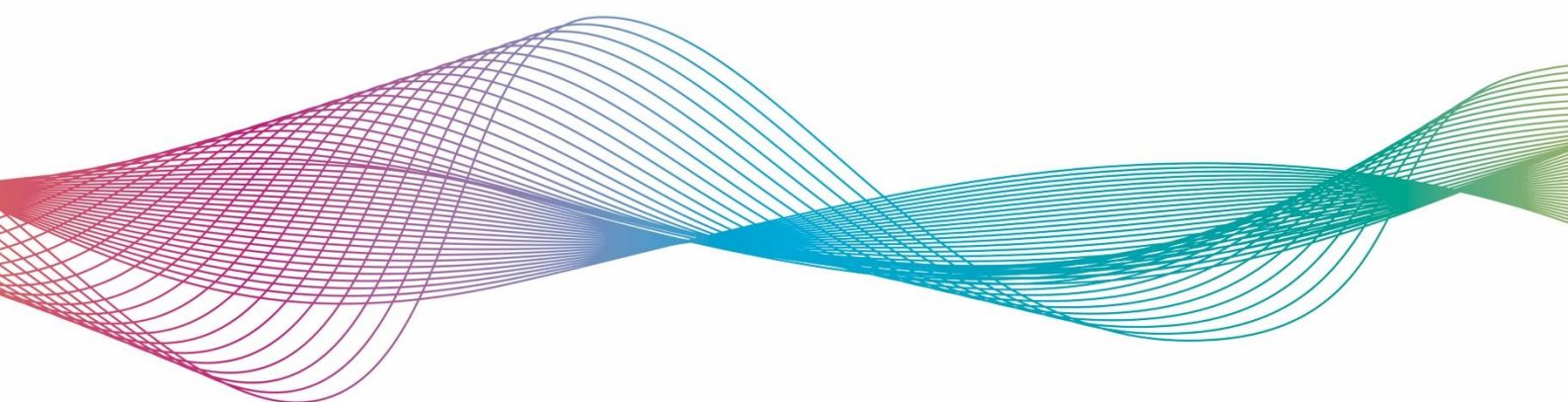




**Midlands and Lancashire**  
Commissioning Support Unit

# Policy for the Pan Mersey Area Prescribing Committee



# Document history

Version	Date	Author	Changes
0.1	October 2012	Erika Baker, Graham Reader, Jenny Lunn	Adapted policy from Mid Mersey MMB April 2010
0.2	November 2012	Erika Baker, Graham Reader, Jenny Lunn	Reviewed and updated
0.3	August 2013	Clare Moss, Anne Henshaw	NHS England section updated; All TOR updated agreed and inserted; Guideline references checked and updated; Application and Case for Introduction of New Medicine Service Developments inserted
0.4	January 2014	Donna Gillespie-Greene	Change to APC quoracy
0.5-7	June 2014	Graham Reader, Anne Henshaw, Clare Moss	FGSG changes to ToR's' NMSG changes to ToR's; Shared Care changes to TORs
0.8	June 2014	Donna Gillespie-Greene	APC changes to TOR
0.9	June 2014	Clare Moss	Safety changes to TORs
1.0	July 2014	Donna Gillespie-Greene	Clarification of voting and non-voting members
1.1	January 2015	Donna Gillespie-Greene	Added sections 2.5.7 - Guests at meetings and 2.5.8 – appropriate behaviour.
1.2	March 2015	Donna Gillespie-Greene	Formatting changes
1.3	March 2015	Jenny Lunn	Appeals process updated
1.4	April 2015	Donna Gillespie-Greene	Remove reference to Patient and Public Involvement Subgroup
1.5	May 2015	Donna Gillespie-Greene	Administrative amendment to include contact email for submission of appeals
2.0	May 2017	Kieron Donlon Donna Gillespie-Greene	Grammar, spelling, formatting, layout, switch to MLCSU from CMCSU Addition of core principles. Review of Subgroup ToRs and appeals process. Addition of statement regarding APC quoracy.
2.1	May 2018	Donna Gillespie-Greene	Addition of devices criteria Inclusion of Wirral CCG, Wirral University Teaching Hospitals and Cheshire and Wirral Partnership to the membership.

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# Midlands and Lancashire CSU Medicines Management on behalf of:

Halton CCG

Knowsley CCG

Liverpool CCG

South Sefton CCG

Southport and Formby CCG

St Helens CCG

Warrington CCG

West Lancashire CCG

Wirral CCG

Aintree University Hospitals NHS Foundation Trust

Alder Hey Hospital Children's NHS Foundation Trust

Bridgewater Community Healthcare NHS Trust (Halton and St Helens Division and Warrington Division)

Cheshire and Wirral Partnership NHS Foundation Trust

North West Boroughs Partnership NHS Foundation Trust

Liverpool Heart and Chest Hospital NHS Foundation Trust

Liverpool Women's NHS Foundation Trust

Mersey Care NHS Trust

MerseyCare, Liverpool and South Sefton Community Services Division

Royal Liverpool and Broadgreen University Hospitals NHS Trust

Southport and Ormskirk Hospital NHS Trust

St Helens and Knowsley Teaching Hospitals NHS Trust

The Walton Centre NHS Foundation Trust

Warrington and Halton Hospitals NHS Foundation Trust

Wirral University Teaching Hospital NHS Foundation Trust

Wirral Community NHS Foundation Trust

# 1. Policy statement/Key objectives

The objectives of this policy are to help constituent organisations:

- Commission medicines and related services using the most effective and efficient management of resources
- Provide unbiased but accountable commissioning, leadership and strategic co-ordination of the use of medicines
- Commission services using medicines that focus on achieving improved clinical outcomes.

## 1.1. Background

The NHS Constitution 2013 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.

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 re-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)

Healthcare commissioners have a statutory responsibility to ensure that care, including medicines and treatments, is commissioned within available resources (Department of Health, 2010). In order to secure the best value healthcare and the greatest health benefit for their populations, commissioners need to prioritise the allocation of limited resources and balance demands for medicines and treatments against a number of considerations. Commissioners may not always be able to fund all the care that is practically possible.

The Pan Mersey Area Prescribing Committee supports a coordinated approach to managing medicines by its key constituent organisations. The overall aim is to take a health economy approach to the commissioning and use of medicines in primary and secondary care, linking with tertiary and specialist provision. This document describes the framework by which this process will take place in a consistent, predictable, open and transparent manner.

## 2. Purpose of the APC

### 2.1. Overview

The aim of the APC is to make recommendations to commissioners with regard to the use of medicines. Recommendations will be made following consensus agreement by stakeholders informed by systematic evidence evaluation and consultation.

Co-ordination of this activity across Merseyside, Warrington and West Lancs through the APC will minimise unnecessary variation in medicines use and policy across the area (“postcode prescribing”) for the benefit of patients, providers and commissioners. The APC will make recommendations to commissioners on the introduction of new medicines, development/review of formularies, guidelines and shared care processes, and patient safety issues regarding medicines. It will include consideration of clinical outcomes; cost-effectiveness, safety, prioritisation, and affordability. Recommendations must be supported and enabled by a clear and equitable ethical framework. The ethical framework is included in Appendix 3.

### 2.2. Core Principles

#### Principle 1

The values and principles driving priority setting at all levels of decision-making should be consistent.

#### Principle 2

The Clinical Commissioning Group has a legal responsibility to commission healthcare, within the areas for which it has commissioning responsibility, in a manner which is consistent with its legal duty not to overspend its allocated budget.

#### Principle 3

The Clinical Commissioning Group has a responsibility to make rational decisions in determining the way it allocates resources to the services it directly commissions and to act fairly in balancing competing claims on resources between different patient groups and individuals.

#### Principle 4

Competing needs of patients and services within the areas of responsibility of the Clinical Commissioning Group should have a fair chance of being considered, subject to the capacity of the Clinical Commissioning Group 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.

#### Principle 5

Access to services should be governed, as far as practicable, by the principle of equal access for equal clinical need. Individual patients or groups should not be disadvantaged or unjustifiably advantaged or on the basis of age, gender, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intellectual/cognitive function or physical functions.

There are proven links 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 sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

### **Principle 6**

The Clinical Commissioning Groups are required to assess the cost effectiveness and clinical effectiveness of all interventions and only invest in treatments which are of:

1. Proven cost-effectiveness; or
2. Likely cost-effectiveness based on balance of probability; or
3. Likely cost-effectiveness to the equivalent current treatment, for which there is the intention to continue commissioning the healthcare intervention.

