Cheshire and Wirral Partnership NHS
NHS Foundation Trust

Document level: Trustwide (TW)
Code: MP6
Issue number: 5

Introduction of new psychotropic medicines and non-formulary named-patient applications

Lead executive	Medical Director
Author and contact number	Senior Clinical Pharmacist – 01244 397494

Type of document	Policy
Target audience	All CWP staff
Document purpose	To outline the processes within CWP for approving new psychotropic and associated medicines, for prescribing across the organisation and local health economy; and for obtaining approval to prescribe medicines deemed non-formulary.

Approving meeting	Medicines Management Group	20-Mar-14
Original issue date	Apr-04	

CWP documents to be read in conjunction with	HR6	Mandatory Employee Learning (MEL) policy
	MP1	Medicines policy
	MP9	Policy for the initiation and maintenance of prescribing medicines for "off-label" indications (licensed medicines for unlicensed indications)
	MP22	Policy for the prescribing of antipsychotics in psychotic conditions (excluding bipolar)

Document change history

Changes made with rationale and impact on practice
1. Revised policy into new policy format 2. Replaced appendix 1 with new flow chart 3. Replaced appendix 2 with new template 4. Updated policy with new definitions, revised application process and acknowledgement of cost implications 5. Removed existing appendix 3 and updated section for named patient requests 6. Inserted a new appendix 3

To view the documents Equality Impact Assessment (EIA) and see who the document was consulted with during the review please click here

Content

1. Introduction

The purpose of this policy is to ensure that all prescribers are aware of:

- The process within Cheshire and Wirral Partnership NHS Foundation Trust (CWP) for approving new psychotropic medicines, for use across the organisation and local health economy where appropriate;
- The new medicines that have been reviewed by the Medicines Management Group (MMG) but are not approved for use i.e. non-formulary;
- The process for obtaining approval to use those medicines deemed 'non-formulary';
- Those new medicines that are awaiting discussion by the MMG and subsequently waiting for approval status or decision on use.

All new psychotropic medicines **must** be considered by the MMG, and when appropriate be subsequently recommended for approval by the Local Area Prescribing Committees / Drug and Therapeutics Committee before they are available to prescribe across the Trust and Local Health Economy irrespective of the method of prescribing i.e.

- Prescribing on inpatient prescriptions;
- Prescribing on outpatient prescriptions;
- Prescribing on FP10s;
- Recommending medicines to Primary Care prescribers.

MMG will have authority to approve any new psychotropic medicine where prescribing will remain solely within CWP. However, for new psychotropic medicines that will impact in Primary Care, MMG can only make a recommendation to approve to the local Area Prescribing Committees (APC's) or equivalent. These committees are:

- Central and Eastern Cheshire Area Prescribing Committee;
- West Cheshire Area Prescribing Committee;
- For Wirral CCG – The Committee / Group for ratification and financial approval is Governing Body via Clinical Strategy Group.

New psychotropic medicine applications will be reviewed against formulary comparators on evidence of efficacy and outcome measures, adverse effect profiles, and prudent considerations around cost. Additions to, or replacements in the CWP mental health formulary must provide a cost effective alternative to current formulary choices and should not produce an overall increase in cost burden to CWP and our commissioners.

1.1 Horizon scanning process

The official Office of Science and Technology definition of horizon scanning is:

- 'The systematic examination of potential threats, opportunities and likely future developments, including (but not restricted to) those at the margins of current thinking and planning'.

CWP's annual horizon scanning process, conducted by the Medicines Management Team in consultation with our commissioners, will have an important role in identifying the majority of new psychotropic medicines, their potential financial impact, possible new cost pressures, and subsequent budget management. In addition, this process will also facilitate their managed entry onto the Trust's formulary. CWP will utilise the annual UKMI Prescribing Outlook resource as part of the horizon scanning process for medicines. Following

1.2 Physical health medicines

The policy does **not** apply to:

- Physical health medicine formulary applications and prescribing decisions;
- Applications to use psychotropic medicines for physical health indications e.g. anticonvulsants / mood stabilisers in the management of pain.

The decision –making for the above applications will fall within the remit of the local acute Trusts and Clinical Commissioning Groups. CWP will abide by the local acute Trusts and Primary Care for physical health medicine formulary choices.

