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

Individual Patient Funding Request (IPFR)

Annual Report 2016/2017

GIG CYMRU NHS WALES

PAMS
Patient Access to Medicines Service
Mynediad Claf at Wasanaeth Meddyginiaethau

Contents

AWTTC Clinical Director's statement 2016/2017 – A year of progress

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2016/17 has proven to be another busy and productive year for the Individual Patient Funding Request (IPFR) process in Wales and I want to acknowledge the continuing commitment of the IPFR panels to delivering and developing the processes.

Implementation of the recommendations following the IPFR review in 2014 was completed this year, including the launch of a new IPFR database to collate data and store evidence. All health boards across NHS Wales are now using the database and this report includes information compiled using it. I would like to acknowledge the hard work of the NHS Wales Informatics Service (NWIS) which developed the system, and the support and commitment of the IPFR teams in providing useful feedback on system improvements. I am looking forward to the roll-out this year of electronic IPFR applications which will further streamline the process.

A second independent review of the IPFR process was announced in September 2016 which focussed on specific areas, namely the number of IPFR panels, the clinical exceptionality criteria and the patients' perspective. An independent panel, expertly Chaired by Mr Andrew Blakeman, was established in September 2016. Several workshops were held across the country and clinicians and patient organisations were invited to share their experiences of the process. The findings of the review were published in January 2017 with 27 recommendations for further improvement. In March 2017, Vaughan Gething, Welsh Government's Cabinet Secretary for Health, Well-being and Sport welcomed the findings of the review and implementation of these recommendations is presently underway.

Following the success last year of the IPFR training workshop, a further workshop was held in Cardiff on March the 22nd 2017. The All Wales Therapeutics and Toxicology Centre (AWTTC) will continue to host these workshops annually. I thank the speakers for their thought provoking presentations which incorporated ethical and legal considerations in relation to IPFR.

I also acknowledge the significant contribution of Dr Sharon Hopkins and the One Wales Interim Pathways Commissioning Group, supported by clinical experts in Wales and elsewhere, in addressing major cohort commissioning issues during the first year since they were established.

I am confident that in 2017/18 there will be even greater robustness in the IPFR process across NHS Wales and greater clarity for patients and clinicians in how IPFRs are accessed.

Executive summary

- There has been an overall 38% decline in the number of IPFRs across Wales in 2016/17 compared with the previous year (from 683 to 422 requests). This reduction was mainly due to a decline in medicine-related applications (from 309 requests in 2015/16 to 209 requests in 2016/17).
- This decline in medicine-related IPFR applications may be due to a better awareness of the most appropriate routes for accessing medicines in Wales. In addition, following publication of positive One Wales Interim Pathways Commissioning decisions, IPFR applications were no longer submitted for these indications.
- IPFR panels had a similar acceptance rate for IPFRs for medicines in 2016/17 (60%) compared with the previous year (57%).
- Bevacizumab for the treatment of cancer remains the most commonly requested medicine via IPFR in Wales. Health boards approved a similar percentage of IPFRs for cancer medicines in 2015/16 compared with previous years.
- The most common non-medicine requests for the latter half of 2016/17 were for positron emission tomography (PET, diagnostic) scans. The majority of which were for people with cancer-related issues.
- Having now implemented the recommendations of the 2014 IPFR review, AWTTC is continuing to work with the IPFR panels and other colleagues across NHS Wales to ensure the timely implementation of the recommendations of the 2017 independent review report.
- These new recommendations are aimed at further improving the robustness and transparency of the IPFR process in Wales, so that there is greater clarity for patients and health professionals in how the processes work and can be most effectively accessed.

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 falls 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. The National Institute for Health and Care Excellence (NICE) and the All Wales Medicines Strategy Group (AWMSG) appraise new treatments to decide whether or not the treatment is both 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 the 2014 review and implementation of its recommendations, the Cabinet Secretary for Health, Wellbeing and Sport agreed the time was right for a new, independent review of the IPFR process. The panel would be independent of the Welsh Government and encompass a range of expertise and knowledge. The 'Independent Review of the IPFR process in Wales' report was published in January 2017 and contains a total of 27 recommendations. These are aimed at improving the commissioning processes within health boards and WHSSC and replacing the 'exceptionality' principle within the IPFR policy. The recommendations will be implemented in 2017 and will be reported in the 2017/18 annual report.

