NHS
Cheshire and Merseyside

Policy

Area Prescribing Group

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Contents

Document version control

Version	Author	Date	Reason for change
V01	MLCSU	June 2023	New document approved by CMAPG
V01.01	MLCSU	Sept 2023	Initial 6 month review of APG and governance arrangements
V02	Anne Henshaw, CMAPG Professional Secretary	May 2024	Annual review of APG and governance arrangements

Cheshire and Mersey Area Prescribing Group

NHS Cheshire and Merseyside Places:

- Cheshire East Place
- Cheshire West Place
- Halton Place
- Knowsley Place
- Liverpool Place
- Sefton Place
- St Helens Place
- Warrington Place
- Wirral Place

Specialist and Acute NHS Trusts:

- Alder Hey Children's NHS Foundation Trust
- Bridgewater Community Healthcare NHS Foundation Trust
- Cheshire and Wirral Partnership NHS Foundation Trust
- Countess of Chester Hospital NHS Foundation Trust
- East Cheshire NHS Trust
- Liverpool Heart and Chest Hospital NHS Foundation Trust
- Liverpool University Hospitals NHS Foundation Trust
- Liverpool Women's NHS Foundation Trust
- Mersey and West Lancashire Teaching Hospitals NHS Trust
- Mersey Care NHS Foundation Trust
- Mid Cheshire Hospitals NHS Foundation Trust
- The Clatterbridge Cancer Centre NHS Foundation Trust
- The Walton Centre NHS Foundation Trust
- Warrington and Halton Teaching Hospitals NHS Foundation Trust
- Wirral Community Health and Care NHS Foundation Trust
- Wirral University Teaching Hospital NHS Foundation Trust

Policy statement and key objectives

The objectives of this policy are to help constituent organisations:

- Enable all clinicians and managers to work together to ensure that patients have safe and consistent access to medicines with the best outcomes
- To advise on implementation of best practice around medicines, including National Institute for Health and Care Excellence (NICE) guidelines and technology appraisals, to encourage and facilitate rapid and consistent implementation
- Provide unbiased but accountable, leadership and strategic co-ordination of the use of medicines
- To secure the best value healthcare and the greatest health benefit for the Cheshire and Merseyside population

Background

The NHS Constitution for England, produced by the Department of Health (2012, updated 2021), provides patients with the right that medicines (and treatments) that have been considered by NICE through the technology appraisal (TA) process and given a positive assessment should be made available to patients, where appropriate, and therefore be included in the formulary adopted by the local healthcare providers and commissioners.

The Constitution states:

'You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.'

In addition, the Constitution provides a second right for patients that states:

'You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.'

Secretary of State Directions (Department of Health, 2009) provide the NHS with clear and concise requirements that must be adopted to ensure compliance with the constitutional statements. To ensure patients have access to medicines and treatments that are recommended for use in the NHS through a NICE TA process, funding must be made available. This was emphasised in 2011:

'Clinicians should be empowered to use these medicines and treatments where they consider their patients would benefit and local processes for pro-active adoption of NICE recommended medicines into local formularies should be in place.' (Innovation Health and Wealth - accelerating adoption and diffusion in the NHS. Department of Health, December 2011)

The Cheshire and Merseyside Area Prescribing Group (CMAPG) will support a coordinated approach across the Cheshire and Merseyside Integrated Care System (ICS) to managing medicines by its key constituent organisations. The overall aim is to take a health economy approach to the use of medicines across the health and social care systems.

This document describes the framework by which this process will take place in a consistent, predictable, open, and transparent manner to develop recommendations for consideration by the delegated Group of

the Integrated Care Board (ICB). The ICB will have responsibility for prioritising the allocation of limited resources and balancing demands for medicines and treatments across Cheshire and Merseyside.

Purpose of the APG - Overview

The Cheshire and Merseyside Area Prescribing Group (CMAPG) serves the ICS community by improving the use of medicines in terms of safety, clinical effectiveness, cost effective care, and ecological profile, across its partnership organisations. It does this by deciding which medicines are recommended and not recommended for local use and developing supporting advice for best use of medicines. Recommendations will be made following agreement by stakeholders, informed by systematic evidence evaluation and consultation.

The APG is a recommending group, and members will be required to work within the governance arrangements of the NHS Cheshire and Merseyside Integrated Care Board (ICB).

Recommendations will be submitted to the ICB Medicines Optimisation and Pharmacy (MOP) Group for approval as per ICB Standing Financial Instructions (SFI) and Scheme of Delegation (SORD) limits and refer further approvals to appropriate responsible ICB officer and/or the Finance, Investment and Resources Committee or the Board depending upon the financial commitment being made, to ensure that the decision is compliant with the SFI.

CMAPG will consider the clinical, financial, organisational, environmental and implementation impact of medicines for the whole system.

Co-ordination of this activity across Cheshire and Merseyside through the APG will minimise unnecessary variation in medicines use and policy across the area ("postcode prescribing") for the benefit of patients.

Core Principles

Principles detailed in this policy are to support decision making by Cheshire and Merseyside ICB relating to the use of medicines and prescribable devices.

Principle 1

The values and principles driving priority setting at all levels of decision-making should be consistent. Consideration of wider health economic principles and implementation responsibilities may be required.

Principle 2

Competing needs of patients and services within the areas of responsibility of the NHS ICB should have a fair chance of being considered, subject to the capacity of the NHS ICB to conduct the necessary healthcare needs and services assessments. As far as is practicable, all potential calls on new and existing funds should be considered as part of a priority setting process. Services and individual patients should not be allowed to bypass normal priority setting processes. In cases where there is an urgent clinical need for an individual patient to receive treatment ahead of such processes being undertaken and following appropriate internal Medicines Governance Group (or equivalent) approval for such use, individual Trusts may proceed to use drugs ahead of the priority setting processes. All such use will be funded directly by the individual Trust.

