



Individual Patient Funding Request (IPFR)

Annual Report 2020/2021



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AWTTC Clinical Director's statement

The COVID-19 pandemic significantly altered the way in which we worked in 2020 and continues to have a profound impact on the NHS in Wales in 2021. Despite significant challenges for our workforce I am incredibly impressed by the way in which the Individual Patient Funding Request (IPFR) teams and panels across Wales continued to provide a service to our patients and clinicians.

The findings indicate that the pandemic has had an impact on the work of the panels. This is the first time in five years that the total number of IPFRs in Wales has bucked the downward trend. It is the second year running that there has been an increase in requests for medicines. From speaking to the IPFR Co-ordinators it would appear that this is due to an increase in requests for



Dr James CoulsonInterim Clinical Director, AWTTC

cancer medicines that limit the need for hospital attendance during the pandemic. An increase has also been seen for non-medicine IPFRs, although this was driven by requests for positron emission tomography (PET) scans. Referrals for second opinions and surgical procedures reduced reflecting the move from routine hospital work to emergency care for COVID-19 patients. Interestingly, the approval rate for all IPFRs has remained static at 74%.

The IPFR Quality Assurance Advisory Group has also seen changes during the pandemic, meeting every six months and through an online platform. The online platform proved to be a success, negating the need for commuting and supporting group member attendance so that going forward we will be continuing with this

method of conducting our meetings. However, six-monthly meetings were less popular and the consensus was to move back to meeting every three months as it is easier to monitor changes and improvements to panels when meeting more frequently.

Due to the commitments on our NHS staff we took the decision to not hold an annual workshop in 2020. However, we are pleased to announce that we are aiming to hold an online workshop in the autumn of 2021. For any healthcare professionals and lay members with a role or interest in IPFR, please keep a look out for more information through our website or contact your local IPFR team.

Executive summary

- The effects of the COVID-19 pandemic on healthcare in Wales during 2020/2021 are clearly reflected in the IPFR data for 2020/2021.
- 2020/2021 saw the first increase in the numbers of IPFRs across Wales for the last five years, an effect attributed to the impact of the COVID-19 pandemic. Overall, during 2020/2021 there were approximately 14% more IPFRs overall: 8% more IPFRs for medicines and 19% more IPFRs for non-medicines.
- The increase in IPFRs for medicines was driven by an increase in requests for medicines for the treatment of cancer. This is most probably an effect of the COVID-19 pandemic, when some patients were not able to access their usual treatments, and some changed to taking oral medicines to avoid having treatment in a clinic or hospital.
- The increase in IPFRs for non-medicines was driven by an increase in requests for positron
 emission tomography (PET) scans. IPFRs for second opinions halved compared with 2019/2020,
 and IPFRs for surgical procedures and medical devices also fell. These reductions are most
 likely due to the COVID-19 pandemic, as are the increases in requests for therapy and other
 treatments.
- The approval rate for all IPFRs was 74%, this rate was the same as 2019/2020.
- The overall approval rate of IPFRs for medicines during 2020/2021 was broadly unchanged at 77% compared with 78% during 2019/2020.
- The approval rate for non-medicine IPFRs for 2020/2021 was 73%, broadly similar to 2019/2020 when it was 72%.
- Where outcome data were available, 11 of 23 patients (50%) were reported to have had a complete or partial response to treatment and 14 of 20 patients (70%) had an improvement in quality of life.

Background

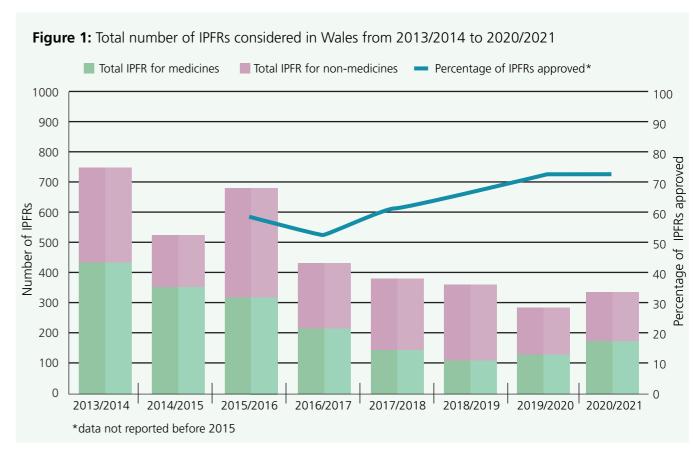
A comprehensive range of NHS healthcare services are routinely provided across health boards in Wales. The Welsh Health Specialised Services Committee (WHSSC), working on behalf of the seven health boards in Wales, commissions specialised services at a national level. However, each year, the health boards and WHSSC receive requests for healthcare that fall outside the range of services agreed. Individual Patient Funded Requests (IPFRs) are defined as 'requests to a health board or WHSSC to fund NHS healthcare for individual patients whose needs fall outside the range of services and treatments that a health board has arranged to routinely provide'. The healthcare requested can include, for example, a request for a surgical device or piece of equipment, a medicine or a surgical intervention.

