AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

Individual Patient Funding Request (IPFR)

Annual Report 2017/2018

GIG CYMRU NHS WALES

PAMS
Patient Access to Medicines Service
Mynediad Claf at Wasanaeth Meddyginiaethau

Contents

AWTTC Clinical Director's statement

2017/2018 – A year of aiming for greater clarity, transparency and quality assurance of the Individual Patient Funding Request process.

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The work during 2017/2018 has focused on continuing to implement the recommendations of the very helpful second independent review of the individual patient funding request (IPFR) process led by Andrew Blakeman, published in January 2017 and endorsed by Vaughan Gething, Welsh Government's Cabinet Secretary for Health and Social Services in March 2017. The independent review aimed to provide greater clarity of the IPFR process for both patients and clinicians. AWTTC has commissioned a short animated video for patients and clinicians explaining the IPFR process and this is available on the AWTTC website at www.awttc.org/ipfr. This website also contains information on how the IPFR process works and the alternative commissioning routes of access to medicines and non-medicines in Wales.

The new IPFR electronic application system has now been launched and can be accessed via a link on the AWTTC website at www.awttc.org/ipfr. The application system links to the IPFR database so clinicians can also access records from the evidence library, which holds journal articles, evidence summaries and links to references to support applications for IPFRs. A help function is embedded in to the system to help the clinician through the completion of the application. It is anticipated that the electronic submissions system will also reduce the administrative burden placed on clinicians and IPFR teams and thus improve the timely processing of IPFR applications.

A new IPFR Quality Assurance Advisory Group was established and met for its first meeting in January 2018. The terms of reference of the group can be viewed on the AWTTC website at www.awttc.org/individual-patient-funding-request-ipfr/ipfr-quality-assurance-advisory-group. The group assesses sample IPFRs from across all panels in Wales to audit how well the panels are adhering to process. It has been very encouraging to see how panels are seeking to meet these requirements in a clear and robust manner. The group reports to the Head of Pharmacy and Prescribing Policy at the Welsh Government and the first report of the group's findings was sent to the Chief Medical Officer in February 2018. Although the date of the 2018 IPFR workshop for IPFR panel chairs and members fell outside the time period covered by this report, the quality assurance element of these annual workshops (case-based simulations of IPFR decision making) also informs the advice of the Quality Assurance Advisory Group.

The One Wales Interim Pathways Commissioning Group continues to address major cohort commissioning issues in Wales. The first set of 12-month reviews of interim decisions have been taking place and it is reassuring to see that the recommendations from the group are proving to be robust, as well as truly interim as some of the decisions have been subsequently superseded by health technology assessment (HTA) advice from the National Institute for Health and Care Excellence (NICE) or the All Wales Medicines Strategy Group (AWMSG).

The next year (2018/2019) will see us building on the work programme to further improve the quality of IPFR applications and to provide the IPFR panels with resources and other tools to support their vitally important work. I wish to express my sincere thanks to all IPFR administrative teams and IPFR panel chairs and members across Wales for their willingness to actively embrace the recommendations of the independent report and thus support improvements in this process on behalf of patients in Wales.

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Executive Summary

- There has been a continuing annual decline in the number of IPFRs across Wales. In 2017/2018, there were approximately 9% fewer IPFRs compared with the previous year (a decrease from 422 requests to 383 requests). This reduction was mainly due to a decline in medicine-related requests (from 209 requests in 2016/2017 to 153 requests in 2017/2018).
- The decline in medicine-related IPFRs may be due to clinicians having a better understanding of the most appropriate route(s) for accessing a medicine on behalf of patients. In addition, following publication of positive One Wales Interim Pathways Commissioning decisions, IPFRs were no longer being submitted for these indications.
- More IPFRs were approved in 2017/2018 (63%) compared with the previous year (55%). For medicines, the approval rate was 67% in 2017/2018 and the rate has increased annually over the last three years. The approval rate for non-medicines was 61% in 2017/2018. This had increased compared with 49% in 2016/2017 and returned to similar approval rates seen in 2015/2016.
- Health boards approved a similar number of IPFRs for cancer medicines compared with previous years.
- Pertuzumab for the treatment of cancer was the most commonly requested medicine via IPFR in Wales in 2017/2018. Bevacizumab was the most commonly requested medicine from 2013/2014 to 2016/2017.
- As in the previous year, the most common non-medicine requests were for positron emission tomography (PET) scans. The majority of which were for the detection or investigation of cancers.
- AWTTC is continuing to work with the IPFR panels and colleagues across NHS Wales to ensure the timely implementation of the recommendations of the 2017 independent review report. These recommendations aim to provide greater clarity of the IPFR process for patients and clinicians.
- Several of the 2017 independent review report recommendations have been implemented. In 2017/2018, AWTTC commissioned a short video for patients and clinicians explaining the IPFR process, the electronic IPFR application system was launched and the new IPFR Quality Assurance Advisory Group was established with its first meeting held in January 2018.

Background

Health boards in Wales have a statutory responsibility for the health of their populations and they discharge this duty, in part, through the provision of safe and high quality clinical services. They are also required to ensure the efficient use and application of their workforce and financial resource.

A comprehensive range of NHS healthcare services are routinely provided across Wales. In addition, 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 requests are received for healthcare that fall outside the range of services agreed. IPFRs are therefore defined as 'requests to a health board or WHSSC to fund NHS healthcare for individual patients who fall outside the range of services and treatments that a health board has arranged to routinely provide'. This can include, for example, a request for a surgical device or piece of equipment, medicine or surgical intervention.

Consideration of the available evidence for clinical and cost-effectiveness is very important to ensure that the best possible care is available to provide interventions that are both clinically and cost-effective. NICE and AWMSG appraise new treatments to decide whether or not the treatment is clinically and cost-effective and whether they should be included in the schedule of services a health board has decided to fund to meet local need within the resource available.

In 2010, the Director General, Health and Social Services, Chief Executive, NHS Wales requested that health boards work together with WHSSC to develop an all Wales policy and standard documentation for dealing with IPFRs. Whilst amendments to the policy have been made, an All Wales policy has been in place since September 2011.

In September 2016, following a 2014 review and implementation of its recommendations, the Cabinet Secretary for Health and Social Services agreed the time was right for a new, independent review of the IPFR process. The panel, independent of the Welsh Government, encompassing a range of expertise and knowledge, published a report in January 2017. A copy of the report can be found at gov.wales/docs/dhss/publications/170117ipfrreporten.pdf.

4 Implementation of recommendations following the 2016 review of the IPFR process

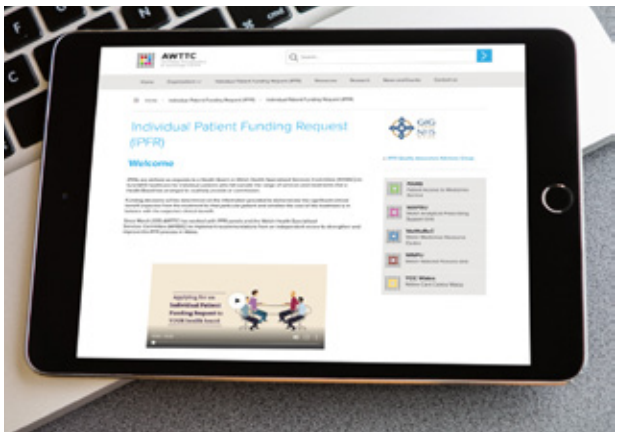
In September 2016, the Cabinet Secretary for Health and Social Services announced an independent review of the IPFR process in Wales to explore how it could be strengthened. Following face-to-face sessions with patients, patient organisations and healthcare professionals across Wales the 'Independent Review of the IPFR process in Wales' report was published in January 2017.

This contains a total of 27 recommendations aimed at improving the commissioning processes within health boards and WHSSC and replacing the 'exceptionality' principle with 'significant clinical benefit' within the IPFR policy. The recommendations are summarised under seven themes and progress with implementation to date is described below. A copy of the report can be found at gov.wales/docs/dhss/publications/170117ipfrreporten.pdf.

1. Commissioning

The report identified a lack of clarity and consistency in commissioning processes which were often attributed to the IPFR process. Several measures have been initiated to make arrangements work smoothly, efficiently and consistently across health boards and WHSSC where possible:

- In some health boards the IPFR application form was being used to request a referral for a patient outside of local services or established contractual arrangements. This process varied across health boards. A clear and consistent national process for dealing with requests to access routine services outside of locally provided or commissioned services has now been developed. The Prior Approval policy has been developed for use by all Welsh health boards and WHSSC. The Prior Approval policy sets out to deliver the national context and provide clarity for referring clinicians and patients. The Prior Approval application form is short, simple and consistent nationally.
- An IPFR webpage has been launched on the AWTTC website. This provides information on the appropriate routes for accessing treatments in Wales. The websites of all health boards and WHSSC have also been updated to ensure the information is easily accessible and consistent across Wales.
- WHSSC has commenced work to improve the clarity and accessibility of services that they commission. This includes a rolling programme to update their commissioning policies.



2. Exceptionality

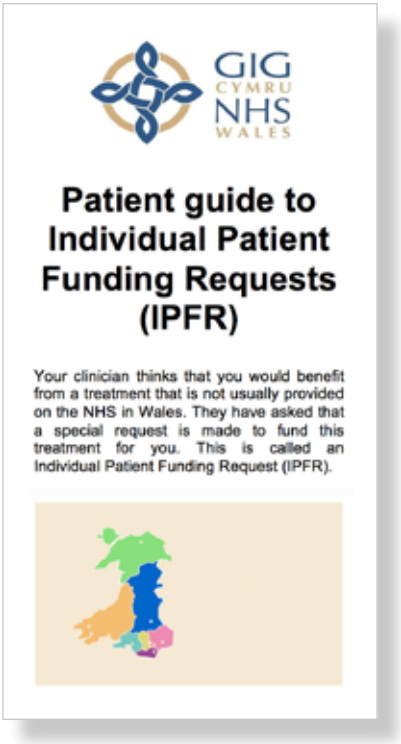
It was found that the concept of 'exceptionality' was not well understood and in some cases was difficult to apply or did not make sense. The report demonstrates that the principle for making decisions about individual patients' access to treatment should be based on the level of expected or likely clinical benefit and whether the intervention offers reasonable value for money. The decision-making factors in the IPFR decision-making guide have therefore been updated.