Principle 3

Access to services for equal clinical need is governed equally and impartially. Individual patients or groups should not be disadvantaged or unjustifiably advantaged based on their protected characteristics: age, intellectual/cognitive function or physical functions/disability, gender reassignment, pregnancy and maternity, race, religion or belief and sexual orientation. There is an established and important correlation between social inequalities and inequalities in health, health needs and access to healthcare. In making commissioning decisions, priority may be given to health services targeting health needs in subgroups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

Principle 4

New treatments should be assessed for funding on a similar basis to decisions to continue to fund existing treatments, namely according to the principles of clinical effectiveness, safety, cost-effectiveness/value for money, and then prioritised in a way which supports consistent and affordable decision-making.

Principle 5

The CMAPG must ensure that the recommendations it makes demonstrate value for money and an appropriate use of NHS funding based on the needs of the population it serves.

Principle 6

No other body or individual, other than those authorised to take decisions under the policies of the NHS ICB, has the mandate to commit the NHS ICB to fund any healthcare intervention unless directed to do so by the Secretary of State for Health.

Principle 7

Interventions of proven clinical effectiveness and cost-effectiveness should be prioritised above funding research and evaluation unless there are sound reasons for not doing so.

Principle 8

The NHS ICB shall strive to consider the environmental implications of implementing medicines recommendations. The APG will, where available, include information about the carbon footprint of medicines to empower prescribers to make more environmentally sustainable prescribing decisions.

Responsibilities

The APG will, on behalf of the NHS health economy, manage the Cheshire and Merseyside Joint Formulary. The Joint Formulary refers to primary and secondary care medicines and prescribable devices that are funded by the ICB.

It will consider applications for medicines and prescribable devices to be added to the Joint Formulary, recommend their adoption or non-adoption, and specify the circumstances under which adopted medicines should be used.

It will oversee the regular review of the Joint Formulary to ensure that it is consistent with the aims of safe, effective, and cost-effective prescribing, and within national guidance.

Use of the Joint Formulary will continue to be incorporated into NHS Trust contracts and will be considered best practice in primary care. NHS Places will work closely with primary care clinicians to maximise formulary adherence. Consideration regarding differing formulary recommendations from neighbouring ICS areas may be required on occasions.

The APG will only consider formulary applications that are to be funded by the ICB.

The APG will review areas where there is inconsistent formulary status and different delivery models across the health economy and make recommendations on their resolution where appropriate.

The APG will consider the cost-effectiveness of existing treatments and make recommendations to the ICB for a change in prescribing practice where appropriate.

The APG will oversee horizon scanning to forecast developments in medicines related healthcare and provide support to ensure effective introduction of new medicines and forecast costs to the system.

The APG will ensure the Joint Formulary is updated in response to national guidance, medicines licence changes, and safety alerts related to medicines. For example, by NICE or the Medicines and Healthcare products Regulatory Agency (MHRA).

The APG will provide a framework to develop evidence-based recommendations that will enable the ICB Medicines Optimisation and Pharmacy Group, which reports to the ICB Clinical Effectiveness Group, to endorse medicines related guidelines that support better use of medicines across the local area. See Appendix 1 for further details of the APG process.

The APG will be cognisant of the outputs of the Regional Medicines Optimisation Committees (RMOCs) and the North West Medicines Optimisation Group (NWMOG) and review any relevant advice/recommendations in a timely manner.

Reference to good practice guidance such as the 'General Medical Council Guideline of Good prescribing', National NHSE or local ICB guidance should be considered.

Subgroups

The APG has established subgroups to perform the role to support with workloads and/or best use of specialist expertise. The responsibility for oversight of subgroups remains the responsibility of the APG. Subgroups report recommendations to the APG.

The APG will seek assurance from subgroups that all considerations have been considered equally throughout the consultation process. A Decision Support Summary has been developed to help with this process.

The following established subgroups support the APG:

- New medicines
- Formulary and guidelines
- Safety
- Interface prescribing
- Antimicrobial prescribing

The subgroups will prioritise work areas on behalf of, and in consultation with the ICB, constituent organisations and the APG.

They will produce initial recommendations for stakeholder consultation prior to submission to the APG using systematic methods to include consideration of clinical outcomes, specialist expertise, cost-effectiveness, safety, priorities of constituent organisations, and affordability.

The APG will use the submissions from the subgroups as a basis for recommendations to the ICB. If consensus has not been reached the subgroups will inform the APG.

Terms of reference for each active subgroup are available as separate documents.

Short-life task and finish groups can be convened to address specific areas of work where more specialist input is needed to develop an APG recommendation than can be provided by one of the established subgroups. These short-life task and finish groups will work within the same governance arrangements and processes as established subgroups.

Documentation

The following documents are used to deliver the functions of the APG:

- APG policy
- Terms of reference
- APG subgroup governance processes
- Formulary application forms
- Decision support summary
- ICB Code of practice for declaring and dealing with conflicts of interests
- APG recommendations/approval report

Formulary Process

Background

The following section describes the process for addition to the formulary. The formulary process commences via two routes:

- Reactive in response to applications from clinicians supported by their NHS Trust Drugs and Therapeutics Committee or Primary Care Medicines Place Leads, or in response to NICE or RMOC guidance
- Proactive by horizon scanning to identify formulary updates, or to resolve inconsistent formulary status across the health area

Process

The APG will operate a process for new formulary applications. Flow charts of the processes are displayed in Appendix 1.

Process Timescales

To ensure responsive and efficient working, there is an overall aspiration that all processes will be completed in the shortest timescale possible, noting there will be a dependence on meeting schedules, evidence reviews required, and stakeholder consultation requirements. Applications will follow one of the following processes depending on the type of application:

New application or significant change to formulary entry - this process will be applied to all new additions to the formulary and significant changes to existing formulary drugs, including RAG change requests. It will involve a review by the appropriate subgroup, full consultation, review of all feedback by subgroup and completion of a decision support summary before submission of recommendation to APG.

