High-Cost Drugs

Final Internal Audit Report

2025/26

Hywel Dda University Health Board

Limited Assurance

Contents

Review Reference	HDU-2526-11
Fieldwork	April - May 2026
Executive Sign Off	21 May 2026
Audit Committee	23 June 2026
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Executive Summary

Purpose

Review governance arrangements and a sample of key controls in relation to the financial approval of high-cost drugs. The scope of this review is focused on the control of costs associated with high-cost drugs dispensed in secondary care and has not considered the clinical appropriateness of prescribing/dispensing decisions.

Overview

We have concluded **limited** assurance on this area. The significant matters requiring management attention include:

- The *Managed Entry Process Policy for Accessing Medicinal Products within the HDUHB Formulary, which* sets out the arrangements for adding medicines to the formulary and the approval requirements for non-formulary requests, is in draft. It requires updating, approval and dissemination to relevant staff.
- Sample testing identified instances where the formulary had not been updated to include drugs with national approval, therefore not requiring any further scrutiny or approval prior to use.
- Approval requirements for the highest volume and value HCDs (immunoglobulins) are not clear. Some but not all are included on the formulary, it is not clear whether those not on the formulary require additional review/approval.
- Sample testing identified instances where an IPFR had not been completed or was retrospective and only covered part of the period reviewed.
- There is no monitoring of high-cost drug use at patient-level to identify costs that could be recharged or ensure that periodic clinical review is undertaken to confirm continued appropriateness of use.
- A centralised database of non-formulary and IPFR requests has not been established.
- Non-formulary drug issues are currently not identifiable within the WellSky system as the functionality has not been enabled. This inhibits monitoring and reporting of non-formulary / HCD use.

Full details of matters arising are detailed within the Findings & Agreed Action Plan.

Scope & Assurance Summary

Objectives (The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.)		Related Findings	Assurance
1	High-cost drugs are subject to appropriate scrutiny and approval prior to commencement of treatment/dispensing	1, 2, 3, 4	**Limited**
2	Mechanisms are in place to monitor high-cost drug usage and compliance with approval requirements	5, 6, 7	**Limited**

Management Actions

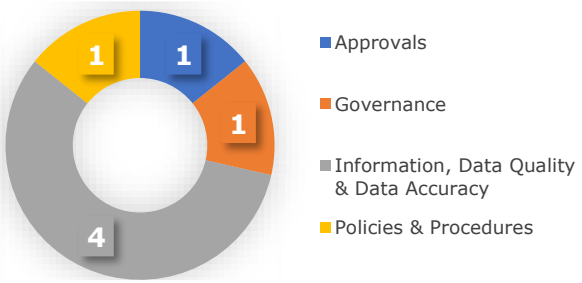
2

High Priority

5

Medium Priority

Themes



Risk Types

Financial Loss

Quality or Safety Issues

Findings & Agreed Action Plan

Objective 1: High-cost drugs are subject to appropriate scrutiny and approval prior to commencement of treatment / dispensing — **Limited**

High-cost drugs (HCDs) are commissioned in Wales either by the patient's health board or via the NHS Wales Joint Commissioning Committee (NWJCC) for certain HCDs within specialised services.

The NHS (Wales) Act 2006 and Managed Introduction of New Medicines into the NHS in Wales Directions 2009 mandate the implementation of NICE and All Wales Medicines Strategy Group (AWMSG) recommendations in Wales. Medicines are added to the Health Board's formulary once approved by NICE and/or the AWMSG.

The Health Board's *Managed Entry Process Policy for Accessing Medicinal Products within the HDUHB Formulary* (the 'Policy') sets out the arrangements for adding medicines to the formulary and the approval requirements for non-formulary requests. This document is in draft and requires updating to reflect recent/imminent changes in Health Board operational governance arrangements prior to approval and publication. **[Finding 1]**

There is no national definition of high-cost drugs although the Policy defines "high-cost" as a drug meeting or exceeding £5000 per course/year per patient. Medicines on the formulary require no further approval from a cost perspective, regardless of cost, on the basis that they are mandated by legislation. Non-formulary medicines, or formulary medicines proposed to be used for an indication other than that stated within the formulary, require a non-formulary request or Individual Patient Funding Request (IPFR).