'Exceptionality' is no longer included as a factor and the guide now refers to 'significant clinical benefit'. This is described as the patient's clinical condition being significantly different from other members of that population such that the patient will derive a greater clinical benefit than other patients with the same condition at the same stage. Alongside this the IPFR panel should be satisfied that the intervention represents reasonable value for money.

3. Non-clinical factors

It was considered whether non-clinical factors (sometimes called social factors) should be taken into account when making IPFR decisions; it was concluded that they should not. NHS Wales is committed to providing care to everyone fairly and equally on the basis of clinical need. The NHS should not discriminate against those without dependants in favour of carers, or against unemployed people in favour of those in work. Several actions have been taken to strengthen this standpoint:

- The text in the IPFR policy has been modified.
- A short animation has been made for patients and clinicians which provides a summary of the process, this also clearly states that non-clinical factors will not be taken into account. The animation is publically available on the IPFR webpage of the AWTTC website (www.awttc.org/ipfr).
- A new patient information leaflet has been produced which explains what is meant by non-clinical factors and that only clinical evidence is considered.
- Guidance notes for clinicians have been developed which clearly state that non-clinical factors will not be taken into account and that this should be explained to the patient before the IPFR form is submitted.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Patient guide to Individual Patient Funding Requests (IPFR)

Your clinician thinks that you would benefit from a treatment that is not usually provided on the NHS in Wales. They have asked that a special request is made to fund this treatment for you. This is called an Individual Patient Funding Request (IPFR).

4. Consistency and number of panels

The review group considered a possible reduction in the number of IPFR panels or a move to a single national panel which would reduce variability in the decision-making process across Wales. However there were no compelling advantages of changing the number of panels, and a number of recommendations were made to ensure the IPFR process is consistently applied across Wales.

Actions taken to provide clarity around the commissioning arrangements as described under point 1 and replacing the principle of exceptionality (point 2) is expected to improve the appropriateness of IPFR applications. In addition a recommendation was made to create a new national quality assurance function to ensure the IPFR process is consistently applied and adhered to by IPFR panels across Wales. The following steps have been taken to address any issues of inconsistency and quality:

- A new IPFR Quality Assurance Advisory Group has been established and their first meeting was held in January 2018. More details of this group are provided in Chapter 12.
- An annual IPFR workshop is held for IPFR panel members and clinicians across Wales where simulation exercises are used to provide feedback on the decision-making process. The 2017 IPFR workshop fell outside of the financial year and therefore was described in last year's annual report.
- Detailed guidance notes and help text have been made available for clinicians to provide more meaningful information when completing the application form.

5. Communication

Several developments in the past year have been implemented to improve communications between IPFR panels, clinicians and patients:

- The short animated video developed for both clinicians and patients provides an overview of the IPFR process, and highlights the need for clinicians to continue to maintain the primary relationship with their patient.
- The new patient information leaflet provides clear information about the IPFR process including contact details should further information be required. This is available on all health boards' websites.
- IPFR co-ordinators have developed a standard decision letter template which allows the inclusion of a detailed rationale of the panel decision to be sent to the requesting clinician.
- Best practice examples have been shared with IPFR co-ordinators and discussions continue on a regular basis via the IPFR Policy Implementation Group to continuously improve the quality of the information provided in relation to decisions made.

6. Paperwork and the IPFR process

The IPFR policy and application form have been updated to include the new decision-making criteria. Prior to implementing the changes to the policy a consultation exercise was undertaken with IPFR panel members including lay members, patient advocates, clinicians and NHS Wales Shared Services Partnership - Legal and Risk services. The new policy was endorsed in June 2017 and fully implemented across Wales by September 2017. No IPFR applications using the old form were accepted after 1 January 2018.

7. Medicines appraisal

It was acknowledged in the report that HTA is much the best way to assess whether a medicine offers clinical benefit and value for money. AWTTC continues to encourage pharmaceutical companies to engage with the AWMSG HTA process in a timely fashion. If a pharmaceutical company could submit a medicine for HTA but chooses not to, there is inevitably less evidence that the medicine offers reasonable value for money. For IPFR panels to approve requests for the use of those medicines that could be, but have not been, submitted for HTA, they should be confident that there is clear evidence of sufficient clinical benefit to justify the cost. AWTTC and the IPFR Policy Implementation Group are working together to develop tools for IPFR panel members to better consider if a treatment would be reasonable value for money.

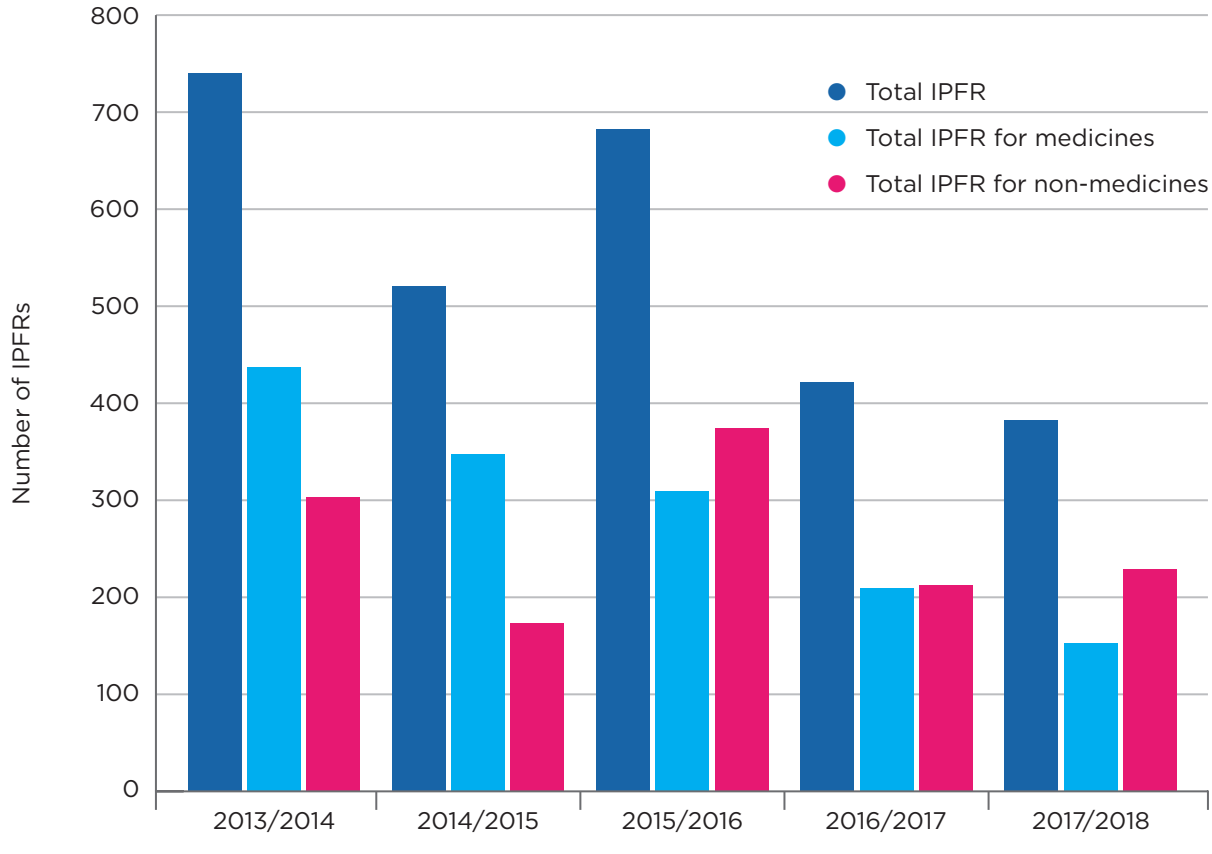
5

IPFRs

This is the first year in which the data for the annual report have been collated entirely from the national IPFR database which was launched on the 1 October 2016.

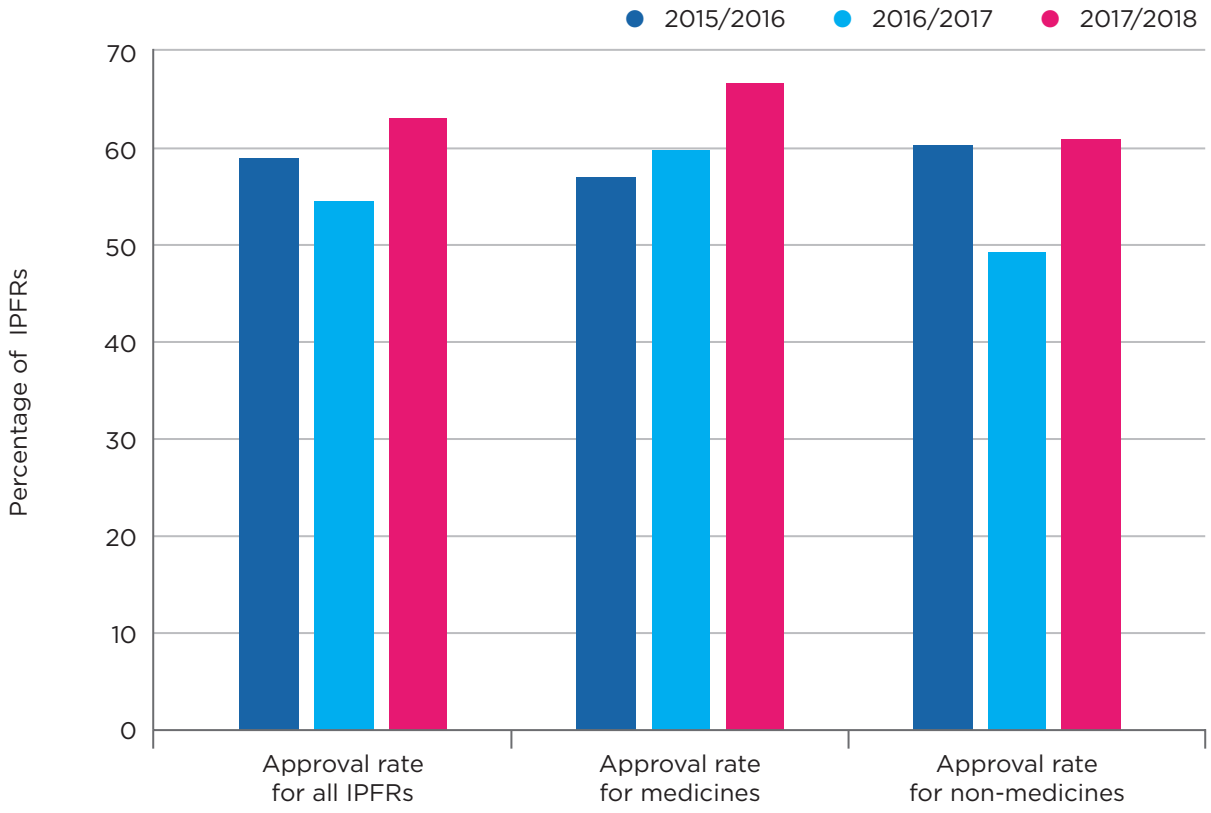
A total of 383 IPFRs were considered between 1 April 2017 and 31 March 2018, 153 (40%) were for medicines and the remainder (n = 230; 60%) were for non-medicine related requests (Figure 1). Overall, 63% of IPFRs were approved compared with 55% in 2015/2016, as shown in Figure 2 overleaf. This figure has remained relatively stable over the last three years. For medicines, the approval rate was 67% in 2017/2018 which has increased annually over the last three years (Figure 2). The approval rate for non-medicines was 61% in 2017/2018 which has increased since the previous year, as shown in Figure 2.