4 Implementation of recommendations following the 2014 review of the IPFR process

In October 2013, the Minister for Health and Social Services announced a review of the IPFR process in Wales to explore how it could be strengthened. An independent review group was established in April 2014 and the group made ten recommendations.

In March 2015 the Welsh Government asked health boards to work with AWTTC to implement the report's recommendations. AWTTC in collaboration with IPFR coordinators developed an implementation plan and these recommendations were completed in 2016/17.

Recommendation 1: The NHS Wales policy and supporting guidance should be updated to define what constitutes an appropriate application to the IPFR panel

- The NHS Wales IPFR policy, application form and supporting guidance have been updated to help define what constitutes an appropriate application to the IPFR panel. This was implemented on 31st May 2016.

Recommendation 2: AWTTC should be placed at the heart of the IPFR process supporting IPFR panels to work more cohesively, collating and monitoring all IPFR applications for appropriateness, identifying emerging trends and compiling the annual report for the process. This arrangement will also strengthen the position of AWTTC to support training for panel members and clinicians

- AWTTC commenced their central co-ordinating role in April 2015.
- A common dataset was agreed to identify emerging trends within IPFR applications.
- The Phase I development of a bespoke IPFR database was completed and fully implemented in October 2016.
- AWTTC compiled an annual report for 2015/2016. The report can be accessed on the AWTTC website (**www.awttc.org/pams/individual-patient-funding-request-ipfr-0**).
- A number of training events were held throughout the year including:
  - An IPFR workshop on 19th April 2016.
  - A database training session with IPFR coordinators on 30th September 2016.
  - A presentation to the Welsh Industry Group in September 2016 and to the Patient and Public Interest Group in October 2016 on the IPFR process and the One Wales Interim Pathways Commissioning process.
  - A further IPFR workshop on 22nd March 2017.

Recommendation 3: For medicines, AWTTC should establish and maintain a central data store for search strategies and key evidence. For non-medicine technologies and other interventions Public Health Wales should establish and maintain a central data store for search strategies and key evidence

- As part of the Phase I development of the IPFR database, the system incorporates a central repository for evidence which has subsequently been populated.

Recommendation 4: The existing IPFR panels linked to the seven health boards and WHSSC should continue. A move to hold joint meetings of neighbouring panels may be considered further once the recommendations of this report have been implemented and reviewed

- As part of the 2016 review recommendation, it was agreed that the existing IPFR panels linked to the seven local health boards and WHSSC should continue.

Recommendation 5: IPFR panels should increase their lay representation to two voting members whilst the Community Health Council (CHC) representative should become a non-voting member. This will allow the CHC representative to focus, unfettered, on their role as a patient representative

- A person-specification has been agreed outlining the roles and responsibilities of the lay member(s).
- The majority of lay members are now in post. Further recruitment is ongoing to meet any current vacancies.

Recommendation 6: Each IPFR panel should have a mechanism in place to ensure appropriate clinical advice is available on or before the day of the panel to clarify clinical issues and avoid unnecessary delays in reaching a decision

- The IPFR application form has been updated which stipulates a requirement for the requesting clinician to provide their contact details should the need arise for them to be contacted.

Recommendation 7: IPFR applications should be screened for appropriateness prior to submission and countersigned by the relevant Clinical Lead/Head of Department

- This has been included in the revised NHS Wales IPFR policy.

Recommendation 8: AWTTC should work with health boards and WHSSC to establish a common dataset and patient consent process, for local and national reporting

- Advice on patient consent processes was received from the Information Commissioner's Office and incorporated into the revised NHS Wales IPFR policy and supporting documentation.
- A dataset has been agreed and a reporting process has been established.

Recommendation 9: AWTTC, in conjunction with IPFR co-ordinators and panel members, should update the NHS Wales policy and supporting guidance on IPFR panels to reflect the recommendations of this report

- NHS Wales IPFR policy and guidance has been updated accordingly.

Recommendation 10: Patient outcomes linked to IPFR decisions should be monitored. AWTTC and health boards should work together to devise a process to collect this information for all technologies

- A patient outcome data form has been produced with input from clinicians and IPFR panel members.
- Outcome data are recorded on the IPFR database where applicable.
- The newly developed IPFR application form specifies to clinicians that on submission of an IPFR request, they are agreeing to provide outcome data in a timely manner on the progress of the patient, regardless of decision.