Other forms of service developments must represent value for money.

### **Principle 7**

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 8**

The Clinical Commissioning Group must ensure that the decisions it takes demonstrate value for money and an appropriate use of NHS funding based on the needs of the population it serves.

### **Principle 9**

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

### **Principle 10**

The Clinical Commissioning Group should strive, as far as practicable, to provide equal treatment to individuals in the same clinical circumstance. The Clinical Commissioning Group should therefore not agree to fund treatment for one patient which cannot be afforded for, and openly offered to, all patients with similar clinical circumstances and needs.

### **Principle 11**

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

### **Principle 12**

Because the capacity of the NHS to fund research is limited, requests for funding to support research have to be subject to normal prioritisation processes.

### **Principle 13**

Patients participating in clinical trials are entitled to be informed about the outcome of the trial and to share any benefits resulting from having been in the trial. The responsibility for this lies with the party initiating and funding the trial and not the Clinical Commissioning Group unless the Clinical Commissioning Group has either itself funded the trial or agreed in advance to fund aftercare for patients entering the trial.

### **Principle 14**

Unless the requested treatment is approved under existing policies of the Clinical Commissioning Group, the Clinical Commissioning Group will not, save in exceptional circumstances, commission a continuation of privately funded treatment even if that treatment has been shown to have clinical benefit for the individual patient.



### **2.3. Emergency/Urgent decisions on medicines**

Secondary care providers may occasionally require access to a drug-based intervention or treatment in an urgent setting, which has not been approved for use within the health economy. In this setting, approval should be sought from the Medical Director/Chair of the D and T Committee of the provider, and the Head of Pharmacy/Deputy, following discussion and support of the clinicians own Clinical Director. The use of medicines in this way will usually be at the expense of the provider trust. Where this is disputed, the medicines will initially need to be funded by the provider, and subsequent discussions with the commissioner should follow, and not precede the decision to provide the urgent intervention. Where the number of requests for a particular treatment suggests that it is not exceptional, clinicians will be required to submit a business case.

### **2.4. Dealing with requests for funding of exceptional treatments that are not included in current NHS commissioning agreements and contracts.**

Individual Funding Requests are considered where the individual or treatment is exceptional. That is the treatment can be described as exceptional when the patient is 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 intervention than might normally be expected for patients with that condition.

### **2.5. Current contracting and payment processes**

Drugs are funded through a variety of routes and differ between providers and commissioners.

Commissioners directly fund drug costs outside of a tariff:

- Through local prices and monitoring arrangements for drugs on the payment by results (PbR) exclusion list. This list specifically defines a range of drugs and devices and HRGs which are excluded from national mandatory PbR tariff where local commissioning arrangements should be made. These include most of the highest cost drugs, e.g. for cancer, HIV and many serious rare illnesses
- Via “pass-through payments”/prior approval where, in exceptional circumstances, new technologies (including medicines) are identified that demonstrate significant health improvement and have high financial or service implications
- Through primary care prescribing budgets; some of this is secondary care initiated and primary care cover the on-going costs of long-term treatments
- Through contracts outside of PbR, which includes those services not currently covered by PbR (including the Mental Health Trust contract), or those locally negotiated by commissioners
- Providers fund the use of drugs:
  - Within national tariff HRG (Health Resource Group) costs i.e. within tariff
  - Within locally negotiated contracts outside of PbR

NHS England has responsibility for the operational management of the Cancer Drugs Fund (CDF). The CDF provides an additional £200m each year to enable patients to access drugs that are not routinely funded by the NHS. There is a single, national list of drugs and indications that the CDF will routinely fund and standard operating procedures for administration of the fund. The NHS England Website has further information (<http://www.england.nhs.uk/ourwork/pe/cdf/>). Individual Cancer Drug Fund requests should be made through NHS England.

NHS England also has responsibility for specialised services. Full information is found in the Manual for prescribed specialised services. The Manual describes which elements of specialised services are directly commissioned by NHS England and which by CCGs.

<https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-may16.pdf>



## 2.6. Operation of APC

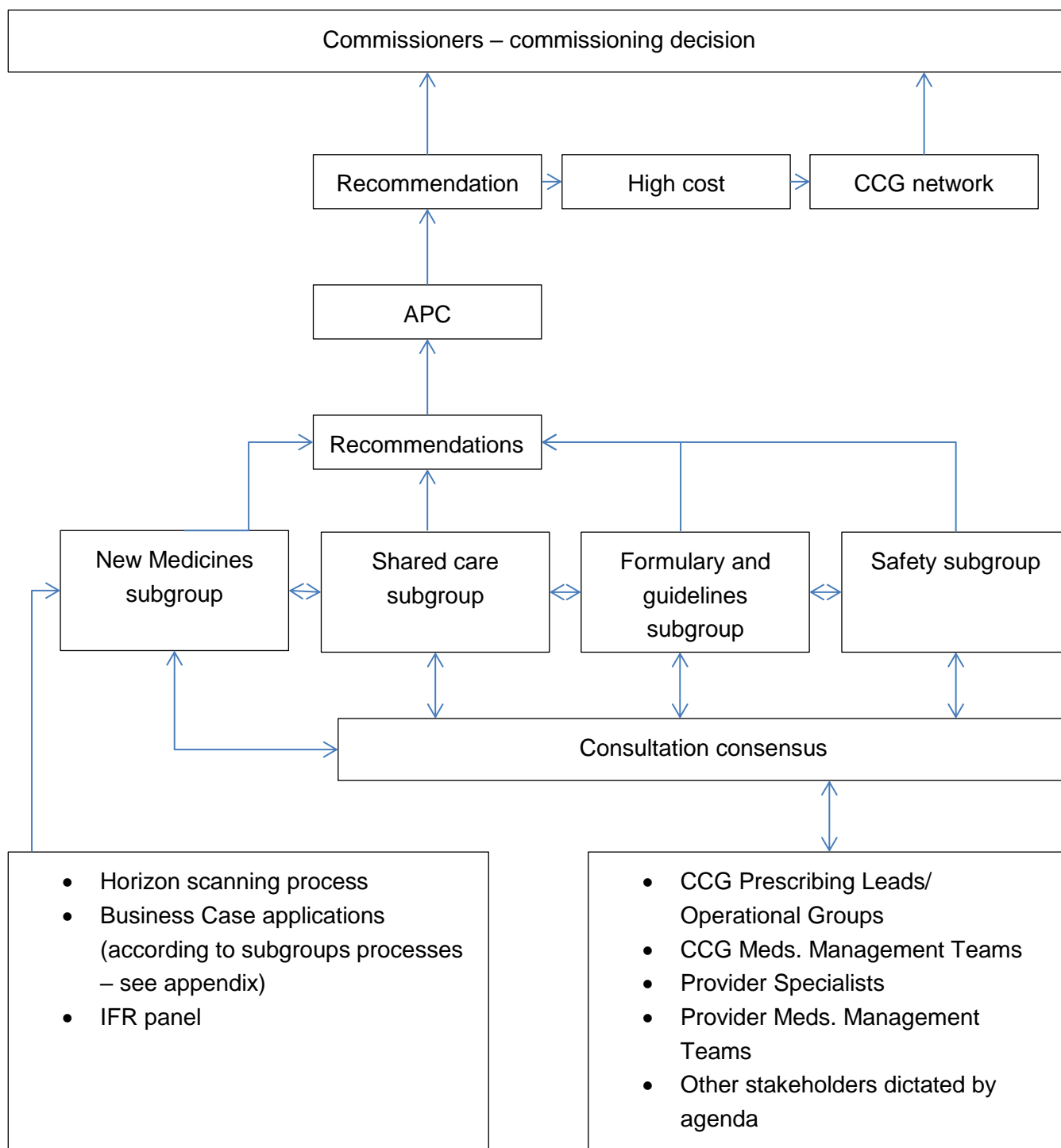


Fig. 1 Schematic representation of APC operation

### 2.6.1. Membership

The membership of the APC is detailed in the terms of reference in appendix 2, Each of the member organisations is invited to send one pharmacist and one medical representative. Representatives are also invited from the Local Medical Committees and the Local Pharmacy Committees, the Local Public Health Network and the Healthwatch Medicines Scrutiny Sub-Group. In addition, Midlands and Lancashire CSU will provide a professional secretary present at all meetings who will organise venues, meeting timetable, agendas and minute-taking on behalf of the constituent organisations.

## **2.6.2. Terms of reference**

See appendix 1.

