Herefordshire & Worcestershire

Medicines and Prescribing sub-Committee (MPC)

Operating Framework

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Version Control Record

Version	Description of change(s)	Reason for change	Author	Date
1.0	Original document		AH	Jan-2022
1.1	Updated to incorporate/reflect: • Integrated Care Board and relevant committees • Clinical policy and position statement templates • Considerations to inform decision making • Escalation to Medicines and Pharmacy Programme Board • Approval of medicines-related content only, necessitating final approval at a different decision making sub-committee • Policy review dates	• Change to ICB status with different governance arrangements. • Recommendations following internal audit. • Review against current practice	FB/LY	Sept 2023

TABLE OF CONTENTS

1.0 Introduction

1.1 The NHS Constitution For England states that patients have a 'right to expect local decisions on funding of 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.' It also states that patients 'have the right to drugs and treatments that have been recommended by National Institute for Health and Care Excellence for use in the NHS, if your doctor says they are clinically appropriate for you.'

1.2 Care, including medicines and treatments have to be commissioned within available resources and to ensure the greatest health benefit for the population, resources have to be prioritised. The aim of the Medicines and Prescribing sub-Committee (MPC) is to provide a safe, high quality, consistent, cost effective and evidence-based approach to the use of medicines across the Herefordshire and Worcestershire (H&W) Integrated Care System (ICS) health economy.

2.0 Purpose

2.1 This document provides the operational detail of the MPC and should be read in conjunction with the MPC Terms of Reference.

3.0. Agenda Setting and Papers

3.1 The MPC administrator will collate the agenda for each meeting, in collaboration with the Chair, using a standard Agenda Template which is broken down into sub sections. Section 4.0 of this document describes these standing agenda sections.

3.2 Items for inclusion on the agenda should be submitted to the MPC administrator via the Medicines and Pharmacy email hw.medicines@nhs.net . Where possible, items will be scheduled for consideration at the next available meeting; subject to receipt of all relevant documents and no further work being required. Clinicians will be invited to attend where relevant to the item.

3.3 Papers will be circulated electronically at least 5 working days before the meeting.

3.4 Documentation should be kept for a minimum of twenty years.

3.5 To aid consistency, agenda items should be presented using standard templates which are referenced in this document and included as a link or in the appendices.

4.0 MPC Agenda Standard Sections

4.1 New Medicine Applications/Proactive Appraisals

4.1.1 The following information applies to medicines which are commissioned by the ICB and does not apply to medicines commissioned by NHSE.

4.1.2 A new medicines application or proactive appraisal is required for any new medicine, not on the Herefordshire & Worcestershire (H&W) Joint Medicines Formulary, likely to be used in more than one similar patient. This applies to any medicine prescribed or supplied at NHS or local authority expense across the ICS. It also applies to new indications for existing products on the formulary.

4.1.3 A new medicines application will be submitted by a clinician wishing to add a medicine to the H&W Joint Medicines Formulary. A proactive appraisal is where a medicine is assessed for inclusion into the H&W Joint Medicines Formulary without a formal application being made.

4.1.4 The Individual Funding Request process should be followed for a medicine where there is only one patient and no other similar patients in Herefordshire and Worcestershire.

4.1.5 A new medicines application form is available to download from the HWICB website, netFormulary or may be obtained from the MPC administrator or the Pharmacy departments of HWHCT, WAHT or WVT:

New Medicines Application (NMA) Form

Guidance to completing a New Medicines Application

4.1.6 Applicants should ensure the application reflects the views not only of other clinicians in the same trust but also those in the relevant speciality in other provider trusts in the ICS. The application should also be discussed with all appropriate pharmacy teams prior to submission of the application.

4.1.7 Incomplete forms received, including those which are not signed by the applicant and necessary counter signatories, will be returned for completion.

4.1.8 Applicants may seek support from the pharmaceutical industry in completing sections of the application but completion of the entire form by the industry is not acceptable.

4.1.9 All applications and supporting papers are to be submitted to the MPC administrator and must be received a minimum of four weeks before the next MPC meeting in order to be discussed at that meeting. The MPC meets monthly and the applicant will be notified when the application is due to be discussed.

4.1.10 If a product is approved for use by MPC, it is highly likely that guidance to include the product's place in therapy will be requested; this may be in the form of a guideline, pathway or position statement. This information may need to be approved by MPC before the product is added to the H&W Joint Medicines Formulary. If appropriate guidance is submitted with the initial application this may expedite the process.

4.1.11 Clinicians are encouraged to present the application themselves. If other commitments prevent this, then a nominated deputy may attend. The presentation should be brief (no more than ten minutes) and provide an overview of the application. Clinicians will then be asked to respond to questions raised regarding the application. Once an item has been presented, any guests attending for that item will be thanked and asked to leave the meeting.

