

Terms of reference

Formulary and Guidelines Subgroup

Introduction

The NHS Cheshire and Merseyside Area Prescribing Group (APG) will provide a platform for consensus decision-making processes relating to the use of medicines across Cheshire and Merseyside.

The Cheshire and Merseyside APG will promote joint working and ensure a consistent and transparent approach to local decision-making for medicines across the local health and care system, in compliance with the principles of the NHS Constitution, and equity in access to medicines and optimisation of medicines use. The Formulary and Guidelines Subgroup (the subgroup), when making recommendations to the APG, will ensure that patient outcomes, safety considerations and cost-effectiveness are at the forefront of the decision-making process.

The APG will make recommendations to NHS Cheshire and Merseyside integrated care board (ICB) for ratification and adoption in order to ensure the best use of medicines and associated resources across the local health and care system.

Role of the subgroup

- 1) Maintain the Cheshire and Merseyside Medicines Formulary including a process for requests for new inclusions / deletions and the process for timely update of the Formulary.
- 2) Identify any need for medicines guidelines in the Cheshire and Merseyside health economy which may have significant clinical or financial impact and produce such guidelines.
- 3) Review all guidelines to ensure incorporation of NICE-approved therapies and guidelines.
- 4) Prioritise, produce, and implement a work plan for maintenance of the formulary and guidelines to address any areas identified which may have significant clinical or financial impact on the Cheshire and Merseyside health economy, in agreement with Commissioner and Provider member organisations lead pharmacists.
- 5) Indicate the prescribing responsibility for each drug by applying the agreed Red/Amber/Green (RAG) criteria consistently.
- 6) Review applications from healthcare professionals to the APG for a new formulations of existing formulary drugs, or a change in the Formulary status of an existing medicine. The New Medicines Subgroup may liaise with Formulary and Guidelines Subgroup where a new medicine that is a member of a drug pharmacological class with several representatives in formulary already may have an impact on existing formulary choices. (See details in footnote below).
- 7) Consider cost-effectiveness alongside clinical-effectiveness where robust cost-effectiveness information is available, and to provide an estimate of potential cost-impact for recommendations where possible.
- 8) Work closely with other sub-groups on the production of medicines guidelines.
- 9) Review and update existing documents at appropriate intervals.
- 10) Ensure that member organisations are consulted according to local arrangements when recommendations are in development.
- 11) Consult and engage local specialists, including clinical networks, in the review of each section of the formulary and in the review and production of medicines guidelines.

- 12) Publish the formulary, guidelines and updates using media to ensure maximum accessibility, ease of use and impact.
- 13) Support the review of adherence to the formulary and local medicines guidelines.
- 14) Undertake specific projects relevant to the management of medicines within the Cheshire and Merseyside health economy as requested by the APG.
- 15) Ensure that any recommendations taken to the APG are consistent with the principles contained in the NHS Constitution and the APG policy on Prioritisation of Medicines.

Footnote:

Work will be allocated to New Medicines Subgroup (NMSG) or Formulary and Guidelines Subgroup (FGSG) according to the principles below:

NMSG will action:

1. New chemical entities (except 4th or subsequent member of a drug pharmacological class with several representatives in formulary already when the emphasis is on comparison with existing drugs in the class and will be actioned by FGSG)
2. All drugs/ new indication subject to NICE TA's
3. Major new indication in new therapeutic area* for existing drug (e.g. dexamethasone intravitreal implant, inhaled insulin)
4. Newly licensed versions of previously unlicensed products that were not in the formulary previously

FGSG will action:

1. New formulations of products already in the formulary for the same indication e.g. additional brands, devices, combination products, m/r formulations – including licensed products of previously unlicensed products already in formulary for that indication
2. New indications (licensed) for existing formulary products (except where indication is a major new indication in new therapeutic area* and constitutes NMSG point 3 above)
3. 4th or subsequent member of a drug pharmacological class with several representatives in formulary already
4. Unlicensed indications for existing formulary products N.B. FGSG cannot cover all potential unlicensed uses for all drugs so priority given to common or problematic uses

N.B. Items marked * require an element of interpretation, and allocation to NMSG / FGSG after discussion between sub-group Chairs.

Responsibilities of members

Members who are unable to attend should send a nominated deputy where possible.

If attendance by subgroup member or nominated deputy is not possible, the subgroup member should ensure they submit comments relevant to agenda items on behalf of their organisation, by email to the Chair prior to the meeting.

Members represent their organisation in a professional capacity and are expected to reflect their organisation's position in their input to discussions.

There is an expectation that attending members engage with subgroup business:

- Members should be familiar with and adhere to the APG policy.
- Providing insight and information as requested to support document authors.
- Familiarise themselves with the agenda and supporting documents before the meeting.
- Represent their organisation's perspective where relevant.
- Undertake work to agreed timescales as necessary between meetings.
- Discussing agenda items with relevant colleagues and recognised specialists before and after the subgroup meeting
- Relay consultation feedback to relevant colleagues within their organisation.
- Inform subgroup Chair of any updates to circulation lists.
- The subgroup and Chair can agree to invite non-member specialists to attend the meeting as guests to support discussions and the development of documents.
- Identify potential implementation issues and escalate via appropriate route to ICB in advance of APG meeting.
- Task and finish groups will be convened where required for relevant items.
- All members are expected to participate in appropriate document authoring and proof reading.

Relevant colleagues may be clinician specialists, consultation responders, and APG attendees.