## **2.6.3. Frequency of meetings**

The APC will meet once per month, with the exception of August and December.

## **2.6.4. Website**

Midlands and Lancashire CSU will create and update the APC website which will contain all agreed recommendations/ CCG commissioning decisions, shared care protocols, red-amber drugs list, joint formulary, guidelines and other documents agreed by the APC. Constituent organisations can create links to this site from their websites to aid dissemination of information.

## **2.6.5. Subgroups**

The APC will perform its function through 4 subgroups

- New Medicines
- Formulary and Guidelines
- Safety
- Shared Care

The terms of reference and other documents describing structure and procedures of each of subgroups are contained in Appendix 2.

The subgroups will prioritise work areas on behalf of, and in consultation with, constituent organisations and the APC. They will produce initial recommendations for stakeholder consultation prior to submission to the APC using systematic methods to include consideration of clinical outcomes, specialist expertise, cost-effectiveness, safety, priorities of constituent organisations, affordability and patient opinions. The APC will use the submissions from the subgroups as a basis for recommendations to commissioners.

Medical devices criteria – see page 11.

Additionally, the APC will provide a forum for the review of prescribing trends/QIPP work areas across the constituent organisations.

## **2.6.6. Orphan Drugs**

The European Union (EU) legislation defines an orphan drug as one that could treat a disease with a prevalence of less than five per 10,000 of the population. Orphan drugs can be designated by the European Medicines Evaluation Authority (EMA) and in due course may be given marketing authorisation by the EMA. This then allows the drug to be marketed across the EU countries but the EMA does not impose any obligation for the orphan drug to be funded by healthcare organisations.

The APC will, in the absence of Direction made by the Secretary of State, consider orphan drugs using the same decision-making principles and processes as are applied to other treatments.

## **2.6.7. Guests at Meetings**

Attendance at the APC 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 APC or subgroup. Guests attending without permission will not be invited to speak and will not be allowed to vote. Any comments made by an unauthorised guest will not be minuted.

### **2.6.8. Appropriate Behaviour**

All members attending the APC 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.

All speakers are asked to be clear and concise, as the APC and subgroups have busy agendas, and are required to keep to time.

### **2.6.9. Medical Devices Criteria**

- Require prescription of ongoing consumables at regular intervals.
- Administered substances that in practice are working as a medicine.
- Related to drug treatment, for example monitoring drug therapy.
- Potentially significant cost implication >£250,000 annually in Pan Mersey area.
- Where an NHS body has already published an evaluation.

The criteria provide a guide and it may be that only one of the criteria would be necessary, but on occasion more than one. The decision to add to the APC workplan would be made by consensus recommendation of Formulary & Guidelines Sub-group and Pan Mersey CCG Medicines Management Leads.

Specifically excluded from evaluation by Pan Mersey APC would be:

- Dressings
- Incontinence products
- Stoma products
- Feeds

These APC-excluded areas need to be evaluated by existing or new bodies set up for the purpose, preferably acting as task and finish groups supported by the APC process. Existing bodies may be, for example, committees currently in operation within service providers that evaluate these products for internal formularies.

## Appendix 1 Pan Mersey Area Prescribing Committee (APC)

### Terms of Reference

#### Strategic Aim

The Pan Mersey Area Prescribing Committee will provide a platform for a consensus decision-making processes relating to the use of medicines across the Pan Mersey footprint, to ensure equity in access to medicines and optimisation of medicines use. The underpinning working groups, when making recommendations to the APC, will ensure that patient outcomes and safety considerations are at the forefront of the decision-making process.

The committee will make recommendations to commissioning groups and provider organisations for adoption in order to ensure the best use of medicines and associated resources across the health and social care system in Merseyside, West Lancashire and Warrington.

#### 1. Current Membership

Member	Comments	Number
Chair	Nominated Deputy Chair	1
Professional Secretary	1 MLCSU MM representative <b>Non-voting</b>	1
DandT Chairs	1 representative from each Trust (and nominated deputy) attendance as per agenda	5 Acute, 6 other
Chief Pharmacist – secondary care	1 from each Trust (and nominated deputy); attendance as per agenda	5 Acute, 6 other
CCG representatives	2 representative from each CCG at least one of which must be a GP (and nominated deputy)	16
Community provider representatives	1 from each community provider <b>Non-voting</b>	4
Lay members	1 representative from the Healthwatch medicines Scrutiny Subgroup (and nominated deputy)	1
LMC	1 regional representative (and nominated deputy)	1
LPC	1 regional representative (and nominated deputy)	1
Finance representative	1 representing the CCGs (and nominated deputy)	1
Public Health representative	1 from the Local Public Health Network (and nominated deputy)	1
Minute Secretary	<b>Non-voting</b>	1
<b>Total</b>		<b>38 - 52</b>

A total of 46 people will be members of the Pan Mersey Area Prescribing Committee (APC).

Members who are unable to attend will be expected to send a nominated deputy where possible.

The Chair and Deputy Chair will be appointed by the committee for a period of one year.

Meetings will be held monthly (except December/August).

Organisations represented include those from the following:

<b>Acute Trust</b>	<b>Clinical Commissioning Groups</b>	<b>Community Providers</b>
Aintree University Hospitals NHS Foundation Trust	Liverpool	MerseyCare, Liverpool and South Sefton Community Services Division
Alder Hey Children's NHS Foundation Trust*	South Sefton	
Liverpool Heart and Chest Hospital NHS Foundation Trust *	Southport and Formby	Southport and Ormskirk Hospital NHS Trust
Liverpool Women's NHS Foundation Trust*	Warrington	Bridgewater Community NHS Trust
Mersey Care NHS Trust*	West Lancashire	North West Boroughs Partnership NHS Foundation Trust*
Royal Liverpool and Broadgreen University Hospitals NHS Trust	Halton	Wirral Community NHS Foundation Trust
Southport and Ormskirk Hospital NHS Trust	St Helens	
St Helens and Knowsley Teaching Hospital	Knowsley	
Warrington and Halton Hospitals NHS Foundation Trust	Wirral	
North West Boroughs Partnership NHS Foundation Trust*		
The Walton Centre NHS Foundation Trust*		
Wirral University Teaching Hospitals NHS Foundation Trust		
Cheshire and Wirral Partnership NHS Foundation Trust*		

Specialist trusts\* and Community Providers to attend if relevant agenda items only

There will be a timed agenda to facilitate authors attend to present their work and take back questions, amendments to policy statements to be completed within 1 week so recommendations can be uploaded to the website.

## 2. Quoracy

The APC will be quorate if six of the medical representatives are present, four from primary care and two from secondary care. If the APC is not quorate, the committee will be made aware, and this will be clearly noted on the APC report, in order that the approving Medicines Management Committees within the CCGs are aware of the lack of quoracy at the APC meeting where the recommendations were made. In the event of this occurring, at the next quorate meeting, the attention of members will be drawn to these recommendations for noting.

## 3. Purpose of the APC

The APC will promote joint working and make recommendations on health policy across the health economy previously covered by The North Sefton and West Lancashire Area Medicines Management Committee, the North Mersey Area Medicines Management Committee and the Mid Mersey Medicines Management Board. This is to ensure a consistent, equitable and transparent approach to all aspects of medicines management throughout the local health system ensuring compliance with the principles of the NHS Constitution.