FIGURE 1: Total number of Individual Patient Funding Requests (IPFRs) considered in Wales from 2013/2014 to 2017/2018



Compared with 2016/2017, the number of IPFRs for medicines in Wales in 2017/2018 decreased by 26%, as shown by the light blue bars in Figure 1. This is the fifth consecutive year in which medicine-related IPFRs have fallen in Wales so that the decline since 2013/2014 has been 65%. In contrast, the number of requests for non-medicines fluctuated over the same period, with the greatest number of requests for non-medicines occurring in 2015/2016. There was only a small increase in the number of IPFRs for non-medicines in 2017/2018 compared with the previous year.

FIGURE 2: Percentage of Individual Patient Funding Requests (IPFRs) approved in Wales from 2015/2016 to 2017/2018



6 IPFRs for medicines by health board and WHSSC

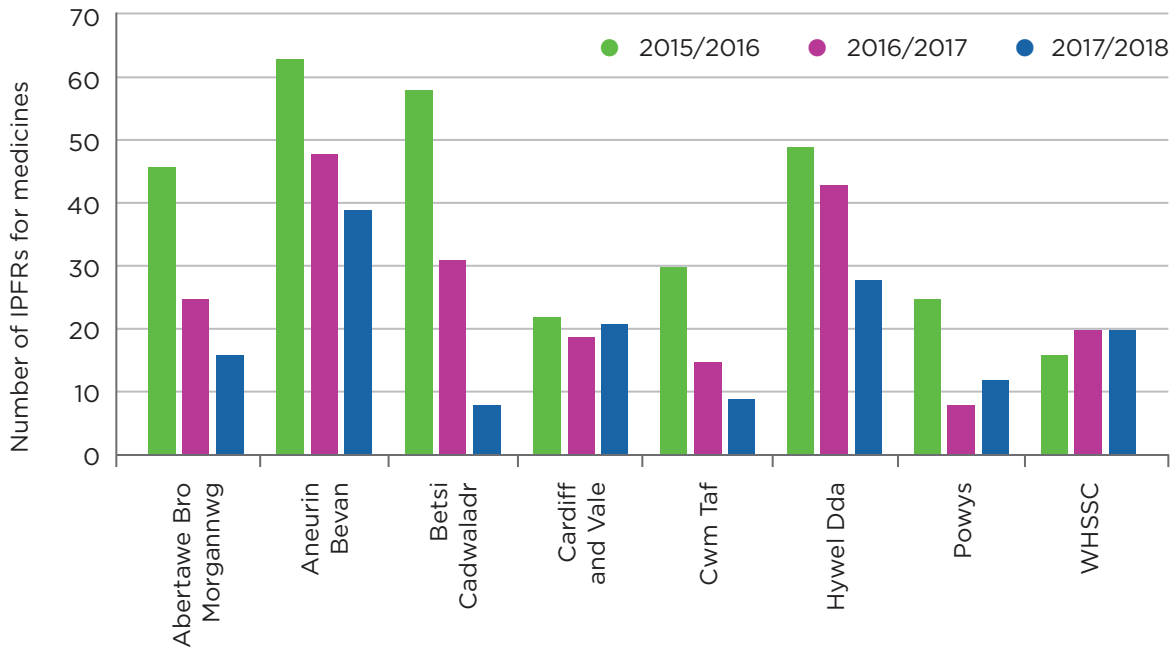
Requests for an IPFR in relation to a medicine occur for three main reasons:

- Advice in relation to a licensed indication is not available from AWMSG or 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 the marketing authorisation (product licence).

Annually Aneurin Bevan University Health Board has considered the highest absolute number of IPFRs for medicines since 2015/2016, as shown in Figure 3. The fewest number of IPFRs were considered by Betsi Cadwaladr University Health Board (n = 8) in 2017/2018, Powys Teaching Health Board (n = 8) in 2016/2017 and WHSSC (n = 16) in 2015/2016, as shown in Figure 3. The number of IPFRs considered by five health boards has decreased over the last three years. For two health boards, there was a slight increase in the number of IPFRs considered in 2017/2018 compared to the previous year. The number of IPFRs for medicines considered by WHSSC in 2017/2018 was the same as the previous year.

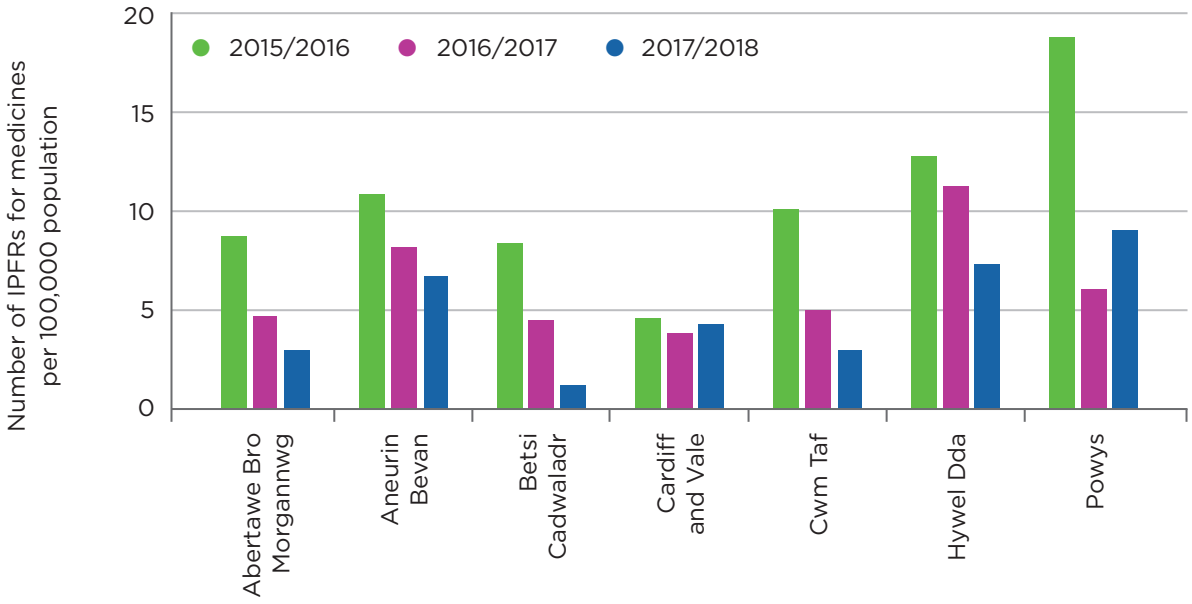
In addition to these requests there was one request for 'continued funding' for a medicine which had previously been approved and now required an extension to that treatment. This request was approved.

FIGURE 3: Number of Individual Patient Funding Requests (IPFRs) for medicines within each health board in Wales and the Welsh Health Specialised Services Committee (WHSSC) from 2015/2016 to 2017/2018



To acknowledge the different population sizes within each health board, these data were expressed as IPFR requests per 100,000 population. The population data were derived from *StatsWales* (mid-year 2015 and mid-year 2016) and the population corrected data are shown in Figure 4.

