

Terms of reference

New Medicines 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 New Medicines 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) Collate and appraise the evidence then provide evidence-based recommendations and proposed RAG rating to the Cheshire and Merseyside APG regarding the introduction of new medicines, or new indications for existing medicines, into the Cheshire and Merseyside health economy.
- 2) Use horizon scanning to prioritise and plan the introduction of new drugs, and new indications and formulations of existing drugs into the Cheshire and Merseyside health economy.
- 3) Prioritise and assist with planning for the introduction of new medicines, changes in license of existing medicines, and implementation of national guidance which has the potential for significant clinical or financial impact on the Cheshire and Merseyside health economy.
- 4) Consider the need for a 'grey' holding statement for newly launched drugs/indications on a case-by-case basis. Holding statements will not routinely be issued for hospital-only in-tariff-drugs, or for new formulations of existing formulary drugs with existing indications.
- 5) Indicate the prescribing responsibility for each drug by applying the agreed Red/Amber/Green (RAG) criteria consistently.
- 6) 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.
- 7) Co-ordinate the timely introduction of NICE Technology Appraisals into the Cheshire and Merseyside health economy, for medicines commissioned by NHS Cheshire and Merseyside Integrated Care System (ICS).
- 8) Receive and prioritise in-year applications from healthcare professionals within the Cheshire and Merseyside health economy for a new medicine or new indication for an existing medicine.
- 9) Ensure that member organisations are consulted according to local arrangements when recommendations are in development, with particular relation to their place in therapy and RAG rating within the Cheshire and Merseyside health economy.
- 10) Make recommendations to the Cheshire and Merseyside APG for managing medicines in relation to the Payment by Results tariff and exclusions.

- 11) Liaise with the other Cheshire and Merseyside APG subgroups as appropriate to ensure consistency of recommendations and within formulary and guidelines, and to inform the on-going updating of the Cheshire and Merseyside APG website and formulary.
- 12) Ensure that any recommendations taken to the Cheshire and Merseyside APG comply with the principles of the NHS Constitution.
- 13) Ensure that member organisations are consulted according to local arrangements when recommendations are in development.
- 14) Review and update existing documents at appropriate intervals.
- 15) Provide updates of the Subgroup work programme to the Cheshire and Merseyside APG when requested.
- 16) Identify additional sources of specialist advice in the appropriate fields, including hospital specialists and GPs with a special interest as required.

Allocation of work between subgroups

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

NMSG will action:

- New chemical entities (except fourth or subsequent member of a drug 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).
- All drugs / new indications subject to NICE TAs.
- Major new indication in new therapeutic area* for existing drug (e.g. dexamethasone intravitreal implant, inhaled insulin).
- Newly licensed versions of previously unlicensed products that were not in the formulary previously.

FGSG will action:

- 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.
- 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).
- 4th or subsequent member of a drug pharmacological class with several representatives in formulary already.
- 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 colleagues and recognised specialists before and after the subgroup meeting, where relevant.
- 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 subgroup 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 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 | The Clatterbridge Cancer Centre NHS Foundation Trust** | Halton |
| Mid-Cheshire Hospitals NHS Foundation Trust | Cheshire and Wirral Partnership NHS Foundation Trust** | Knowsley |
| Mersey and West Lancashire Teaching Hospitals NHS Trust - Southport and Ormskirk | Liverpool Heart and Chest Hospital NHS Foundation Trust** | Liverpool |
| Mersey and West Lancashire Teaching Hospitals NHS Trust - St Helens and Knowsley | Liverpool Women's NHS Foundation Trust** | St Helens |
| Warrington and Halton Hospitals NHS Foundation Trust | Mersey Care NHS Foundation Trust** | Sefton |

| NHS acute trusts | Other NHS trusts | Primary care places |
|---|---|----------------------------|
| 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 on the second Friday of each month, 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.

Refer to the Cheshire and Merseyside APG policy for the appeal process.

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
- Workplan
- NICE TA tracker
- 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, with the exception of newly published NICE TAs which will not be sent for consultation due to mandatory NICE timescales. 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.