## 4. Terms of Reference

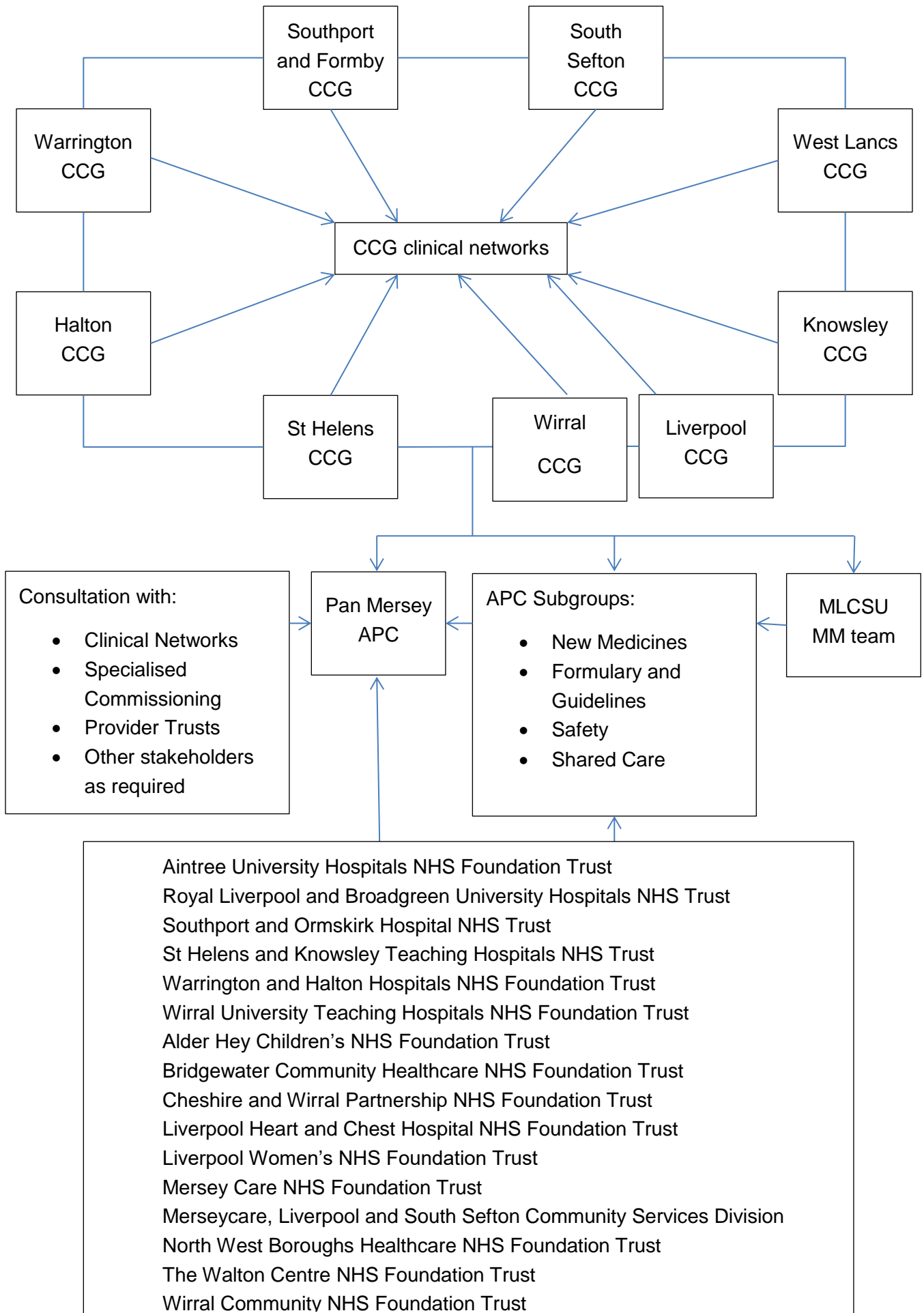
- a) To provide advice regarding the implications of new drugs in development to the local health economy
- b) Use horizon scanning to collate and appraise evidence, to reach a consensus regarding the place in treatment of relevant new drugs and formulations, or of existing drugs with new indications.
- c) To review the medicines usage of existing treatments, to make recommendations to CCGs and provider organisations to work towards a consistent approach to medicines management across the area. This work will be informed by the New Medicines and Formulary and Guidelines Subgroups with recommendations for BLACK, RED, AMBER, GREY or GREEN listings.
- d) To monitor and co-ordinate the implementation of local and national guidelines by assessing local impact, reviewing implementation plans and commissioning audit through CQUIN targets
- e) To review the implication of ongoing clinical trials on future prescribing.
- f) To review and facilitate the development of local therapeutic guidelines and protocols, involving the use of medicines across the primary and secondary care interface. This work will be informed by the Shared Care Subgroup
- g) To recommend that the implications of decisions made by the APC will be given full financial consideration by all stakeholder organisations
- h) To ensure member organisations are consulted in full when recommendations are in development. This includes Clinical Networks, Specialised Commissioning and Public Health (where appropriate).
- i) To ensure all recommendations are uploaded to the APC website within 1 week of agreement and a monthly e-newsletter is disseminated to all member organisations for internal distribution.
- j) To ensure member organisations communicate the decisions of the APC to the appropriate healthcare professionals across the local healthcare system and to relevant clinical networks.
- k) To support and co-ordinate responses to recommendations made by the Safety subgroup as part of an overall risk management strategy.
- l) To provide information and advice to provider organisations and CCGs on medicines management issues.
- m) To receive updates and to influence the work programme of the established Merseyside Medicines Management Subgroups. These include:
  - a. New Medicines
  - b. Formulary and Guidelines
  - c. Safety

d. Shared Care

**5. Glossary of Terms**

CCG	Clinical Commissioning Groups
MLCSU	Midlands and Lancashire Commissioning Support Unit
D and T	Drug and Therapeutics Committee
LMC	Local Medical Committee
LPC	Local Pharmaceutical Committee
MM	Medicines Management
QIPP	Quality, Innovation, Productivity and Prevention
Trust	Community/ Secondary/ Tertiary Care Provider





# Formulary and Guidelines Subgroup

### Terms of Reference

#### 1. Aim

The Sub-Group will:

Systematically work to update the Joint Mersey Formulary

- Develop, review and update local guidelines and policy recommendations for safe and cost-effective use of medicines

#### 2. Membership

The Formulary and Guidelines Subgroup membership consists only of Pharmacists, for logistical purposes. The Subgroup routinely obtains expert advice from Clinicians as part of the document development and stakeholder consultation processes.

The Subgroup Chair, administrative support and overall operational management of the Formulary and Guidelines Subgroup will be provided by the Midlands and Lancashire Commissioning Support Unit Medicines Management Mersey Core Offer Team.

Membership is specific to individuals, but members who are unable to attend will be expected to send a nominated deputy where possible.

Organisations represented include those from the following:

<b>Acute Trusts</b>	<b>CCGs</b>	<b>Specialist Trusts</b>
Aintree University Hospitals NHS Foundation Trust	Halton CCG	The Walton Centre NHS Foundation Trust
Warrington and Halton Hospitals NHS Foundation Trust	Knowsley CCG	North West Boroughs Partnership NHS Foundation Trust
Royal Liverpool and Broadgreen University Hospitals NHS Trust	Liverpool CCG	Liverpool Women's NHS Foundation Trust
Southport and Ormskirk Hospital NHS Trust	South Sefton CCG	Alder Hey Hospital Children's NHS Trust
St Helens and Knowsley Teaching Hospitals NHS Trust	Southport and Formby CCG	MerseyCare NHS Trust
Wirral University Teaching Hospitals NHS Foundation Trust	St Helens CCG	Liverpool Heart and Chest Hospital NHS Foundation Trust
	Warrington CCG	Bridgewater Community Healthcare NHS Foundation Trust

	West Lancashire CCG	Merseycare, Liverpool and South Sefton Community Services Division
		Wirral Community NHS Foundation Trust
		Cheshire and Wirral Partnership NHS Foundation Trust

\*Specialist Trust members to attend if relevant agenda items only.

### 3. Quoracy

The Formulary and Guidelines Subgroup will be quorate if there are representatives present from four CCGs, three acute Trusts and a Chair/Deputy from MLCSU.

### 4. Frequency of Meetings

Meetings will be held monthly. Normally there will be 12 meetings each year, with a minimum of 10 meetings each year.

### 5. Purpose

The Formulary and Guidelines Subgroup will make recommendations on the content of the joint formulary to be used across the Pan Mersey area and will review the formulary on a regular basis. It will devise guidelines and treatment pathways on medicines use in managing conditions in the Pan Mersey area. It will work in conjunction with stakeholders to promote a consistent approach to the use of medicines in the Pan Mersey health economy.

### 6. Reporting Mechanism

The Formulary and Guidelines Subgroup will report directly to the Pan Mersey APC.