4.1.12 For new medicines applications and proactive appraisals, a search for relevant supporting information, including national guidance (NICE, SMC, AWMSG) and critical appraisal of the supporting evidence (as available) will be undertaken using a Medicines Resources Checked Record Form. This work will be undertaken by a pharmacist from H&W ICS.

4.1.13 A cover sheet will be drafted for new medicines applications or proactive appraisals, using a Cover Note Template. This provides a summary and details who has been involved. Clinicians in the relevant speciality in all provider trusts should have been consulted and their views included in the information presented.

4.2 Policies, Guidance and Position Statements

4.2.1 A policy is defined in the HWICB Policy Development Guide as a "Set of statements documenting the standards, intentions and/or expectations of how a practice or course of action will be implemented and adopted". It formally and explicitly sets out requirements which all clinicians are expected to follow.

4.2.2 Any policy, position statement or guideline (including shared care guidance where appropriate) relating to medicines should be presented to MPC for approval. The following templates should be used:

- ICB Clinical Commissioning Policy Template
- ICB Commissioning Position Statement

4.2.3 NICE technology appraisals will be submitted as an item within this section and are mandated for commissioners to fund. A local review of the NICE guidance will be undertaken and summarised in the NICE Technology Appraisal Template, highlighting any particular issues, the financial implications of the guidance and where the medicine sits within any local pathways.

4.3.4 A cover sheet will be drafted for all policies, guidelines and position statements submitted for MPC consideration, using a Cover Note Template. Clinicians in the relevant speciality in all provider trusts should have been consulted and their views included in the information presented.

4.3 Formulary

4.3.1 Papers relating to medicines which are not a new medicines application or proactive appraisal will be included in this section of the agenda. For example, a review of products already included on the formulary to reflect new evidence.

4.3.2 A cover sheet will be drafted for all formulary items to provide a summary and details about who has been involved, using a Cover Note Template. Clinicians in the relevant speciality in all provider trusts should have been consulted and their views included in the information presented.

4.4 Primary Care Rebate Schemes and Post Marketing Access Schemes

4.4.1 Primary care rebate schemes (PCRS) are contractual arrangements offered by pharmaceutical companies which pay a retrospective discount to Integrated Care Boards (ICBs) based on General Practice prescribing expenditure within the community.

4.4.2 All PCRS will be considered by the MPC before the ICB signs a rebate contract.

4.4.3 The MPC will only consider a PCRS if the medicine it relates to has already been approved for addition to the H&W Joint Medicines Formulary. Where a new medicine application is being considered by the MPC, the final decision of whether the medicine is approved will be based on the full cost price rather than a discounted price, that is the scheme will not be considered in the decision-making process.

4.4.4 Details of proposed PCRS should be submitted for consideration by the MPC and a cover note using a Cover Note Template included. Where the scheme has been assessed by PrescQIPP's Pharmaceutical Industry Scheme Governance Review Board (PISGRB) their recommendations will be summarised and included for MPC consideration.

4.4.5 Where a PCRS has not been assessed by PISGRB, the scheme will be assessed against the current PrescQIPP assessment questions.

4.4.6 Post marketing access schemes are where the pharmaceutical companies may choose to provide discounted or free of charge stock once marketing authorisation has been granted, pending a policy decision (either by NICE or the commissioner). These schemes are in use for a number of medicines which are within NHSE's commissioning responsibility; a number of zero cost stock programmes are currently available.

4.4.7 Any potential scheme must be considered by the relevant specialist/directorate with Trust pharmacy involvement. If the clinical view is that access to the treatment under the scheme would benefit patient care and the Trust wish to sign up to the scheme, a summary of the scheme and likely impact should be submitted to the MPC for consideration using the Discounted or FOC Scheme Request Form and if the treatment in the scheme is not already on the H&W Joint Medicines Formulary, a new medicines application will need to be submitted.

4.4.8 A Discounted or FOC Scheme Assessment Form and a cover note using the Cover Note Template will be drafted for post marketing access schemes to provide a summary and details about who has been involved. Clinicians in the relevant speciality in all provider trusts should have been consulted and their views included in the information presented.

4.4.9 The MPC will keep a record of all approved schemes across the ICS.

4.4.10 Trusts should keep a record of relevant approved schemes and are responsible for ensuring appropriate governance standards are in place and that the written agreement complies with national requirements outlined in NHS England » Free of charge (FOC) medicines schemes – national policy recommendations for local systems.

4.5 Drug Safety Updates/ National Patient Safety Alerts

4.5.1 A summary of Drug Safety Updates and National Patient Safety Alerts relating to medicines and published since the last MPC meeting will be included on each MPC agenda along with any actions already taken. .