FIGURE 4: Number of Individual Patient Funding Requests (IPFRs) per 100,000 population within each health board in Wales from 2015/2016 to 2017/2018

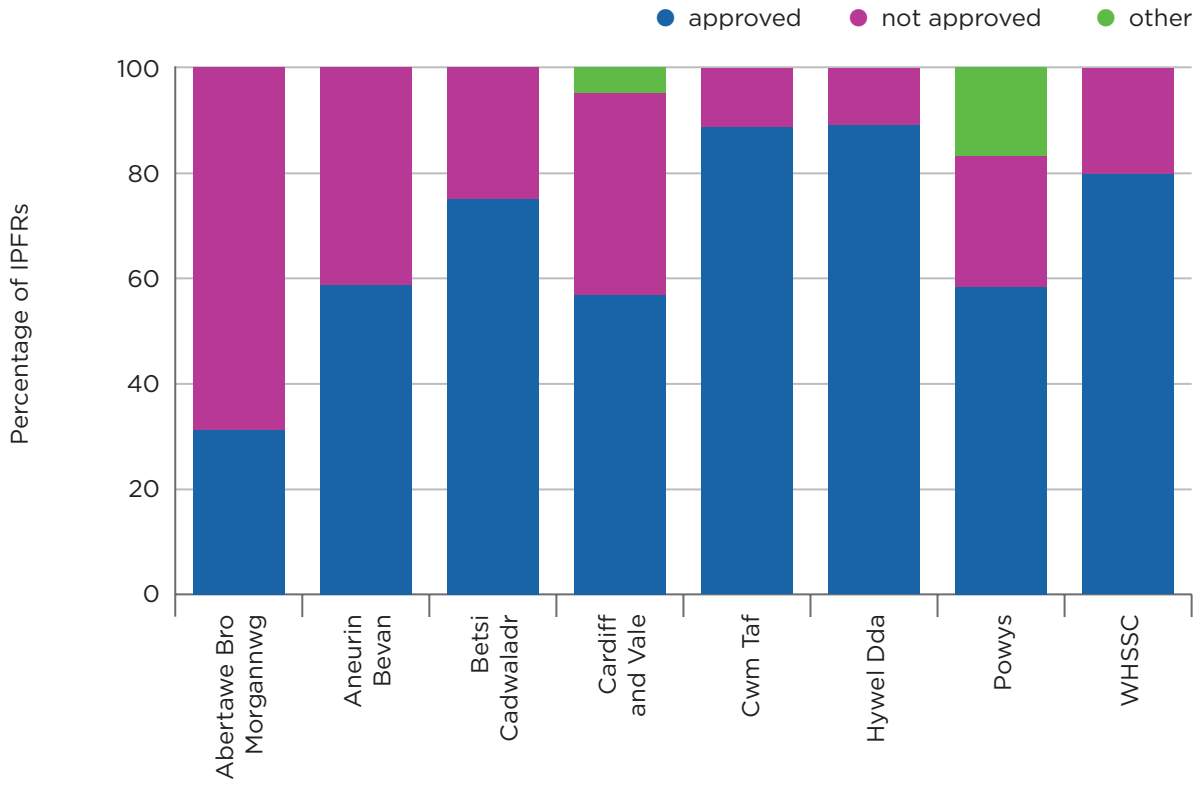


In 2017/2018 Powys Teaching Health Board received the highest number of IPFR applications for medicines per head of population (9 per 100,000 population). Similarly, in 2015/2016 this Health Board received the highest number of IPFRs for medicines per head of population, although the number was more than double (19 per 100,000 population) that in 2017/2018. In 2016/2017 Hywel Dda University Health Board received the highest number of IPFR applications for medicines per head of population (11 per 100,000 population). The fewest number of applications were considered by Betsi Cadwaladr University Health Board in 2017/2018, and Cardiff and Vale University Health Board in the previous two years. Reasons for such variation in the number of IPFRs considered by each health board may include differences in local commissioning policies and the availability of services (including specialised services) in each health board.

The outcome of IPFRs for medicines considered by each health board and WHSSC in 2017/2018 are shown in Figure 5. Over the last three years, the percentage of IPFRs approved by Cwm Taf University Health Board, Hywel Dda University Health Board and WHSSC has consistently increased. Compared with 2016/2017, the percentage of IPFRs approved within Betsi Cadwaladr University Health Board has increased from 39% to 75%. However only a small number of IPFRs were considered by this Health Board in 2017/2018 (n = 8) compared to the previous year (n= 31) so caution in interpretation is necessary. The percentage of IPFRs approved within the remaining health boards decreased in 2017/2018 compared with the previous year.

The 'other' outcomes shown in Figure 5 include IPFRs for medicines that have been considered but the panel were unable to make a decision whether to approve or not approve funding at the initial consideration. This may be due to several reasons, including deferral of a decision pending receipt of further required information.

FIGURE 5: Percentage of Individual Patient Funding Requests (IPFRs) for medicines approved, not approved, or with another (other) outcome within each health board in Wales and the Welsh Health Specialised Services Committee (WHSSC) from 1 April 2017 to 31 March 2018



The medicines most frequently considered annually between 1 April 2013 and 31 March 2018 are shown in Table 1. Bevacizumab has been one of the most frequently requested medicines each year since 2013/2014. However, it is important to note that many of the medicines applied for via the IPFR process, including bevacizumab, are requested for several indications, different treatment regimens and for different stages of the treatment pathway in relation to those different clinical indications.

The differences in the medicines requested between each year may be due, in part, to the fact that a proportion of the requests occurred prior to advice being given by AWMSG or NICE, and following positive advice from either of these organisations, the IPFR route was no longer required for the particular medicine/indication. Additionally, since the launch of the One Wales Interim Pathways Commissioning process in 2016, suitable cohorts of medicines/indications have been assessed via this route and the IPFR route was no longer required. This is evident for adalimumab which has been frequently requested annually up to 2016/2017 (with the exception of 2014/2015), and following publication of a One Wales decision in October 2016, adalimumab was not a commonly requested medicine via IPFR in 2017/2018, as reflected in Table 1.

Table 1: The most commonly requested medicines (in rank order)				
2013/2014	**2014/2015**	**2015/2016**	**2016/2017**	**2017/2018**
Bevacizumab	Bevacizumab	Bevacizumab	Bevacizumab	Pertuzumab
Cetuximab	Axitinib	Cetuximab	Rituximab	Rituximab
Rituximab	Brentuximab	Adalimumab	Adalimumab*	Bevacizumab*
Axitinib	Bendamustine	Pertuzumab	Omalizumab*	Ibrutinib*
Adalimumab*	Cetuximab	Rituximab*	Pertuzumab	Daratumumab
Eribulin*	NR	Bendamustine*	Infliximab*	NR
Infliximab*	NR	Trastuzumab emtansine	Nivolumab*	NR

** The same numbers of applications were reported for these medicines in the relevant column*
NR = not reported
NB only medicines for which more than five requests were approved/not approved are reported for data protection purposes.

Table 2 shows the medicines most frequently approved or not approved by IPFR panels from 1 April 2015 to 31 March 2018. Interestingly, in 2017/2018 there were very few medicines approved or not approved for which there were more than five requests. One of the reasons for the fewer cohorts of approved or not approved requests is likely due to the introduction of the One Wales Interim Pathways Commissioning process in 2016. Suitable cohorts of medicines/indications have been assessed via this process and the IPFR route is no longer required for those medicines/indications supported for use.

Table 2: The medicines most frequently approved or not approved from 2015/2016 to 2017/2018 (in rank order)					
2015/2016		**2016/2017**		**2017/2018**	
Approved	**Not approved**	**Approved**	**Not approved**	**Approved**	**Not approved**
Bevacizumab	Bevacizumab	Rituximab	Bevacizumab	Rituximab	Pertuzumab
Adalimumab	Cetuximab	Adalimumab	Pertuzumab	Ibrutinib	NR
Rituximab	Pertuzumab	Infliximab	NR	NR	NR
Apremilast	Trastuzumab emtansine	Bevacizumab*	NR	NR	NR
Bendamustine	NR	Omalizumab*	NR	NR	NR
Ibrutinib*	NR	Bendamus-tine	NR	NR	NR
Ruxolitinib*	NR	NR	NR	NR	NR

** The same numbers of applications approved/not approved were reported for these medicines in the relevant column*
NR = not reported
NB only medicines for which more than five requests were approved/not approved are reported for data protection purposes.

The top two indications for which the most commonly requested medicines were considered are outlined in Table 3 below. Requests for both medicine-indication combinations were made prior to positive HTA advice by NICE.

Table 3: Top two medicine-indication combinations considered by IPFR panels in 2017/2018

Medicine	Indication	License status
Pertuzumab*	First-line treatment of metastatic advanced breast cancer	Licensed
Daratumumab*	Relapsed and refractory multiple myeloma	Licensed

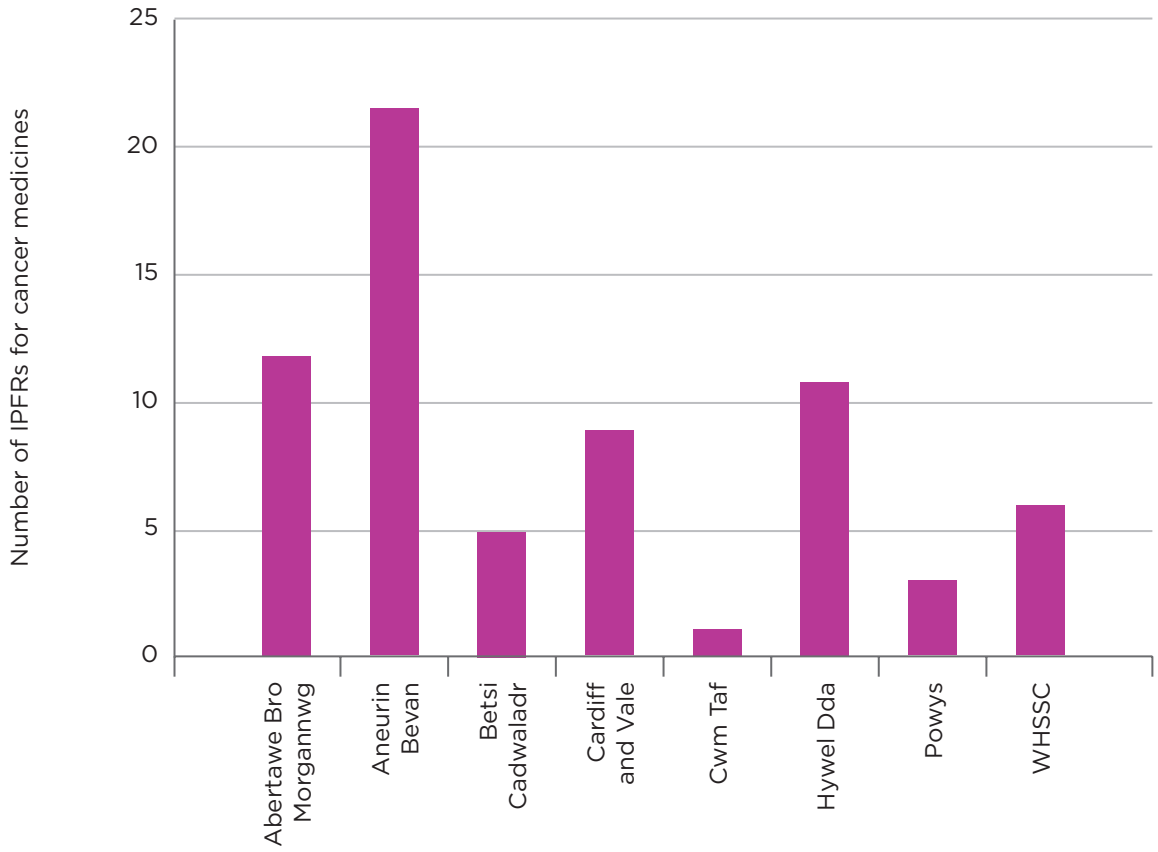
** IPFR requests prior to health technology assessment advice becoming available*
NB only medicine-indication combinations for which there were more than five requests are reported for data protection purposes.