1.2.1 CWP West Physical Health

Physical health medicine applications for use within CWP West Physical Health are **not** covered by this policy. All physical health medicine applications need to be discussed by the joint Countess of Chester NHS Hospital Trust, West Cheshire Clinical Commissioning Group and Cheshire and Merseyside Commissioning Support Unit New Drugs and NICE Formulary sub-group, and approved by the West Cheshire Area Prescribing Group before they can be prescribed.

1.3 Clinical Trials

Non-formulary psychotropic medicines being used as part of clinical trials are excluded from this policy.

2. Definitions

2.1 New psychotropic medicine:

For the purpose of this policy a new psychotropic medicine can be defined as a:

- New psychotropic medicine promoted on the UK market;
- A branded generic;
- New formulation of an existing licensed medicine e.g. oro-dispersible formulation;
- New indication of existing licensed medicine e.g. community initiation of clozapine;
- Medical device that requires procurement via pharmacy;
- An unlicensed medicine.

2.2 Formulary

A list of medicines that have been approved for prescribing within the Trust and local health economy, whose selection has been based on sound clinical evidence.

2.3 Non-formulary medicine

A psychotropic medicine will remain non-formulary in status until it has a new psychotropic medicine application approved by the Medicines Management Group; this also applies to existing formulary medicines that gain new prescribing indications. An application is needed prior to approval.

2.4 Medicines Management Group (MMG)

This group comprises of cross organisation representation from CWP and the local health economy. It includes representatives from each partner Clinical Commissioning Group (CCG), including GPs and medicines management pharmacists; and CWP, including, consultants from each clinical service unit, lead nurses and pharmacists. The full membership can be reviewed within the terms of reference of the group and is available from the Chief Pharmacist.

2.5 Clinical Commissioning Group (CCG)

This is a locality based group that is led by GPs and is responsible for planning and buying healthcare across the locality area to meet the needs of the local population. CWP are a service provider for our local CCGs.

2.6 Red Amber Green (RAG) list

This is a locally approved list of medicines, agreed between Primary and Secondary Care that have a Red, Amber or Green status dependent on specialist prescribing and monitoring requirements. Red status limits prescribing within Secondary Care; amber permits suitability for shared care prescribing and green has no restrictions on prescribing. Each CCG has a RAG list, or RAG rated formulary that should be made available to CWP whenever updates are made.

2.7 Pharmacy preferred supplier

This is a specified organisation with contractual obligation to CWP for the procurement and supply of medicines to in-patients and community teams.

2.8 Area prescribing committee/Drug and Therapeutic committee

This is a locality based committee with delegated authority from the relevant CCG for decision-making and approval of new medicines up to a predefined financial limit. New medicines imposing a financial impact above this predefined limit need approval from the CCG before prescribing can take place.

3. Making an application for a new psychotropic medicine

The main driver for new psychotropic medicine applications will be the horizon scanning process, with the CWP Medicines Management Team informing on priority areas with a position statement on expected timescales for applications and decisions. It is expected that the Medicines Management Team will coordinate the majority of applications, working with Consultants, GPs and Primary Care Medicine Management Pharmacists in the completion of an application form. However, an application can be independently requested by the above.

Clinicians will be expected to assist in the completion and support of applications.

The process for a new psychotropic medicine application will follow these main stages (appendix 1):

- New psychotropic medicine request identified and logged onto a new psychotropic medicine tracker by CWP Medicines Management Team;
- Application form completion (appendix 2) and submission to Lead Pharmacist, Medicines Management;
- Review of content of application form by CWP Medicines Management Team and overview provided (appendix 3). Application and overview sent to MMG secretary;
- Allocation on MMG agenda by secretary and applicant(s) invited to attend MMG meeting to present their application, where appropriate;
- Discussion and advisory status by MMG;
- Communication of decision.

3.1 Application form completion

The applicant requesting to use the new medicine must submit a completed application form (appendix 2) to the MMG with accompanying evidence (see table below) and any proposed local guideline/procedure for using the product if approved.