4.6 New Developments

4.6.1 NICE guidance and other publications, including those from the Regional Medicines Optimisation Committee (RMOC) will be added to this section of the agenda and any divergence from existing formulary or guidance will be highlighted.

5.0 MPC Considerations to Inform Decision Making

5.1 New Medicine Applications/Proactive Appraisals

5.1.1 The MPC members will consider the information presented and supporting evidence, specifically taking into account the following criteria:

- Alignment with ICB/ICS and national priorities
- Alignment with ICB and national policies and guidance (NICE TAs, GiRFT, EBI etc)

- Scope of governance process undertaken including:
    - Level of confidence in the evidence underpinning the application
    - Scope of impact of change
    - Engagement with relevant clinicians and providers

- Clinical implications
    - Clinical effectiveness
    - Equity/access
    - Nature of health outcomes/benefits to be gained & impact on the patient group, community, or service
    - Patient choice
    - Safety, including compliance with digital assurance requirements where necessary
        - DCB0129 (clinical risk management standard for manufacturers of health IT systems) and
        - DCB0160 (clinical risk management standard for NHS organisations when they implement these systems).

- Service implications, to include an assessment of risks, which requires completion and sign off of:
    - Quality Impact Assessment (as appropriate)
    - Equality Impact Assessment (mandated)
    - Data Privacy Impact Assessment (as appropriate)

- Financial implications
    - budgetary impact
    - cost-effectiveness/value for money

- Environmental sustainability, which requires completion and sign off of:
    - Sustainability Impact Assessment (as appropriate)

5.2 Policies/Guidance/Position Statements

5.2.1 The MPC will assess any policies, guidelines and position statements in line with criteria in 5.1.1

5.3 Formulary

5.3.1 The MPC will assess any formulary items in line with criteria in 5.1.1

5.4 Primary Care Rebate Schemes and Post Marketing Access Schemes

5.4.1 When deciding whether a PCRS should be adopted locally, the MPC will consider:
Benefit:

- Does the scheme make the agent the most cost-effective intervention?
- What thresholds are included? How easy will it be to achieve any thresholds?
- What is the payback?
- Are the benefits clear and transparent?

Burden:

- Is the scheme simple to operate/administer?
- Are the benefits guaranteed?
- What is the length of the scheme? Are there any market uncertainties?
- Are there significant penalty clauses?

5.4.2 The MPC will consider requests for access to a medicine via a post marketing access scheme in line with the Regional Medicines Optimisation Committee Guidance on Free of Charge Medicines Supply. MPC will seek to ensure that the medicine will benefit patients and meet an unmet clinical need, and meets the other considerations outlined in the Discounted or Free of Charge Medicines Scheme Assessment Form (Appendix Six).

5.5 Drug Safety Updates/ National Patient Safety Alerts

5.5.1 The MPC will consider any actions that are required by any of the ICS member organisations in relation to drug safety updates or national patient safety alerts.

5.6 New Developments

5.6.1 NICE guidance and other publications such as those published by the Regional Medicines Optimisation Committee (RMOC) will be considered in relation to any requirements for action by MPC or member organisations arising from divergence from the H&W Joint Medicines Formulary, current guidance, policy and position statements or from other issues identified.

6.0 Decision Making

6.1 The MPC will make all recommendations and decisions in accordance with the Terms of Reference.

6.2 Recommendations and decisions will have one of five outcomes:

- Recommendation for further work in advance of a decision
- Recommendation not to approve
- Recommendation to approve, under delegated authority, with no decision needed from HWICB SCC.
- Recommendation to approve but needs decision from HWICB Strategic Commissioning Committee (SCC) if there are financial implications, the decision represents a high risk to organisations involved or if there is a policy document.

Recommendation to approve medicines-related content only, prior to review and decision from the relevant governance process (eg Clinical Assurance Sub Committee CASC).

6.3 The MPC will escalate to the Medicines and Pharmacy Programme Board (MPPB) any decisions which impact on service delivery or where there are issues with lack of engagement from clinicians/other staff in relation to MPC agenda items.

6.4 The MPC decisions will be communicated to relevant clinicians within seven working days of the decision being made. Where decisions have been referred to SCC, the applicant will be informed within seven working days of the SCC meeting.

6.4 If the product is not recommended for use, an appeal may be made and a further presentation made to the MPC, by arrangement with the MPC administrator and Chair; see section 7.0.

7.0 Resubmission and Appeals Process

7.1 The criteria for resubmission or an appeal is where:

- Significant new information such as a safety alert or a new formulation is available/identified.
- A decision was based on significantly inaccurate or incomplete information.

- It is felt that the MPC has not followed due process or where it is felt that with the evidence presented, a reasonable committee could not have reached the same decision.

7.2 Where new information or a new formulation is identified/available a new medicines application should be completed and submitted.