Minor formulary amendment - this process will apply to simple updates or license changes for formulary recommendations, including paediatric license extension. It does not include RAG change requests. Minor formulary amendments will not be subject to consultation and will be reviewed by the appropriate subgroup, including consideration of any additional costs and, for paediatric license extensions, the appropriate RAG rating determined. Following completion of a decision support summary, a recommendation will be submitted straight to APG.

Fast-track process - this is to be used to progress urgent medicines advice or recommendations through a robust and agreed process when the full APG process is either unavailable due to system pressures or will not provide a timely enough outcome. The fast-track process aims to be reactive to issues that require timely consideration whilst ensuring adequate governance and accountability.

Reactive Process: Submitting a formulary request

Applications must be submitted using the appropriate APG application form.

NHS Trust clinicians must seek endorsement from their NHS Trust Drug and Therapeutics Committee Chair or Medical Director prior to submitting to the APG secretariat for consideration.

Applications from GPs or clinicians within primary care, must seek endorsement from their Place-based Medicines Lead or Medicines Management Committee prior to APG submission.

The full new medicine application form is used to request consideration of addition to the formulary for all new drugs, significant new indications, or prescribable devices. Applications considered via the fast-track process will be progressed by the appropriate subgroup and require the appropriate application form to be completed.

The minor formulary amendment application should be used to request consideration of minor changes to indication for existing formulary medicines, paediatric license extensions, or to remove or amend the use of a drug on the existing formulary. This does not include RAG change requests.

The RAG change request application form should be used to request a review and potential change of the existing formulary RAG status for a medicine.

Applications are required for all prescribable items that will be funded by the ICB.

Specialist services will need to engage with the APG where there may be resource implications, or funding is required by the ICB, as a result of introducing new treatments.

Applicants should consult with their peer networks across the NHS Trusts to gain consensus and a joined-up approach to the introduction of new drugs or prescribable devices. Views from peer networks or other organisations can be reflected in the application form or submitted during the subgroup review or consultation process.

The APG subgroups will review the application form, complete evidence reviews as appropriate and produce initial recommendations for stakeholder consultation prior to submission to the APG using systematic methods. Recommendations will be based on consideration of clinical outcomes, specialist expertise, cost-effectiveness, safety, priorities of constituent organisations and affordability. All APG members will have the opportunity to comment on APG recommendations via the consultation process and contribute to discussions via subgroup representatives prior to submission to APG.

A decision support summary (DSS) will assist subgroups determine final recommendations to APG.

The APG will use the submissions from the subgroups as a basis for final recommendations to the ICB Medicines Optimisation and Pharmacy (MOP) Group. Submissions to APG will include a summary of the consultation feedback and the decision support summary.

The APG will not accept applications developed by or received from the Pharmaceutical Industry or device manufacturers.

Proactive identification of medicines for consideration

Horizon scanning is carried out by the relevant subgroup to review medicines that are recently licensed that are not yet subject to NICE review, utilising Specialist Pharmacy Service (SPS) resources.

Medicines not subject to NICE will be prioritised for review based on defined criteria. Prioritisation will be based on a threshold of meeting a range of criteria such as:

- Impact on patient care
- Severity of disease and patient numbers affected
- Clinical effectiveness
- Patient safety
- Gaps in treatment or other available treatments
- Cost effectiveness or resource impact

- Inappropriate variation in current practice

Exceptional and Immediate Clinical Need

Most prescribing should be in accordance with the CMAPG Joint Formulary. However, it is recognised that a formulary will not provide the most appropriate treatment for every patient with all clinical conditions, so processes are required to enable clinical decision making to allow non-formulary prescribing where this is appropriate.

The following principles can be applied for exceptional and immediate clinical need:

- Formulary drugs are preferred for patients
- Use of drugs outside the formulary requires an established clinical rationale which should be documented in the patients' clinical records
- If the use of a drug outside the formulary applies to a cohort of patients, then an APG formulary application should be made

If a non-formulary medicine is required for a patient who has exceptional clinical need, processes are available to request commissioning funding using the Individual Funding Request (IFR) process. This process is only applicable to hospital-only tariff-excluded drugs.

Individual Funding Requests are considered where the individual is considered to be clinically exceptional. Exceptionality is defined as being significantly different to the general population of patients with the condition in question and the patient is likely to gain significantly more clinical benefit from the intervention than might normally be expected for patients with that condition.

If there is immediate clinical need within a secondary care setting for a patient without clinical exceptionality, NHS Trusts can utilise their internal one-off non-formulary approval process for urgent use of a drug prior to a formulary application. In this setting, approval should be sought from the Medical Director/Chair of the Drug and Therapeutics (D&T) Committee of the provider, and the Head of Pharmacy/Deputy, following discussion with and support of the clinician's own Clinical Director. This process should not be used to avoid submitting an IFR application. The use of medicines in this way will usually be at the expense of the provider trust. If a clinician wishes to use a non-formulary drug for a cohort of patients, a full formulary application should be made.

If there is immediate clinical need within a primary care setting, clinicians may, if required, contact their Place medicines management team for advice.

Patients who have been previously established on non-formulary drugs may normally continue with their treatment if this is the most appropriate treatment for the individual.

Receipt of the application

Completed application forms are received by the APG Secretariat via the APG email mailbox apg@cheshireandmerseyside.nhs.uk. An email acknowledgement will be provided to the applicant upon receipt.

The application form will be screened by the secretariat to check all fields have been completed satisfactorily. The secretariat will liaise with the applicant for points of clarification if required. Incomplete forms will be rejected on receipt with a request for completion and advice for the applicant.

Consideration of applications will allow time for screening and peer review consultation.

