AGENDA ITEM
3.2.11

QUALITY & SAFETY COMMITTEE

CWM TAF MORGANNWG INDIVIDUAL PATIENT FUNDING REQUESTS (IPFR) ANNUAL REPORT 2021/22

Date of meeting	19/07/2022
FOI Status	Open/Public
If closed please indicate reason	Not Applicable - Public Report
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Approving Executive Sponsor	Executive Director of Public Health
Report purpose	FOR NOTING

Engagement (internal/external) undertaken to date (including receipt/consideration at Committee/group)		
Committee/Group/Individuals	**Date**	**Outcome**
(Insert Name)	(DD/MM/YYYY)	Choose an item.

ACRONYMS	
IPFR	Individual Patient Funding Request
AWTTC	All Wales Toxicology and Therapeutic Committee (AWTTC)
NICE	National Institute of Clinical Effectiveness
QA	Quality Assurance
HTW	Health Technology Wales
WHSSC	Welsh Health Specialised Services Committee

1. SITUATION/BACKGROUND

1.1 This report briefs members of the decisions made by the Cwm Taf Morgannwg University Health Board (CTM) Individual Patient Funding Request (IPFR) panel during 2021/22.

1.2 The All Wales IPFR Policy was introduced in 2011 and revised in 2015 and 2017 following Ministerial reviews. Its aim is to ensure there is a fair, transparent and consistent approach to decision making across Wales for medicine and non-medicine treatments not routinely commissioned on the NHS as they are new, novel or experimental. Where a medicine or treatment has not been appraised or approved for use in the NHS in Wales, a clinician can apply for it to be made available under the IPFR process. This process allows access to treatments where there is clear evidence a patient will derive significant clinical benefit from the treatment compared to other patients and that there is evidence that the treatment will be clinically effective and represents a cost effective use of NHS resources.

1.3 The membership of the health boards IPFR panel is outlined in the All Wales IPFR policy. Within CTM, the panel membership is set out as follows:

Director of Public Health (Chair)
Head of Medicines Management (Vice Chair)
Public Health Consultant (Vice Chair)
Director of Nursing
Medical Director
Director of Therapies and Health Sciences
Assistant Director of Commissioning & Transformation
Lay representative (2 vacant posts)

1.4 The CTM IPFR panel is scheduled to meet every fortnight to ensure applications are considered in line with the required timescales requested in the application. However, the CTM panel is cancelled if there are no IPFR applications to consider.

1.5 There is also an established mechanism to consider urgent applications within 24-48 hours. For urgent/life threatening applications and when a panel cannot be convened or discussion facilitated virtually within 24-48 hours, the Chair of the IPFR panel can undertake Chair's Action. During 2021/22 the CTM IPFR panel was convened on 10 occasions, while Chair's Action was taken for 8 cases.

1.6 Governance structures related to the All Wales IPFR process

Following the independent review of the IPFR process in Wales in 2017, a key recommendation was to 'establish a national IPFR quality function to support IPFR panels to ensure quality and consistency in decision making. It would include facilitation, advice training and auditing of the IPFR process and have an obligation to report on the quality of processes, highlighting any concerns through the existing quality and clinical governance processes in Wales. The Quality Assurance (QA) panel was therefore established to undertake this function and is hosted by the AWTTC.

1.7 The governance structure for the established QA panel is clearly laid out in the terms of reference which were approved as part of the IPFR review through existing health board governance structures, including WHSSC and by the Deputy Chief Medical Officer for Wales for whom the group reports to. The group's role is to scrutinise a randomly selected IPFR from each IPFR panel to ensure the process had been followed in line with the All Wales IPFR Policy.

1.8 The All Wales Therapeutics and Toxicology Centre (AWTTC) plays a pivotal role in supporting IPFR panels, ensuring consistency in approach via the QA group, establishing an All Wales IPFR database which seeks to identity any cohorts thus enabling a rapid review of the evidence and possible early access to treatment, for both medicines and non-medicines, and supporting the requirement for ongoing IPFR training events.

1.9 When a patient cohort is identified through cases submitted to the All Wales IPFR database, this links with the One Wales Commissioning Process.

1.10 Health Technology Wales (HTW) forms part of the QA group and are alerted to any non-medicine cohorts identified via the All Wales database thus enabling them to carry out an evidence appraisal. They also provide support for rapid evidence appraisals to IPFR panels when required. During 2021/22, CTM requested 1 rapid appraisal to assist the IPFR panel decision making process. Individual clinicians can also submit a topic for consideration. In addition to rapid appraisals, HTW considered more than 80 new topic referrals from across the health and care communities and published six new HTW guidance documents in 2021/22, including its first social care guidance, as well as nine new evidence appraisal reports.