### 7. Terms of Reference

- a) To maintain a single Pan Mersey Medicines Formulary.
- b) Prioritise, produce and implement a work plan to address any areas identified which may have significant clinical or financial impact on the Pan Mersey health economy. To agree a standard format for the formulary.
- c) Maintain a process for requests for new inclusions and also the processes for timely update of the Formulary.
- d) To identify key medicines guidelines in use within the Pan Mersey Health Economy and determine if there are any key differences between trusts. Prioritise, produce and implement a work plan to address areas identified which may have significant clinical or financial impact on the Pan Mersey health economy, agreed with Commissioner and Provider member organisations lead pharmacists.
- e) Identify any areas which require the development of new guidelines e.g. to support the implementation of NICE technology appraisals and clinical guidelines. Review all policies for NICE-approved indications which vary from specific elements of NICE guidance e.g. dosage. Ensure that all such variances are brought to the attention of the APC
- f) To work closely with the New Medicines Subgroup who will receive and initially review applications from healthcare professionals to the APC for a new medicine, or a change in the Joint Formulary status of an existing medicine.
- g) To work closely with other sub-groups on the production of medicines guidelines

- h) To consult and engage local specialists in the review of each section of the formulary and in the review and production of medicines guidelines.
- i) To make recommendations to the APC on the formulary or medicines guidelines.
- j) To publish the formulary, guidelines and updates using media to ensure maximum accessibility, ease of use and impact.
- k) To support the review of adherence to the formulary and local medicines guidelines.
- l) To undertake specific projects relevant to the management of medicines within the Pan Mersey health economy as requested by the Area Prescribing Committee.
- m) To ensure that any recommendations taken to the Pan Mersey APC are consistent with the principles contained in the NHS Constitution and the Pan Mersey policy on Prioritisation of Medicines.

## **8. Glossary of Terms**

CCG	Clinical Commissioning Group
MLCSU	Midlands and Lancashire Commissioning Support Unit
APC	Area Prescribing Committee
Trust	Community/Secondary/Tertiary Care Provider

# Safety Subgroup

## Terms of Reference

### 1. Aim

The Safety Subgroup will provide a forum for the review of alerts, guidance and locally collated information with regard to the safe use of medicines. Recommendations will be made by the subgroup to the Pan Mersey Area Prescribing Committee (APC) in order to support a consistent approach to managing medicines safety issues and provide assurance to individual organisations

### 2. Membership

The membership of the group will be formed by a representative from each of the following organisations. Specialist trust representatives will attend the group as and when relevant matters arise.

<b>Acute Trusts</b>	<b>CCGs</b>	<b>Specialist Trusts</b>
Aintree University Hospitals NHS Foundation Trust	Halton CCG	Alder Hey Hospital Children's NHS Trust
Royal Liverpool and Broadgreen University Hospitals NHS Trust	Knowsley CCG	Bridgewater Community Health Trust
Southport and Ormskirk Hospital NHS Trust	Liverpool CCG	Merseycare, Liverpool and South Sefton Community Services Division
St Helens and Knowsley Teaching Hospitals NHS Trust	Southport and Formby CCG	Liverpool Heart and Chest Hospital NHS Foundation Trust
Warrington and Halton Hospitals NHS Foundation Trust	South Sefton CCG	Liverpool Women's NHS Foundation Trust
Wirral University Teaching Hospitals NHS Foundation Trust	St Helens CCG	Merseycare NHS Trust
	Warrington CCG	North West Boroughs Healthcare NHS Foundation Trust
	West Lancashire CCG	The Walton Centre
	Wirral CCG	Cheshire and Wirral Partnership NHS Foundation Trust
		Wirral Community NHS Foundation Trust

Two senior pharmacists from Midlands and Lancashire Commissioning Support Unit (chair and deputy)

### 3. Quoracy

The subgroup will be quorate if there are representatives from three CCGs, two acute trusts, one other trust and one CSU representative. One representative may represent more than one organisation.

#### **4. Purpose**

The Safety Subgroup will promote joint working and provide evidence-based recommendations to the Pan Mersey APC to support the safe use of medicines across the Pan Mersey health economy.

#### **5. Terms of reference**

- 1) Capture medicines safety issues:
  - a) Actively monitor national safety publications
  - b) Support and encourage local reporting of interface incidents, adverse events and near misses
- 2) Review medicines safety issues:
  - a) Review, risk assess and agree on an appropriate action for each issue
  - b) Identify trends from interface incidents, adverse events and near misses
  - c) Provide a forum for shared learning
- 3) Respond to medicines safety issues:
  - a) Respond in a timely manner
  - b) Develop a Pan Mersey, cross-organisational approach to implementation of agreed actions
  - c) Produce and publish recommendations, policy statements, and supporting information
- 4) Develop a work programme to monitor response
- 5) Report progress regularly to the Pan Mersey Area Prescribing Committee

#### **6. Meeting frequency**

The subgroup will meet every two months unless a need arises for an interim meeting.

#### **7. Reporting**

The subgroup chair or deputy will report to the APC every two months unless there has been a need for an interim meeting. The report will detail outcomes and achievements and areas for action and completion.

#### **8. Review**

Originally issued: March 2014; Updated: June 2017; Review: June 2019

# New Medicines Subgroup

## Terms of Reference

### 1. Aim

The New Medicines Subgroup will provide a forum for review of the current evidence and to provide evidence-based recommendations to the Pan Mersey Area Prescribing Committee (APC) in order to support the managed entry of new medicines or new indications for existing medicines into the Pan Mersey health economy. Recommendations from the New Medicines Subgroup will support the safe and effective prescribing of new medicines whilst ensuring that patient outcomes and safety considerations are at the forefront of the decision making process.

### 2. Current Membership

The membership of the group will be formed by a pharmacist representative from each of the following organisations. Specialist trust representatives will attend the group as and when relevant matters arise. The Subgroup routinely obtains expert advice from relevant clinicians as part of the document development and stakeholder consultation processes.

The Subgroup Chair, administrative support and overall operational management of the New Medicines Subgroup will be provided by the Midlands & Lancashire Commissioning Support Unit.

<b>Acute Trusts</b>	<b>CCGs</b>	<b>Specialist Trusts</b>
Aintree University Hospitals NHS Foundation Trust	Halton CCG	Alder Hey Children's NHS Foundation Trust
Royal Liverpool and Broadgreen University Hospitals NHS Trust	Knowsley CCG	Bridgewater Community Healthcare NHS Foundation Trust
Southport and Ormskirk Hospital NHS Trust	Liverpool CCG	Cheshire and Wirral Partnership NHS Foundation Trust
St Helens and Knowsley Teaching Hospitals NHS Trust	Southport and Formby CCG	MerseyCare, Liverpool and South Sefton Community Services Division
Warrington and Halton Hospitals NHS Foundation Trust	South Sefton CCG	Liverpool Heart and Chest Hospital NHS Foundation Trust
Wirral University Teaching Hospitals NHS Foundation Trust	St Helens CCG	Liverpool Women's NHS Foundation Trust
	Warrington CCG	Mersey Care NHS Foundation Trust
	West Lancashire CCG	North West Boroughs Healthcare NHS Foundation Trust
	Wirral CCG	The Walton Centre NHS Foundation Trust
		Wirral Community NHS Foundation Trust



### **3. Quoracy**

The subgroup will be quorate if there are representatives present from four CCGs, three Acute Trusts and a Chair/Deputy from MLCSU.

### **4. Purpose**

The New Medicines Subgroup will promote joint working and provide evidence-based recommendations to the Pan Mersey APC to support the safe and effective prescribing of new medicines across the Pan Mersey health economy. This will ensure a consistent, equitable and transparent approach to the introduction of new medicines into the local health economy whilst ensuring compliance with the principles of the NHS Constitution.

### **5. Terms of Reference**

- a.** To collate and appraise the evidence then provide evidence-based recommendations and proposed RAG rating to the Pan Mersey APC regarding the introduction of new medicines, or new indications for existing medicines, into the Pan Mersey health economy.
- b.** To 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 Pan Mersey health economy.
- c.** To co-ordinate the timely introduction of NICE Technology Appraisals into the Pan Mersey health economy, for medicines commissioned by CCGs.
- d.** To receive and prioritise in-year applications from healthcare professionals within the Pan Mersey health economy for a new medicine or new indication for an existing medicine.
- e.** To 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 Pan Mersey health economy.
- f.** To make recommendations to the Pan Mersey APC for managing medicines in relation to the Payment by Results tariff and exclusions.
- g.** To liaise with the other Pan Mersey APC subgroups as appropriate to ensure consistency of recommendations and within formulary and guidelines, and to inform the on-going updating of the Pan Mersey APC website and formulary.
- h.** To review and update existing documents at appropriate intervals.
- i.** To ensure that any recommendations taken to the Pan Mersey APC comply with the principles of the NHS Constitution.
- j.** To provide updates of the New Medicines Subgroup work programme to the Pan Mersey APC when requested.

### **6. Meeting Frequency**

The subgroup will meet every month, with the exception of August.

### **7. Reporting**

The New Medicines Subgroup reports directly to the Pan Mersey APC. The subgroup chair or deputy will report to the APC every month with outcomes, achievements and relevant updates.

