**[Name of group/APC] (Group acronym)**

**TERMS OF REFERENCE**

**AIM**

The group will provide a platform for making consensus recommendations relating to the use of medicines and medical devices which are available on NHS prescription across the **[Region]** NHS footprint, to ensure equity in access and optimisation of use, the integration of medicines and prescribed medical devices into care pathways and the promotion of inter- and intra-professional collaborative working across organisations. The group will make recommendations to commissioning groups and provider organisations for adoption in order to ensure the best use of medicines and prescribed medical devices and associated resources across the health and social care system in **[Region]**.

**OVER-ARCHING FUNCTION**

Ensure that processes underpinning **[Region]** -wide recommendations and subsequent local decision-making about medicines and medical devices which are available on NHS prescription are consistent with the NHS Constitution and in accordance with common law.

**CORE BUSINESS**

* Horizon scan and plan for the introduction of new medicines and medical devices which are available on NHS prescription, National Institute for Health and Clinical Excellence (NICE) guidelines, revised use of existing medications and medical devices which are available on NHS prescription, and unlicensed and or off label use of medication, where these impact on the business of commissioning organisations across the **[Region]** health economy (Clinical Commissioning Groups [CCGs] and Local Authorities), that is, where they involve primary care prescribing or relate to medicines excluded from PbR tariff.
* Receive and consider applications for approval to use a new medicine and medical devices which are available on NHS prescription, or a new indication for an established preparation, in accordance with the criteria above. Note: applications that do not meet the above criteria, or which require an urgent, clinical decision are to be dealt with through internal provider processes.
* Facilitate a process to inform local decisions on the funding of those medicines and medical devices which are available on NHS prescription not considered by NICE, in accordance with the requirements of the NHS Constitution and Secretary of State Directions to the NHS on Local Decision Making.
* Engage relevant clinical opinion from stakeholder organisations in the development of proposals and recommendations on the management of medicines and medical devices which are available on NHS prescription, with particular focus on their place in therapy within care pathways, formulary status, and traffic light status.
* Engage representative patient opinion in the development of proposals and recommendations e.g. by consulting relevant patient interest groups as appropriate.
* Make prescribing formulary recommendations for the use of medicines and medical devices which are available on NHS prescription incorporating recommendations from NICE and local commissioning decisions for high cost drugs. The methodology will include a Traffic Light system to ensure that the provision of care in respect of medicines management is delivered within the most appropriate care setting.
* Facilitate the production of shared care arrangements and treatment guidelines for the prescribing, supply and utilisation of medicines and medical devices which are available on NHS prescription within the most appropriate care settings across the **[Region]** health and social care system.
* Consider recommendations from NICE and MHRA Drug Safety Updates relating to the use of medicines and medical devices which are available on NHS prescription and advise on required amendments to prescribing formularies to facilitate the safe, effective and prompt implementation of advice.
* Consider how the impact of new medicines and medical devices which are available on NHS prescription affects policies relating to the commissioning of services. Consider potential service implications associated with the managed introduction of a new medicines or the use of an established medicine for a new indication
* Provide an overview of the uptake and adoption of any recommendations made by the group.
* Ensure that patient outcomes and safety considerations are at the forefront of recommendations made.

**WIDER CONTEXT**

* Consider funding pathways and work with commissioners, providers and contractors to ensure that systems are in place to manage high cost medicines within the context of existing and future financial frameworks (for example PbR tariff exclusions).
* Highlight to stakeholder organisations the potential clinical, financial and service impact and benefits of medicines under review, for consideration as part of decision making processes.
* Support commissioning organisations in their processes for managing individual funding requests (IFRs) and exceptional case requests by making evidence-based policy recommendations where appropriate.
* Consider changes in service delivery that impact on medicines management across **[Region]**, promoting the integration of prescribing and medicines use issues with the mainstream commissioning process and wider healthcare service planning.
* Consider social and local authority issues relating to medicines management including relevant recommendations from joint Pharmaceutical Needs Assessments.
* Support risk management, audit and research relevant to medicines-related issues.
* Ensure that any recommendations made by the committee are communicated to the relevant commissioning group and provider organisation for due consideration
* Identify working groups to undertake projects as necessary.
* Receive recommendations from working groups for discussion and ratification where appropriate.
* Ensure there are communication links in place with other relevant bodies, including Trust Drugs and Therapeutics Committees, health economy medicines management groups, Health and Wellbeing Boards, NHS England Area Team (including specialist commissioning team), Clinical Networks, CCG medicines management committees and other groups as appropriate.