Further information about the IPFR service in Wales can be found on the AWTTC website (www.awttc.org/ipfr).

AWTTC supports the IPFR service in Wales by the development and updating of the IPFR database, audit and maintenance of the quality and desired level of service, identification of cohorts and medicines for the One Wales Medicines Process, hosting an annual workshop and training event for members.

Individual Patient Funding Requests

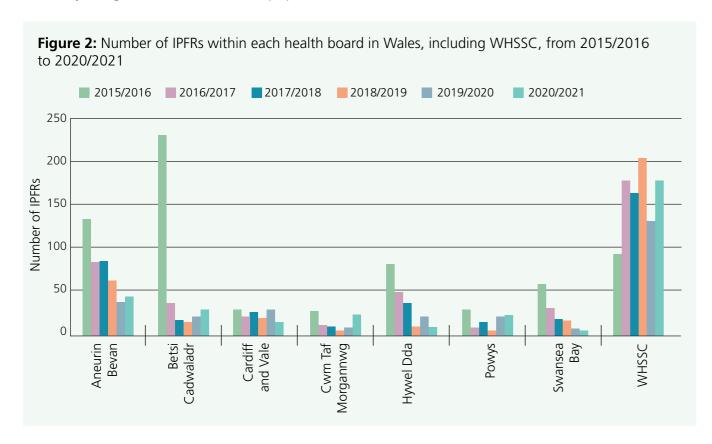
A total of 328 IPFRs were considered between 1 April 2020 and 31 March 2021: 141 for medicines and 190 for non-medicines; three applications included requests for medicines and non-medicines. This is a slight increase in total IPFRs compared with 2019/2020, and is the first increase in total IPFRs in the past five years (Figure 1).



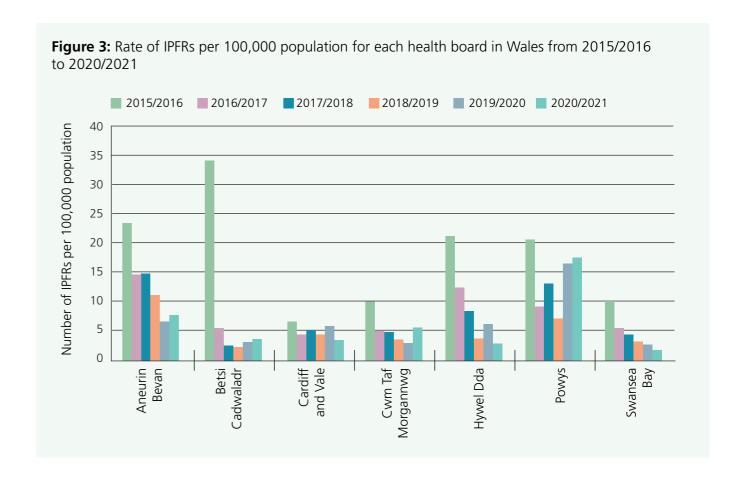
The numbers of requests for medicines and non-medicines both increased slightly during 2020/2021 compared with 2019/2020. This increase in total IPFRs is most likely due to the COVID-19 pandemic, during which some patients may not have been able to access their usual treatments. The increase in IPFRs was not seen across all health boards in Wales; IPFRs from WHSSC showed an increase, as did some of the health boards, while some health boards showed a decrease in IPFRs.

The approval rate of all IPFRs during 2020/2021 stayed the same as for 2019/2020, at 74%. The approval rate data were not reported for the years before 2015; AWTTC took on this role in 2015.

The numbers of IPFRs considered by each panel over the last six years are shown in Figure 2. Four panels showed an overall increase in IPFRs in 2020/2021, and three panels showed slight decreases. The total number of IPFRs across the health boards (excluding WHSSC) increased from a median of 22 in 2019/2020 to a median of 23 in 2020/2021. These differences were maintained after adjusting for the health board populations.



The rate of IPFR requests per 100,000 population for each health board during 2020/2021 ranges from 2 to 17, as shown in Figure 3. Most health boards showed only small changes in the rate in 2019/2020. One health board informed AWTTC that the rate of IPFRs decreased during the first quarter, decreased even more during the second quarter, but then increased during the third and fourth quarters. It was thought that the decrease was due to the COVID-19 pandemic. Powys Teaching Health Board still has the highest rate of IPFRs per 100,000 population in 2020/21. This may in part be due to its geography as Powys commissions services from both Welsh and English providers.