### **8. Review**

Originally issued: March 2014; Partial update: January 2018; Review: June 2019

# Shared Care Subgroup

## Terms of Reference

### 1. Aim

To provide a harmonised approach to the development of shared care frameworks across Merseyside and Warrington. Recommendations will be made by the subgroup to the Pan Mersey Area Prescribing Committee (APC) to support a consistent approach to managing the shared care of appropriate medicines across the interface between primary care and secondary/tertiary care organisations.

### 2. Membership

The membership of the group will be formed by a representative from each of the following organisations. The Shared Care Subgroup membership consists only of medicines management personell, for logistical purposes. The Subgroup routinely obtains expert advice from Clinicians as part of the document development and stakeholder consultation processes. Specialist trust representatives will attend the group as and when relevant matters arise.

<b>Acute Trusts</b>	<b>CCGs</b>	<b>Specialist Trusts</b>
Aintree University Hospitals NHS Foundation Trust	Halton CCG	The Walton Centre
Warrington and Halton Hospitals NHS Foundation Trust	Knowsley CCG	North West Boroughs Partnership NHS Foundation Trust
Liverpool Heart and Chest Hospital NHS Foundation Trust*	Liverpool CCG	Liverpool Women's NHS Foundation Trust
Royal Liverpool and Broadgreen University Hospitals NHS Trust	South Sefton CCG	Alder Hey Hospital Children's NHS Trust
Southport and Ormskirk Hospital NHS Trust	Southport and Formby CCG	Mersey Care NHS Trust
St Helens and Knowsley Teaching Hospitals NHS Trust	St Helens CCG	Bridgewater Community Healthcare NHS Foundation Trust
MerseyCare, Liverpool and South Sefton Community Services Division	Warrington CCG	Cheshire and Wirral Partnership NHS Foundation Trust
Wirral University Teaching Hospitals NHS Foundation Trust	Wirral CCG	Wirral Community NHS Foundation Trust
Two senior Pharmacists from Midlands and Lancashire Commissioning Support Unit (Chair and deputy)		

### 3. Quoracy

The subgroup will be quorate if there are representatives from 3 CCGs, 1 hospital trust and one CSU representative. One representative may represent more than one organisation.

#### **4. Purpose**

The Shared Care Subgroup will provide a forum for the assessment of need, development and review of shared care frameworks and prescribing support information across Merseyside and Warrington. The Shared Care Subgroup will promote joint working and provide evidence-based recommendations to the Pan Mersey APC to support the appropriate use of shared care across the Pan Mersey health economy.

#### **5. Terms of Reference**

- a) To develop a Pan Mersey, cross-organisational approach to the development and harmonisation of shared care frameworks across the Pan Mersey health economy
- b) To identify a work programme of shared care frameworks and prescribing support information to be developed and reviewed each year, accommodating the priorities of CCGs, secondary and tertiary care trusts.
- c) To ensure that any draft frameworks or recommendations to the APC are consistent with NICE Guideline recommendations and with the Pan Mersey Red Amber Green (RAG) list of recommendations for primary and secondary care prescribing, as appropriate.
- d) To maintain and update existing documents approved by the APC on the APC website.
- e) To identify additional sources of specialist advice in the appropriate fields, including hospital specialists and GPs with a special interest as required.
- f) To ensure that any recommendations taken to the Pan Mersey APC are consistent with the principles contained in the NHS Constitution and the Pan Mersey Policy on Prioritisation of Medicines
- g) To report progress regularly to the Pan Mersey Area Prescribing Committee.

#### **6. Reporting**

The Shared Care subgroup will report directly to the APC

#### **7. Meeting Frequency**

To meet monthly, with a minimum of 6 meetings per annum.

## Appendix 3 Ethical Framework

### Purpose of the Ethical Framework

The purpose of the ethical framework is to support and underpin the decision-making processes of constituent organisations through the APC to support consistent commissioning policy through:

- Providing a coherent structure for discussion, ensuring all important aspects of each issue are considered
- Promoting fairness and consistency in decision-making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity
- Providing a means of expressing the reasons behind the decisions made
- Reducing risk of judicial review by implementation of robust decision-making processes that are based on evidence of clinical and cost-effectiveness and an ethical framework
- Supporting and integrating with the development of commissioning plans

Formulating policy recommendations regarding healthcare priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and outwith the APC. Although there is no objective or infallible measure by which such recommendations can be based, the Ethical Framework enables recommendations to be made within a consistent setting which respects the needs of individuals and the community. The APC recognise that their recommendations may be affected by National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance and Secretary of State Directions to the NHS.

The Ethical Framework is especially concerned with the following:

#### 1. Evidence of clinical and cost-effectiveness

The APC, through its subgroups, will seek to obtain the best available evidence of clinical and cost-effectiveness using robust and reproducible methods. Methods to assess clinical and cost-effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of the APC. Choice of appropriate clinically and patient-centred outcome needs to be given careful consideration and, where possible, quality of life measures and cost utility analysis should be considered.

The APC will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment that is shown to be ineffective. Issues such as safety and drug licensing will also be carefully considered. When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients' health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies.

Evidence may be available from other sources and this will also be considered. Patients' evidence of significant clinical benefit is relevant.

The APC will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. They will consider technical cost-benefit calculations (e.g. quality adjusted life years), but these will not by themselves be decisive. The APC may use the ethical framework to guide context-specific judgements about the relative priority that should be given to each topic.

## **2. Equity**

The APC believe that people should have access to healthcare on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community. However, the APC will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, gender identity, race, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning. However, in some circumstances, these factors may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment.

## **3. Healthcare need and capacity to benefit**

Healthcare should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. The APC will consider the health needs of people and populations according to their capacity to benefit from healthcare interventions. So far as possible, it will respect the wishes of patients to choose between different clinically and cost effective treatment options, subject to the support of the clinical evidence.

This approach leads to three important principles:

- In the absence of evidence of health need, treatment will not generally be recommended solely because patients request it
- A treatment of little benefit will not be provided simply because it is the only treatment available
- Treatment which effectively treats “lifetime” or long term chronic conditions will be considered equally to urgent and life-prolonging treatments

## **4. Cost of treatment and opportunity costs**

Because each CCG is duty-bound not to exceed its budget, the cost of treatment must be considered. The cost of treatment is significant because investing in one area of healthcare inevitably diverts resources from other uses. This is known as opportunity costs and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way. The concept derives from the notion of scarcity of resources. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high.

## **5. Needs of the community**

Public health is an important concern of the APC and it will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE). Others are produced locally. The APC also recommend effective policies to promote preventive medicine which helps stop people becoming ill in the first place.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient’s condition or to stop, or slow the progression of disease. Where commissioners have not commissioned a treatment because it has a low priority, the patient’s clinician may still seek to persuade the relevant CCG that there are exceptional circumstances which mean that the patient should receive the treatment.

Such requests are considered by the relevant CCG individual funding procedure. Where the number of requests for a particular treatment suggests that it is not exceptional, the IFR panels are requested to bring the treatment to the attention of NMSG who will request that the relevant clinician/s submit a business case.

## **6. Policy drivers**

The Department of Health issues guidance and directions to NHS organisations which may give priority to some categories of patient, or require treatment to be made available within a given period. These may affect the way in which health service resources are allocated by individual commissioners. The Committees operate with these factors in mind and recognise that their discretion may be affected by NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

For NICE TAs its funding Directions provide commissioners with a period of three months within which to make a healthcare intervention available to NHS patients in recognition of the fact that it can take some time to put the necessary funding arrangements in place.

Locally, choices about the funding of healthcare treatments will be informed by the needs of each individual commissioner and these will be described in their commissioning plans.

## Appendix 4 Appraising end of life medicines

### 1. Summary

The APC may be asked to appraise life-extending medicines licensed for terminal illnesses affecting small numbers of patients, which, following appraisal, are deemed to have an incremental cost-effectiveness ratio in excess of the upper end of the range normally approved by the APC (in line with the NICE thresholds), but which nevertheless offer demonstrable survival benefits over current NHS practice. **NICE have recently amended their advice to their appraisal committees, and the APC will also follow this advice in full.**



## Appendix 5 Evidence for relative treatment effects

### Introduction

The treatment effect of a medicine can be summarised as the difference between the duration and state of health or Health-related Quality of Life (HRQL) (including the impact of any adverse effects of treatment) that would be experienced on average by patients receiving the medicine and that experienced by the same group were they to receive alternative care.