Preparation for the APG: Subgroups

The relevant APG subgroup will assess the application, established evidence base and costs, consult with stakeholders, discuss with other centres and specialists, and form a preliminary recommendation on adoption and prioritisation. The subgroup may be one of the existing APG subgroups or a short-term task and finish group set up to explore specialist clinical areas if additional subject matter expertise is required.

When an application is received, the subgroup will complete an initial review and agree a recommendation for consultation. Following consultation feedback, a decision support summary (DSS) will be completed by subgroup as part of the final assessment of the formulary application. A recommendation will be agreed for submission to APG. See Appendix 3 for example DSS.

For minor formulary amendments there will be no wider consultation process. The appropriate subgroup will complete a decision support summary to accompany the final recommendation to APG to provide assurance of due process and consideration.

Additional information may need to be requested from relevant NHS Trust pharmacists and/or input from appropriate specialists.

All evidence reviews will be compiled using recognised sources of medicines information where they are available to formulary pharmacist/appropriate pharmacist. The following resources are recommended (list not exhaustive):

- Electronic Medicines Compendium
- BNF/Children's BNF
- NICE
- Specialist Pharmacy Services website
- Scottish Intercollegiate Guidelines Network (SIGN)
- All Wales Medicines Strategy Group (AWMSG)
- Cochrane library
- MHRA drug safety alerts and regulatory authority alerts relating to medicines
- Medline
- Embase

Presenting to the APG

The APG will make their recommendation based on the information they have to hand as prepared by the appropriate subgroup, including consultation feedback, decision support summary and expert clinical experience.

The APG subgroup chair will present the final recommendation to the APG, summarising evidence and recommendations and answering arising questions.

Manufacturers and applying clinicians are not eligible to present to or attend the APG meeting.

Committee decision making

The APG members will assess all application recommendations, following appropriate subgroup review and stakeholder consultation. Recommendations will be based on a range of criteria and the rationale documented using the APG decision support summary. See appendix 3

The decision support summary will include assessment of:

- Patient safety
- Clinical effectiveness
- Cost effectiveness or resource impact
- Strength of evidence
- Place in therapy relative to available treatments
- National guidance and priorities
- Local health priorities
- Equity of access
- Stakeholder views

Decisions will be categorised using the locally agreed RAG definitions and criteria.

Where appropriate, the decision will provide guidance on the place in therapy, for example whether a first- or second-line medicine and any other relevant issues such as high cost or specialist initiation

Minutes of APG meetings will be ratified at subsequent meetings and the APG approvals report will be published on the APG website.

Resubmission and Appeals process

Resubmission process

Once a formulary review has been completed or a new drug application has been rejected, a resubmission would normally require a minimum interval of 12 months.

The Chair has the discretion to shorten the resubmission period on receipt of significant new information such as trial evidence or appropriate clinical guidance.

Where new published information significantly affects previous decisions, the appropriate subgroup will review and request a resubmission or a proactive formulary review.

Appeals process

The decision to issue a Cheshire and Merseyside recommendation is made by the Cheshire and Merseyside Area Prescribing Group. It does this after consideration of the recommendations of its sub-committees, and in consultation with its stakeholders.

In line with good practice, it is recommended that a clinician is best placed to submit a formal appeal on behalf of their patient population.

The appeals process is open to clinicians (GPs, consultants, senior nurses, senior pharmacists, or non-medical independent prescribers) with relevant expertise and who work within the Cheshire and Merseyside Health Economy for an NHS commissioned service. It exists to give those clinicians who feel that the Cheshire and Merseyside APG policy statement recommendation may result in a compromise in care to patients, an opportunity to make their case for the recommendation to be amended.

Appeals from pharmaceutical companies will not be accepted.

Appeals must be received within 60 calendar days of ICB ratification of the APG recommendation.

Grounds for appeal

Appeals will be accepted for the following circumstances:

- Appeal against a recommendation made by the Cheshire and Merseyside APG to accept, reject or position an application for a specific medicine because vital evidence was not considered or incorrect information was considered in the original application
- Appeal against a recommendation made by the Cheshire and Merseyside APG because the Cheshire and Merseyside APG procedures and policies were not followed

The applicant cannot appeal against a decision just because they do not agree with the decision or because new evidence has come to light since the original decision was made. In this case, a resubmission should be made highlighting the new evidence.

The applicant cannot appeal against a decision because a neighbouring APG/APC came to a different decision.

An intention to appeal should be made in writing to the APG secretary within 60 calendar days of the APG's decision. A template appeal form has been developed to support the appellant.

The appeal must state the following:

- Name of drug/s
- Date of APG decision
- Reason for appeal, stating the potential failing

Once an appeal has been received:

- The APG secretariat will send an acknowledgement to the appellant to confirm receipt
- The appeal will be screened and reviewed by the APG Secretary and Chair to confirm that it is an appeal in relation to a process issue

An independent ICB appeal panel will be set up to process appeals when received. The panel will include the Assistant Chief Executive and Director of Finance of Cheshire and Merseyside ICB, and an independent ICS Chief Pharmacist.

The appellant is invited to attend the appeal panel to present the case for the appeal. A member of the CMAPG would also attend the appeal panel to present the APG decision making process.

The role of the appeal panel is not to review the evidence and make a decision, but to decide if the grounds for appeal are valid and whether the appeal is to be upheld. The fact that the Cheshire and Merseyside APG will reconsider recommendations if the appeal is upheld, does not necessarily mean that it will reach a different decision.

Following review of the appeal, recommendations will be made by the appeal panel to the APG as follows:

- Appeal upheld and the Cheshire and Merseyside APG is directed to reconsider the original application considering procedural failure or misinterpretation of the evidence presented, depending on the grounds for appeal. No new information can be submitted as part of the appeal process
- Appeal dismissed and reasons why

The appellant will be informed in writing of the outcome of the appeal within ten working days of the appeal panel meeting.