Continued funding

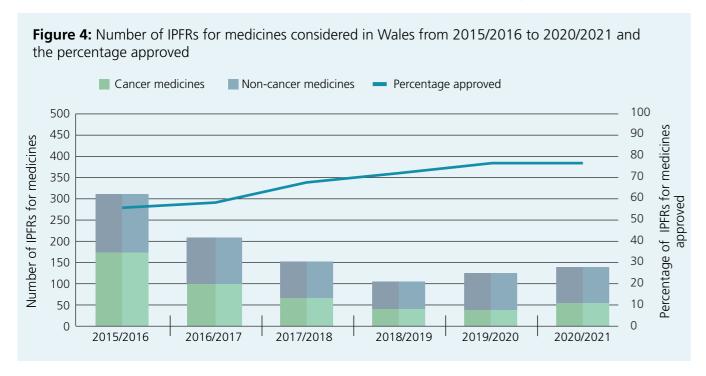
Continued funding requests are for treatments that had previously been approved and require an extension to treatment. In 2020/2021 there were 54 continued funding requests for medicines and seven requests for non-medicines; 12 requests were for medicines and non-medicines.

Independent reviews

For IPFRs that are reviewed and then not recommended by the panel, and where the patient and their clinician feel that the process has not been followed in accordance with the IPFR policy, an independent review of the IPFR process may be requested. In 2020/2021 one request for a review was submitted. The request was made based on all three grounds for review as per the IPFR policy: the Health Board has failed to act fairly and in accordance with the All Wales Policy on Making Decisions on Individual Patient Funding Requests; the Health Board has prepared a decision which is irrational in the light of the evidence submitted; and the Health Board has not exercised its powers correctly. The review panel stated that if new or additional information were to be provided by the applicant then the IPFR panel could reconsider the request.

IPFRs for medicines by health board and Welsh Health Specialised Services Committee (WHSSC)

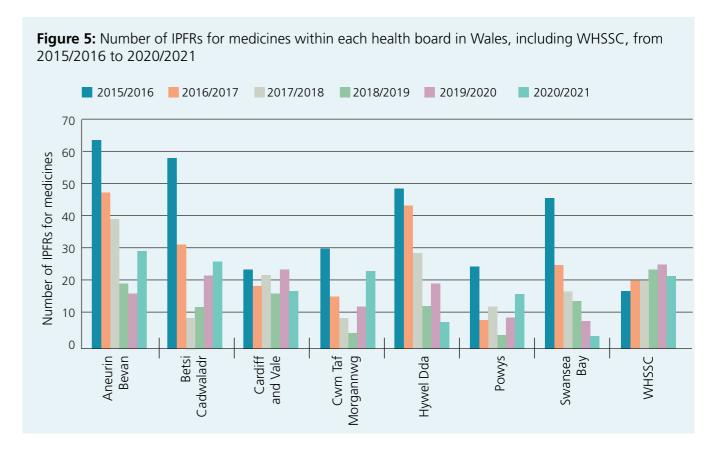
The number of IPFRs for medicines increased in 2020/2021 (n = 141) compared with 2019/2020 (n = 131). This is the second year running that IPFRs for medicines increased. The approval rate was 77% compared with 78% in 2019/2020: 108 IPFRs for medicines were approved, 30 were not approved and three were deferred (Figure 4).



Requests for an IPFR in relation to a medicine occur for three main reasons:

- Advice in relation to a licensed indication is not available from the All Wales Medicines Strategy Group (AWMSG) or the National Institute for Health and Care Excellence (NICE).
- AWMSG or NICE has given advice, and has not recommended the technology.
- The medicine is being used 'off-label', i.e. medicine used outside the terms of its marketing authorisation (product licence).

The number of IPFRs for medicines for the treatment of cancer increased, from 38 in 2019/2020 to 54 in 2020/2021 (Figure 4). The number of IPFRs for other (non-cancer) medicines was similar to the previous year: 87 in 2020/2021 compared with 93 in 2019/2020. The increase in IPFRs for cancer medicines may be explained by the COVID-19 pandemic during 2020-2021, during which some patients were not able to access their usual treatments. Some patients changed to taking oral medicines or to other treatment options that avoided or reduced visits to a clinic or hospital for their treatment, others were changed to less immunosuppressant options.



In March 2020, NICE published a COVID-19 rapid guideline on the delivery of systemic anticancer treatments (NG161)¹. The purpose of the guideline was to maximise patient and staff safety, making the best use of NHS resources and service capacity. The guideline linked to a list published by NHS England of interim treatment options during the COVID-19 pandemic. These treatment options provided greater flexibility for managing patients. The guideline and list of treatments were adopted for use in Wales².