IPFRs for medicines for the treatment of cancer

Almost half (45%) of the medicines requested via IPFR in 2017/2018 were for the treatment of cancer.

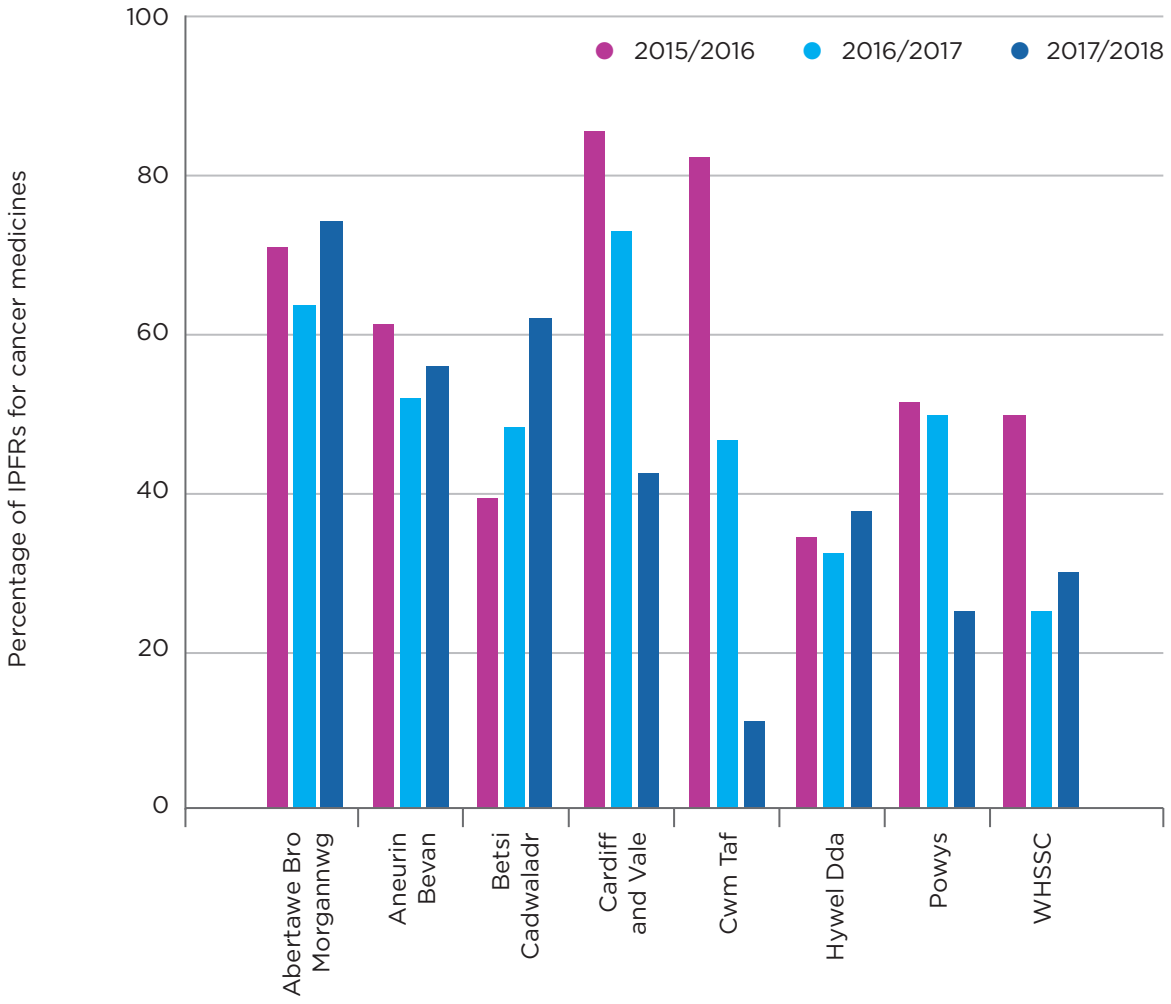
The greatest number of IPFRs for medicines for the treatment of cancer were received by Aneurin Bevan University Health Board (n = 22) and the fewest were submitted in Cwm Taf University Health Board (n = 1), as shown in Figure 6.

FIGURE 6: Number of Individual Patient Funding Requests (IPFRs) for cancer medicines within each health board in Wales and the Welsh Health Specialised Services Committee (WHSSC) from 1 April 2017 to 31 March 2018



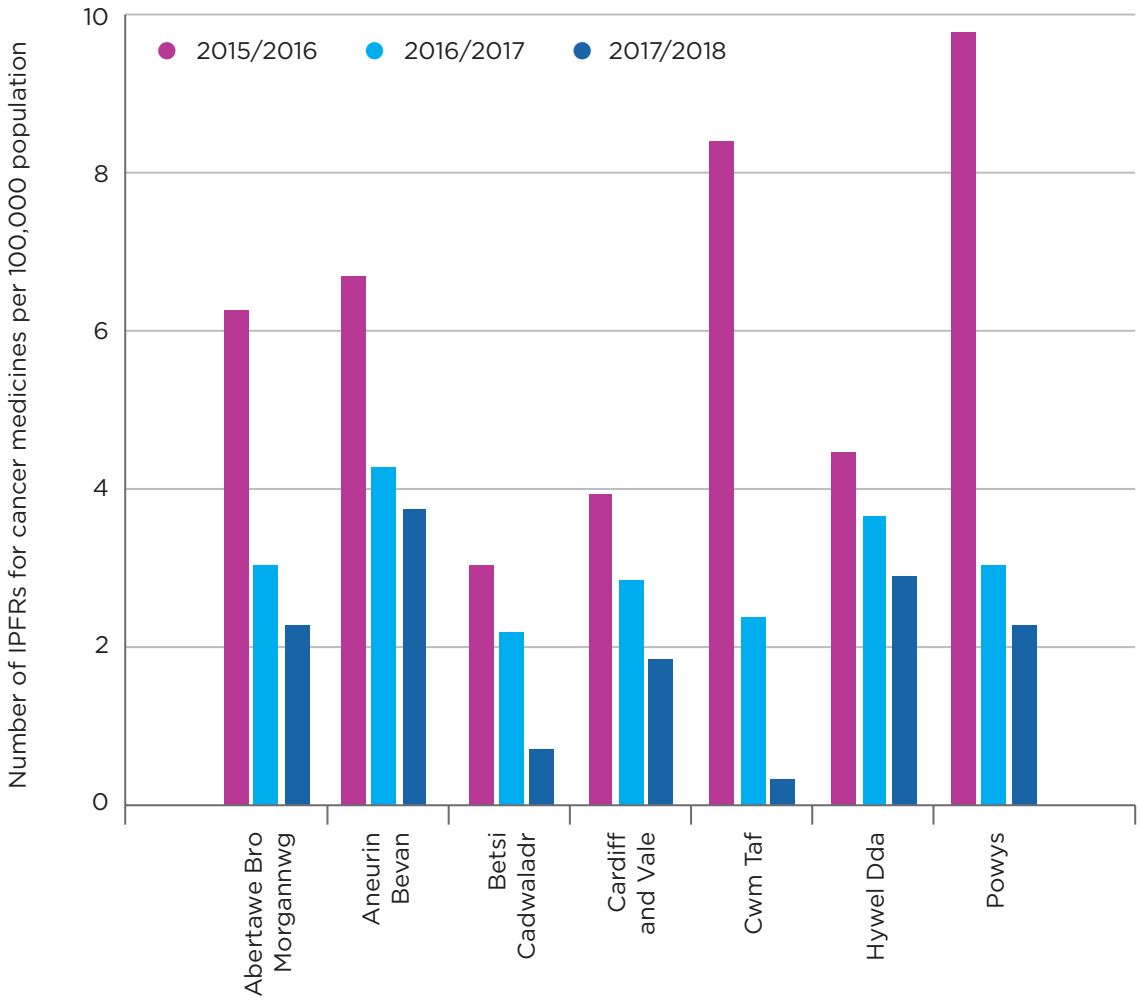
The percentage of IPFRs for cancer medicines slightly increased in 2017/2018 compared with the previous year in WHSSC and in four of the seven health boards, as shown in Figure 7. The greatest increase was in Betsi Cadwaladr University Health Board, an approximate 15% increase compared with the previous year. However, it is important to note that the number of IPFRs considered by this Health Board has decreased from 31 in 2016/2017 to 8 in 2017/2018. Therefore it is possible that the small number of IPFRs are influencing the high rise in the proportion of cancer medicines. The percentage of IPFRs for cancer medicines has increased annually in this Health Board, concurrent with a decrease in the total number of IPFRs. Cardiff and Vale University, Cwm Taf University and Powys Teaching Health Boards received between 25% and 36% fewer IPFRs for cancer medicines in 2017/2018 compared with the previous year. These Health Boards have seen a decrease in IPFRs for cancer medicines annually since 2015/2016.

