Humber
Area Prescribing Committee

TERMS OF REFERENCE

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Author/Contact: Jane Morgan

Purpose

To establish a collective strategic and ethical approach to prescribing & medicines optimisation issues across the Humber health community, in relation to the safe, clinical, and cost-effective use of medicines. Facilitate cross-organisational, rational clinical decision making, following appropriate consideration of any evidence 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 and identify associated resource implications.

The aim is to ensure robust governance arrangements are in place for the effective delivery of medicine policy within a framework of the whole patient care pathway. Area prescribing committee (APC) members will make commissioning decisions/ recommendations on prescribing issues on behalf of member organisations, while monitoring uptake and compliance by all APC member organisations of decisions made by the APC; to provide a forum for the raising and resolution of non-compliance of an APC member organisation with APC decisions and other commissioning/contracting issues related to prescribing or medicines optimisation.

Membership

Membership is drawn from senior positions within each organisation represented and must fulfil the following responsibilities:

- Represent the views of their constituent organisations and professional groups
- Ensure that decisions taken by the committee are communicated and implemented by their organisation and professional groups
- Commit to attend meetings regularly
- Nominate a deputy if they cannot attend
- Contribute agenda items
- Commit to work outside the meeting where required
- Come to meetings prepared with all documents and ready to contribute to the debate and vote, when required, on behalf of and with the authority of their organisations.
- Declare any outside financial or personal conflicts of interest at the start of each meeting
- Review the terms of reference biannually

The Committee should 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.
- Members with responsibility for developing/managing the shared formulary
- At least one representative from each provider organisation
- At least one representative from each place within the Humber
- Representatives from Medicines Optimisation Teams
- Chairs of sub-groups of the APC

- Paediatric representation
- A community pharmacist nominated by the Local Pharmaceutical Committee (LPC).
- A medic representative nominated by the Local Medical Committee (LMC).
- A lay person as a patient representative.
- Other individuals will be co-opted as required e.g. Local Authority, NHS England, Academic Health Science Networks (AHSN), Strategic Clinical Networks

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 Chair will provide a written report for the Boards of all trusts on an annual basis.
- 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 have a professional secretary.
- The administrative and secretarial services to the committee will be provided by Hull University Teaching Hospitals and funded as agreed between it and all other affiliated organisations which are members of the Humber Area Prescribing Committee.
- Officers may stand for re-election
- Quoracy:
    - Chair or Vice Chair
    - Two secondary care doctors
    - Two pharmacists representing primary care
    - Two pharmacists representing secondary care
    - ICS GP Clinical Lead for Primary Care
    - One further GP representative e.g. LMC, GP.
- 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

Co-opted members

Additional members may be invited to attend the meeting for the purpose of providing advice and/or clarification to the group, to include:

- Commissioning managers from member organisations
- Infection Control specialist – must be present / consulted for decisions involving use of antimicrobials
- Procurement representative
- Specialist commissioning representative
- Clinical network representative
- Individual specialists, including nursing, in relation to specific agenda items, with prior agreement of committee

- Additional members of providers drug and therapeutics committees to support discussions

Deputising arrangements

Members must endeavour to send a representative or a deputy if they cannot attend. Each member can appoint a nominated deputy to attend meetings on their behalf. Members must send a representative with appropriate authority and experience, wherever possible, if they are unable to attend.

Accountability and Reporting Arrangements

- Each organisation will need to agree accountability and reporting arrangements for the Committee
- The committee will need to ensure clear links/accountability with Commissioning, Finance groups and Governance Groups
- The decisions made by the APC and the consequences of implementation are binding on member organisations unless stated otherwise at the time of meetings and recorded formally in the minutes

Conditions of Membership

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[1] 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 and implementation within their different organisations. Members may resign from the committee at any time by communicating this to the Chair or professional secretary.

Recommendation/ 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.

- When a core member is unable to attend, providing the meeting is quorum, a member may vote by proxy or select a suitable representative to attend the meeting and vote on their behalf.
- The Formulary should be updated within 2 weeks of decisions being made and the information will be disseminated to the Trusts involved and other relevant parties.

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).
- 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 considered, after a patient and prescriber have discussed all treatment options and only if they have no preference about which medicine, they want to use[2].

Subgroups

- Two subgroup/ sub-committees of the APC exist:
    - Medicines Guideline and Use Group
    - Formulary Sub-committee

The Medicines Guideline and Use Group is responsible for:

- 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
- Recommendations regarding the content and format of information leaflets on drugs included that are specialist initiated or guideline led where deemed appropriate
- Audit/review of formulary decisions to ensure that any conditions stipulated as part of formulary approval have been adhered to.