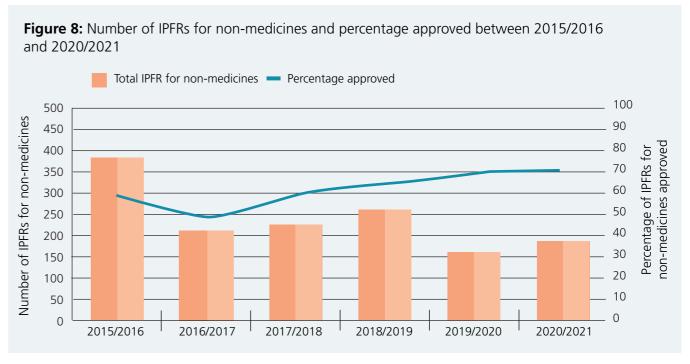
The most IPFRs for medicines in 2020/2021 were considered by two health boards: Aneurin Bevan (n = 29) and Betsi Cadwaladr (n = 26); Figure 5). In previous years, WHSSC had considered the most IPFRs for medicines. The numbers of IPFRs considered by the health boards varied: four health boards showed increases; one showed a large decrease and two showed slight decreases. Figure 6 shows the rate of IPFRs for medicines per 100,000 population for each health board in Wales in 2020/2021. The WHSSC medicine IPFRs for each health board have been added to the

¹National Institute for Health and Care Excellence. NICE Guideline, NG161. COVID-19 rapid guideline: delivery of systemic anticancer treatments. Apr 2020. Available at: https://www.nice.org.uk/guidance/ng161.

²All Wales Medicines Strategy Group. All Wales implementation of COVID-19 NICE rapid guidelines. Updated May 2020. Available at: https://awmsg.nhs.wales/covid-19-therapeutic-hub/all-wales-medicines-access-guidance/

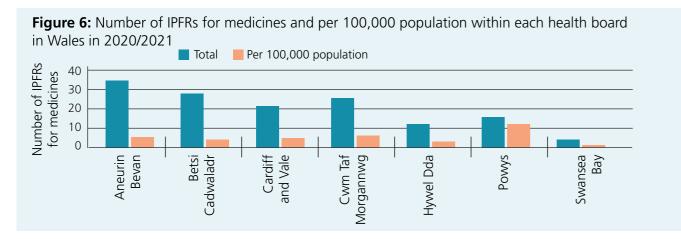
IPFRs for non-medicines by health board and WHSSC

The numbers of IPFRs for non-medicines showed a slight increase in 2020/2021 (n = 190) compared with those for 2019/2020 (n = 160; Figure 8). The approval rate for non-medicine IPFRs was similar to that for 2019/2020, at 73%. During 2020/2021 a total of 138 non-medicine IPFRs were approved, 45 were not approved and seven were deferred.



As in previous years, WHSSC considered most of the non-medicine IPFRs (n = 152; Figure 9). This is an increase of 35% compared with last year. This is largely driven by an increase in the number of requests for positron emission tomography (PET) scans: 73 during 2020/2021 compared with 53 during 2019/2020. The next highest number of non-medicine IPFRs considered was by Aneurin Bevan University Health Board (n = 16), where the number of non-medicine IPFRs decreased by 27% since last year. As in previous years, there were low numbers of non-medicine IPFRs in most health boards. The annual median number of IPFRs across health boards for non-medicines reduced from 9 in 2015/2016 to 5 in 2020/2021, although this reduction was not statistically significant.

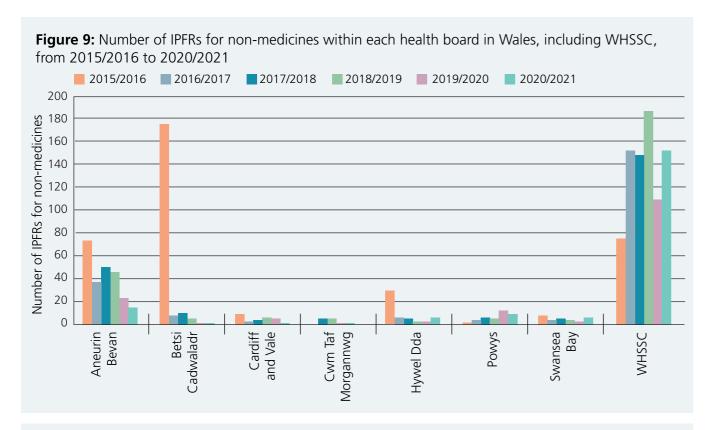
Figure 10 shows the number of non-medicine IPFRs and rate per 100,000 population for each health board in Wales. The WHSSC non-medicine IPFRs for each health board have been added to the local panel non-medicine IPFRs. The rate of non-medicine IPFRs per 100,000 population is similar across most health boards, ranging from 4 to 8 (Figure 10). Powys Teaching Health Board is the exception with 14 non-medicine IPFRs per 100,000 population; this represents a total of 19 non-medicine IPFRs, of which nine were considered by the WHSSC panel.