Cost (per annum or treatment course)	HCD	Request Route	Approval Requirement
<£2000	N	Non-Formulary Request Form	Site Lead Pharmacist (or deputy dispensary lead/clinical service)
£2000 - £5000			Site Lead Pharmacist (or deputy dispensary lead/clinical service) with acknowledgement to Hospital Clinical Lead (or deputy) or Directorate Clinical Lead for CCG escalation
>£5000	Y	IPFR	IPFR Panel

Analysis of medicines dispensed to secondary care patients during the period April 2024 – November 2025 identified 2408 patients on a course of treatment with an annual pro-rata cost exceeding £5000[1]. The total annual value of these high-cost drugs exceeds £29m. Data analytics was used to compare this data to a formulary extract to identify non-formulary drugs. Whilst some data quality issues were identified with the extract, the data was sufficient to enable identification of a population of patients in receipt of non-formulary drugs for review. Sample testing identified:

1. The highest cost drugs in our sample related to immunoglobulins. Some brands of immunoglobulin are included on the formulary, those in our sample weren't and there was no rationale for inconsistency. There are no approval requirements from a pharmacy dispensing perspective. **[Finding 1 & 2]**
2. Instances where the formulary was out of date as it had not been updated to reflect NICE/AWMSG approved drugs. **[Finding 3]**
3. Where a non-formulary drug is prescribed/dispensed in line with national guidance due to shortages of the formulary alternative, it is not clear whether an individual patient non-formulary request or a blanket formulary application should be completed, or temporary addition to the formulary during supply shortages. **[Finding 4]**

	Non-Formulary Population	Sample Selected for Review	
Number of patients/drugs[2]	79	20	25%
Total Value of Drugs Dispensed (Apr 24 – Nov 25)	£1,610,791.18	£770,936.32	48%
Pro-Rata Equivalent	£966,474.71	£462,561.79	48%

4. Instances where an IPFR had not been completed or was retrospective and only covered part of the period reviewed. For the period reviewed, this amounted to just over £90k which could have been recovered if an IPFR had been submitted to and approved by JCC. **[Finding 4]**

[1] There is insufficient data available to enable analysis by duration of course of treatment

[2] Number of patients/drugs is based on one drug for one patient, consisting of multiple scripts/issues during the period reviewed (Apr 24 – Nov 25)

Key Findings		Risk & Impact	Agreed Management Action
1	**Policies and Procedures** The *Managed Entry Process Policy for Accessing Medicinal Products within the HDUHB Formulary* sets out the arrangements for adding medicines to the formulary and the approval requirements for non-formulary requests. It remains in draft and requires updating to reflect recent/imminent changes in Health Board operational governance arrangements prior to approval and publication as it currently references outdated committees and groups. Our sample testing has highlighted the need to clarify arrangements in relation to HCDs such as immunoglobulins (see finding 2); and instances where non-formulary HCDs are dispensed in line with national directions during periods of supply shortages for the formulary alternative (see finding 3) - policy does not stipulate whether an individual patient non-formulary request form should be completed for short term use or temporary addition to the formulary during longer term supply issues.	Lack of clarity regarding non-formulary/HCD approval requirements, potentially resulting in inconsistency and/or additional/ unnecessary financial burden for the Health Board.	**Agreed Action:** The policy will be updated, finalised and disseminated to clinical and pharmacy staff. Clarification on process around individual patient or blanket application to be included in the updated policy.
			Expected Evidence of Implementation: Updated/finalised policy. Evidence of dissemination to staff/publication on intranet.
	Theme: Policies & Procedures	**Medium Priority** Control Design	**Officer:** Aled Richards, Lead Pharmacist for Clinical Innovation & Value Based Healthcare **Target Implementation Date:** 31 August 2026 (Following July Medicines management Oversight Group)
2	**Immunoglobulins** Nine of our sample (accounting for 75% of the total value of our sample) related to immunoglobulins. Some brands are included on the formulary, those in our sample weren't and we were unable to determine a rationale for this. However, the brands dispensed were confirmed to be in line with all-Wales product selection guidance issued by the all-Wales Immunoglobulin Strategy Group. Hywel Dda is one of two health boards in Wales where immunoglobulins are ordered and dispensed via hospital pharmacies. The health board needs to review its approach to immunoglobulins to decide which should be included on the formulary and whether other formal governance/formulary approval processes are required. This needs to be considered in	Lack of control over HCD spend placing additional financial pressures on the Health Board.	**Agreed Action:** Supply of immunoglobulins will continue to align with all-Wales product selection guide. Hywel Dda formulary to be updated to reflect the range of products available for use, with clarity on first-line options.
			Expected Evidence of Implementation: Documented agreed approach for immunoglobulins.