Adoption of NICE Technology Appraisals (TA)

NICE TAs that are relevant to the local health economy within the ICS will be considered by the new medicines subgroup in accordance with the agreed NICE TA process.

The APG approvals report will contain information to confirm ratification. NICE TAs will be implemented as soon as is practical and within 90 days of publication or in line with national recommendations.

The APG will engage clinicians to identify the position for therapies in the relevant care pathways in line with NICE recommendations where required.

Meeting Attendance

Terms of Reference and Membership

The membership of, and representation at, the APG and APG subgroups is detailed in the separate terms of reference documents.

Guests at Meetings

Attendance at the APG and subgroups is governed by the membership.

Intended attendance by any guests should be notified to the Chair and/or Professional Secretary in advance of the meeting to seek permission to attend and, if agreed, in order that the attendee can be briefed on the working of the APG or subgroup.

Uninvited guests are not welcome to attend meetings.

Appropriate Behaviour

All members attending the APG or subgroups to represent an organisation or present a paper do so in a professional capacity, and all participants should be treated with courtesy, respect, and consideration.

Participants should only speak when they are invited to by the Chair and should raise a hand to be recognised as having something to say. A person should not be interrupted while speaking or asking a question.

Transparency

Website

All relevant documentation and the APG approvals report will be published on the CMAPG website maintained by the APG secretariat.

Reporting

An annual report will be published detailing the overall activity of the Group.

Declaring and dealing with conflict of interest

A Standards of Business Conduct policy is available that requires conflicts of interest to be managed appropriately for members of the Group. Details are available via the NHS Cheshire and Merseyside ICS website.

All members of the APG are expected to conform to the NHS Cheshire and Merseyside ICB Conflict of Interest policy regarding registering and declaring potential Conflicts of Interest.

All APG members will complete an annual declaration of interest as per Cheshire and Merseyside ICS Conflict of Interest policy and return to the ICB Governance Team and the APG secretariat. APG and subgroup members are expected to declare any potential Conflicts of Interest during meetings, which will be recorded fully in the minutes and the decision support summary for transparency.

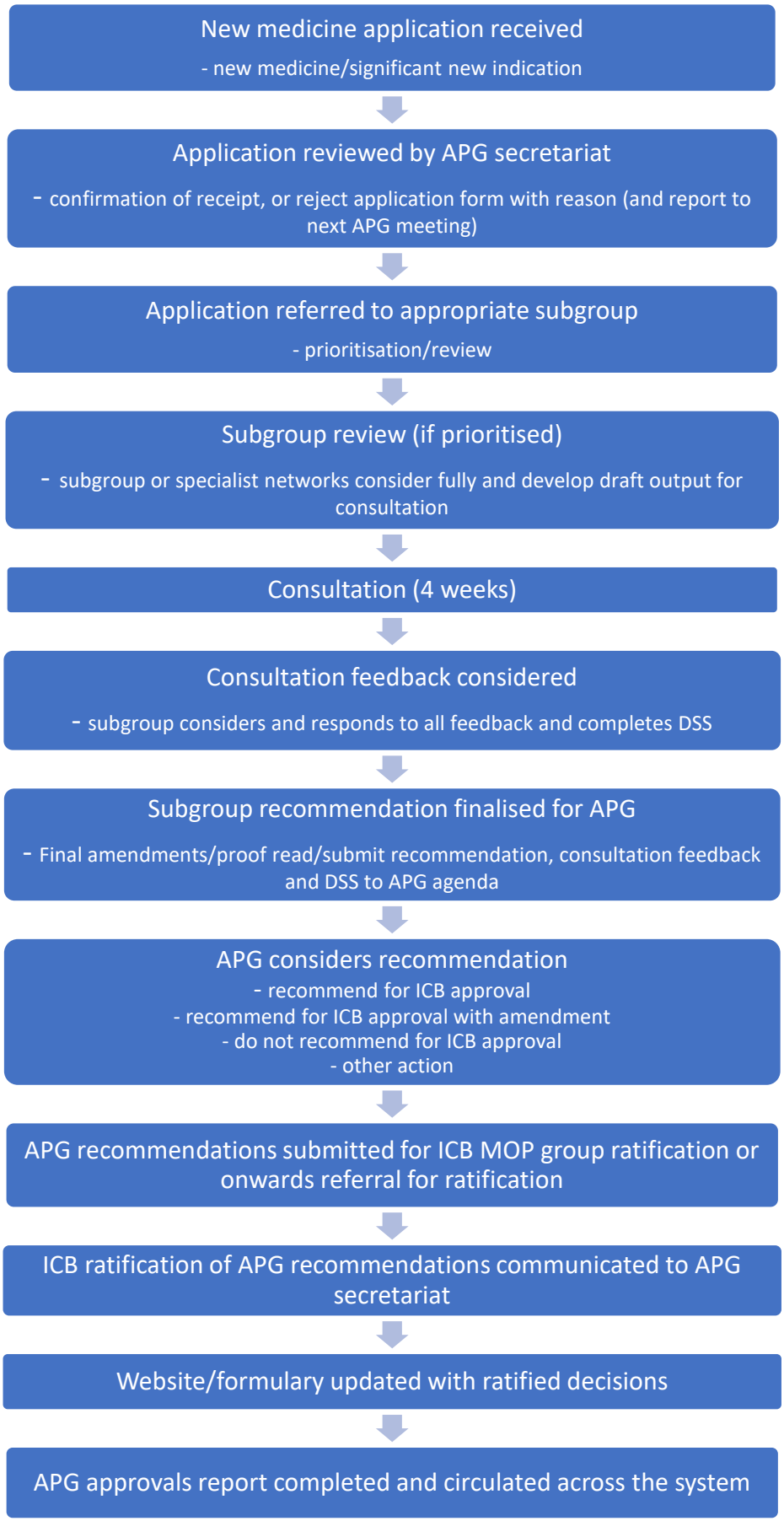
Formulary applicants are required to declare their interest within the application form and at each meeting.