Hierarchy of evidence sources accepted:

Type of review	Publication examples
National reviews	NICE, SMC, SIGN, AWMSG
Independent review of systematic reviews	Bandolier, NYRDTC, LNDG (UKMI)
Systematic reviews of original research	Cochrane Library, Effectiveness Matters
Independent reviews of original experimental papers	Evidence-Based Medicine, Drug & Therapeutics Bulletin
Peer reviewed original experimental papers	General: BMJ, Lancet Speciality: BJ Psychiatry
Journals offering peer-reviewed overviews	Prescriber
Non peer-reviewed publications	GP, Doctor,

Application forms should be requested from the Lead Pharmacist, Medicines Management (medicines.management@cwp.nhs.uk).

Ideally the form should be completed electronically, but the signatures can be either written or electronically added. The Lead Pharmacist, Medicines Management will indicate the deadline for submission to MMG and will log request of application form on the new medicines tracker. The aim of the spreadsheet is to track the progress and consultation process of the application form. Feedback on the process can be requested from the Lead Pharmacist, Medicines Management by the applicant.

For Secondary Care led applications, the Lead Pharmacist, Medicines Management will notify the Medicines Management team or Commissioning Support Unit (CSU) for each CCG of the potential application, and invite feedback from Primary Care; and similarly, Consultants within Secondary Care will be notified of applications from Primary Care.

3.1.1 Applications from CWP

If there is potential that more than one clinician will use a new psychotropic medicine within the Trust, it is recommended that the product should first be discussed at the locality consultants meetings and be endorsed by the Locality Service Director and Clinical Director.

3.1.2 Applications from Primary Care

GP applications should be discussed within Primary Care before submission to MMG. If the Primary Care partner organisation feels it is appropriate, the Director of Medicines Management and the GP Prescribing Lead can both endorse the application to acknowledge any financial impact.

All completed forms, including references and guidelines, should be emailed / posted / faxed / to the Lead Pharmacist, Medicines Management on:

- Lead Pharmacist, Medicines Management – medicines.management@cwp.nhs.uk;
- Lead Pharmacist, Medicines Management, Management Suite, Springview Hospital, Clatterbridge, Wirral, CH63 4JY;
- Fax: number 01514827930 (safe haven fax).

3.2 Assessment of content of application form

On receipt of a completed new medicine application form, the CWP Pharmacy Medicines Management Team will be responsible for assessing the content. The team will ensure that all sections have been completed, supporting evidence is enclosed and referenced, and the necessary signatures have been obtained**.** If not complete the Principal author will be requested to furnish the requirements before the submission is taken any further.
The assessment will include:

- A review of available evidence for:
  - Efficacy;
  - Safety to patients.

- Potential cost implications to Trust and Primary Care:
  - Cost of product and predicted usage;
  - Payment by Result inclusion or exclusion recommendation;
  - Resources required to safely implement usage of the product e.g. monitoring requirements.

- Risks taken by Trust and Primary Care:
  - By introducing new product;
  - By not introducing new product.

- Clinical guideline impact:
  - Do existing guidelines need updating or have been updated;
  - Has a new guideline been written and subject to full consultation.

- Consideration of relevant NICE guidance;
- Place in therapy – addition to formulary or replacement;
- Feedback on the application received from other organisations within the local health economy.

In addition to the evidence provided by the consultant / GP with the application, the CWP Pharmacy Medicines Management team will also carry out an independent review of the evidence, and provide an overview of the application for MMG (appendix 3).

The CWP Pharmacy Medicines Management Team will then forward the completed form and overview to the secretary of MMG for inclusion on the next agenda.

The secretary will invite the applying or supporting consultant / GP to the MMG meeting to present their application. Non-attendance at the meeting will automatically remove the paper from the agenda.

3.3 Discussion and Outcome by Medicines Management Group (MMG)

It is the intention of the MMG to support applications in a fair manner.

The MMG that interfaces with Primary Care meets every two months. The meeting dates are available on the Pharmacy page of the intranet and via CWP internet page.

The new medicine application and overview will be discussed at the next scheduled MMG meeting. The applying clinician will be given an opportunity to present their application at the meeting, but will not be involved in the final outcome decision making process.