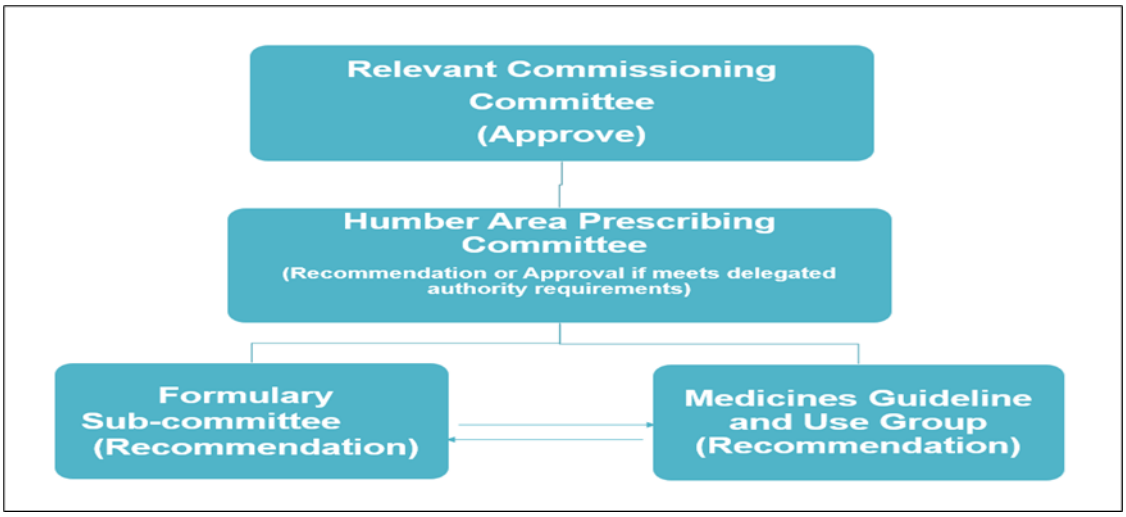
The group links, as required, with other committees and organisations to ensure that any changes are comprehensively considered and delivered and to ensure consistency of approach and achieve economies of scale where possible.

The Formulary sub-committee is responsible for:

- The development and maintenance of a list that classifies locally approved medicines into the appropriate traffic light classifications
- New product applications (for all prescribable products) and leading the development of the shared formulary.

- The alignment of HERPC and NLAPC formularies and ongoing review of the formulary
- A recommendation to approve, defer or reject an application, with a rationale for the recommendation, to be presented to the APC.
- New line requests should have been considered by the relevant D&T process and considered the evidence to support the request. The requests should also have been clinically reviewed by a pharmacist as part of the D&T process prior to being submitted to the formulary committee.

Interdependence of APC and subgroups:



Duties

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

The APC 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
- To recommend approval of prescribing policies, formularies, shared care agreements and prescribing guidelines/frameworks for implementation across primary and secondary care and establish a robust governance framework for the delivery of medicines policy
- To provide advice and input into the commissioning and contracting process for the introduction of new drugs and priorities for funding. Establish a consensus, based on the available evidence, regarding the place in care pathways for relevant new drugs/formulations, or for existing drugs with new indications, and ensure that such advice is disseminated to all stakeholder organisations
- To establish, maintain and monitor a joint formulary between the member organisations. Examine the clinical and cost effectiveness of different preparations within clinical areas and agree on 'drugs of choice' to be applied

consistently across both primary and secondary care. The APC will accept onto the formulary all drugs approved by NICE plus 90 days

