High-Cost Drugs Policy

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Scope:	PTHB policy for use in commissioned/provider services	

The latest approved version of this document is online.
If the review date has passed please contact the Author for advice.

Powys Teaching Health Board is the operational name of Powys Teaching Local Health Board
Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Version Control

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	April 2025
1.1	Update to reflect IPFR application process	July 2025

ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Principal Pharmacist Formulary Management and High Cost Drugs

Circulated to the following for Consultation

Date	Role / Designation
March 2025	Commissioning and Finance Teams
June 2025	Commissioning Team re. IPFR process update

Evidence Base
Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area? 1. NHS Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), 2017. *Update imminent*

IMPACT ASSESSMENTS

Equality Impact Assessment Summary					
	No impact	**Adverse**	**Differential**	**Positive**	**Statement** ***Please provide supporting narrative for any adverse, differential or positive impacts that may arise from the implementation of this policy***
Age	X				
Disability	X				
Gender reassignment	X				
Pregnancy and Maternity	X				
Race	X				

Religion or Belief	X				
Sex	X				
Sexual Orientation	X				
Marriage and Civil Partnership	X				
Welsh Language	x				

Risk Assessment Summary

Have you identified any risks arising from the implementation of this policy / procedure / written control document?

No risks identified.

Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document?

None identified.

Have you identified any training and / or resource implications as a result of implementing this?

None identified. Blueteq currently funded by Welsh Government.

1 Introduction

High Cost Drugs (HCDs) are commissioned in Wales either by the patient's health board, or by NHS Wales Joint Commissioning Committee (NWJCC) for certain HCDs used within specialised services.

When prescribing a HCD commissioned by Powys Teaching Health Board (PTHB), provider teams request prior approval from the health board, to ensure the patient is treated in line with national commissioning guidance. With the introduction of Blueteq in Wales, it will become increasingly likely that completion of a Blueteq form is required to secure commissioning of a HCD.

Blueteq is an online portal which facilitates the submission of HCD funding requests by completion of electronic forms. The funding approval criteria on Blueteq are based on the recommendations in a NICE technology appraisal, AWMSG advice or One Wales decision. Therefore, as well as acting as an invoice reconciliation tool, Blueteq also provides a means of assurance that medicines use aligns with relevant national policies. Blueteq templates should be developed and revised on an All-Wales basis.

2 Objective

This document provides generic guidance and outlines the process for the commissioning of HCDs by PTHB. It builds on the principles outlined in the document: Commissioning for Quality in Medicines Management, 2025. It is for use by providers treating patients who are the commissioning responsibility of PTHB.

This policy applies to commissioners and providers (medical, nursing, pharmacy staff and other key staff involved in any aspects of requesting funding for HCDs).

3 Definitions

- **AWMSG** - All Wales Medicines Strategy Group
- **FAD** – Final Appraisal Document
- **HCD** – High-Cost Drug
- **IPFR** – Individual Patient Funding Request
- **NICE** - National Institute for Health and Care Excellence
- **NWJCC** - NHS Wales Joint Commissioning Committee
- **PTHB** – Powys Teaching Health Board
- **TA** – Technology Appraisal

4 Responsibilities

	4.1 Commissioner • Collaborate with the provider and where appropriate, other commissioning teams to ensure access to HCDs. • To resolve all queries relating to HCDs in an appropriate timescale. • Treatment will be commissioned under AWMSG advice, NICE TA or One Wales decision. NICE TAs are to be funded within 60 days of publication of the FAD; except where there are named exceptions as per WHC/2024/020. • Ensure the provider is aware of the established process of prior funding approval, or has access to a Blueteq form for the intended HCD. • Ensure that Blueteq initiation and continuation forms are enabled, and formulary pages are updated with the relevant links, supporting information and formulary status. • To work with the national Welsh Blueteq Steering Group to support the development of All-Wales Blueteq templates. • Ensure that the providers are made aware of new Blueteq templates via their HCD Pharmacy Team. • Ensure that where possible Blueteq forms are set to auto-approve. Where this is not possible, the provider will be informed. • Use the Blueteq system to maximise efficiencies to validate data by matching retrospective data to the request for funding. This will improve transparency, and it will facilitate invoice sign-off, thus ensuring that providers are reimbursed swiftly. • To validate/challenge provider HCD data within agreed timelines and undertake audit of the Blueteq system as relevant. N.B. If Blueteq approval has been falsely gained and the patient does not meet the approval criteria, PTHB will not pay for the HCD, in line with the contract challenge process.
	4.2 Provider – Clinical team • The team are responsible for ensuring that the patient meets the commissioning criteria (typically a NICE TA, AWMSG advice or One Wales decision) for the HCD and consults PTHB (newmedicines.powys@wales.nhs.uk) where this is in doubt. • Approval for HCD should be obtained before treatment is initiated via established funding application routes, or via the high-cost drug management system, Blueteq, where available. • Funding approval should be sought close to the actual start of the patient's treatment so review date is in line with treatment timelines. • To ensure that continuation of funding requests for the intended HCD are made where appropriate, within the given timescales • If it is intended to commence a HCD which is not approved under a NICE TA, AWMSG guidance, One Wales decision or any local commissioning agreements, it may be necessary to apply for funding in advance of commencing treatment, via the IPFR route. In this case, see Submit an IPFR Application and contact newmedicines.powys@wales.nhs.uk

