Commissioning for Quality in Medicines Management

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Version Control		
Version	**Summary of changes**	**Issue Date**
1	Initial issue	Sept 2023
2		Sept 2024
2.1	As below	Sept 2025
2.2	Removal of 'Welsh Health Circular' from 3.8.2 and addition of 3.8.3. Addition of biosimilar switches 'where clinically appropriate' to section 3.12.	January 2026

Changes – September 2025:

Section	Change
General	Addition of numbers instead of bullet points to aid navigation
3	Removed statement after consultation with Medicines Value Unit: *Welsh health boards and trusts must stop outsourcing of the preparation of nivolumab, atezolizumab and rituximab to the commercial sector and should purchase all future supplies from the NHS Wales Shared Services Partnership.*
3.9.1	Corrected course of action if treatment subject to an IPFR is commenced before the IPFR application is made or approved
3.18	Updated to reflect *Healthcare associated infections and antimicrobial resistance goals 2024 to 2025 (WHC/2024/038)*
4.6.1	Added to reflect *Prescribing of branded generics in NHS Wales: Position statement, Oct 2024*
5.6	Regarding the provision of a shared care guideline from a specialist team to primary care, have removed 'specific to an individual patient' to reflect the shared care agreements of local providers.
10.11	Home Oxygen Therapy section updated in consultation with Respiratory Clinical Lead, to reflect current practice.

Commissioning for Quality in Medicines Management

Introduction

This document details the Medicines Management (MM) related requirements in the commissioning contracts that Powys Teaching Health Board (PTHB) has with both Welsh and English provider organisations. Outlined are the roles and responsibilities of our provider organisations in ensuring a transparent and collaborative approach to the safe and cost-effective management of medicines, seamless care of patients between NHS organisations and ensuring high quality prescribing. The document will be updated annually for changes in process and best practice and taken to the PTHB Area Prescribing Group (APG) to ensure that its requirements are both fair and reasonable. The details will then be included as part of the contract requirements from providers for the following contract year. We welcome any feedback from and joint working with our providers.

Providers are responsible for ensuring that all clinicians are aware of these expectations along with any detailed prescribing guidance that might be in place.

The requirements set out in this document also apply to private providers of healthcare where patients are treated on an NHS treatment pathway. Where 'medicines' are described in this document this should be read to include medicines (all categories), prescribable appliances, vaccines, medical gases, dressings and medical devices.

Contents

1. Glossary

APG	Area Prescribing Group
AWMSG	All Wales Medicines Strategy Group
AWTTC	All Wales Therapeutics and Toxicology Centre
AOT	Ambulatory Oxygen Therapy
CD	Controlled Drug
CDAO	Controlled Drug Accountable Officer
CQC	Care Quality Commission
DAL	Discharge Advice Letter
DGH	District General Hospital
DMR	Discharge Medicines Review
FAD	Final Appraisal Document
HCD	High Cost Drug
HIW	Healthcare Inspectorate Wales
IPFR	Individual Patient Funding Request
LTA	Long Term Agreement
LTOT	Long Term Oxygen Therapy
MM	Medicines Management
NICE	National Institute for Health and Care Excellence
PAS	Patient Access Scheme
PbR	Payment by Results
PIL	Patient Information Leaflet
PTHB	Powys Teaching Health Board
SCG	Shared Care Guideline
TA	Technology Appraisal
WPAS	Welsh Patient Access Scheme

2. Key Legislation, Policy and Guidance

2.1 All pharmaceutical services and advice provided should comply with The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022.

2.2 Whether treated in Wales or in England, people in Wales should be able to access a quality of care in line with the Welsh Health and Care Quality Standards 2023 (WHC/2023/013).

2.3 Aseptic preparation of medicinal products in NHS pharmacy aseptic facilities in Wales must be in line with WHC (2024) 004 – 'Assurance of aseptic preparation of medicines in NHS Wales'

2.4 Follow the 'AWTTC: Items identified as low value for prescribing in NHS Wales' guidance to minimise the prescribing of medicines offering limited clinical benefit and identify where more cost effective treatments may be available.