1.11 One Wales Interim Pathways Commissioning process

The IPFR cases considered by the CTM IPFR panel and other health boards across NHS Wales including WHSSC, is also used to inform

other aspects of the AWTTC work programme, and in particular the One Wales Interim Pathways Commissioning process which has been assessing medicines since May 2016. The process has been developed to facilitate one single agreed decision for NHS Wales on access to particular medicines for a group of patients (a patient 'cohort'). Medicines and patient cohorts are identified for the One Wales Interim Pathways Commissioning process by signals from activity in the IPFR panels, from WHSSC, the Chief Pharmacist Peer Group or clinician groups.

1.12 Ongoing monitoring of the IPFR data has shown that soon after publication of a positive One Wales Interim Pathways Commissioning (IPC) decision, applications are no longer submitted for these indications. This positively demonstrates that the process effectively reduces the burden on IPFR panels and encourages equity of access to these medicines across Wales. During 2021/22, there have not been any IPFR cohorts identified that have led to One Wales assessments for medicines. The medicines considered via the IPFR process were diverse and did not meet the criteria for the IPC process. The following medicines have been put forward for consideration via the IPC process by clinicians:

Abiraterone for treatment of high risk, non-metastatic, hormone sensitive prostate cancer (off-label);

Vonicog alfa for treatment of bleeding during surgery in paediatric patients with Von Willebrand disease (off-label);

2. SPECIFIC MATTERS FOR CONSIDERATION BY THIS MEETING

2.1 IPFR data 2021/22

2.1.1 The requests submitted to the CTM IPFR panel vary in terms of complexity. The majority of applications relate to non-NICE approved/unlicensed drugs. The number of non-medicine requests received has been historically low, however a slight increase in the number of requests was noted in 2021/22 (table 1). IPFR decisions are recorded centrally on the All Wales IPFR database.

Table 1: Requests submitted to the CTM IPFR panel 2021/22

2021/22	Approved	Not approved	Total
Medicine	16	6	22
Non medicine	5	1	6
Total	21	7	28

2.1.2 The following table details the number of Cwm Taf Morgannwg IPFR requests during 2018/19, 2019/20 and 2020/21, and demonstrates only a slight increase in the total number of IPFR applications considered by the CTM IPFR panel considering the Bridgend Boundary Change taking effect from April 2019.

Table 2: IPFR applications considered by the CTM panel by year.

	Approved	Not approved	No. of IPFR applications considered
2018/19	9	3	12
2019/20*	12	2	14
2020/21	21	4	25
2021/22	21	7	28

*Bridgend Boundary Change April 2019

2.1.3 The Health Board has seen a slight increase in the number of applications received in 2021/22 totalling 28, which could be attributed to COVID and the lack of medical procedures being undertaken. With some drug requests, there was a need to avoid hospital attendance for routine drug administration, particularly with immuno-suppressed patients. This led to off license scenarios as the pre-requisite 1st / 2nd line treatment criteria may not have been met, rather than the use of new/un-appraised drugs.

2.2 Financial commitment

2.2.1 The very nature of IPFR spend is unpredictable and will vary year by year due to the requests received. The table below highlights a reduction in the committed spend when compared to previous years, despite the number of IPFR applications considered have increased year on year:

Table 3: IPFR financial commitment by year

Year	Total commitment (£)
2018/19	96k
2019/20*	219k
2020/21	308k
2021/22	178k

*Bridgend Boundary Change April 2019

2.3 Feedback from QA Panel

2.3.1 As outlined in section 1.8, there are strict timescales around the IPFR process for which the Health Board is audited on a quarterly basis by the QA panel. After each QA panel, the health board will receive a formal update. For 21/22, the health board has performed well and has been considered consistent in its approach in terms of process and timeliness.

2.4 Amendment to Directions concerning Cross Border Directive (2011/24/EC) and the S2 funding route process

2.4.1 Following the UK's withdrawal from the European Union (EU) on 31st December 2020, the EU Directive funding route ceased. Welsh Government issued a Welsh Health Circular (2021/005) instructing Health Boards that the EEA Directive could no longer be used by UK citizens to access healthcare treatment in the EU.