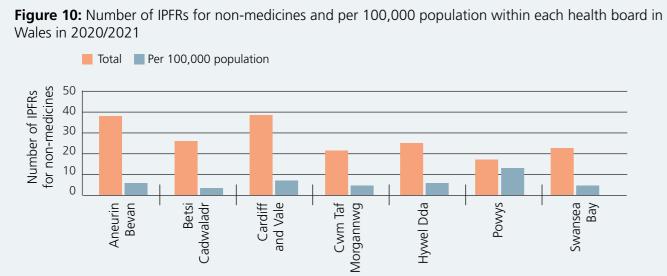


local panel medicine IPFRs. The rate of IPFRs for medicines per head of population ranged from 1 per 100,000 in Swansea Bay University Health Board to 12 per 100,000 in Powys Teaching Health Board (Figure 6). The total number of IPFRs for medicines was higher in 2020/2021 than in 2019/2020 for all health boards except Swansea Bay, which stayed the same. The mean annual number of IPFRs for medicines across health boards reduced from 41 in 2015/2016 to 17 in 2020/2021. The mean number of requests in 2015/2016 was statistically significantly higher (p < 0.05) than those in each of the subsequent years.

The percentage of IPFRs approved by each health board and WHSSC during 2020/2021 ranged from 66% to 100% (Figure 7). The percentages of IPFRs approved increased in most health boards and WHSSC compared with 2019/2020. Hywel Dda and Swansea Bay University Health Boards approved 100% of IPFRs in 2020/2021. Approval rates for IPFRs varied between health boards, and it is difficult to compare them directly because the overall numbers of IPFRs were small for some health boards. A small change in the number approved may markedly affect the percentage approval rate.

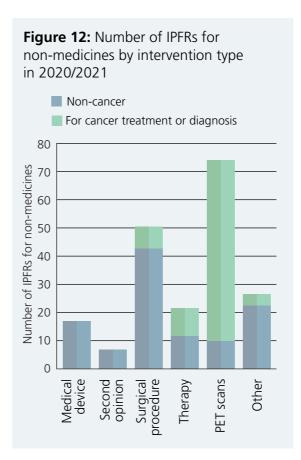


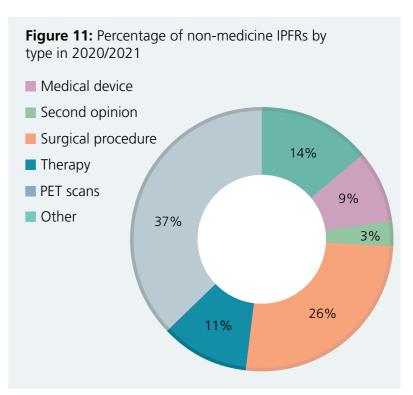




The types of non-medicine interventions requested through IPFR are shown in Figure 11. The numbers of PET scan requests increased from 53 in 2019/2020 to 73 in 2020/2021. This is despite expectations that such requests would decrease once WHSSC's updated PET-Computed Tomography commissioning policy (which included several new indications) had been in place for a full year. The policy is undergoing further review with new indications expected to be added, this

may lead to a decrease in PET scans over the next year. The second most frequent non-medicine IPFR was for *in vitro* fertilisation (IVF) (n= 10; 5%), followed by requests for microprocessor-controlled knee (MPK) devices (n = 9; 5%). The numbers of IPFRs for second opinions halved during 2020/2021 compared with 2019/2020, and there were fewer requests for surgical procedures or medical devices. These reductions are likely due to the COVID-19 pandemic during 2020/2021. The pandemic is probably also driving the increases seen in requests for therapy and for other treatments.





In 2020/21 a total of 85 IPFRs were for non-medicine interventions for the treatment or diagnosis of cancer (Figure 12). Most of these IPFRs were for PET scans (n = 64; 88%), an increase compared with 2019/20 (n = 38; 57%). This increase is likely to have been driven by the COVID-19 pandemic which changed the delivery of healthcare during 2020/2021. The second most frequent non-medicine IPFR for cancer was for stereotactic ablative body radiosurgery (n = 5; 6%). Of the non-medicine requests for therapy, 10 of these were for the treatment or diagnosis of cancer, in contrast to the previous year in which only a small percentage were for cancer. Of the 51 requests for surgical procedures during 2020/2021, only eight were for the treatment or diagnosis of cancer, compared with 21 during 2019/2020. None of the IPFRs for medical devices or second opinions were for cancer. Of the 22 requests for other treatments, only four were for cancer. Figure 12 shows the number of IPFRs for cancer and non-cancer indications by intervention type.

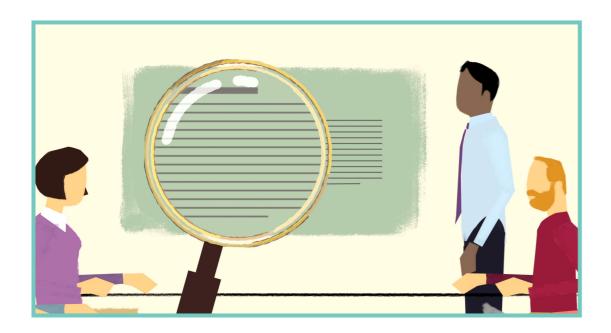
IPFR and the One Wales Interim Pathways Commissioning process

Analysis of IPFR submission data from health boards across Wales has been 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. More information on the One Wales Medicines process and current One Wales decisions are available on the AWTTC website (www.awttc.org/pams/one-wales-interim-commissioning-process).