2.5 Any specific commissioning arrangements will be published on the PTHB Medicines Management internet pages under 'Policies'.

3. Medicines Governance

3.1 The provider has an up-to-date Medicines Policy and associated procedures and can evidence implementation throughout the organisation through audit.

3.2 The provider has a rolling programme for review of its clinical pharmaceutical services to ensure that they comply with Royal Pharmaceutical Society (2022): Professional Standards for Hospital Pharmacy Services.

3.3 All prescribing, including Non-Medical Prescribing is within prescriber competencies and is appropriately managed and monitored in line with the provider's governance processes and any national standards for competency assurance.

3.4 Audit of any NHS WP10 or FP10 outpatient prescribing is expected to be undertaken and reviewed to ensure prescribed in line with the provider's formulary and antimicrobial stewardship requirements.

3.5 Medicines management training for all staff handling medicines is planned and delivered, including on induction of new staff and at appropriate intervals thereafter including medical gas training.

3.6 NHS Wales commissions medication according to All Wales Medicines Strategy Group (AWMSG) guidelines and/or NICE technology appraisal (TA) guidance. PTHB is committed to meeting its statutory obligations of funding NICE TAs within 60 days of publication of the final appraisal document (FAD); except where there are named exceptions as per WHC/2024/020. The provider is expected to ensure that processes are in place so that patients who meet the requirements for treatment under a NICE FAD or TA have access to the medicine(s). Find guidance | NICE.

3.7 Where a 'One Wales' commissioning position has been published, 'One Wales Medicines Interim Decisions' may provide a Welsh commissioning position for some medication.

3.8 The provider should maintain adequate records to demonstrate compliance with AWMSG advice and NICE TAs and provide periodic reports demonstrating this.

3.8.1 In an English NHS Trust, when it is intended to commence a Payment by Results (PbR) excluded drug, covered by a NICE TA, prior approval must be sought from PTHB MM, via the usual pathways. This must be completed prior to initiation of the medication and at agreed follow up intervals.

3.8.2 If an English NHS Trust intends to treat a PTHB patient, they have an obligation to adhere to NICE TA and to any AWMSG policies which may take precedence to a NICE TA.

3.8.3 If a Welsh Health Circular relevant to an English provider is published, PTHB will share this with the provider to review any actions required.

3.9 If it is intended to commence medication which is not approved under a NICE TA or AWMSG guidance (including a One Wales Medicine Interim Decision) and is not routinely commissioned for use, prior approval must be obtained before commencing treatment and it may be necessary to apply for funding via the Individual Patient Funding Request (IPFR) route. In this case, see All Wales IPFR guidance and contact newmedicines.powys@wales.nhs.uk and/or monitoring.powyslhb@nhs.net for further information and see the LTA, Schedule 6, section 1.4.

3.9.1 In the event that treatment subject to an IPFR is commenced before the IPFR application is made or approved, funding will not be provided retrospectively, however the application to provide ongoing funding may be considered. This practice is discouraged.

3.10 Once available for use, funding for HCDs (in England, PbR excluded drugs) must be applied for via the Blueteq High-Cost Drug system as per Welsh Health Circular 2022 032, March 2023.

3.11 PTHB requires assurance regarding HCD being charged for by the provider and expects an appropriate level of detail in the backing data to the invoice as stipulated in the LTA. Detail regarding the dataset required is specified within the PTHB/provider contract. From this data, PTHB MM must be satisfied that the HCD has been used in accordance with NICE or AWMSG guidance or other HCD agreement (as relevant). Drug costs are to be charged in accordance with the expected Welsh Patient Access Scheme (WPAS), PAS prices or a Commercial Access Agreement.

3.12 PTHB requires assurance that the use of biosimilar drugs are maximised, with patients being actively switched from the originator to the most cost-effective biosimilar. The commencement of the originator product will not be approved where a biosimilar to the product is available. Where a biosimilar is available, all new patients must be prescribed the best value biological medicine when treatment is initiated. Existing patients who are prescribed originator products must be switched to the biosimilar within 6 months (or preferably sooner) of the biosimilar being made available (target ≥ 95% switched), where clinically appropriate.