2.4.2 Whilst the EU Directive funding route has ceased, S2 arrangements will continue as part of agreed reciprocal healthcare arrangements with Europe post Brexit. The S2 route enables CTM patients to apply to have their planned treatment in another EEA country at the expense of their home state. This can be in state provider or private healthcare provider that accepts an S2 certificate for which treatment will be provided under the same conditions and payment as for a resident of the country of treatment.

2.4.3 As the Directive route is no longer an option for patients to seek treatment in Europe, the Health Board had anticipated an increase in the number of S2 applications. However during 2021/22, CTM UHB did not receive any S2 funding requests which is attributed to continued travel restrictions due to COVID-19. However the Commissioning team will closely monitor the number of S2 applications in 22/23 and escalate appropriately if the number of requests increase.

3. KEY RISKS/MATTERS FOR ESCALATION TO BOARD/COMMITTEE

3.1 CTM UHB representation on the All Wales IPFR panel

3.1.1 The Terms of Reference of the All Wales IPFR Panel requires five out of the seven Health Boards to be present, at Director or Deputy/Assistant Director level, three of which need to be clinical representatives, in order to be quorate.

3.1.2 CTMUHB is unable to identify more than one representative (the Director of Public Health) to attend the All Wales IPFR Panel which due to availability has in turn contributed to the All Wales IPFR panel not being quorate. This has resulted in WHSSC colleagues having to rearrange the All Wales panel at short notice which is a significant risk as a delay in consideration of an IPFR application can delay patient care.

3.1.3 The Health Board IPFR Panel has recently discussed how to attract further clinicians to be members of the All Wales IPFR Panel. Correspondence was sent to the Medical Director to the Clinical Advisory Group and to the Director of Nursing and Director of Therapies and Health Sciences to circulate to colleagues, however no interest has been forthcoming.

3.1.4 Whilst a representative with a clinical background is the preference due to the need for the All Wales IPFR Panel to have at least three clinical representatives, the Interim Assistant Director of Commissioning and Transformation who had a background in WHSSC, has attended Panels to ensure quoracy, however they have now moved to another role and will no longer be involved in the IPFR process. Therefore, identification of a further CTM representative is urgently required.

3.2 Lay representation on the CTM IPFR panel

CTM UHB is required to recruit two lay representatives to the local IPFR panel as per the IPFR TOR. There has been great difficulty in attracting suitable candidates to the role in spite of information being circulated to the CTM Community Health Council (CHC) and external stakeholders. In a more recent attempt to generate interest, colleagues at the AWTTC when advertising for lay representatives to their internal committees, extended the advertisement to include Health Board and WHSSC IPFR panels. Unfortunately, no interest has been expressed so far.

3.3 Vacant Patient Flow Manager post

The IPFR function is managed on a day to day basis by the Patient Flow Manager. The role falls under the portfolio of the Director of Strategy and Transformation. Unfortunately, the Patient Flow Manager role has been vacant since 1st August 2021 due to a secondment opportunity. Since August 2021, the Patient Flow Manager role has been covered by the Commissioning Manager alongside their day to day role which is involved in overseeing contractual elements and disaggregation's associated with the Bridgend Boundary Change. Covering both roles has been difficult and challenging at times and is unsustainable in the long term.

Ensuring adequate cover for the IPFR function remains a risk when the Commissioning Manager has to take leave. It is hoped the vacant Patient Flow Manager role can be advertised on its current banding in the near future. The IPFR role is unique to the health board and thus there is a limited pool of individuals who have the required knowledge or experience to undertake this role.

4. IMPACT ASSESSMENT

Quality/Safety/Patient Experience implications	There are no specific quality and safety implications related to the activity outined in this report.
Related Health and Care standard(s)	Effective Care
	If more than one Healthcare Standard applies please list below: Safe Care Timely Care
Equality Impact Assessment (EIA) completed - Please note EIAs are required for <u>all</u> new, changed or withdrawn policies and services.	Yes If yes, please provide a hyperlink to the location of the completed EIA or who it would be available from in the box below. If no, please provide reasons why an EIA was not considered to be required in the box below.
	EQIA undertaken on an All Wales basis
Legal implications / impact	Yes (Include further detail below)
	WHC (2021/005) EEA Directive cessation
Resource (Capital/Revenue £/Workforce) implications / Impact	There is no direct impact on resources as a result of the activity outlined in this report.
Link to Strategic Goals	Improving Care

5. RECOMMENDATION

The Committee is asked to **NOTE**:

- The content of this report;
- The need for CTM representation at the All Wales IPFR panel to ensure panel quoracy; and
- The need to recruit lay representation to the CTM IPFR panel.