**SUB-GROUPS**

The **[Region]** Care NHS Foundation Trust Drug and Therapeutics Committee will provide expert advice in relation to the prioritisation and commissioning of mental health drugs, including formulary recommendations. Its membership will include commissioner representation.

Working groups (professionally supported by the **[Name of CSU]**) will be established to undertake specific pieces of work according to need, e.g., wound care formulary, continence formulary group.

**MEMBERSHIP**

Membership will be representative of the stakeholder organisations across **[Region]** and include:

* Representative from the **[Region]** CCG Chairs Network (to act as Chair of the group)
* Clinical Commissioning Group (CCG) senior medical representation
* Clinical Commissioning Group (CCG) senior pharmacist representation
* NHS Trust / Foundation Trust senior medical representation
* NHS Trust / Foundation senior pharmacist representation
* NHS England Area Team representative
* Local Authority public health representative
* Pharmacist representative from the **[Region]** Local Pharmacy Network

**Members should:**

* Commit to regular attendance of the committee to ensure continuity and balance of input into the formulation of recommendations
* Review the agenda and supporting papers in advance of the meeting
* Act as a representative of their organisation within the committee
* Send a nominated deputy to meetings if they are unable to attend
* Communicate discussions and recommendations back to the organisations they represent, enabling ratification of recommendations as appropriate
* Act as representative of the committee within their own organisation
* Declare any relevant interests relating to the agenda at each meeting and declare all pertinent interests through the Annual Declaration of interests process
* Undertake any post meeting actions, as agreed at the meeting
* Maintain the confidentiality of material marked as confidential, received in accordance with the business of the **[Name of group/APC]**
* Update the Group on relevant business from stakeholder groups and organisations relevant to the business of the **[Group acronym]**

**In attendance**

* Commissioning Support Unit Medicines Management lead / professional support
* Other relevant persons (including clinical experts) may be invited to attend the meeting for the purpose of providing advice and / or clarification to the group.

**FREQUENCY OF MEETINGS AND QUORACY**

A minimum of 8 meetings per year will be held. A quorum of 8 members will be required, with representation from CCGs and provider Trusts.

**SCHEME OF DELEGATION AND VOTING**

The group has delegated authority to make *recommendations* to stakeholder organisations that are ultimately accountable for their individual organisational endorsement of the **[Group acronym]** decisions in accordance with their integrated governance processes.

Recommendations will be made in accordance with stakeholder agreed principles for the commissioning of health and healthcare, taking into consideration evidence of efficacy, cost effectiveness, patient outcomes, safety, affordability and projected cost, and patient benefits. The group will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and is affordable.

When there are conflicting opinions within the meeting and a consensus agreement cannot be reached, the decision will be put to a majority vote. Voting will be on the basis of one vote per organisation, with the Chair having the casting vote.

**APPEALS PROCESS**

The Group will consider appeals against its recommendations. Appeals will be accepted from **[Group acronym]** member organisations only. Appeals will be accepted within three months of the **[Group acronym]** meeting at which a recommendation was agreed. The following grounds for appeal will be considered:

* that the **[Group acronym]** process had not been appropriately followed; or
* that the **[Group acronym]** recommendation was perverse in light of the evidence considered.

Appeals should be submitted in writing, stating which of the above grounds forms the basis of the appeal. Appeals should be addressed to the Chair of **[Group acronym]** and submitted via **[Blank]@nhs.net** the email address.

**REPORTING ARRANGEMENTS**

NHS Trust, Foundation Trust and CCG representatives are responsible for agreeing and ratifying Board level reporting arrangements within their own organisations, consistent with their own integrated governance arrangements and with regard to Regulatory requirements.

Copies of the minutes will be sent for information to the **[Region]** CCG Network.

Relationship maps are presented in Appendix 1.

**REVIEW OF TERMS OF REFERENCE**

These terms of reference will be reviewed every 12 months, or sooner if circumstances dictate.

**Date of last review**: **[Date]**

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