3.14 Welsh providers must maximise the purchase of on-contract medication and highlight where these are not available. Claims for reimbursement must be submitted to the manufacturer where an on-contract medication is not available, necessitating the purchase of a more expensive off-contract product. Procurement and Finance Teams must work with NHS Wales Procurement to ensure that the reimbursements are recovered and passed through to PTHB.

3.15 The provider should recognise the importance of a system wide approach to managing allergies in line with NICE CG183: Overview | Drug allergy: diagnosis and management | Guidance | NICE, including critically reviewing any allergy status including Penicillin allergy de-labelling as per AWMSG guidance. All Wales guidance for penicillin allergy de-labelling in adults in secondary care - All Wales Therapeutics and Toxicology Centre (nhs.wales)

3.16 The provider should recognise the importance of a system wide approach to antimicrobial stewardship in line with NICE NG15: Overview | Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use | Guidance | NICE and ensure that all prescribers receive induction and training in prudent antimicrobial use and are familiar with the antimicrobial resistance and stewardship competencies. The provider will be expected to validate their antibiotic prescribing data against local Antimicrobial Prescribing Guidance.

3.17 The provider will act in accordance with the Welsh Health Circular: Healthcare associated infections and antimicrobial resistance goals 2024 to 2025 (WHC/2024/038) | GOV.WALES, specifically:

3.17.1 Improvement goal 11a: a reduction in total antimicrobial use in primary care consistent with a trajectory required to achieve a minimum 10% reduction against the 2019 to 2020 baseline by 2029 to 2030. The measure is Defined Daily Doses and will be reported as DDDs/1000 STAR PU.

3.17.2 Improvement goal 11b: a reduction in total antimicrobial use in secondary care consistent with a trajectory required to achieve a minimum 5% reduction against the 2019 to 2020 baseline by 2029 to 2030. Reported as DDDs/1000 occupied bed days.

3.17.3 Improvement goal 12: attain a trajectory required to achieve a minimum of 70% of total antibiotic use from the Access category of antibiotics by 2029 to 2030 in both primary and secondary care. The measure is Defined Daily Doses and will be reported as % total antibiotic use."

3.18 Each organisation will adhere to locally approved provider's antibiotic guidelines.

3.19 If a provider organisation's clinician is giving advice to a PTHB clinician for the management of patients within PTHB settings, the provider Microbiologists will refer PTHB clinicians to PTHB antimicrobial guidelines for empiric treatment.

3.20 The PTHB primary care antimicrobial guidelines can be found on Eolas (formally known as Microguide.)

4 Formularies/ Prescribing Guidelines

4.1 PTHB recognises that patients will be treated in line with provider's formulary and approved policies, however the provider must ensure that any specific AWMSG commissioning policies are implemented for PTHB patients. Contact newmedicines.powys@wales.nhs.uk for further advice.

4.2 PTHB expect that providers have a robust process to ensure that new medicines or medicine for a new indication, are not prescribed unless the new medicine/new indication has been approved through a robust governance process.

4.3 Clinicians must not ask primary care clinicians to prescribe medicines that have not been approved for use by the provider's medicines decision making group, nor should they suggest to patients that a non-approved medicine or treatment can be obtained from primary care.

4.4 Providers must ensure that any medicine required to support a clinical procedure undertaken by the provider, is prescribed by the provider.

4.5 Where medication is classified on PTHB formulary as 'Red - Medicines for hospital or specialist use only', clinicians should not ask primary care to prescribe medication unless agreed by the APG.

4.6 Clinicians should prescribe generic products whenever possible, except for those agents where it is clinically necessary to indicate the brand prescribed for therapeutic or safety reasons as per formulary recommendations.

4.6.1 The prescribing of branded generics should not routinely be undertaken in NHS Wales unless there is a specific, clinical reason for doing so in line with AWTTC Position Statement – Branded Generic Prescribing in Primary Care, October 2024

4.7 The prescribing of 'special'[1], unlicensed or 'off label' medication should only be considered when suitable alternative licensed options have been exhausted. The provider should have a clear policy in place to agree use where this is not covered by accepted recognised clinical guidelines.