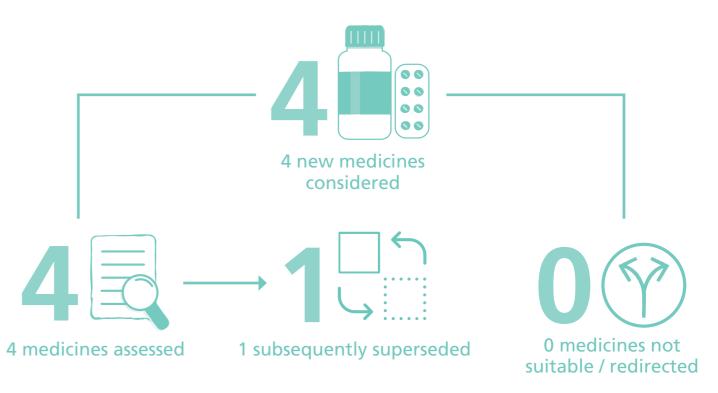
Despite a slight increase in IPFRs for medicines (due to COVID-19) in 2020/2021, emerging cohorts of IPFRs have continued to decrease since the inception of the One Wales Interim Pathways Commissioning process. This is also attributed to the implementation of the New Treatment Fund in 2017, earlier guidance from NICE around the time of licence and the Cancer Drugs Fund recommendations now applying in Wales. In addition, the NICE COVID-19 rapid guideline (NG161) and list of interim treatments published by NHS England were adopted for use in Wales allowing access to some alternative treatments.

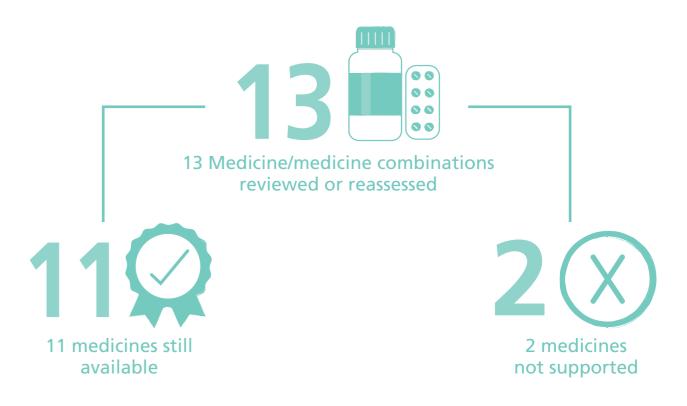
Ongoing monitoring of the IPFR data has shown that soon after publication of a positive One Wales Interim Pathways Commissioning decision, applications are no longer submitted for these indications. This positively demonstrates that the process effectively reduces the burden on IPFR panels and encourages equity of access to these medicines across Wales.

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One Wales Interim Pathways Commissioning process activity in 2020/2021



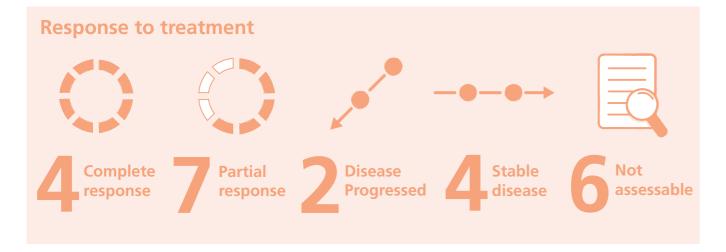


Patient outcomes

Of the data collected during 2020/2021, patient outcome data were available for 24 patients. This represents outcome data for 7% of all IPFRs for the year, markedly lower than the 13% reported in 2019/2020.

Thirteen of the outcomes were reported with applications for continued funding of medicines which had been previously approved.

The figures below give an overview of information provided about the patient's response to treatment, effect on quality of life and reasons for stopping treatment (where applicable). One patient died before they were able to receive the approved treatment. Of the feedback provided, 11 of 23 patients (48%) were reported to have a complete or partial response to treatment and 14 of 20 patients (70%) had an improvement in quality of life. Treatment was discontinued in four cases, two patients had died, one had disease progression and one had completed the prescribed treatment course.



At time of follow-up, two patients could not be assessed due to a delay in starting treatment. Four patients could not be assessed as the therapies were either adjuvant or diagnostic in nature. Four patients were reported to have died, one before the approved treatment could be administered, three patients died shortly after receiving treatment. The third patient received treatment for 12 weeks with disease stabilisation and an improvement in quality of life reported before treatment was stopped due to their death.



The majority of IPFRs approved in 2020/2021 were associated with evidence of clinical benefit and maintenance or improvement in quality of life. The number of cases for which outcome data are available was particularly low in 2020/2021, this may reflect the added burden of COVID-19 on clinician workload and on the ability to assess patients in the hospital setting.



patients received treatment

continue to receive treatment

Reasons for stopping treatment

Death Disease progre

End of treatment course

The collection of outcome data is important to monitor and analyse whether or not a treatment has been effective. The majority of outcomes reported are submitted as part of the application process for continued funding for treatment. AWTTC will continue to work with IPFR panels and clinician to identify barriers to recording outcomes for all IPFRs to provide information on the impact of IPFR decisions in relation to patients.