For new psychotropic medicine applications that will impact on Primary care, one of these outcomes will be decided:

- Recommendation to approve the product for general use;
- Recommendation to approve the product with restrictions – RAG list status indicated if appropriate;
- Cost implications outside existing budget. Submit for consideration within the commissioning agenda as a cost pressure. This happens annually in the autumn;
- Recommendation to approve the product for an evaluation period;
- Decline the product.

For new psychotropic medicine applications that solely affect CWP, one of these outcomes will be decided:

- Approve the product for general use;
- Approve the product with restrictions ;
- Cost implications outside existing budget. Submit for consideration within the commissioning agenda as a cost pressure. This happens annually in the autumn;
- Approve the product for an evaluation period;
- Decline the product.

Where an application has a supporting CWP clinical guideline, MMG must provide an approval status for the guideline, especially if the medicine is a fundamental component of the guideline and is adopted onto the formulary.

4. Communication of outcome

It is the responsibility of the secretary of MMG to notify, in writing, the requesting consultant(s)/ GP(s) the outcome of the new medicine application. In addition, and where appropriate, any restrictions, evaluations, audit follow ups and general recommendations for the product will be included in the communication. This will happen once the recommendation to approve, when applicable, has been considered by the locality commissioning decision-making committees and their decisions received.

Copies of the outcome letter will be circulated across the health economy (Trust and CCGs) and to the pharmacy preferred supplier, to facilitate cross organisation communication. In this way all prescribers in the Trust are kept up to date with decisions made by the MMG.

Trust wide communication of the decision will also be delivered via the monthly Medicines Management Newsletter and, if appropriate, via a communications bulletin.

The Lead Pharmacist, Medicines Management is responsible for updating the new medicine tracker with details of discussion outcome, communications and identified follow up actions e.g. evaluations and audits. If not approved the lead pharmacist will add the medicine to the non formulary list and circulate to the preferred pharmacy supplier.

5. Review process

A review of a decision made by the MMG will be undertaken in the following circumstances:

- New evidence becomes available;
- NICE guidance is issued;
- Product approved by commissioning agenda and funding available.

A review can be instigated by the original requesting, or different consultant/GP or the secretary of MMG can request a review in light of new evidence or availability of funding.

6. Non-formulary named-patient requests

Occasionally, in a one-off situation, a consultant may wish to prescribe a medicine that has not yet been approved, or is awaiting discussion by the MMG. In these circumstances a non-formulary named-patient request can be made to the Chief Pharmacist as secretary of MMG, and Chairperson of MMG for consideration for an individual case. All named-patient non-formulary requests are recorded on a non-formulary request spreadsheet.

The request should be in letter format detailing:

- The medicine being requested;
- Patient demographics;
- Diagnosis and previous / current medication;
- Response and symptom control to previous / current treatment;
- Adverse effects to previous / current medication;
- Relevant test results;
- Other mitigating circumstances.

The letter should be emailed and/or sent to the Chief Pharmacist:

- Chief Pharmacist – Chief.pharmacist@cwp.nhs.uk;
- Chief Pharmacist, Management Suite, Bowmere Hospital, Countess of Chester Health Park, Liverpool Rd, Chester CH2 1BQ

The Chief Pharmacist and the Chairperson of the MMG will then consider the application and make a decision within 5 working days of receipt of the letter, and if satisfied it is appropriate, will then notify the applicant that the medication can be initiated for that **case only**.

Also a decision will be made, where appropriate, if on-going prescribing will be held by CWP or be passed to Primary Care. Each approved non-formulary application will have a reference number that must be quoted in all correspondence with Primary Care.

The Chief Pharmacist will update the non-formulary request spreadsheet with the outcome of the request.

Approved requests for non-formulary named-patient medicines will be reviewed twice a year by the MMG.

7. Unapproved UK licensed medicines (non-formulary)

A list will be held within the Trust of those UK licensed psychotropic medicines that have not been approved for use across the CWP footprint i.e. non-formulary. http://nww.cwp.nhs.uk/medicinesandpharmacyservices/Pages/FormularymedicinesapprovedforuseintheTrust.aspx

Any **new** psychotropic medicine, as defined in section 2.1, that is launched and has not been discussed by MMG will automatically be classed as non-formulary and added to this list.

Prescribing from the "unapproved list" of UK licensed medicines will be monitored on a six monthly basis by the MMG. Prescribers will have to justify their prescribing practice to the MMG.