FIGURE 7: Percentage of Individual Patient Funding Requests (IPFRs) for cancer medicines within each health board in Wales and the Welsh Health Specialised Services Committee (WHSSC) from 2015/2016 to 2017/2018



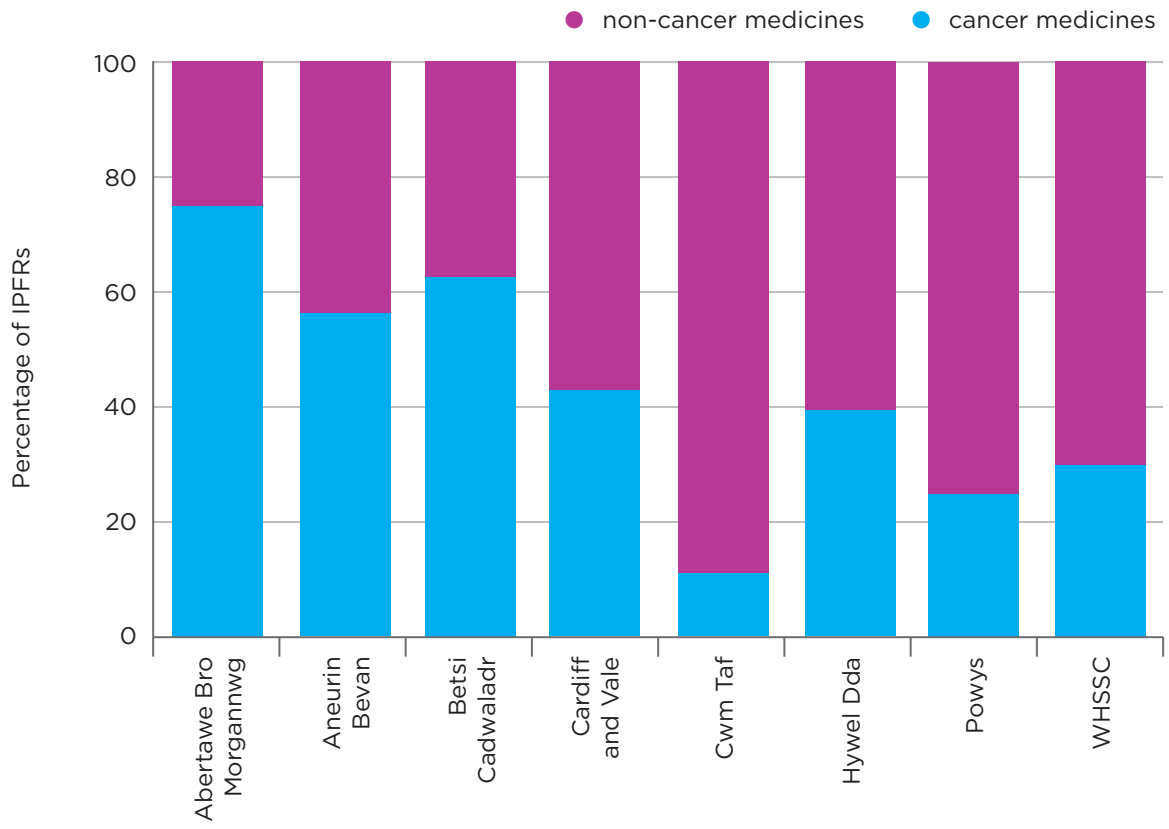
The data were also expressed as the number per 100,000 population in each health board and are shown in Figure 8. Aneurin Bevan University Health Board received the greatest number of IPFRs for cancer medicines per 100,000 people (n = 3.8) and Cwm Taf University Health Board received the fewest (n = 0.3). Interestingly, the number of IPFRs for cancer medicines per 100,000 people has decreased annually in each health board since 2015/2016 (Figure 8). Since January 2017 medicines added to the Cancer Drugs Fund list are funded in Wales through the New Treatment Fund which may have reduced the number of cancer medicines requested via IPFR.

FIGURE 8: Number of Individual Patient Funding Requests (IPFRs) for cancer medicines per 100,000 population within each health board in Wales from 2015/2016 to 2017/2018



The percentage of IPFRs for cancer medicines within each health board and WHSSC are compared to non-cancer medicines in Figure 9. More than 50% of IPFRs considered by Aneurin Bevan University Health Board (n = 22) and Betsi Cadwaladr University Health Board (n = 5), and more than 70% of IPFRs considered by Abertawe Bro Morgannwg University Health Board (n = 12) were for cancer medicines. In contrast, 30% or fewer of IPFRs considered by WHSSC (n = 6), Powys Teaching Health Board (n = 3) and Cwm Taf University Health Board (n = 1) were for cancer medicines. Possible reasons for the variation in the percentages of IPFRs for cancer medicines between the health boards may be due to differences in commissioning arrangements and in the delivery of cancer treatment services. There may also be differences in local policies or treatment pathways.

FIGURE 9: Percentage of Individual Patient Funding Requests (IPFRs) for cancer and non-cancer medicines within each health board in Wales and the Welsh Health Specialised Services Committee (WHSSC) considered by IPFR panels between 1 April 2017 and 31 March 2018



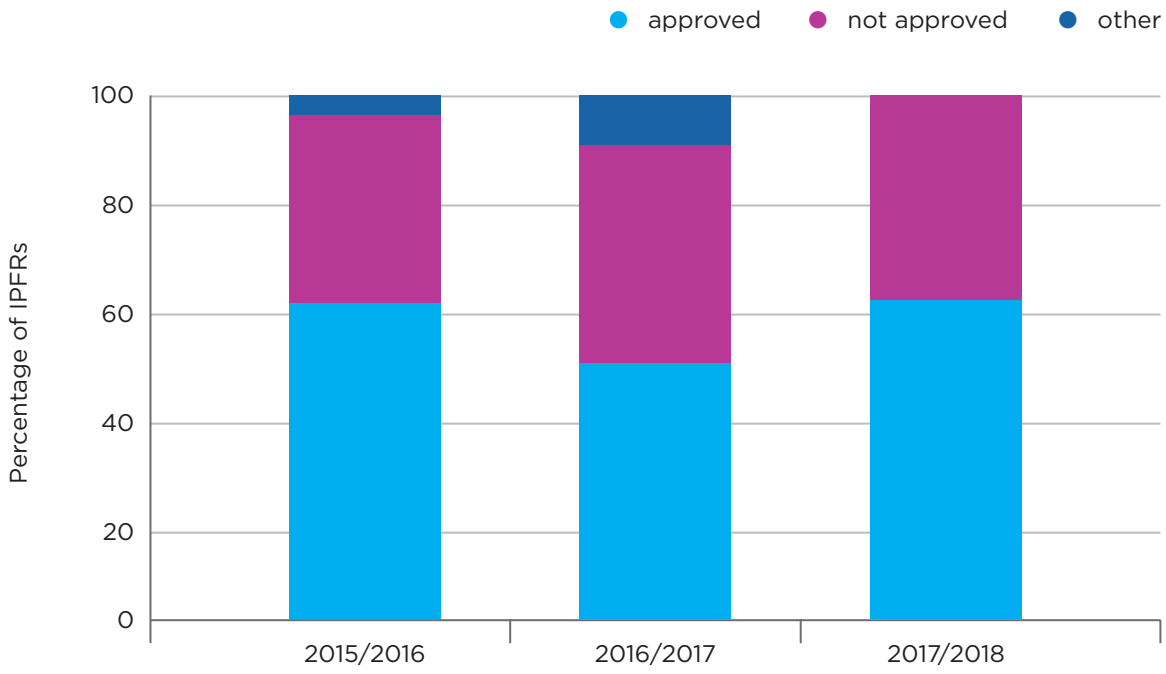
At least 60% of IPFRs for cancer medicines were approved by three of the health boards. Abertawe Bro Morgannwg University Health Board approved the lowest percentage of cancer medicines (16%), with the exception of Cwm Taf University Health Board (0%) which only considered one cancer medicine. However, it is important to highlight the small number of IPFRs considered and the associated limitations of interrogating and interpreting such data in those circumstances.

IPFRs for non-medicines by health board and WHSSC

The number of non-medicine IPFRs increased slightly in 2017/2018 (n = 230) compared with the previous year (n = 213; Figure 2). The number of requests has fluctuated over the last five years ranging from 173 requests in 2014/2015 to 374 requests in 2015/2016.

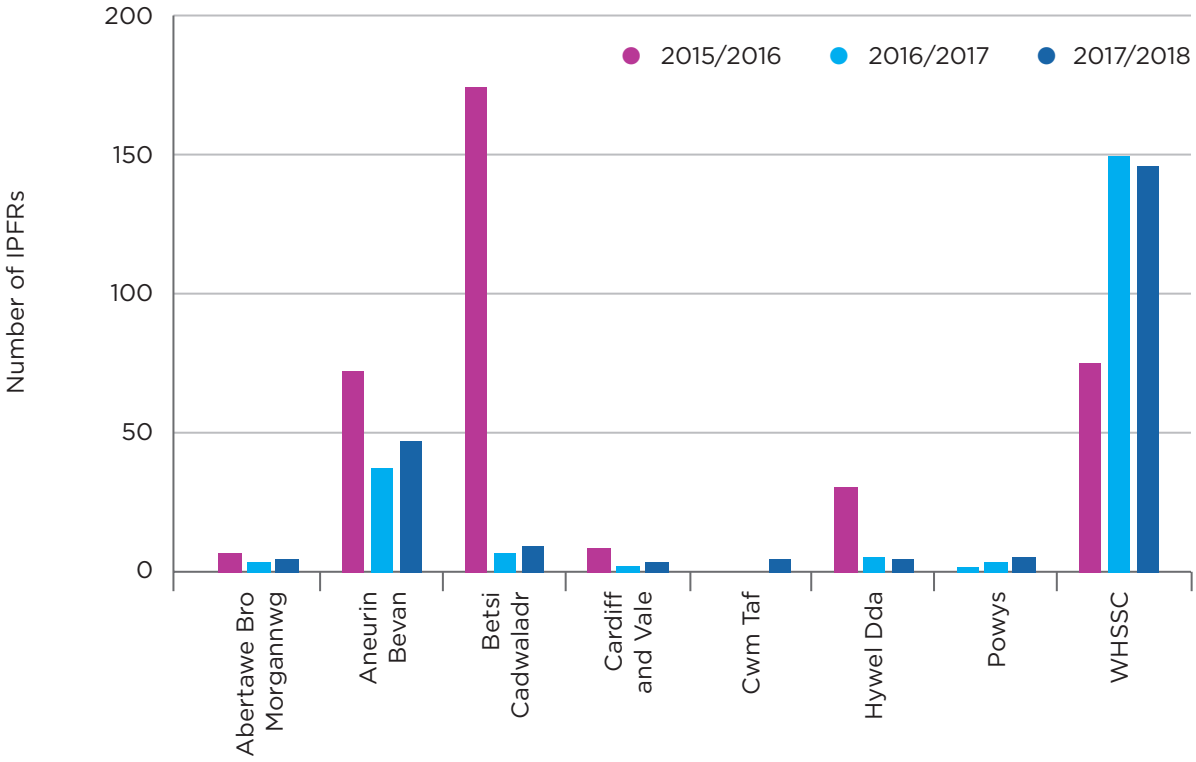
The outcomes of non-medicine IPFRs considered between 2015/2016 and 2017/2018 are illustrated in Figure 10 below. Data were not available for 2013/2014 and 2014/2015 for comparison. Of the total IPFRs for non-medicines (n = 230) considered in 2017/2018, 140 (61%) were approved and 90 (39%) were not approved. The 'other' outcomes (n = 0 in 2017/2018) include IPFRs for non-medicines that were considered initially, but the panel were unable to make a decision. This is most often due to insufficient information being available to the IPFR panel and the decision on the application is deferred pending receipt of that important information. In 2017/2018, the percentage of IPFRs approved increased by 12% compared with 2016/2017, which is comparable to the percentage approved in 2015/2016 (Figure 10).