Quality Assurance Advisory Group

In 2020, despite the challenges of the COVID-19 pandemic, IPFR panels across health boards in Wales continued to provide a timely and efficient service with minimum reduction in the percentage of assessment criteria met noted by the group.

The IPFR Quality Assurance Advisory Group was established in January 2018 to examine and address variation between panels in relation to consistency in the decision-making process. In the year 2020/2021, due to the priorities of Quality Assurance Advisory group members and the disruption to normal working practices of IPFR teams during the pandemic it was considered prudent for the group to reduce meeting frequency from quarterly to every six months. The group therefore met in July 2020 and February 2021 to assess IPFRs covering the 2020 calendar year. Figure 13 shows the percentage of criteria met for each quarter from October 2017 to December 2020. The application process and decision process (pink and green bars respectively) suffered in the two quarters April to June and July to September with the panel process also meeting fewer criteria in the latter of these quarters. In the final quarter of 2020 all processes had recovered with more than 90% of criteria met for application and decision processes and 87.5% of criteria met for the panel process.

The Group is provided with all paperwork associated with a randomly selected IPFR from each quarter including the application form, supporting documentation and correspondence with the applicant clinician. Paperwork is fully redacted by the local IPFR team to remove patient identifying details before it is sent to AWTTC. Aspects of the application process, the panel process and decision process are assessed against pre-defined criteria and in line with the IPFR policy. The IPFR policy and Terms of Reference for the Group are available on the AWTTC website (www.awttc.org/ipfr).

A detailed report is sent to each panel providing feedback on the IPFR application assessed, with an action plan to address any issues arising. Examples of good practice and any common themes are shared across all panels. A combined summary report is sent to the Deputy Chief Medical Officer and the Head of Pharmacy every six months.

Action points raised thorough these assessments have resulted in a general year on year continued improvement in IPFRs meeting these criteria. In 2020 the exceptional circumstances of the pandemic have resulted in a dip in improvements due to short term local adaptions which meant some processes have fallen outside of the assessment criteria. In the second quarter of 2020 (April to June) a drop in cases which met urgency was noted whilst IPFR teams adapted to homeworking and virtual panel meetings due to disruption by COVID-19 pandemic. There was also

a noted increase in the use of Chair's action decisions for non-urgent cases where there have been difficulties convening a full IPFR panel.

Despite the challenges of 2020 the Group were impressed that the core IPFR service has been maintained throughout a difficult year. The process has continued to be followed well overall and in the first quarter and final quarter of 2020 over 90% of IPFRs met the criteria for the application and decision process and 87.5% for the panel process.

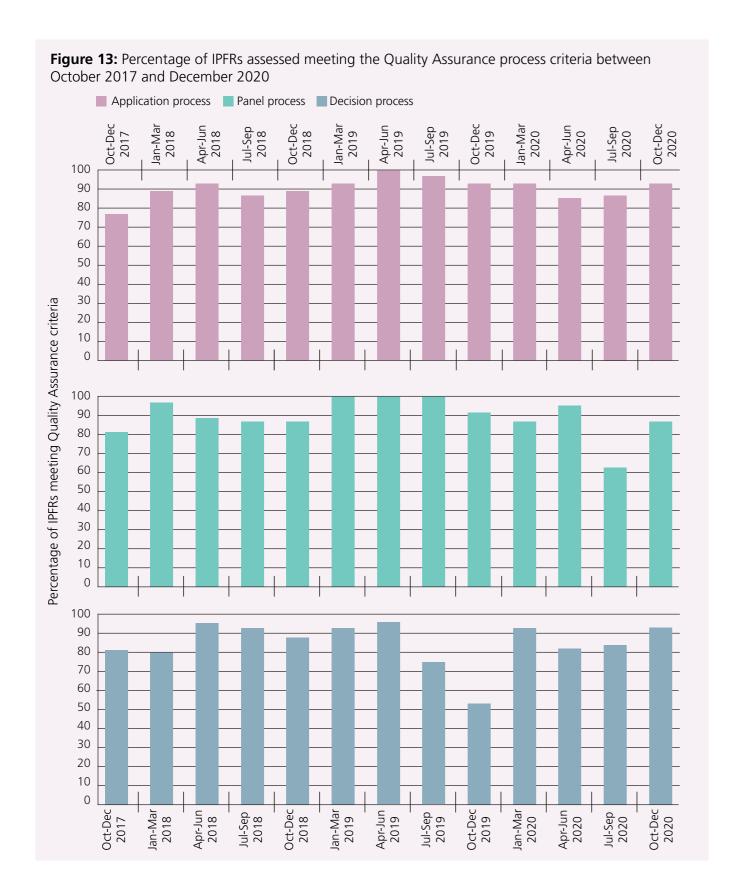
Action points from 2019/2020

In the previous year an example of good practice was shared across panels to improve the reporting of patient outcomes by applicant clinicians. The group recommended that patient outcome questionnaires be sent to clinicians as part of the continued funding process. In 2020/21 the collection of patient outcome data remains a challenge, with increased pressure on clinicians and IPFR staff further hampering efforts. This will be an ongoing action until such time that the reporting of patient outcomes has become routine.