References

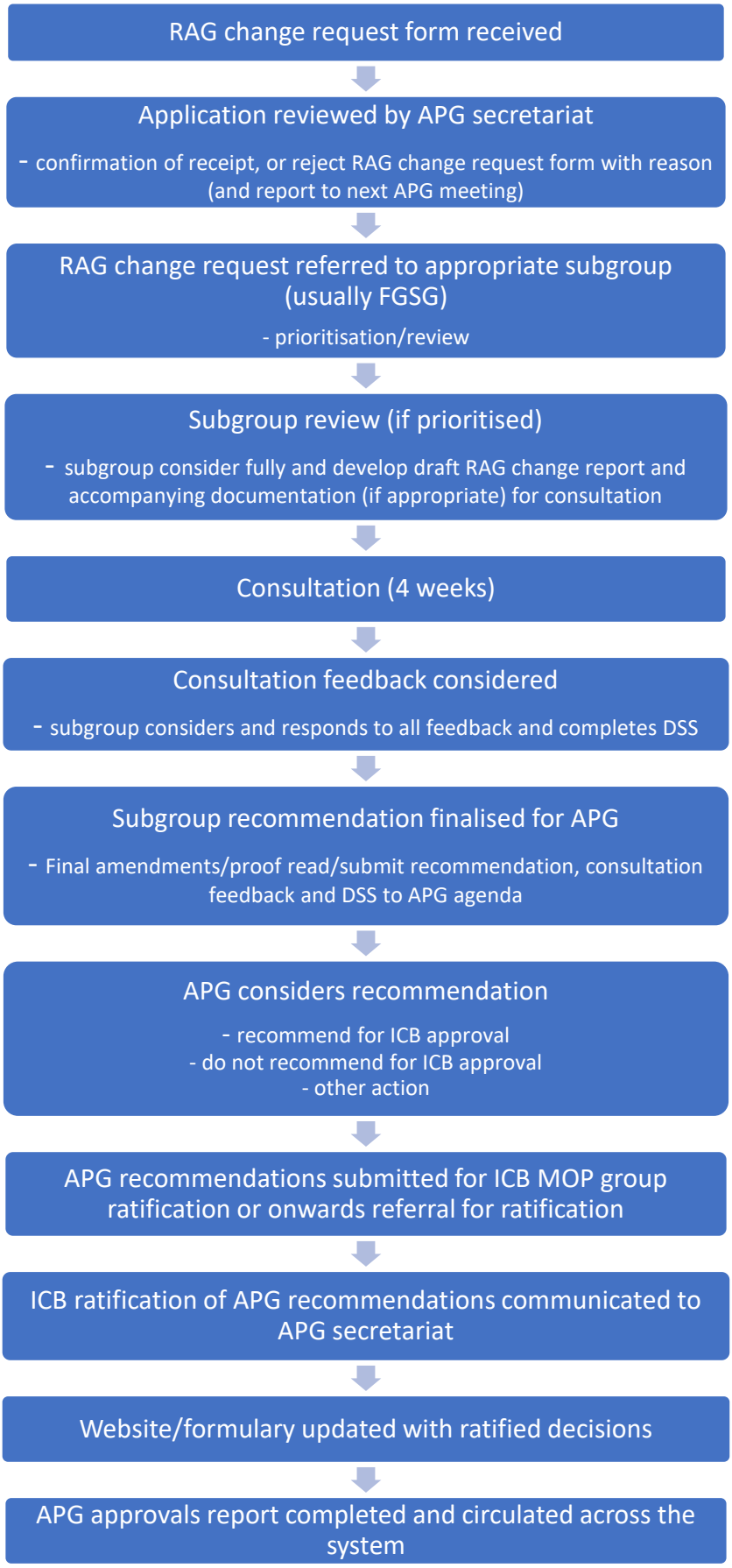
1. National Institute for Health and Care Excellence. Medicines practice guideline MPG1: Developing and updating local formularies. Last updated 28 Oct 2015. Accessed 14 May 2024.
2. General Medical Council. Professional standards: Good practice in prescribing and managing medicines and devices Last updated 15 Mar 2022. Accessed 14 May 2024.
3. NHS Cheshire and Merseyside. Consensus on the Primary and Secondary Care Interface June 2022. Accessed 14 May 2024.