Reports on individual's non-formulary prescribing will be submitted for discussion as part of the supervision/appraisal process with line managers.

8. Off-label indications and unlicensed UK medicines

Approval of medicines for "off-label" indications are dealt with in a separate policy, (policy for the initiation and maintenance of prescribing medicines for "off-label" indications (licensed medicines for unlicensed indications).

Where there is not a robust body of evidence to support the off-label use of a medicine then a named patient request must be submitted each time.

9. Duties and responsibilities

9.1 Medical Director, Compliance, Quality and Assurance

Responsible for overseeing the review and updating of this policy in line with national guidance and changes in practice.

9.2 Chief Pharmacist (as secretary of MMG) and MMG Chairperson

Ensuring adherence to the process for new medicine applications and ensuring onward communication of outcome decisions across the Local Health Economy.

9.3 Medicine Management Group (MMG)

Ensuring due process followed when reviewing new medicine applications, and requesting evaluation and follow up reports where identified as part of outcome decisions. Reviewing non-formulary medicine prescribing on a regular basis and identifying appropriate action with prescribers.

9.4 CWP Pharmacy Medicines Management Team

Ensuring that new medicine application forms have been suitably completed and provide an impartial overview and summary for all new psychotropic medicine applications prior to discussion at MMG.

9.5 Prescribers

- Responsible for completing new medicine applications in accordance with this policy;
- Responsible for completing non-formulary named-patient requests / off-label requests;
- Responsible for prescribing only those formulary medicines that have been approved by MMG.

9.6 Non-medical Prescribers (suitably qualified / authorised practitioners / prescribers)

- Responsible for prescribing only those formulary medicines that have been approved by MMG;
- Prescribing of non-formulary medicines is only permitted after a consultant named-patient request has been made to the MMG secretary and approved.

9.7 Clinical Directors and Locality Service Directors

Responsible for endorsing the new psychotropic medicine application and ensuring it meets current practice and can be managed within current drug budget allocation for their service.

9.8 Preferred pharmacy supplier

Ensuring a standard operating procedure (SOP) is in place to manage the supply of a new medicine; and gain authorisation from the CWP pharmacy team before supplying any non-formulary medicine. The SOP must be in line with the processes outlined in this policy.

9.9 GP's and Primary Care representatives

Responsible for highlighting requests from CWP to prescribe unapproved non-formulary named – patient psychotropic medicines to the secretary of MMG for follow up action.

Appendix 1 - Introduction of new medicines flowchart

Horizon scanning process with commissioners:
- Identifies new psychotropic medicine or formulation licensed for UK market;
- Identifies new indication for existing psychotropic medicine;
- Recommends and prioritises new medicine applications.

▼

- New medicines application form requested from CWP Lead Pharmacist Medicines Management;
- Request logged on new medicine application tracker.

▼

Requesting consultant or GP completes application form, supported by CWP Medicines Management Team

Application to include:
- Evidence to support superior or non-inferior clinical efficacy;
- Evidence to support superior or non-inferior clinical safety / tolerability;
- Monthly prescribing costs to both Primary and Secondary care;
- Place in therapy – what will it replace;
- Supporting clinical guidelines.

▼

- Application reviewed by CWP Medicines Management Team and overview written.

▼

- Application form and overview submitted to MMG agenda;
- Requesting clinician invited to MMG meeting to present application (where applicable).

▼

Outcome of application for medicines to be prescribed by CWP and local health economy:
- Accepted and no prescribing restrictions – recommendation to approve by APC's;
- Accepted with prescribing restrictions – recommendation to approve by APC's
- Accepted subject to financial implications – financial discussions with commissioners before recommendation to approve by APCs;
- Declined – inform APC's.

Outcome of application for medicines to be prescribed by CWP ONLY:
- Approved and no prescribing restrictions – inform APC's;
- Approved with prescribing restrictions – inform APC's;
- Approved subject to financial implications – inform APC's;
- Declined – inform APC's.

Outcome updated on new medicines application tracker.
Communication of outcome to requesting clinician.
Formulary status communicated across Local Health Economy.

▼

Review process for declined requests:
- New evidence;
- NICE guidance issued;
- New commissioning available.