Action points from 2020/2021

- The use of the bilingual patient letter should now be routine practice for all panels.
- Each IPFR panel should schedule meetings routinely every two weeks to ensure timely decisions for applications with urgency stipulated as 'soon' (within three weeks) or 'non-urgent' (within four to six weeks).
- The use of Chair's action for decisions should be reserved for applications which require an urgent decision (within 24-48 hours). All other applications should be considered by a full panel.

The Quality Assurance Advisory Group considers that overall the IPFR process was being followed in line with the IPFR policy. Following a rapid transition to virtual meetings and homeworking the percentage of quality criteria met had returned to pre-pandemic levels by the last quarter of 2020. The Quality Assurance Advisory Group are returning to quarterly meetings as of May 2021 to ensure timely feedback and monitoring of recommendations.



Actions following the 2019 review of the IPFR Quality Assurance process

The Group conducted a review of the quality assurance process in May 2019. This is reported in the 2019/2020 Annual Report. Actions taken in 2020/2021 arising from the review are summarised below:

- The Quality Assurance process should continue to assess one IPFR per panel on a quarterly basis. In 2020 the group reduced meeting frequency to every six months in response to the pandemic. In 2021 the group are resuming quarterly meetings.
- The format of the reports should provide an upfront summary of the findings and recommendations; the rest of the report to remain unchanged. Reports have been re-designed with bulleted findings for the individual panel and for all panels as a short summary on the front page of each panel report.
- It should be arranged for Group members to attend panel meetings as observers, because previous visits had been made before the Quality Assurance Advisory Group was formed. Due to the disruption of the pandemic to normal IPFR panel and Quality Assurance Advisory Group operations this has not yet been implemented. It is expected that members of the Group will have the opportunity to observe panel meetings in 2021/2022.
- AWTTC will align lay member training with the annual IPFR Workshop. There was no IPFR Workshop held in 2020. The next IPFR Workshop will be held in autumn 2021, lay member training will be included on the Workshop programme.
- In 2019/2020 a process was piloted and IPFR teams can now request non-medicine evidence summaries from Health Technology Wales (HTW). *In 2020/2021 HTW have provided evidence summaries for nine topic areas to support IPFR decision making.*

Summary of the data

Overall the data for 2020/2021 indicate:



In 2020/2021 the number of IPFRs across Wales increased for the first time since 2015/2016, an effect attributed to the impact of the COVID-19 pandemic.

In 2020/2021 the number of IPFRs for medicines increased again. There were 8% more requests for medicines in 2020/2021 compared with the previous year.



The number of IPFRs approved remained stable, with 74% of all IPFRs approved in

2020/2021, the same

as 2019/2020.



There were 19% more requests for non-medicines in 2020/2021 compared with the previous year. This increase was driven by a rise in requests for PET scans (up 38% from 2019/2020) despite an update to WHSSC's PET-Computed Tomography commissioning policy in June 2019 which included several new indications. The policy is undergoing further review with new indications expected to be added.

For medicines, the approval rate was broadly unchanged at 77% in 2020/2021 compared with 78% in 2019/2020.

77%

73%

The approval rate for non-medicines was 73% in 2020/2021 and this has increased over the last five years, from 49% in 2016/2017. There continues to be a decrease in the number of cohorts identified via the IPFR process. AWTTC will continue to monitor for cohorts for medicines and non-medicines.

Glossary and additional note

AVA # 46.6	All Marie Control Cont
AWMSG	All Wales Medicines Strategy Group
AWTTC	All Wales Therapeutics and Toxicology Centre
НТА	Health Technology Assessment
HTW	Health Technology Wales
IPCG	Interim Pathways Commissioning Group
IPFR	Individual Patient Funding Request
Licence	Marketing authorisation
Medicine	A drug or other preparation for the treatment or prevention of disease
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
Off-label	Medicine used outside the terms of the marketing authorisation (product licence)
PET	Positron emission tomography
WHSSC	Welsh Health Specialised Services Committee

Additional note

Where small numbers are involved, we are unable to provide the names of specific treatments as the potential risk of identifying individual patients becomes significant. Therefore, this information is considered personal information and is withheld under Section 40(2) of the Freedom of Information Act 2000. This information is protected by the Data Protection Act 1998, as its disclosure would constitute unfair and unlawful processing and would be contrary to the principles set out in Schedules 2 and 3 of the Act.