Appendix 1 Schematic representation of APG operation

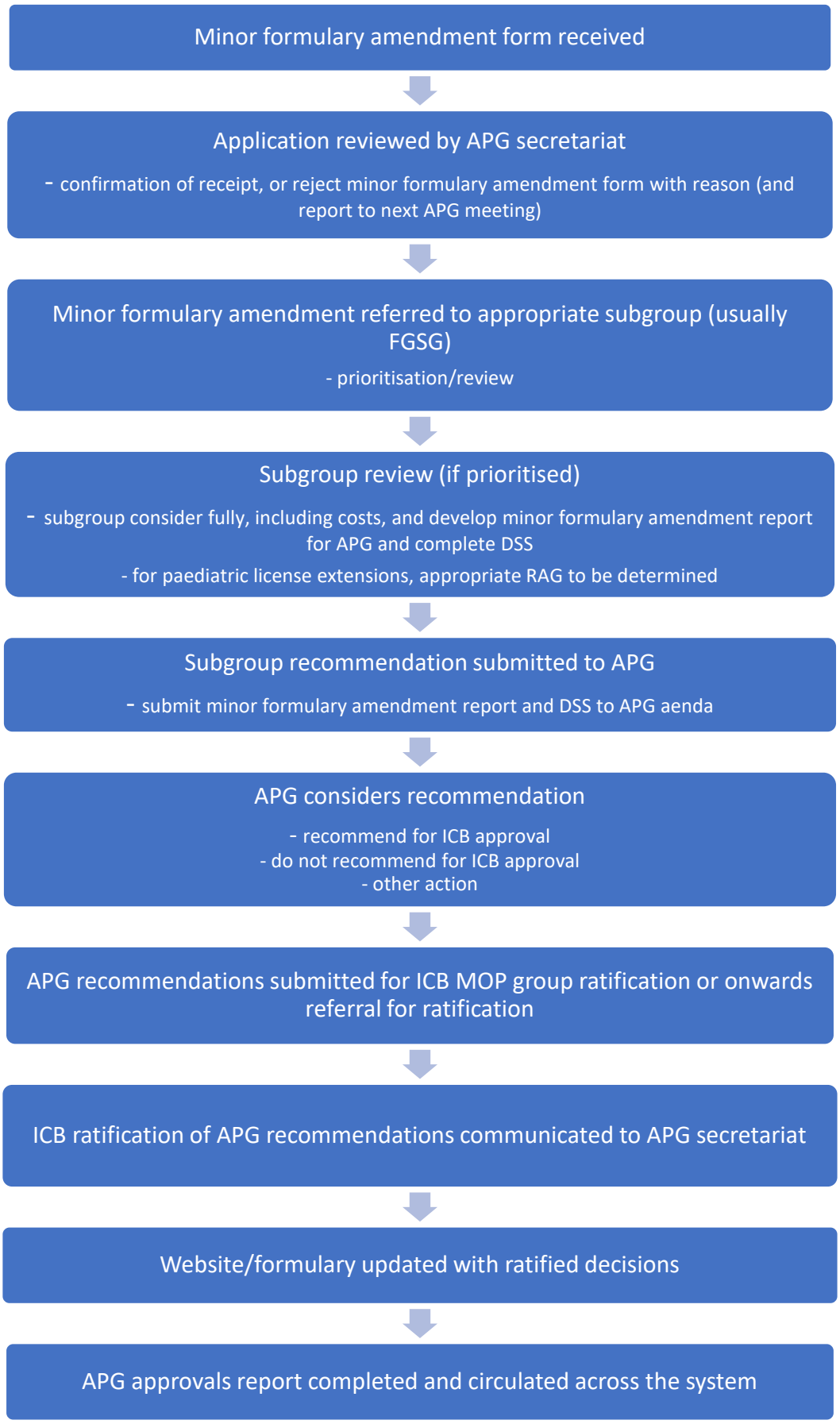
Full New Medicines Process



RAG Change Request Process



Minor Formulary Amendment Process



Appendix 2 NHS Cheshire and Merseyside Area Prescribing Group organogram

Clinical networks: TBC

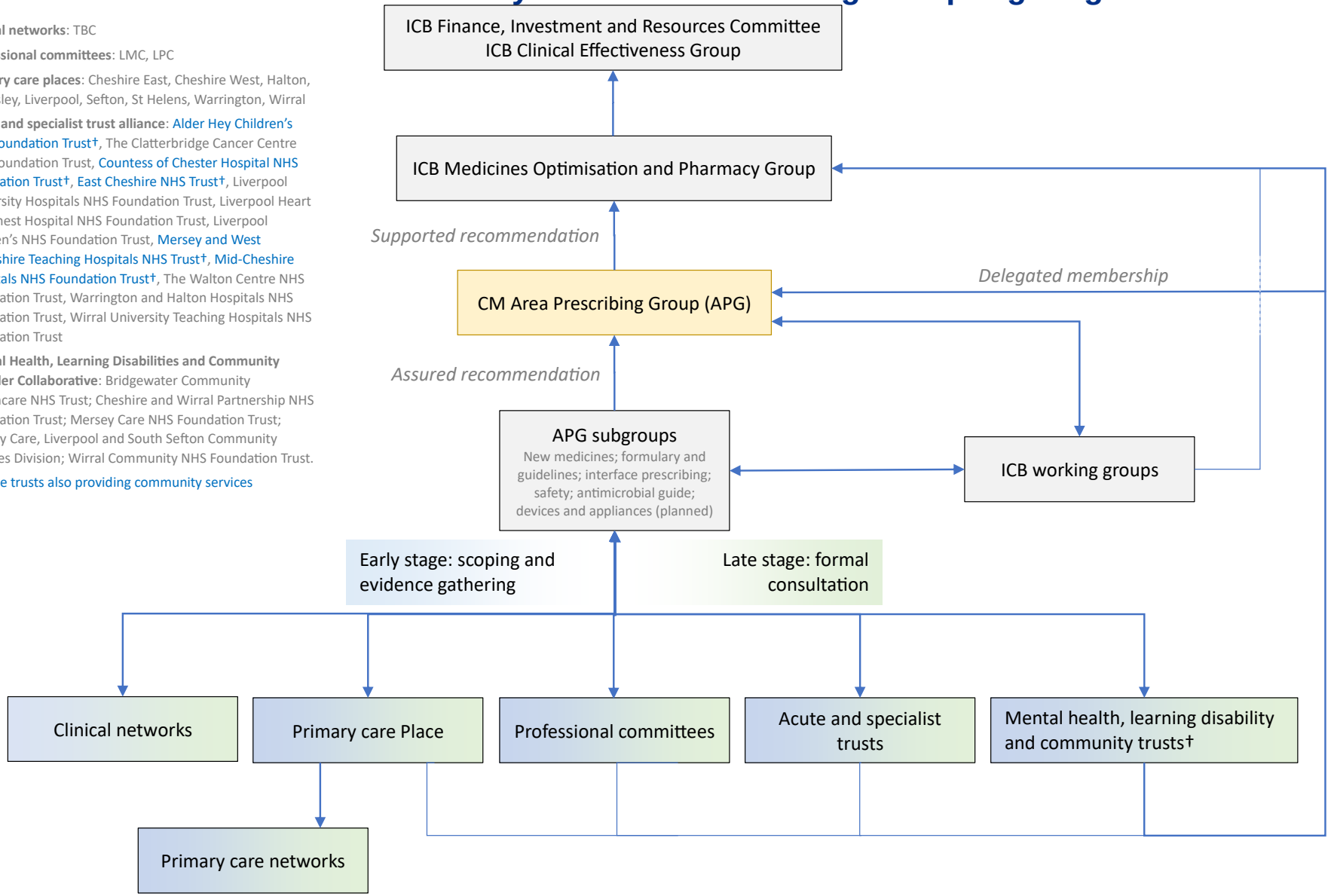
Professional committees: LMC, LPC

Primary care places: Cheshire East, Cheshire West, Halton, Knowsley, Liverpool, Sefton, St Helens, Warrington, Wirral

Acute and specialist trust alliance: Alder Hey Children's NHS Foundation Trust†, The Clatterbridge Cancer Centre NHS Foundation Trust, Countess of Chester Hospital NHS Foundation Trust†, East Cheshire NHS Trust†, Liverpool University Hospitals NHS Foundation Trust, Liverpool Heart and Chest Hospital NHS Foundation Trust, Liverpool Women's NHS Foundation Trust, Mersey and West Lancashire Teaching Hospitals NHS Trust†, Mid-Cheshire Hospitals NHS Foundation Trust†, The Walton Centre NHS Foundation Trust, Warrington and Halton Hospitals NHS Foundation Trust, Wirral University Teaching Hospitals NHS Foundation Trust

Mental Health, Learning Disabilities and Community Provider Collaborative: Bridgewater Community Healthcare NHS Trust; Cheshire and Wirral Partnership NHS Foundation Trust; Mersey Care NHS Foundation Trust; Mersey Care, Liverpool and South Sefton Community Services Division; Wirral Community NHS Foundation Trust.

† Acute trusts also providing community services



Appendix 3 Decision support summary

Proposal	Notes	Approval
Add the drug and indication as a human readable hyperlink. Add the RAG designation. **APG subgroup**: meeting date **APG**: meeting date	[optional] **Date of NICE TA publication**: date [optional] **Approval for implementation**: 30 or 90 days [optional] **Deadline for implementation**: date Brief summary of the most important reasoning. Include costings and links to other information if applicable.	**MOP**: start with the meeting date and add relevant commentary. [optional] **FIRC/CEG**: start with the meeting date and add relevant commentary

Recommendation

What is the 'ask'?

Rationale

How did we come to this decision? Is it a new therapy for a gap in treatment or a 'better' new therapy? Why 'this' argument vs 'that' argument? Are there other options? Why were the other options not used and what are the consequences. What is the impact on therapy?

Supporting information

