consistency of approach and achieve economies of scale where possible. It also seeks to avoid duplication of work where national guidance has been issued.