4.8 Where appropriate, the provider could consider suggesting a class of medicine rather than a specific agent, so that primary care can prescribe in line with PTHB formulary option.

4.9 Providers are expected to proactively engage with Horizon Scanning, including the identification of more affordable treatments e.g. biosimilars.

4.10 Sample packs of medicines/devices should not be provided to patients unless robust governance processes are in place, the 'sample' is approved for use by the providers Medicines Management/Pharmacy Team and the patient is aware that there is no guarantee or obligation that the sample will be available for ongoing supply via their GP or any other NHS funded route.

4.11 Contact newmedicines.powys@wales.nhs.uk for advice regarding the prescribing of medication not included in PTHB formulary.

4.12 PTHB Medicines management team must be consulted before providing a service that uses Patient Group Directions (PGDs). All PGDs require approval via the PTHB governance process.

4.13 For further information see Patient Group Directions in Complex Commissioning Scenarios – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice.

5 On-going Prescribing of Specialist Medicines

5.1 It may be appropriate for primary care to continue some specialist medicines, once initiated by the specialist team. PTHB Formulary classifies medication as either:

5.1.1 Amber: Medicines which should only be initiated/recommended by specialists, but which may then be passed to primary care prescribers for prescribing

or,

5.1.2 Amber (Shared Care): Medicines initiated by hospital specialist, but where continuing treatment by Primary Care Prescribers may be appropriate under a shared care arrangement.

If a specialist team requires on-going prescribing of medication by primary care, they should have an awareness of the PTHB formulary classification for the medication. If there are any discrepancies between the provider and PTHB formulary status, they should work with the PTHB MM team to resolves any issues. Contact newmedicines.powys@wales.nhs.uk to discuss.

5.2 Provision of medication under Shared Care Guidelines (SCGs) may be appropriate when some of the patient care in relation to medicines and their monitoring can be delivered by the primary care prescriber, on behalf of the specialist. This ensures that all parties are aware of their obligations.

5.3 The use of SCGs allows for primary care prescribers to prescribe specialist medicines and have confidence that the practice is safe and appropriate.

5.4 Development and approval of SCGs will be led by the relevant provider specialist team and agreed through their governance procedures e.g Area Prescribing Committees. Any new SCGs and revisions should be communicated to PTHB MM via newmedicines.powys@wales.nhs.uk for update to the PTHB Area Prescribing Group.

[1] Specials are individually prepared unlicensed formulations of existing medicines made for a specific patient. They are usually considerably more expensive than standard preparations.

5.5 Primary care prescribers must be asked if they are willing to participate in shared care in line with the requirements of the specific shared care agreement and only where agreement is confirmed, can prescribing responsibility be transferred to primary care.

5.6 The Specialist is responsible for providing the primary care clinician with a shared care agreement, at the time that the request to transfer prescribing responsibility is made.

5.7 Specialist teams must maintain prescribing responsibility until the patient's primary care prescriber has indicated they are happy to accept prescribing responsibility in line with the shared care agreement.

5.8 A primary care prescriber has the right to refuse to enter a shared care prescribing arrangement, but to refuse on the grounds of medicine cost alone is unacceptable. When a primary care prescriber has refused to enter a prescribing arrangement, the specialist will continue to have prescribing responsibility. Providers should notify PTHB MM of primary care prescribers who do not routinely accept responsibility for the prescribing of medicines considered appropriate for shared care.

6 Clinical Trials

6.1 Medicines being used as part of a hospital-initiated clinical trial will be supplied by the hospital.

6.2 Funding arrangements for the period following completion of a clinical trial must be agreed with PTHB prior to the trial commencing. It should be noted that PTHB does not routinely fund medicines that are part of a trial either during the trial period, following completion of a trial, or after withdrawal of compassionate funding by a pharmaceutical company.

6.3 Ethically, patients participating in a clinical trial must be made aware that there is no guarantee that the medicine(s) will be continued at the end of the trial, irrespective of the results.