	the context of any national governance arrangements for immunoglobulins.	**Medium Priority**	**Officer:** Aled Richards, Lead Pharmacist for Clinical Innovation & Value Based Healthcare
	Theme: Governance	Control Operation	**Target Implementation Date:** 31 May 2026
3	**Formulary** In three instances, evidence was provided to confirm that two drugs should have previously been added to the formulary, therefore not requiring any further review or approval.	Unnecessary scrutiny and approval of drugs already approved for inclusion on the formulary, resulting in inefficient use of resources.	**Agreed Action:** There is an existing process in place for updating the formulary, this is detailed within the draft Policy (see key finding 1). The formulary will be updated to include the identified drugs.
			Expected Evidence of Implementation: Completed application for inclusion on the formulary. MFGG minutes confirming approval. Identified drugs included on the formulary.
		Medium Priority	**Officer:** Aled Richards, Lead Pharmacist for Clinical Innovation & Value Based Healthcare
	Theme: Information, Data Quality & Data Accuracy	Control Operation	**Target Implementation Date:** Already completed
4	**Scrutiny & Approval of HCDs** Sample testing of 20 patients in receipt of HCDs identified four patients where an IPFR should have been completed. All related to long-term/lifetime treatment commenced prior to the period reviewed (April 2024 - November 2025). In three cases the treatment would have been initiated by specialists outside of Hywel Dda. It is possible that an IPFR was completed by the tertiary service but the arrangements for ongoing funding where treatment is transferred to the Health Board from a tertiary service are not clear. One had been identified by Pharmacy and an IPFR submitted and approved by NHS Wales Joint Commissioning Committee in November 2025, so future costs are now recoverable from JCC. The costs relating to these three cases for the period of review exceed £82k. The fourth case would be a Health Board IPFR and therefore costs would not be recoverable. Sample testing also identified one patient in receipt of a non-formulary HCD due to supply shortages of the formulary alternative. A non-formulary request form had not been completed. *(See also finding 1)*	Lack of control over HCD spend placing additional financial pressures on the Health Board.	**Agreed Action:** As per agreed action for finding 6, the non-formulary flag will be enabled within WellSky which will enable identification of non-formulary drugs dispensed. This will be regularly cross-referenced to the database of non-formulary and IPFR requests (as per agreed action for finding 5) to ensure that all non-formulary HCDs are appropriately approved. Clarity on funding process for treatments initiated by tertiary services external to the Health Board, with expectation for Health Board to continue ongoing treatment.
			Expected Evidence of Implementation: Documented evidence of cross-referencing the non-formulary/IPFR database to reports of non-formulary drugs dispensed to identify any that have not been appropriately approved.
		High Priority	**Officer:** Dilesh Khandhia, Associate Clinical Director of Pharmacy

	Theme: Approvals	Control Operation	**Target Implementation Date:** 31 December 2026

Objective 2: Mechanisms are in place to monitor high-cost drug usage and compliance with approval requirements — **Limited**

Mechanisms are in place to monitor total drugs costs, and this would facilitate identification of significant spikes in cost for further investigation. However, there is no monitoring of costs per patient per treatment course/per annum so high-cost drugs usage (formulary or non-formulary) is not identifiable or monitored. **[Finding 5]**