Appendix 2 - New Medicine Application to CWP Medicines Management Group (MMG)

- To be completed by the Consultant(s) OR General Practitioners (GPs) within Cheshire & Wirral Partnership NHS Foundation Trust (CWP) / Primary Care;
- The form can be completed electronically (preferred option) or handwritten. ALL sections must be completed;
- The relevant Clinical Director and Locality Service Director, or Director of Medicines Management, must sign the form to indicate their awareness of the application and any potential budgetary implications. Signatory does not necessarily indicate support; purely the budgetary implications at an early stage in the process;
- This form and any accompanying information/evidence, along with a draft of any proposed local guideline / procedure for using the product, should then be forwarded to: Lead Pharmacist, Medicines Management, Management Suite, Springview Hospital, Clatterbridge, Wirral CH63 4JD or emailed to medicines.management@cwp.nhs.uk or faxed to 0151 482 7930;
- Applicants will be expected to attend MMG to present their application.

Once considered by the Trust Medicines Management Group a written response of any decision made regarding the application will be sent to the principal applicant. The product **cannot** be prescribed until a decision has been made by the MMG. Non-formulary requests by a CWP Consultant for the patient's GP to prescribe may result in the GP redirecting the patient back to the consultant.

Applicant's Details	
Name and Service Area	
New Medicine Details	
Name of medicine, strength and form*	
Brand Name and Manufacturer	
Licensed Indication	
BNF therapeutic class	
Dosage, frequency and route of administration	
Anticipate duration of treatment	
Formulary and Prescribing Implications	
Proposed place in therapy – indicate which current formulary medicines it is intended to replace or if in addition to current treatment, will it be 1st / 2nd / 3rd line	
Are new/updated clinical guidelines required? Are they included with the application?	
Estimated number of patients per annum	
Who will be prescribing the medicine? - Primary Care / Secondary Care / both Indicate position on RAG list	

Will it be subject to shared care guidelines? If yes, these must be included with the application?		
Cost Implications		
	Primary Care	**Secondary Care**
Unit cost and comparative costs E.g.: monthly prescribing costs - indicate source of costs -indicate if VAT excluded or included Indicate total cost impact to CWP and Primary Care		
Would costs be covered within current PbR income? Or proposed local exclusion subject to funding		
Clinical Evidence **Clinical evidence must demonstrate cost effective non-inferiority or superiority over existing formulary medicines**		
Evidence for efficacy – include comparative clinical trial data	List clinical trials and outline their evidence –attach PDF version if possible:	
Evidence for safety – include comparative clinical trial data	List clinical trials and outline their evidence –attach PDF version if possible	
Risk management issues e.g. monitoring requirements		
Other supporting references e.g. NICE, SMC, SIGN		

***** if the application is for an injection, a formal risk assessment needs to be carried out by a pharmacist and attached with the application using the embedded form below. Section 2 needs to be carried out for the injectable drug submitted; and section 1 needs to be completed by the wards/departments using the injectable with their locality pharmacist.

NPSA – Risk assessment tool kit

Requested by:	
Name (principal author)	Signature and date**
Supporting clinicians/GPs:	
Name	Signature and date**

Name	Signature and date**
Name	Signature and date**
Name	Signature and date*
CWP applications - Clinical Director & Locality Service Director	
Name	Signature and date**
Name	Signature and date**
Primary Care applications – Director of Medicines Management & GP Prescribing Lead	
Name	Signature and date**
Name	Signature and date**

**Electronic signatures accepted

Appendix 3 - Medicines management team new psychotropic medicine / indication overview

Name of medicine	
Summary	
Recommendations / Implications	
Brand Name, (Manufacturer)	
BNF Therapeutic Class	
Licensed Indications	
Dosage and Administration	
Marketed	
Cost Comparisons	
Introduction	
Evidence	
Safety	

NHS / CWP Impact
Risk management issues

Injections – if the application is for an injection a formal risk assessment needs to be carried out by a pharmacist and attached with the application using the form embedded below. Section 2 needs to be carried out for the injectable drug submitted; it is the responsibility of the wards/departments using the injectable to complete section 1 with their locality pharmacist

NPSA – Risk assessment tool kit

Author
References:

Ref No	Trial design	Trial population	Treatment	Primary outcomes