	and/or monitoring.powyslhb@nhs.net. 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. • To keep patient information up to date with respect to stopping and switching treatments or where patients are deceased.
	4.3 Provider – Pharmacy Department • Ensure that a patient has HCD funding agreed before processing the prescription. • Ensure that the monthly report data contains the relevant Blueteq ID number (when available). • Resolve invoice challenges promptly by allocating responsibility to a named lead. • Share with the commissioner the results of any audits conducted relating to HCDs.
5 Management	
	5.1 Financial arrangements • The commissioner will only fund high-cost drug treatments that have been approved via existing established pathways, or where a Blueteq template is available, via the Blueteq system. • For new NICE TAs or AWMSG guidance where there is existing prescribing, then prescribing may continue without change to the funding arrangements that were agreed prior to the publication of the new NICE TA or AWMSG guidance, until the patient and their NHS clinician consider it appropriate to stop. • For patients with existing funding arrangements (i.e. where funding was approved before Blueteq initiation templates were available) the commissioner expects that a Blueteq continuation template (where available) is completed at the appropriate review threshold (where specified in guidance) to secure on-going funding. Where no Blueteq template is available then the existing funding request pathway must be followed. • Retrospective funding will not be provided. • The Commissioner will recover any funding made if subsequent information demonstrates that the provider has submitted claims for treatment used outside NICE TA or AWMSG advice, without seeking approval via the correct route.

5.2 Determining the responsible commissioner

See '*Appendix 1 – Who is the responsible commissioner?'* to determine which organisation is responsible for funding the HCD.

- If the patient moves either residence or GP practice to outside of PTHB, *Appendix 1* should be consulted to confirm if PTHB remains the responsible commissioner.
- Providers will be required to complete a new funding application to the new commissioner.
- If a patient moves into the commissioning responsibility of PTHB after having already commenced a HCD, a funding application must then be submitted to PTHB via an established method or via Blueteq.
- Liaise with Medicines Management Team by contacting newmedicines.powys@wales.nhs.uk

5.3 Changing provider

- The new provider must obtain clinical notes from the previous provider.
- The new provider will be required to submit a funding application to PTHB via an already established route or via Blueteq.
- Liaise with Medicines Management at PTHB via newmedicines.powys@wales.nhs.uk

5.4 High-Cost Drug Optimisation

- Switches of HCD must be implemented when there is a difference in cost that provides an opportunity for a significant annual saving, but only when all else is equal e.g. switch of a biological originator brand to biosimilar brand, with the licensed indications for both being the same. This must be undertaken at the earliest opportunity (e.g. within 3 months of the biosimilar becoming available).
- Where two or more drugs are in the same therapeutic class and the only difference is the cost, the drug with the lowest acquisition cost should be used preferentially for new patients.

6 Monitoring Compliance, Audit & Review

This document will be reviewed every three years or earlier should audit results or changes to legislation / practice within PTHB indicate otherwise.

7 References

1. Blueteq High Cost Drug System - All Wales Therapeutics and Toxicology Centre (nhs.wales) Hi-Cost Drugs Database - WHSSC System (blueteq-sys.co.uk)
2. High Cost Medicines Policy. Version 2. Issued by: NHS Shropshire and Telford & Wrekin. Updated 1/12/24. Review date 30/03/26.
3. Further extending the use of Blueteq in secondary care

4. Commissioner High Cost Drugs - Blueteq Ltd
5. AWMSG in relation to NICE
6. NHS Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), 2017. *Update imminent*

Appendix 1 – Who is the responsible commissioner?