- a) The primary research methods and designs that are used to measure the treatment effect can be broadly categorised into experimental or observational studies. The most reliable evidence about the relative treatment effects of a medicine is obtained from experimental studies with high internal and external validity. For an assessment of internal validity, the different types of study design can be ranked according to design features that affect their validity for estimating relative treatment effect, ranging from RCTs to uncontrolled observational studies.
- b) The potential for bias, including performance, measurement and attrition bias, is greater in studies lower in the ranking. However, it is important to recognise that, even for the analysis of relative treatment effects, RCT data are often limited to selected populations and may include comparator treatments and short time spans that do not reflect routine or best NHS practice. Therefore, good-quality non-randomised studies may be needed to supplement RCT data. In addition, the value of evidence from anywhere in the ranking will depend on its quality and relevance to the appraisal.
- c) If relevant, up-to-date and well-conducted systematic reviews that include studies least open to bias are available, these should be considered.

### Randomised controlled trials (RCTs)

- a) RCTs are designed to minimise potential external influences so that the effects of one or more interventions in a precisely defined patient group are isolated. Randomisation aims to prevent selection bias in the allocation of interventions to participants and ensure balance between the intervention groups in known and unknown factors. The outcome of the trial should, in principle, be a minimally biased estimate of the magnitude of any benefits or risks associated with the medicine relative to those that are associated with the control. RCTs are therefore considered to be most appropriate for measures of relative treatment effect.
- b) The APC has a strong preference for evidence from 'head-to-head' RCTs that directly compare the medicine with the appropriate comparator in the relevant patient groups. When such evidence is available and includes relevant outcome evidence, this is preferred over other study designs.
- c) The relevance of RCT evidence to the appraisal depends on both the external and internal validity of each trial. Internal validity is assessed according to the features of the design and conduct of a trial that are important for eliminating bias. These features include blinding (when appropriate), the method of randomisation and concealment of allocation, and the completeness of follow-up. Other important considerations are the size of the trial, the selection and measurement of outcomes, and analysis by intention to treat. External validity is assessed according to the generalisability of the trial evidence; that is, the applicability of the results to wider patient groups over a longer follow-up than is reported in the trials and to routine clinical practice, including appropriate comparator technologies.

### Non-RCT evidence

- a) Non-RCT, both experimental and observational, evidence will be required, not just for those situations in which RCTs are unavailable, but also to supplement information from RCTs when they are available. The problems of confounding, lack of blinding, incomplete follow-up and lack of a

clear denominator and endpoint will usually be much worse in non-randomised studies than in RCTs. But in some circumstances, evidence from these studies will be needed in addition to RCT data, in particular to estimate relative treatment effect over longer time horizons or to measure particular outcomes that have not been included in the RCTs. In the absence of valid RCT evidence, evidence from studies least open to bias will be considered preferentially with reference to the inherent limitations of the specific design.

- b) Inferences about relative treatment effects drawn from non-RCT evidence will necessarily be more circumspect than those from RCTs with properly controlled evidence. The bias that may be present in non-randomised data means the results should be interpreted cautiously. When possible, the use of more than one independent source of such evidence needs to be examined to gain some assurance of the validity of any conclusions drawn.

### **Supporting references:**

A suite of NHS Confederation publications entitled:

Priority Setting: An overview

Priority Setting: Managing Individual Funding Requests

Priority Setting: Managing New Treatments

Priority Setting: Legal Considerations

Priority Setting: Strategic Planning

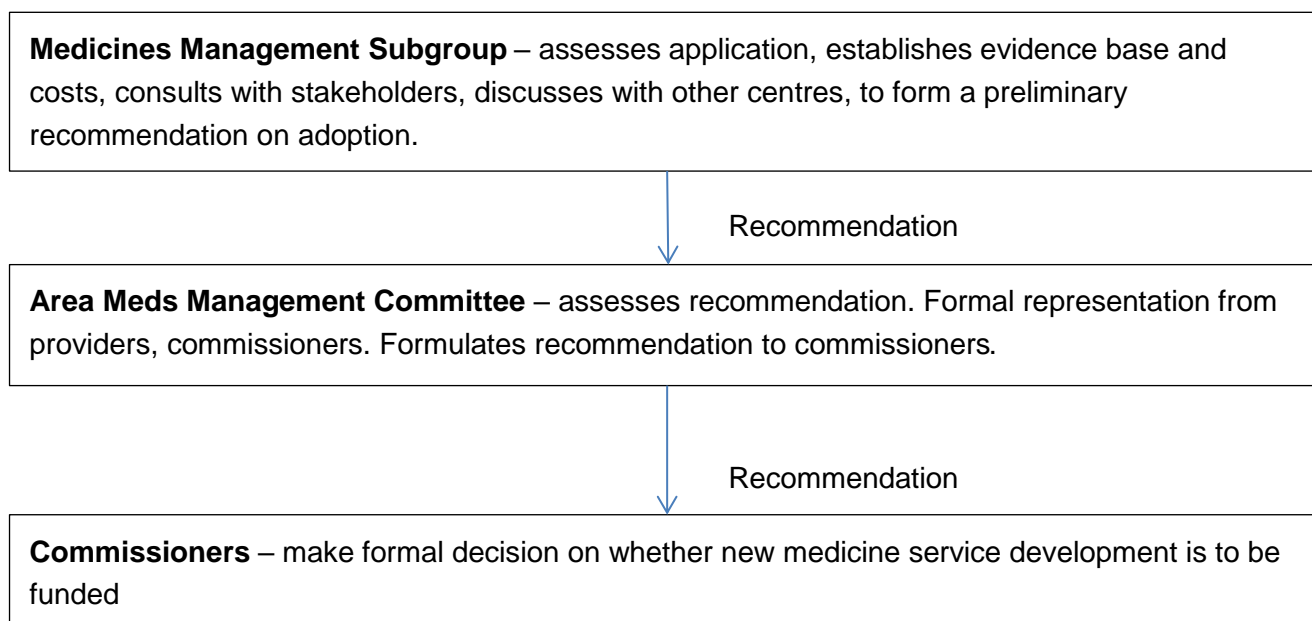
## Appendix 6 Application and Case for Introduction of New Medicine Service Developments

**Purpose of this form:** for providers to apply to commissioners for in-year funding of any new drug or extended use of an existing drug (e.g. new indication, new patient group) that will impact on prescribing costs in primary care. This includes where the prescribing will be passed on to primary care prescribers or where the drug is prescribed in hospital but generates additional PBR costs or is excluded from the Payment by Results Tariff and costs are passed on to commissioners. The annual horizon scanning process will identify the majority of new developments.

For simple new medicine service developments with no major funding implications please just complete the clinical section 1 and conflict of interest section 3.

**This form is not to be used for Individual Funding Requests (IFR).** These are considered where the individual or treatment is exceptional; i.e. where the treatment can be described as exceptional by virtue of the rarity of the condition or the difference of the individual from the generality of similar patients. Separate IFR documentation is available. Sometimes new, innovative treatment options are presented as exceptional: in this case, every effort is made to direct the clinical team to the commissioning decision route, via this service development application, although the first few requests via the exceptional treatment route may be considered so as to offer benefit to patients where this is likely.

### Process:



**Please complete this form as fully as possible.** Please complete all relevant sections legibly. Any missing or illegible information will delay the application. You must discuss this application with the relevant Pharmacy Dept./Medicines Management team. Applications completed by pharmaceutical companies are not acceptable.

**Please submit completed form to your organisation's representative on the Subgroup in your Pharmacy Dept./Medicines Management Team**

## Section 1 Clinical information

Name of medicine (generic and brand name):	
Strength(s) and form(s) of preparation: Dose and schedule of administration:	
Licensed indication(s):	
Proposed Indication (if different from or in addition to the above):	
Is this treatment instead of or in addition to any current treatment? Please give details:	
The reason for proposed change. If replacing current treatment please state how it compares regarding efficacy and safety/tolerability	
Proposed place in therapy relative to other therapies (include protocol for use if available)	
Predicted clinical impact on Primary Care e.g. will it be initiated in hospital only but then prescribed in primary care, or may it be initiated in primary care? Will it require shared care? Please describe:	
Monitoring requirements (e.g. for efficacy, side-effects) – if any? Do these differ from the current situation?	
A brief summary of evidence in support of requested medicine/additional use. Meta-analyses, systematic reviews, double-blind randomised controlled trials in peer-reviewed journals. Ensure that evidence to support advantages/benefits of the new medicine over existing treatments is included where appropriate, including criteria for treatment success. Include any relevant morbidity, mortality, health economic and quality of life benefits.	

