Individual Patient Funding Requests
Final Internal Audit Report

December 2022

Hywel Dda University Health Board

NWSSP Audit and Assurance

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
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Audit and Assurance Services

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Executive Summary

Purpose

The overall objective of this audit is to establish and review the systems and processes in place to assess, make decisions on, and monitor spend related to Individual Patient Funding Requests (IPFR's).

Overview

IPFR applications were generally comprehensive and supported with evidence of medical studies and journals. Panel minutes demonstrate diligent assessment of applications with additional information or evidence requested for complex cases. Whilst this often caused delay in the decision and response, it was evident that significant effort is made to adhere to policy timescales.

We have concluded **Reasonable** assurance overall with one high priority matter arising. There is lack of clarity regarding responsibility for monitoring IPFR expenditure, and the majority of this expenditure flows through 'business as usual' processes so is not separately identified as IPFR related. As a result, IPFR expenditure is not monitored on a case by case or Health Board-wide basis.

Full details are provided in Appendix A.

Report Classification

		Trend
Reasonable 	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.	n/a

Assurance summary[1]

	Assurance objectives	Assurance
1	IPFR's are processed in line with the all-Wales IPFR Policy	Substantial
2	There is appropriate representation at IPFR panel meetings. Decision-making is in line with guidance in the all-Wales IPFR policy and the decision and rationale is clearly documented within the minutes.	Substantial
3	Approved IPFR's are monitored to identify expenditure beyond the agreed funding limit and timeframe.	Limited

Matters Arising

		Objective	Control Design or Operation	Recommendation Priority
1	Identification & Monitoring of IPFR Spend	3	Design	High

[1] The objectives and associated assurance ratings are not necessarily given equal weighting when formulation the overall audit opinion

1. Introduction

1.1 The Individual Patient Funding Request review has been completed in line with the 2022/23 Internal Audit Plan. The relevant lead Executive Director for the assignment is the Medical Director, HDUHB.

1.2 Our review has focused on the arrangements in place for clinicians to apply for funding for individual patients which will normally be for one of the following reasons:

a. A patient requires a treatment which is new, novel, developing or unproven and is not within the Health Board's routine schedule of services and treatment

b. A patient requires a treatment which is outside of existing clinical policy criteria

c. A treatment is required for a patient with a rare or specialist condition and is not eligible for treatment in accordance with the clinical policy criteria.

1.3 The review has excluded other services (All Wales Prior Approval Policy, Funding for Planned Treatment in Europe (S2) and Bariatric Referrals to the Welsh Institute of Metabolic & Obesity Surgery (WIMOS)) also undertaken by the Referral Management Centre (RMC).

1.4 The All Wales Therapeutic and Toxicological Centre (AWTTC) independently audit one IPFR case per quarter and undertake an IPFR panel review. None of the AWTTC audited cases were reviewed.

1.5 The potential risks considered in the review are as follows:

- applications are poor quality and/or non-compliant with policy
- inappropriate decisions and/or lack of transparency in the IPFR panel review and decision-making process
- decisions are made which do not reflect Welsh Government communications setting out the key factors for 'good decision making', and do not align to IPFR Policy demonstrating 'clinical benefit' and 'value for money'

Potentially resulting in:

- patient harm due to delays in receiving treatment
- reputational damage due to legal challenge
- financial loss

2. Detailed Audit Findings

Objective 1: IPFR's are processed in line with the all-Wales IPFR Policy

2.1 The IPFR database identified 44 IPFR applications received during 2022 to date:

	Number of Applications
Panel Approved – New Applications	22
Panel Approved – Continuation of Treatment	3
Panel Rejected	1
Screened Out / Withdrawn	18

2.2 We sampled 13 approved IPFR applications from the database for testing to assess compliance with the key requirements of the all-Wales IPFR policy, with the findings summarised in the sections below:

Completeness and approval of applications

2.3 Twelve applications utilised the correct all-Wales IPFR application form. Most forms were thoroughly completed with many having been noted by the Panel as extensively so, including evidence of journals, medical studies and with some requesting clinicians having obtained support from peers and other experts in the field.

2.4 One application relating to the annual extension of an existing approved case was received via email instead of using the IPFR application form, although relevant supporting evidence was provided. We were advised that this is permitted for extensions, although this is not explicit in the all-Wales policy.