7 Controlled Drugs (CDs)

7.1 The provider must have CD Standard Operating Procedures in place and be able to evidence implementation throughout the organisation through audit.

7.2 The provider has a named accountable officer for CDs who is registered with Healthcare Inspectorate Wales (HIW) or the Care Quality Commission (CQC).

7.3 The organisation has completed the assessment tool contained in NG46 – Controlled drugs: safe use and management within the previous 12 months and has an action plan in place for resolving any issues rated as amber or red and this action plan is available to PTHB for assurance purposes.

7.4 Prescribers will adhere to local prescribing guidance for the safe management of CDs such as prescribing by brand to ensure consistency of supply and reduce the risk of error.

7.5 The provider must be able to demonstrate safe systems for managing requests for potentially addictive drugs.

7.6 The provider should share any appropriate intelligence with PTHB Controlled Drug Accountable Officer (CDAO), regarding patients, practitioners or incidents that are relevant to PTHB.

8 Medicines Handling & Assessment

8.1 The provider should be fully compliant with the requirements and standards outlined in accordance with NICE NG5: Overview | Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes | Guidance | NICE

8.2 The provider should be fully compliant with the requirements and standards outlined in accordance with NICE CG76: Overview | Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence | Guidance | NICE

8.3 The provider should be fully compliant with the requirements and standards outlined in accordance with NICE MPG2: Overview | Patient group directions | Guidance | NICE

8.4 The provider should ensure processes are in line with Royal Pharmaceutical Society: Safe and Secure Handling of Medicines (SSHM) guidance and in Wales, meet the requirement detailed in Patient Safety Notice PSN055 – The Safe Storage of Medicines: Cupboards.

8.5 Providers are encouraged to have a policy of supporting self-administration of medication where possible and safe to do so, in order to maintain independence.

9 Medicines Brought into Healthcare Settings

9.1 Providers should have systems and procedures in place to maximise the appropriate use of patients own medicines. Only labelled, original packs, in date and in usable condition should be used. Procedures should ensure that there is no inappropriate destruction of such medicines and patient verbal consent is sought before destruction.

9.2 Medicines in compliance aids should not be used during an admission.

10 Medicines Supply

10.1 When a patient is discharged and on-going care is required, medicines, appliances and dressings will be supplied to last for either the complete course of treatment or a minimum of 14 days, whichever is the shorter. It may be necessary to supply smaller quantities where clinical or safety concerns are identified. The full balance of the required amount should be supplied for medicines that are not on-going (e.g. antibiotics).

10.2 On the discharge letter, information must be clearly stated regarding discharge medication requirements including drug (brand if appropriate), form, strength, dose, frequency and course length and start date (if appropriate). If a medicine has been stopped during the patient's admission, this should be made clear in the discharge letter, along with the rationale. There must be a clear indication for use stated and a treatment plan for newly started medication and whether onward prescribing is necessary. Usual arrangements should be followed for communication of the information to the patient's GP and community pharmacy. *In Wales*, the Discharge Medicines Review (DMR) referral service should be utilised. In order to maximise this a copy of the DAL should either be sent to the patient's nominated pharmacy or given to the patient directly.

10.3 When a patient is discharged specifically to a ***PTHB Community Hospital***:

10.3.1 The provider must supply at least 7 days' supply of a complete set of discharge medication (this can include patient's own drugs, if suitable for use).

10.3.2 A full discharge letter and a copy must be sent with the patient on transfer and normal arrangements followed for communication to their GP and community pharmacy.

10.3.3 If a patient is discharged from a *Welsh District General Hospital (DGH)*, the Medicines Transcribing and Electronic Discharge system Discharge Advice Letter (MteD DAL) must be completed – a copy must either be sent on transfer or accessible via Welsh Clinical Portal.

10.3.4 Information is to be provided through discharge prescription and/or copy of inpatient medication chart (with continuation requirements clearly indicated).

10.3.5 DGH teams must liaise with their assigned PTHB Care Transfer Co-ordinator (where in place) to ensure safe discharge with medicines and for other transfer arrangements to PTHB community hospitals.