CSU responsibilities

- Scheduling subgroup meetings, informing subgroup members and circulating calendar invites.
- Maintaining up to date circulation lists.
- Compiling and circulating meeting agendas within agreed timescales.
- Chairing meetings and arranging deputy when Chair isn't available.
- Produce minutes that clearly specify actions and circulate in a timely manner.
- Differences of opinion and subsequent decision should be clearly documented in the minutes and include the rationale.
- Co-ordinate requests for additional information from members in order to support development of subgroup documents.
- Maintain standardised document templates for all document types.
- Provide templates / previous Word versions to document authors.
- Maintain list of contacts in specialist networks and facilitate their inclusion where relevant.

- Ensure that subgroup documents go on to consultation email and send collated feedback to the document author to address feedback prior to the next subgroup meeting. Circulate finalised document and feedback to members to inform their organisation’s consultees prior to the APG meeting.
- Ensure the Decision Support Summary has been completed, with input from the subgroup, prior to the APG meeting.
- Present subgroup documents at APG meetings.
- Finalise agreed documents for website upload.

Confidentiality and information sharing

The subgroup does not control or process any data. Where a new function for the subgroup would be expected to require it to be a data controller or processor, a data protection impact assessment (DPIA) will first be undertaken.

Draft documents are confidential to the NHS and should not be otherwise shared.

Declaration of interest

As part of the APG commitment to openness and transparency in its work and decision making, all APG and subgroup members, guest attendees and relevant specialists are required to declare any actual or potential conflicts of interest in accordance with the NHS Cheshire and Merseyside ICB conflicts of interest policy. This is in addition to completing and submitting an annual declarations of interest form.

Membership

A total of 29 people will be members of the subgroup, of which 27 are voting members.

Member	Comments	Number
Chair	Midlands and Lancashire Commissioning Support Unit senior pharmacist. Non-voting *	1
NHS trusts	One representative, or their nominated deputy, from each trust including acute, specialist, mental health, and community providers. Attendance as per agenda for specialist trusts.**	8 acute and 10 others
NHS primary care	One representative, or their nominated deputy, from each place.	9
Minute secretary	Midlands and Lancashire Commissioning Support Unit In attendance	1

* Non-voting members can engage in and influence the subgroup discussions. However, in the case of the subgroup chair calling a formal vote they will not be able to cast a vote or further influence the subgroup decision.

** Specialist, mental health, and community provider trusts are required to attend subgroup meetings only when agenda items are relevant.

Organisations represented at Cheshire and Merseyside APG

NHS acute trusts	Other NHS trusts	Primary care places
Countess of Chester Hospital NHS Foundation Trust	Alder Hey Children's NHS Foundation Trust **	Cheshire West
East Cheshire NHS Trust	Bridgewater Community Healthcare NHS Trust**	Cheshire East
Liverpool University Hospitals NHS Foundation Trust	Cheshire and Wirral Partnership NHS Foundation Trust **	Halton
Mersey and West Lancashire Teaching Hospitals NHS Trust Southport and Ormskirk	The Clatterbridge Cancer Centre NHS Foundation Trust	Knowsley
Mersey and West Lancashire Teaching Hospitals NHS Trust St Helens and Knowsley	Liverpool Heart and Chest Hospital NHS Foundation Trust **	Liverpool
Mid-Cheshire Hospitals NHS Foundation Trust	Liverpool Women's NHS Foundation Trust **	St Helens
Warrington and Halton Hospitals NHS Foundation Trust	Mersey Care NHS Foundation Trust **	Sefton
Wirral University Teaching Hospitals NHS Foundation Trust	Mersey Care, Liverpool and South Sefton Community Services Division **	Warrington
	The Walton Centre NHS Foundation Trust **	Wirral
	Wirral Community NHS Foundation Trust*	

** Specialist Trusts and community providers are required to attend subgroup meetings only when agenda items are relevant.

Frequency of meetings

Meetings will be held monthly or at a frequency determined by the subgroup.

Quorum

The subgroup will be quorate if ten representatives are present, five from primary care and five from provider trusts including relevant specialist trusts according to agenda items. A member may represent more than one organisation.

Subgroup decisions require a majority of two thirds of attending members at quorate meetings. The decision support summary will be used to capture the range of views expressed, which will be reported to APG.

If the meeting is not quorate, the subgroup will be made aware, and this will be clearly noted on the minutes. In the event, the subgroup may choose to satisfy its quorum either by email to absent members after the meeting or at the next quorate meeting.

Secretariat

Operational oversight and administrative duties will be provided by Midlands and Lancashire Commissioning Support Unit.

Governance and accountability

The subgroup is responsible for providing unbiased advice to help the APG inform stakeholder organisations about using the most effective and efficient management of resources to achieve improved clinical outcomes.

Subgroup recommendations are subject to a consultation process to accommodate the views of NHS Cheshire and Merseyside stakeholders before being reported to an APG meeting.

Standing items

The agenda for each meeting will include the following standing items:

- Welcome and apologies
- Declarations of interest
- Quoracy
- Minutes of the last meeting
- Matters arising
- APG reports
- Any other business
- Date and time of the next meeting

Reporting and communications

The subgroup is accountable to and reports to the Cheshire and Merseyside APG.

Before making recommendations to the APG, the subgroup will share draft documents with NHS trust stakeholders and primary care stakeholders as part of the APG consultation process. The subgroup may also contact stakeholders directly before consultation, for example, where a document is expected to court controversy or where greater insight is needed than subgroup members can provide.

Finalised draft documents will be reported to the APG before final approval for implementation at the Cheshire and Merseyside ICB.

Minutes of the subgroup meeting are shared with members but are not made publicly available except upon request and in accordance with the MLCSU Freedom of Information policy.