## Section 2 Financial information

<p>Costs: (excluding VAT)</p> <p>Cost per patient per year of medicine:</p> <p>Number of patients per year to be treated for the whole organisation:</p> <p>Additional costs e.g. day case tariff, tests per patient per year:</p> <p>Any impact on PBR activity? Please give details:</p> <p>Overall financial impact:</p>	
<p>Current treatment(s) usually used (if any):</p> <p>Cost per patient per year currently treated (excluding VAT):</p> <p>Number of patients per year currently treated:</p> <p>Current additional costs e.g. day case tariff, tests per patient per year:</p>	
<p>Predicted financial impact on Primary Care.</p> <p>e.g. Is the medicine hospital only but PBR excluded, will it be initiated in hospital only but then prescribed in primary care, or may it be initiated in primary care? Please describe:</p>	

## Section 3 Conflicts of Interest

<p>Please state any potential conflicts of interest</p> <p>e.g. funding of research, equipment, consulting or speaking fees, other personal or non-personal or family interest etc. in relation to this request:</p>	
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.....  
Name of Applicant

.....  
Role

.....  
Organisation name

**I confirm I have sent a copy of this form to my organisation's Drug and Therapeutics Committee/Medicines Management Committee or equivalent, and it has been approved following the appropriate procedure within my organisation.**

.....  
Signature of Applicant

.....  
Name of Clinical Director/CCG Prescribing Lead

.....  
Signature Clinical Director/Prescribing Lead

.....  
Name of Chief Pharmacist/Head of Medicines Management

.....  
Signature of Chief Pharmacist/Head of Medicines Management

**Please note that the application will not be considered unless the Chief Pharmacist/Clinical Director/Prescribing Lead/Head of Medicines Management in your organisation have signed this form.**

## Appendix 7 Pan Mersey Area Prescribing Committee (APC) Appeals Process

### Introduction

The decision to issue a Pan Mersey policy statement recommendation is made by the Pan Mersey Area Prescribing Committee. It does this after consideration of the recommendations of its sub-committees, and in consultation with its stakeholders (see <http://www.panmerseyapc.nhs.uk/index.html>).

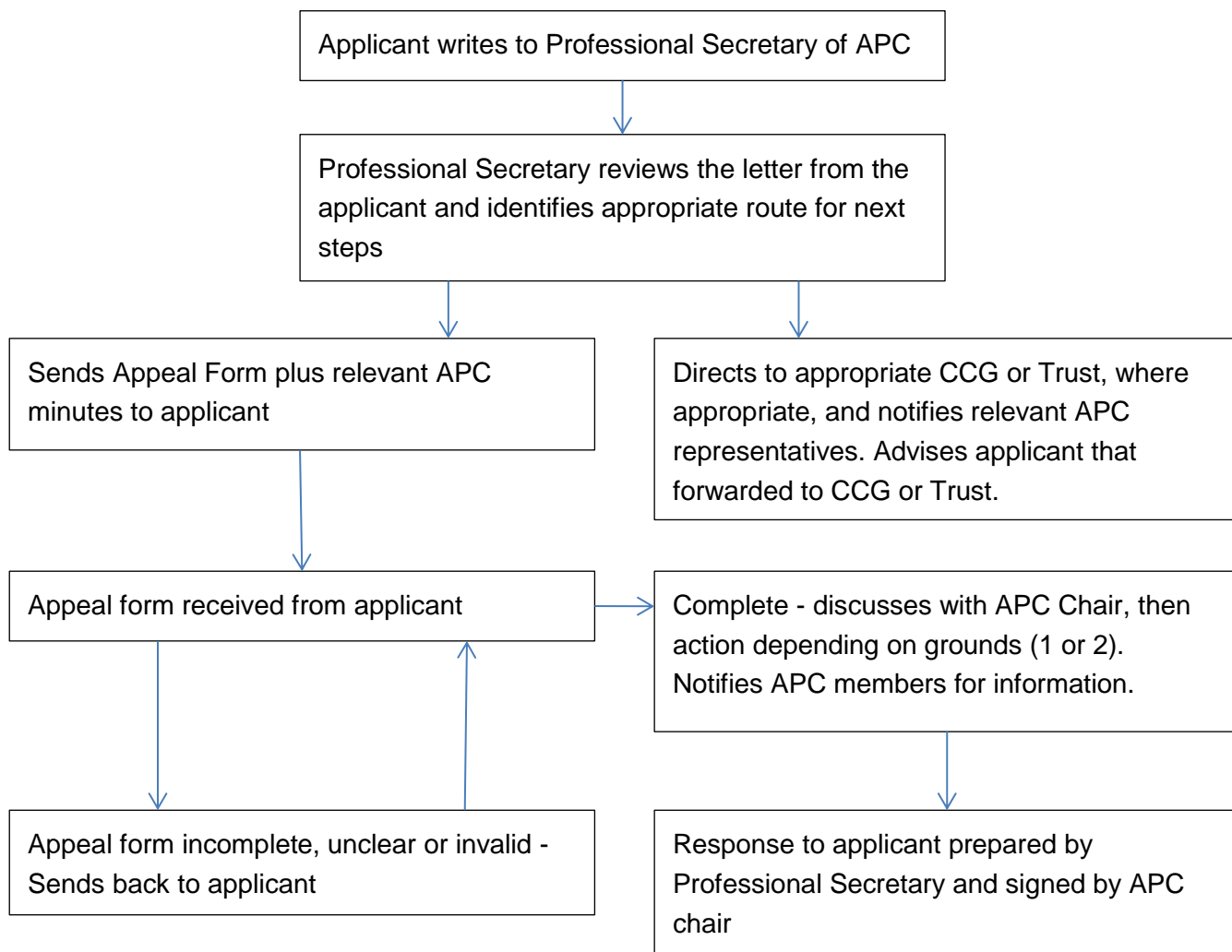
In line with good practice recommendations that a clinician is best placed to submit a formal appeal on behalf of their patient population<sup>1</sup>, the appeals process is open to clinicians (GPs, Consultants, Senior Nurses, Senior Pharmacists or non-medical independent prescribers) with relevant expertise and who work within the Pan Mersey Health Economy for an NHS Commissioned Service. It exists to give those clinicians who feel that the Pan Mersey 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.

### Grounds for appeal

1. **Appeal against a recommendation made by the Pan Mersey APC 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** – refer to appropriate subgroup for review, then to APC for consideration, then APC decision relayed to applicant (complete within 90 days)
2. **Appeal against a recommendation made by the Pan Mersey APC because the Pan Mersey APC procedures and policies were not followed** - refer to APC for consideration, then APC decision relayed to applicant (complete within 60 days)

Note: The applicant cannot appeal against a recommendation because new evidence has come to light since the original recommendation was made. In this case, a new business case, highlighting the new evidence, should be submitted (see <http://www.panmerseyapc.nhs.uk/> for “Application and Case for Introduction of New Service Development” form)

## Appeals process



## Reference

1. NICE. Developing and updating local formularies. December 2012. Accessed on 26.9.14 at: <http://www.nice.org.uk/guidance/MPG1>



## Pan Mersey Area Prescribing Committee (APC) Appeal form

Use this form to make an appeal against a policy statement recommendation issued by the Pan Mersey APC.

You can use this form if you are a clinician (GP, Consultant, Senior Nurse, Senior Pharmacist or non-medical independent prescriber) with relevant expertise and who work within the Pan Mersey Health Economy for an NHS Commissioned Service, and for the following reasons:

1. You are appealing against a recommendation made by the Pan Mersey APC 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.
2. You are appealing against a recommendation made by the Pan Mersey APC because its procedures and policies were not followed.

You cannot use this form if:

- You are appealing against a recommendation because new evidence has come to light since the original recommendation was made. In this case, a new business case, highlighting the new evidence, should be submitted (see <http://www.panmerseyapc.nhs.uk/> for “Application and Case for Introduction of New Service Development” form)
- You are appealing on behalf of a pharmaceutical company

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Name of Applicant

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Role

---

Organisation Name

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Contact Details

Name of medicine (generic and brand name):	
Strength(s) and form(s) of preparation:	
Date of APC recommendation the appeal relates to	
Reason for the appeal (state 1 or 2 as above)	
Basis for the appeal	
Please state any potential conflicts of interest e.g. funding of research, equipment, consulting or speaking fees, other personal or non-personal or family interest etc. in relation to this request:	

.....  
Signed

.....  
Date

Please submit appeals to [medsmanagement.bevan@nhs.net](mailto:medsmanagement.bevan@nhs.net)