10.4 Where patients being discharged to a residential setting, usually receive their medicines in a compliance aid, providers need to ensure consideration is given to issuing a WP10/FP10 to be dispensed by the patient's usual community pharmacy. Only if there is not sufficient time to arrange this, a routine supply of medicines will be made. Please refer to Prescqipp Bulletin 321: Multi-compartment Compliance Aid Standards – March 2023.

10.5 When a patient is being discharged with new medication, they must be counselled regarding its use with the healthcare professional checking that they understand how to take the medication. This process should also be undertaken to support the patient to take their current medication. Written patient information leaflets (PILs) must also be provided.

10.6 Patients attending 'day clinics' for minor surgery etc. will be provided with sufficient dressings and associated medicines to meet their post-operative needs, or, patients should be given advice on appropriate self-care.

10.7 Patients attending out-patient clinics who do not require medicines immediately (i.e. within 14 days of attending the clinic) will be referred to their primary care prescriber to obtain a prescription. They must be advised to allow a minimum of 7 working days for the primary care prescriber to receive the written information prior to the patient contacting the practice. The clinic must provide legible information to the GP practice within 5 working days, whenever possible recommending a class of medicine as opposed to a specific medicine.

10.8 If a prescriber considers that the medication need can't wait to obtain the prescription from the primary care prescriber, a supply should be made for a minimum of 14 days (original pack applies) unless a shorter course of treatment is indicated. The full balance of the required amount should be supplied for medicines that are not on-going (e.g. antibiotics).

10.9 The primary care prescriber must be provided with adequate information before the patient attends for further medication.

10.10 The provider must have adequate processes for handling medicines shortages

10.11 **Home Oxygen Therapy:** If after an assessment for Long Term Oxygen Therapy (LTOT) whilst an inpatient, a Home Oxygen Order Form (HOOF) for LTOT is clinically indicated, please do a HOOF A and refer to the PTHB Home Oxygen Service. (Contact- respiratory.powys@wales.nhs.uk or 01686 414227). The PTHB Home Oxygen Service will assess LTOT and Ambulatory Oxygen Therapy (AOT) needs in line with the British Thoracic Society (BTS Guidelines for Home Oxygen Use in Adults, June 2015. Vol. 70, Supp. 1) and the soon to be published All Wales Guidelines (awaiting ratification – Sept 2025). Please do NOT prescribe AOT equipment for discharge – if required, AOT will be facilitated by the PTHB team post discharge. All oxygen follow-up appointments, including home based risk assessments, will be carried out by the PTHB Home Oxygen Service, facilitating care closer to home.

11 Medicines Safety

11.1 The Provider has a named lead for Medicines Safety including a dedicated Medication Safety Officer. They should also have a forum that has overall responsibility for medication safety issues; reviews compliance with current regulations, approves up to date procedures / policies and is the focal point for all issues related to the safety of medicines. The Provider will be able to demonstrate the governance structures that link the committee to the Board or similar and have clear processes for escalation of issues.

11.2 The Provider has an up-to-date procedure for identifying medicines that may be designated 'high risk' in terms of their raised potential for harm in normal use or has procedures in place to mitigate the risk of harm to patients. This also applies to medicines which may not be regarded as high risk but are used in procedures which are inherently high risk.

11.3 All providers are required to have processes in place to implement national alerts, recalls and drug safety updates. This includes (but is not exhaustive) National Patient Safety Alerts, alerts from Welsh Government (via notification from commissioner), Medicines and Healthcare Products Regulatory Agency (MHRA) alerts, or NHS Wales Delivery Unit alerts.

12 Incidents Involving Medicines

12.1 The Provider has a standard operating procedure (or equivalent) for the identification of prescribing and dispensing errors, reporting and severity classification of incidents involving medicines, which includes the sharing of learning in order to prevent recurrence, including with PTHB where appropriate. These SOPs and systems must include those which incidents which extend into or across primary and secondary care sectors

12.2 Medication-related patient safety incidents are monitored, reported and actions taken where necessary.