Additional facts useful to understanding in order of importance. What has been considered?

APG decision

Assurance of process and all relevant factors considered	☐ Yes	☐ No	☐ Not applicable
This submission is supported for ICB approval	☐ Yes	☐ No	☐ Not applicable
The proposed RAG designation is supported	☐ Yes	☐ No	☐ Not applicable
Declarations of interest have been managed	☐ Yes	☐ No	☐ Not applicable
Comments:			
Declarations of interest:			

APG subgroup summary

Formal application submitted and prioritised	☐ Yes	☐ No	☐ Not applicable
Formulary status (RAG) agreed	☐ Yes	☐ No	☐ Not applicable
Consultation feedback addressed	☐ Yes	☐ No	☐ Not applicable
Declarations of interest managed	☐ Yes	☐ No	☐ Not applicable
Comments:			
Declarations of interest:			

Implementation

Implementation requirements identified	☐ Yes	☐ No	☐ Not applicable
Impact on existing workload, existing pathways, or expertise considered	☐ Yes	☐ No	☐ Not applicable
ScriptSwitch message developed	☐ Yes	☐ No	☐ Not applicable

Impact monitoring identified	☐ Yes	☐ No	☐ Not applicable
Access for the whole of Cheshire and Merseyside is equitable	☐ Yes	☐ No	☐ Not applicable
Border issues considered	☐ Yes	☐ No	☐ Not applicable
Workforce capacity considered	☐ Yes	☐ No	☐ Not applicable
Governance requirements or prescribing restrictions identified	☐ Yes	☐ No	☐ Not applicable
Delivery of a net zero carbon NHS is supported	☐ Yes	☐ No	☐ Not applicable
ICB ability to meet its statutory requirements considered	☐ Yes	☐ No	☐ Not applicable
Comments:			

Appropriateness

Outcomes identified	☐ Yes	☐ No	☐ Not applicable
Aligned with ICB and local priorities	☐ Yes	☐ No	☐ Not applicable
Safety concerns identified	☐ Yes	☐ No	☐ Not applicable
Patient factors identified	☐ Yes	☐ No	☐ Not applicable
Place in therapy identified	☐ Yes	☐ No	☐ Not applicable
Effect on health inequalities considered	☐ Yes	☐ No	☐ Not applicable
Effect on protected groups considered	☐ Yes	☐ No	☐ Not applicable
Comments: (include place in therapy and any safety mitigations)			

Effectiveness

Evidence for clinical effectiveness reviewed	☐ Yes	☐ No	☐ Not applicable
Evidence for cost-effectiveness reviewed	☐ Yes	☐ No	☐ Not applicable
The submission supported by national or local commissioning policy	☐ Yes	☐ No	☐ Not applicable
Comments:			

Financial considerations

Drug savings and costs assessed	☐ Yes	☐ No	☐ Not applicable
Additional savings and costs assessed	☐ Yes	☐ No	☐ Not applicable
Comments:			