The draft Policy states that all non-formulary and IPFR requests will be recorded and tracked through a centralised database maintained by the Pharmacy & Medicines Management team. This is yet to be established. **[Finding 6]**

The WellSky pharmacy system is able to distinguish between formulary and non-formulary drugs, but this functionality is not operational in Hywel Dda. **[Finding 7]**

Key Findings		Risk & Impact	Agreed Management Action
5	**Monitoring of High-Cost Drug Use** There is no monitoring of costs per patient per treatment course/per annum to identify high-cost drug use and ensure that these are subject to periodic clinical review to assess appropriateness of ongoing use and facilitate identification of costs that could be recharged. Patient level data is available but requires manual analysis. There would be benefit in incorporating this into a dashboard to facilitate ongoing monitoring and oversight.	High-cost drugs use is not monitored or controlled resulting in additional financial burden for the Health Board.	**Agreed Action:** Patient level data will be built into a dashboard to facilitate monitoring and oversight of formulary and non-formulary high-cost drug use. **Expected Evidence of Implementation:** Dashboard enabling patient level monitoring.
		High Priority	**Officer:** Dilesh Khandhia, Associate Clinical Director of Pharmacy
	Theme: Information, Data Quality & Data Accuracy	Control Design	**Target Implementation Date:** 31 March 2027
6	**Centralised Database of Non-Formulary & IPFR Requests** A centralised record of non-formulary and IPFR requests has not been established by Pharmacy & Medicines Management team. A record of IPFRs is maintained by the IPFR Manager but this is not visible to Pharmacy. The absence of a central record limits the Health Board's ability to maintain effective oversight of non-formulary and HCD approvals which would facilitate approvals checking prior to dispensing by Pharmacy.	Non-formulary and HCDs may be issued without appropriate approval, potentially resulting in additional/ unnecessary financial burden for the Health Board.	**Agreed Action:** Create an electronic non-formulary and unlicensed request form and link this to the EPMA system to be completed at the point of prescribing. A centralise record of non-formulary requests will be established and used as reference for checking approvals prior to the issue of non-formulary drugs. Increase visibility of IPFR-approved treatments. **Expected Evidence of Implementation:**

			Centralised record of non-formulary & IPFR requests.
		Medium Priority	**Officer:** Dilesh Khandhia, Associate Clinical Director of Pharmacy **Target Implementation Date:** 31 December 2026
	Theme: Information, Data Quality & Data Accuracy	Control Design	
7	**Identification of Non-Formulary Drugs** The WellSky pharmacy system includes functionality to apply a flag to non-formulary drugs. This functionality has not been enabled for Hywel Dda and would require the mapping of the formulary within the WellSky system. As a result, non-formulary drug issues cannot be readily identified, which limits the ability to effectively monitor non-formulary activity and HCD usage.	Non-formulary and HCD issues are not monitored or controlled, potentially resulting in additional/ unnecessary financial burden for the Health Board.	**Agreed Action:** The formulary will be mapped to WellSky and the non-formulary flag functionality enabled.
			Expected Evidence of Implementation: Non-formulary drugs identifiable within WellSky. Reports of non-formulary drug issues produced from WellSky system.
		Medium Priority	**Officer:** Dilesh Khandhia, Associate Clinical Director of Pharmacy **Target Implementation Date:** 31 December 2026
	Theme: Information, Data Quality & Data Accuracy	Control Design	

Appendix A

Assurance Opinion

 **Substantial**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
 **Reasonable**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
 **Limited**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
 **Unsatisfactory**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
 **Advisory**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Findings

Priority	Explanation
High	Significant risk to achievement of a system objective OR evidence present of material loss, error, or misstatement. Poor system design OR widespread non-compliance.
Medium	Some risk to achievement of a system objective. Minor weakness in system design OR limited non-compliance.

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Public Sector Internal Audit Standards

Audit work undertaken by NHS Wales Audit and Assurance Services conforms with the International Standards for the Professional Practice of Internal Auditing and associated Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Chartered Institute of Public Finance & Accountancy in April 2023.

Website: [Audit & Assurance Services - NHS Wales Shared Services Partnership]

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