2.5 It is evident that where possible rather than strictly adopting the All-Wales screening process which effectively "rejects" outright an incomplete application, the IPFR team have sought to create open communication with the requesting clinician to obtain further required information in the most expedient manner and further, have engaged with other services such as Health Technology Wales to undertake Rapid Evidence Reviews to have the best chance of being able to progress the IPFR application to panel.

Timescales for processing by the IPFR Team line with All Wales Policy

2.6 The 13 sampled cases were categorised as follows:

	Timescale for Assessment & Response	Number of Sampled Cases
Clinically Urgent	24 - 48hrs	4
Soon	Within 3 weeks	5
Non-Urgent	4-6 weeks	3
Extension	Not stipulated within policy	1

2.7 Only three cases (one Clinically Urgent, two Non-Urgent) were processed within the required timescale from receipt of the application. Nine cases exceeded the stipulated timescales as a result of further information required due to the complexity of the case, to enable thorough assessment of the application. All were promptly processed following receipt of this information, with the exception of one which was a more complex case requiring escalation over and above the IPFR Panel.

2.8 It was clear that significant effort is made to adhere to the policy timescales, with a Chair's action taken where necessary to ensure timescales were met. Where additional information had been required for the case to progress the IPFR team had been efficient and diligent in obtaining it and communication between clinicians, IPFR panel members and the IPFR team appears to be well managed and recorded.

Conclusion:

2.9 Whilst the timescales set out in the all-Wales policy had not been met in many of the cases reviewed, it was evident that this was largely due to the diligence of the IPFR Team, with additional information required to allow thorough assessment of complex applications. Allowing for the delays associated with this, all but one application sampled had been promptly assessed in line with policy. Accordingly, we have concluded **Substantial** assurance for this objective, with no recommendations raised.

Objective 2: There is appropriate representation at IPFR panel meetings. Decision-making is in line with guidance in the all-Wales IPFR policy and the decision and rationale is clearly documented within the minutes

2.10 IPFR Panel minutes evidence consistent quorate attendance and administrative follow up such as recording of outcomes and actions processed in an efficient manner. The role of the Panel is set out within the all-Wales IPFR policy.

2.11 For each sampled case, the IPFR Panel minutes demonstrated thorough consideration of the three decision making criteria set out within the all-Wales IPFR Policy - clinical benefit, economic benefit, and ethical and other considerations.

2.12 Where Chair's action had been taken to approve a Clinically Urgent Case, the reason for approval had been recorded and where necessary had been escalated through the delegation scheme, obtaining emailed approval.

2.13 Fourteen of the rejected/screened out applications were submitted by the same clinician and related to a clinically similar cohort of patients. The applications lacked clinical information and following a Rapid Evidence Appraisal by Health Technology Wales, the Panel concluded that IPFR was not the most appropriate route for these patients.

Conclusion:

2.14 Noting the above, we have concluded **Substantial** assurance for this objective.

Objective 3: Approved IPFR's are monitored to identify expenditure beyond the agreed funding limit and timeframe

2.15 The IPFR database records all applications received, including the approved costs and duration of treatment for successful applications. For 2022 to date approved costs amount to £247,562.

2.16 Approved IPFRs are not monitored to ensure that expenditure remains within the agreed funding limit and timeframe. It is the responsibility of the clinician to ensure that treatment is within the approved limits, and a new application should be submitted if continuation of treatment is required. The database identifies three approved continuation of treatment applications approved during 2022 to date.

2.17 The majority (91%) of IPFR expenditure relates to drugs and is processed through Pharmacy. This expenditure is not separately identified as IPFR related or recharged to an IPFR budget, so monitoring is not feasible.

2.18 Discussion with the IPFR Panel Pharmacy representatives noted that confirmation of IPFR approval is required for drugs outside of standard NICE pathways and checks are undertaken with the clinician to confirm ongoing suitability for treatment from a clinical perspective, but utilisation of approved funding is not monitored. Consequently, there is a risk that approved funding and treatment durations are exceeded.

2.19 Non-pharmacy related IPFR expenditure (e.g., for therapeutic treatment) and recharges from other Health Boards are identifiable as invoices are received directly by the IPFR Team. This expenditure is accrued against the Referrals Management Centre (RMC) budget by Finance based on the costs approved by Panel, with accruals verified to invoices received.