- To establish, maintain and review a “Traffic Light” Classification of medicines
- To advise and assist local organisations and other providers in the formation, development, and implementation of plans for the introduction of new treatments, local policies, and national guidance with implications for prescribing
- To provide advice and recommendations to the commissioning process in partner organisations on the resource implications of new prescribing policy, to ensure that prescribing and medicines use issues are given due weight in wider healthcare planning and service delivery agreements locally
- To make recommendations to assist in the resolution of problems relating to prescribing at the interface between primary, secondary, tertiary, and social care
- To develop effective communication channels with neighbouring APCs to enable sharing of proposed advice where this might impact significantly on another locality
- To respond in a timely manner to local, regional, and national changes in NHS policy that will affect prescribing and medicines optimisation locally, including NICE guidance, NICE Technology Appraisals (TA) and National Service Frameworks. Provide advice on the local implementation of such policy within the health community
- To act as a focus for developing and refining local professional opinion on prescribable products and associated pharmaceutical issues, and to convey such opinions to all relevant organisations and bodies, including those not directly represented on the committee
- To make recommendations on medicines optimisation governance standards and support the inclusion of these into service agreements with local providers of primary, secondary, tertiary, and social care
- To consider recommendations made by the Regional Medicines Optimisation Committees (RMOCs)
- To advise on policy and procedures for the clinically appropriate use of medicines outside their marketing authorisation
- To identify and alert all stakeholders to financial pressures associated with drug 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 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
- To liaise with the Local Medical Committee (LMC) and Local Pharmaceutical Committee (LPC) as appropriate
- 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
- To provide local advice on working with the Pharmaceutical Industry and Sponsorship and register declarations of interest for committee members
- To receive summary information on research and development activity across the health community and identify potential implications for prescribing as appropriate
- To review each section of the Formulary on a bi-yearly basis and ensure that any new evidence, NICE Clinical Guidelines and TA are acted upon promptly
- To ensure patient safety is incorporated as a specific issue in all decisions and recommendations made by the committee, including the safety aspects of the way medicines are used in practice
- Consideration of actions needed across the interface in response to patient safety alerts

Other items will be prioritised according to following criteria

- Severity of disease and patient numbers affected
- Gaps in treatment or other available treatments
- Inappropriate variation in local current practice

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.

Documentation

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. Draft minutes of the meeting and summary sheet will be circulated to members within one week of each meeting, and decisions disseminated within 2 weeks of the meeting. 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.

Frequency of meetings

- Humber APC meetings will be bi-monthly (virtually or in person). However, additional meetings may be arranged should the need arise.
- Formulary Sub-committee meetings will be monthly (virtually or in person)
- Medicines Guideline and Use Group meetings will be monthly (virtually or in person)

Voting

The committee will aim to make recommendations where a consensus is reached between all representatives. Where a consensus is not reached, the Chair and Vice-chair have the right to defer any disputed recommendations to:

- ERYCCG -Service Redesign and Planning Committee (clinical policy subgroup)
- HULLCCG – Planning and Commissioning Committee
- NLCCG – Planning and Commissioning Committee
- NELCCG – Primary Care Commissioning Committee

This may result in a different commissioning decision for the different CCGs.

Appeals

Applicants of new products/formulations can appeal against the recommendations by the committee. In circumstances in which significant new information becomes available or a decision was based on incomplete or inaccurate information, the committee will review the new information and reconsider their recommendation or decision at the next meeting. An intention to appeal should be made in writing within 4 weeks of notification of the original recommendation.

Grounds for appeal are as follows:

- Significant clinical evidence available at the time 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.

In circumstances where the committee is judged not to have followed the process for making a recommendation or decision published in the Terms of Reference, concerns should be raised with the Chair of the committee. Where concerns remain, unresolved arrangements will be made for a review of the decision-making process to be undertaken by the North Yorkshire and York Area Prescribing Committee or equivalent organisation, as per NICE Medicines Practice Guidelines[3].

Equality Act (2010)

We are committed to promoting a pro-active and inclusive approach to equality which supports and encourages an inclusive culture which values diversity.

- Is committed to building a workforce which is valued and whose diversity reflects the community it serves, allowing organisations to enable all staff to achieve their full potential in an environment characterised by dignity and mutual respect.

- Aims to design and provide services, implement policies and make decisions that meet the diverse needs of our patients and their carers the general population we serve and our workforce, ensuring that none are placed at a disadvantage.
- We therefore strive to ensure that in both employment and service provision no individual is discriminated against or treated less favourably by reason of age, disability, gender, pregnancy or maternity, marital status or civil partnership, race, religion or belief, sexual orientation or transgender (Equality Act 2010).

References

[1] 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

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

[3] https://www.nice.org.uk/guidance/mpg1/chapter/recommendations#reconsidering-and-appealing-local-formulary-decisions

Other sources of information;

- North of Tyne, Gateshead and North Cumbria Area Prescribing Committee, Terms of Reference, July 2020.
- Northern Lincolnshire Area Prescribing Committee, Terms of Reference, September 2020
- Hull and East Riding Prescribing Committee, Terms of Reference, January 2016, Reviewed March 2018
- North Yorkshire & York Area Prescribing Committee, Terms of Reference
- Equality Act 2010 https://www.gov.uk/guidance/equality-act-2010-guidance