7.3 An intention to appeal should be made in writing to the MPC Chair within four weeks of the MPC decision. The appeal must include the name of drug/s, date of MPC decision and the basis for appeal.

7.4 An acknowledgement will be sent to the appellant to confirm receipt.

7.5 The appeal will be screened and reviewed by the MPC Chair to confirm the nature of the appeal

7.6 Resubmissions/appeal papers relating to:

- Significant new information such as a safety alert or a new formulation is available/identified OR
- A decision based on significantly inaccurate or incomplete information.

will be reconsidered at the next available MPC meeting in accordance with this operating framework.

7.7 Appeal papers relating to due process or where it is felt that with the evidence presented, a reasonable committee could not have reached the same decision will be escalated to SCC who will review and make recommendations as follows:

- Appeal upheld and actions to be taken
- Appeal dismissed and reasons why

8.0 Implementation and Dissemination of MPC Decisions

8.1 **For New/Revised Commissioning Policies/Guidance**

All policies, that are MPC approved, will be processed by the Responsible Author within 2 weeks of the MPC meeting as follows:

- Feedback of outcome to interested parties
- Allocation of review date:
    - For new documents – 12 months
    - For revised documents:
        - 3 years after first review
        - 5 years after second and subsequent reviews

  Note: Earlier revisions may be agreed dependant on published updates to local and national evidence of effectiveness and cost effectiveness and/or recommendations and guidelines from local, national and international clinical professional bodies.
- Finalise the policy approval information and version control and PDF
- Finalise the Member Practice Update newsletter for Primary Care – send to Primary Care Team for publication, where appropriate
- Send PDF of Policy to the administrator for upload to the HWICB website and TeamNet
- Where appropriate, send PDF of Policy and updated Policy List to Contracts Team for formal contract variation into the contracts of our key provider organisations as appropriate.

8.2 H&W Joint Medicines Formulary (NetFormulary) is the publicly available means of dissemination of status of a medicines. Any updates to the H&W Joint Medicines Formulary or published guidance will be done within two weeks of approval by MPC or SCC or when implementation is due (eg. NICE technology appraisal guidance).

8.3 HWICB will issue a monthly newsletter to all organisations/providers. In addition, nominated organisation representatives are responsible for ensuring timely feedback on actions and dissemination of decisions made by the MPC:

- HWHCT: Via the Medicines Management and Safety sub-Committee (MMSSC) and Trust dissemination via site specific intranet publications; with specific information on formulary/new medicine requests/introduction of new medicines directed at relevant prescribers.
- WAHT: Via the Medicines Safety Committee (MSC); with specific information on new medicine requests/introduction of new medicines directed at relevant clinicians/departments.
- WVT: Written summary for Pharmacy colleagues including any specific actions. Direct feedback to specialty via Division/Directorate Pharmacist. Trust wide decisions dissemination will include specific memos and Trust Talk/Medicines Matters newsletters where appropriate.
- HWICB: To primary care via direct communication, newsletter, prescriber software, HWICB website, TeamNet, contracting team as appropriate. Specific information on new medicine requests/introduction of new medicines directed to other commissioned providers as necessary.

8.4 Chief Pharmacists/Medical Directors should ensure that organisational colleagues are aware of how, when and to whom they should feed in issues for consideration by the MPC.

9.0 Monitoring and Reporting

9.1 Recommendations requiring SCC approval will be referred to the next available SCC meeting.

9.2 A quarterly report will be presented to HWICB SCC to note decisions taken by MPC under delegated authority.

9.3 The internal functions of the MPC will be monitored using the following key performance indicators:

KPI	Standard:
Meeting is quorate	100%
New medicine applications completed and supporting information provided	100%
Resources checklist completed	100%
MPC papers circulated electronically at least 5 working days before meeting	100%
Decision-making criteria applied to all new drug applications/proactive appraisals	100%
Rationale for decision made documented within resources checklist	100%
Applicant(s) informed of MPC decision within 7 working days of final decision being made	100%

9.4 A KPI report will be included with the quarterly report to the HWICB SCC.

10: Glossary of Terms

Term	Definition
Clinical effectiveness	*Clinical effectiveness* is a measure of how well a healthcare intervention achieves the pre-defined clinical outcomes of interest in a real-life population under real life conditions.
Consensus	*Consensus* is defined as: 'a group decision making process that seeks the consent of all participants; it may be defined professionally as an acceptable resolution, one that can be supported, even if not the 'favourite' of each individual'. The term 'consensus' describes both the decision and the process of reaching a decision. Consensus decision-making is thus concerned with the process of deliberating and finalising a decision, and the social and political effects of using this process.
Cost effectiveness	*Cost effectiveness* is an assessment as to whether a healthcare intervention provides value for money.
Treatment	*Treatment* means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare. Included
Value for money	*Value for money* in general terms is the utility derived from every purchase or every sum spent.