FIGURE 10: Percentage of non-medicine Individual Patient Funding Requests (IPFRs) approved, not approved, or with another (other) outcome from 2015/2016 to 2017/2018



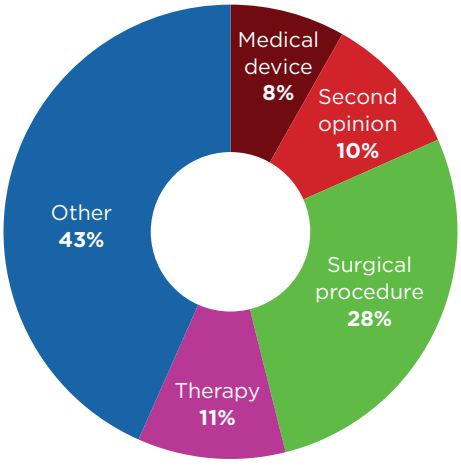
In 2017/2018, the highest number of non-medicine IPFRs were considered by WHSSC (n = 147; 64%) and the fewest were considered by Cardiff and Vale University Health Board (n = 4; 2%), as shown in Figure 11. The numbers considered by the health board panels in 2017/2018 were relatively low and remained relatively consistent with the previous year.

FIGURE 11: Number of Individual Patient Funding Requests (IPFRs) for non-medicines within each health board in Wales, including Welsh Health Specialised Services Committee (WHSSC) from 2015/2016 to 2017/2018



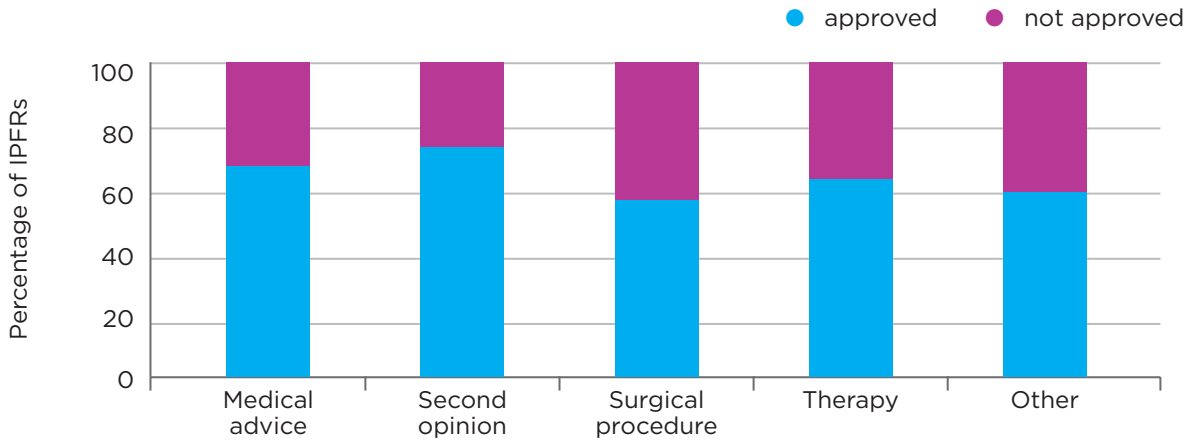
This is the first year in which there are detailed data available over 12 months for non-medicine IPFRs, collated from the national IPFR database which was launched on 1 October 2016. Figure 12 shows the percentage of requests for each type of intervention for the period 1 April 2017 to 31 March 2018. The largest number of non-medicine IPFRs were for 'other' interventions (43%). Of these interventions classed as 'other', the majority (68%) are for PET scans. It should be noted that more than one type of intervention may be requested as part of a single application and therefore the total figures are higher than the total number of IPFRs for this period.

FIGURE 12: Percentage of Individual Patient Funding Requests (IPFRs) for types of non-medicines within each health board in Wales, including Welsh Health Specialised Services Committee (WHSSC), between 1 April 2017 and 31 March 2018



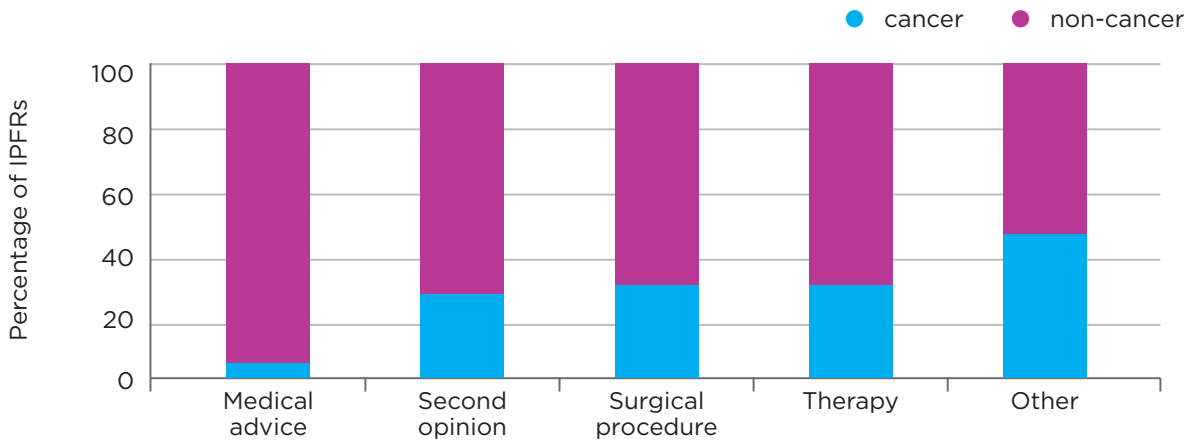
The outcomes of the IPFRs for the different types of non-medicines considered by health boards and WHSSC are shown in Figure 13. More than 50% of IPFRs for all types of non-medicines were approved in Wales.

FIGURE 13: Percentage of Individual Patient Funding Requests (IPFRs) for types of non-medicines approved or not approved within each health board in Wales, including Welsh Health Specialised Services Committee (WHSSC), between 1 April 2017 and 31 March 2018.



Of the 230 non-medicine IPFRs considered by health boards and WHSSC between 1 April 2017 and 31 March 2018, a total of 74 (32%) requests were for interventions to diagnose or treat cancer. The majority (65%) of these were for PET (diagnostic) scans, of which 63% were approved. Figure 14 shows the percentage of non-medicine IPFRs for interventions to diagnose or treat cancer versus non-cancer by non-medicine type. The largest percentage of non-medicine IPFRs for cancer diagnosis or treatment were for 'other' interventions. Of these interventions classed as 'other', the majority (90%) were for PET scans.

FIGURE 14: Percentage of Individual Patient Funding Requests (IPFRs) for cancer and non-cancer non-medicines by intervention type from 1 April 2017 to 31 March 2018



9

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 in operation since May 2016.

The One Wales Interim Pathways Commissioning 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") where an unmet clinical need for treatment of the condition has been identified. A patient cohort is defined as several patients with the same clinical presentation who may benefit from a particular medicine. In such circumstances the IPFR process may not be considered appropriate and may result in a variation in access to a medicine across Wales.

If a medicine meets the criteria for the One Wales process, it is considered by the Interim Pathways Commissioning Group (IPCG), membership of which includes representation from every IPFR panel in Wales. The IPCG reports to the NHS Wales Executive Board of Chief Executives, who makes the final decision concerning interim commissioning in Wales.

Medicines and patient cohorts are identified for the One Wales process by signals from activity in the IPFR panels, from WHSSC, the Committee of Chief Pharmacists or clinician groups. In 2017/2018 a total of 26 medicines were considered for the One Wales process. Half (50%) were identified by compiling IPFR data which provided early intelligence of emerging cohorts. Of the 26 medicines, the majority (n = 25) were excluded by AWMSG Steering Committee as they were not considered suitable for One Wales Interim Pathways Commissioning. The reasons for excluding medicines included:

- the medicine was already on either the NICE or AWMSG HTA work programme (n = 8)
- clinical experts did not identify an unmet need (n = 8)
- NICE or AWMSG restricted or negative recommendation published (n = 3)
- suitable for HTA (n = 2) or WHSSC commissioning (n = 2)
- NICE recommendation published (IPFRs made before NICE guidance had been published; n = 1) or no commitment to engage in HTA process (n = 1).