2.20 Discussions throughout the audit noted an assumption that the IPFR budget is underspent, although we were unable to substantiate this. Whilst the annual budget for RMC (£681k) has a year-to-date underspend of £36k as at month 7, we were unable to determine the budget specifically for IPFR. Non-drug IPFR expenditure to date (£11,740 as at M7) is in line with the annual value of approved non-drug IPFRs to date (£22,240 as at M7), but pharmacy related IPFR spend is not quantifiable.

2.21 The budget is managed by Finance as part of the wider commissioning budget and therefore sits outside of the IPFR Team. However, there is lack of clarity regarding responsibility for monitoring cumulative IPFR spend, with Finance citing it as an IPFR Team responsibility, but the team do not have sufficient information to do so.

[See Matter Arising 1]

Conclusion:

2.22 IPFR expenditure is not identifiable (with the exception of non-drug related expenditure, which accounts for less than 10% of approved IPFR costs). As a result,

IPFR spend is not monitored either cumulatively or on a case-by-case basis to ensure expenditure is within the approved cost and treatment duration. Accordingly, we have concluded **Limited** assurance for this objective.

Appendix A: Management Action Plan

Matter Arising 1: Identification and Monitoring of IPFR Spend (Design)	Impact
Approved IPFRs are not monitored to ensure that expenditure remains within the agreed funding limit and timeframe. The majority (91%) of IPFR expenditure relates to drugs and is processed through Pharmacy. This expenditure is not separately identified as IPFR related or recharged to an IPFR budget so monitoring individual or even cumulative IPFR spend is not feasible. Whilst some monitoring is undertaken by Pharmacy from a clinical perspective, the utilisation of approved funding is not monitored so there is a risk that approved funding and treatment durations are exceeded. We discussed the feasibility of monitoring utilisation of funding with the Lead Clinical Development Pharmacist who agreed that this could be incorporated into wider plans to improve monitoring arrangements for high-cost drugs across the Health Board (not just IPFR). Discussions throughout the audit noted an assumption that the IPFR budget is underspent, although we were unable to substantiate this as we were unable to determine the budget specifically for IPFR (although note that non-drug spend to date is in line with the value of non-drug IPFRs to date), and pharmacy related IPFR spend is not quantifiable. The budget is managed by Finance as part of the wider commissioning budget and therefore sits outside of the IPFR Team. However, there is lack of clarity regarding responsibility for monitoring cumulative IPFR spend, with Finance citing it as an IPFR Team responsibility, but the team do not have sufficient information to do so.	Potential risk of: • IPFR expenditure exceeds the value approved by Panel • Overspend against the IPFR budget
Recommendations	**Priority**
The IPFR Team, Finance and Pharmacy should collectively agree and establish a suitable mechanism for capturing and monitoring IPFR spend to ensure that approved costs and treatment duration are not exceeded.	**High**

Noting that the IPFR budget sits outside of the IPFR Team, responsibility and arrangements for monitoring cumulative IPFR spend should be agreed. If this is outside of Finance (as budget holder), sufficient information needs to be provided Clarify ownership and accountability for the IPFR budget, including responsibility for monitoring spend.		
Agreed Management Action	**Target Date**	**Responsible Officer**
To agree a mechanism with Finance (budget holder) and pharmacy to ensure spend is monitored and not exceeding the approved treatment duration. Agree a reporting process for monitoring cumulative IPFR spend against defined budgets and within standing budgetary control requirements.	31/3/23	Dan Binding - Senior Finance Business Partner, John Evans – Assistant Director, Lisa Davies – Head of Effective Clinical Practice & QI

Appendix B: Assurance opinion and action plan risk rating

Audit Assurance Ratings

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

	**Substantial assurance**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
	**Reasonable assurance**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
	**Limited assurance**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
	**No assurance**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
	**Assurance not applicable**	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 Recommendations

We categorise our recommendations according to their level of priority as follows:

Priority level	Explanation	Management action
High	Poor system design OR widespread non-compliance. Significant risk to achievement of a system objective OR evidence present of material loss, error, or misstatement.	Immediate*
Medium	Minor weakness in system design OR limited non-compliance. Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. Generally, issues of good practice for management consideration.	Within three months*

* Unless a more appropriate timescale is identified/agreed at the assignment.

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