Analysis of the IPFR data identified two medicines suitable for the standard HTA route and the marketing authorisation holders have been duly contacted by AWTTC to encourage engagement with AWMSG's HTA process.

In 2017/2018, three new medicines (two of which were considered by AWMSG Steering Committee in the previous financial year) were assessed through the One Wales Interim Pathways Commissioning process. Two decisions were superseded or partially superseded by HTA and six medicines were reviewed 12 months after endorsement. Table 4 shows the One Wales Interim Pathways Commissioning decisions which were endorsed, reviewed or superseded in 2017/2018.

Table 4: One Wales Interim Pathways Commissioning decisions endorsed, reviewed or superseded in 2017/2018

Medicine	Indication	One Wales Interim Decision	Chief Executive endorsement date	Review decision	Chief Executive endorsement date of review decision
Adalimumab (Humira®)	Treatment of paediatric patients with severe refractory non-infectious uveitis	Supported	11/10/2016	Interim decision to continue for 12 months – partially superseded by positive AWMSG advice 08/12/2017	23/11/2017
Adalimumab (Humira®)	Treatment of adult patients with severe refractory non-infectious uveitis	Supported – superseded by positive NICE guidance 26/07/2017	11/10/2016	–	
Arsenic trioxide (TRISENOX®)	Acute promyelocytic leukaemia - 1st line therapy in patients unsuitable for anthracycline-based therapy	Supported	24/10/2016	Interim decision to continue for 12 months	05/02/2018
Axitinib (Inlyta®)	Treatment of advanced renal cell carcinoma after failure of prior treatment with pazopanib	Supported	03/08/2016	Interim decision to continue for 12 months	23/11/2017
Bevacizumab (Avastin®)	At a dose of 7.5 mg/kg in combination with carboplatin and paclitaxel for the front-line treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer	Not supported	03/08/2016	Interim decision to continue for 12 months	20/12/2017
Denosumab (Prolia®)	Treatment of osteoporosis in men at increased risk of fractures	Supported	06/03/2017		

Medicine	Indication	One Wales Interim Decision	Chief Executive endorsement date	Review decision	Chief Executive endorsement date of review decision
Docetaxel	In combination with androgen deprivation therapy for the treatment of hormone-naive metastatic prostate cancer	Supported	03/08/2016	Interim decision to continue for 12 months	22/09/2017
Rituximab + bendamustine	Treatment of indolent lymphomas, first line and relapsed. To include follicular lymphoma, Waldenstrom's and marginal zone lymphoma	Supported	28/04/2017		
Rituximab + bendamustine	Treatment of mantle cell lymphoma, first line and relapsed	Supported	28/04/2017		
Rituximab	Treatment of pemphigus and pemphigoid disease in adults and children where third- or fourth-line treatments, including steroids and steroid-sparing treatments have failed	Supported	20/07/2017		

The analysis of IPFR data for the One Wales Interim Pathways Commissioning process has allowed AWTTC to identify medicines suitable for the standard HTA route. In 2016, a cohort of IPFRs for Duodopa® for the treatment of Parkinson's disease were identified. AWTTC contacted the marketing authorisation holder to highlight the clinical need and encourage engagement with AWMSG's HTA process. Following company engagement, in early 2018 AWMSG appraised and recommended this medicine, which is now available for restricted use within NHS Wales.

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 new One Wales process effectively reduces the burden on IPFR panels and encourages equity of access to these medicines across Wales.

More information on the One Wales Interim Pathways Commissioning process is available on the AWTTC website at www.awttc.org/pams/one-wales-interim-commissioning-process.

Patient outcomes

Of the data collected during 2017/2018 patient outcome information was available for 41 people, 35 following applications where the intervention was approved and six which were not approved. A total of 25 outcomes were associated with medicine IPFRs and 16 with non-medicines, five were following continued funding of medicines which had previously been approved.

Of the 35 patients for whom treatment was approved, 19 reported evidence of clinical benefit, six followed requests for a second opinion of which one was still pending and one patient was too early in the treatment pathway to assess. Two patients demonstrated no clinical benefit and two had not received treatment. For five patients only basic outcome information was provided, four were reported to have not deceased and one had deceased. Of the six patients for whom treatment was not approved three were reported as not deceased, one had disease progression, one stable condition and one patient had died.

The collection of outcome data is very important in order to monitor and analyse whether or not a treatment has been effective. It is encouraging to note that of the outcomes reported the majority of interventions approved (not including second opinions) were associated with evidence of clinical benefit. The number of patients for which outcome data are available in 2017/2018 is over twice as many as that provided in 2016/2017 but still represents a small proportion (approximately 10%) of all IPFRs considered during the period 2017/2018. AWTTC will continue to work with IPFR panels and clinicians to encourage and improve the reporting and recording of outcomes to provide information on the impact of IPFR decisions in relation to patients.

11

Independent review of an IPFR decision

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, a review of the IPFR process may be requested. A review can be requested on one or more of the following three strictly limited grounds:

- the Health Board has failed to act fairly and in accordance with the All Wales Policy on making decisions on IPFRs
- the Health Board has prepared a decision which is irrational in the light of the evidence submitted
- the Health Board has not exercised its powers correctly.

From 1 April 2017 to 31 March 2018, three requests for a review of the IPFR process followed were referred to review panels. In two cases the panel upheld the grounds of the reviews and the original panels reconsidered the requests. In one case the grounds for review were not upheld.

Quality Assurance Advisory Group

The 'Independent Review of the IPFR process in Wales' report published in January 2017 highlighted concerns about inconsistencies in the IPFR process across Wales.

The report did not recommend changing the number or structure of the panels, but did recommend that a national IPFR quality function should be established to ensure quality and consistency. A Quality Assurance Advisory Group was established and the inaugural meeting was held on 31 January 2018.

The objectives of the group are to monitor and support all IPFR panels to ensure quality in decision making and consistency across Wales. The terms of reference are shown in Table 5.

Table 5: IPFR Quality Assurance Advisory Group Terms of Reference
The group will scrutinise the workload and efficiency of the IPFR processes in the health boards and the Welsh Health Specialised Services Committee.
The group will receive and comment upon quarterly reports of anonymised random sample IPFR reports in relation to their completeness, timeliness and efficiency of communication.
The group will report (via the Chair) to the Deputy Chief Medical Officer for Wales on the quality of the processes and highlight any concerns through the existing quality and clinical governance processes in NHS Wales.
The group will normally meet on a quarterly basis and whenever appropriate, conduct its business online or by videoconference.
The group will contribute to simulation exercises conducted with all panels at the annual IPFR training day and comment on the feedback from this exercise.
The group will comment on aspects of quality assurance of the IPFR process raised by stakeholders as appropriate and required.
The group will obtain professional and administrative support from the All Wales Therapeutic and Toxicology Centre (AWTTC).

At the first meeting an anonymised random sample of IPFR reports (one from each IPFR panel in Wales) from between 1 October and 31 December 2017 were considered in relation to the criteria shown in Table 6 in line with the NHS Wales IPFR policy process.

Table 6: Criteria considered by the IPFR Quality Assurance Advisory Group		
Process	**Evidence to assess whether the process has been adhered to**	**Criteria**
Application process	IPFR application form, clinic letters/associated emails and IPFR panel minutes	Was this an appropriate request to consider via the IPFR route?
		Was the IPFR application form signed?
		Was there sufficient information provided for the case to proceed to panel?
	Date of receipt of IPFR versus date of IPFR meeting versus urgency ticked	Was the case taken to panel within the timescale stipulated on the application form?
Panel process	IPFR panel minutes	Was the panel quorate?
		Was the discussion held by the panel in line with the decision-making guide?
		Was the decision and rationale for the decision clearly described in the minutes?
Decision process	IPFR panel minutes, IPFR decision letter to clinician, IPFR decision letter to patient, date on letter versus date of meeting	Did the letter to the clinician clearly state the decision and explain the reason for the decision?
		Was the decision letter sent to the clinician within 5 working days of the panel's decision?
		Did the letter to the clinician state the review deadline date, and enclose the review form and guidance notes where applicable?
		Was the letter to the patient sent within 5 working days of the panel's decision?

Following the meeting individual detailed reports were provided to each IPFR panel to provide feedback on their IPFR application including an action plan to address any issues arising. In addition, examples of good practice or common themes were shared across the panels. A combined report was sent to the Deputy Chief Medical Officer and the Head of Pharmacy and Prescribing Policy at the Welsh Government. This combined report will be sent bi-annually.

The detailed outcomes are confidential, however, the Quality Assurance Advisory Group were impressed by the quality of the documentation provided as part of the quality assurance assessment. The group considered that, based on the small number of randomly selected cases they assessed in detail at the meeting, the IPFR process was generally being used for appropriate cases and was fair.

Summary of the data

Overall the data for 2017/2018 indicate:

- A continuing decline in the number of IPFRs across Wales compared with previous years. Possible reasons for the decline in requests for medicines may be due to the submitting clinicians having a better understanding of the most appropriate route(s) for accessing a medicine on behalf of patients. In addition, following publication of positive One Wales Interim Pathways Commissioning decisions, IPFR applications were no longer being submitted for these indications.
- This decline is largely associated with a reduction in requests for medicines rather than non-medicines.
- Overall, 63% of IPFRs were approved compared with 55% in 2015/2016.
- For medicines, the approval rate was 67% in 2017/2018 and the rate has increased annually over the last three years.
- The approval rate for non-medicines was 61% in 2017/2018 and this had increased compared with 49% in 2016/2017 and was similar to the percentage approved in 2015/2016.
- Health boards approved a similar number of IPFRs for cancer medicines compared with previous years.
- The most commonly requested medicines were for the treatment of cancer and in that group of medicines, pertuzumab has replaced bevacizumab as the most commonly requested cancer medicine via IPFR.
- As in the previous year the most common non-medicine requests were for PET scans, of which the majority were for the detection or investigation of cancers.

14

Glossary and additional note

AWMSG	All Wales Medicines Strategy Group
AWTTC	All Wales Therapeutics and Toxicology Centre
HTA	Health Technology Assessment
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 of 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.