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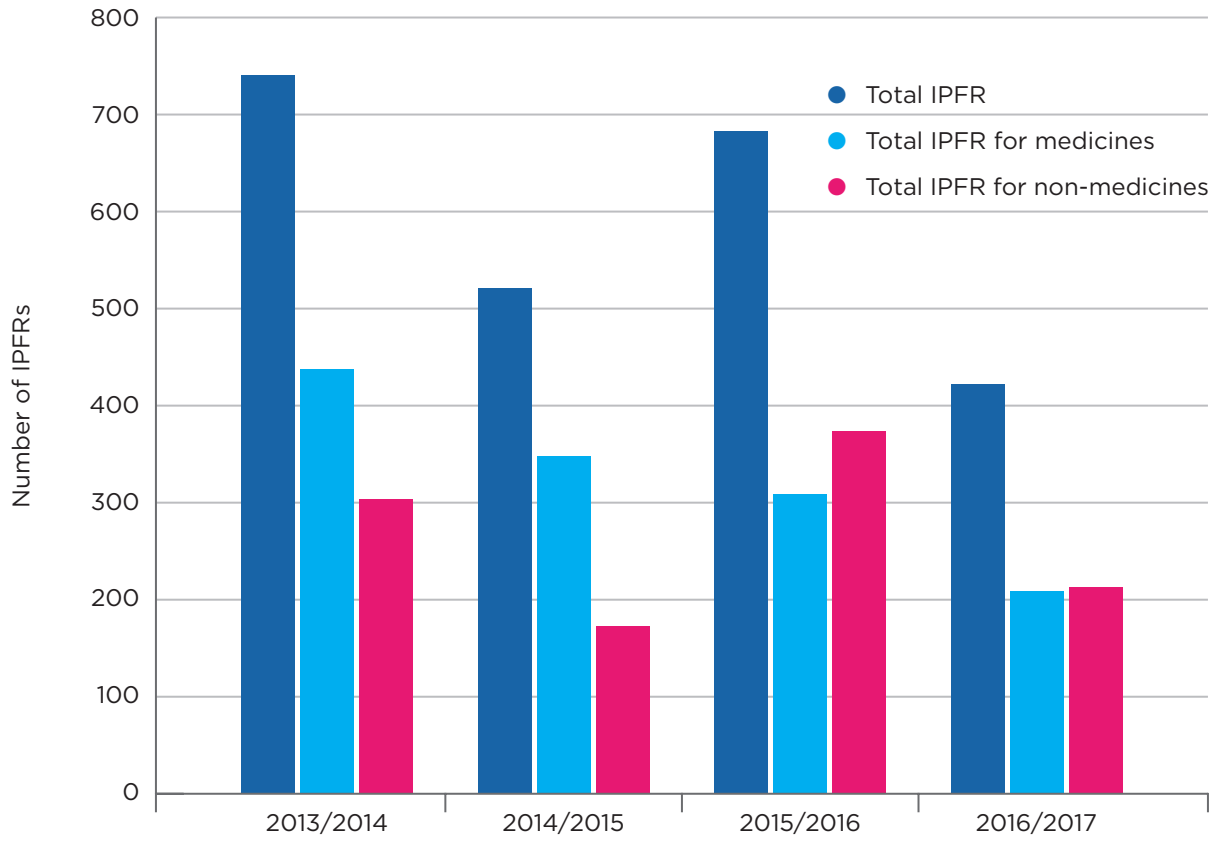
Total IPFRs considered in Wales

As in the previous year IPFR data for the first six months of the 2016/17 annual report were submitted to AWTTC by spreadsheet on a monthly basis and collated into a single data set. On 1st October 2016 the new national IPFR database was launched and since this date the IPFR teams in local health boards and WHSSC have recorded all new applications directly onto the system. The two sets of data have been amalgamated to provide total figures for the 2016/17 report.

A total of 422 IPFRs were considered between 1 April 2016 and 31 March 2017, 209 (50%) were for medicines and the remainder (n = 213; 50%) were for non-medicine related requests. Overall, 55% of IPFRs were approved compared with 59% in 2015/16. For medicines, the approval rate was 60% (57% in 2015/16) and for non-medicines it was 49% (60% in 2015/16).

Compared with 2015/16, the number of IPFRs for medicines in Wales in 2016/17 decreased by 32%, as shown in Figure 1. This is the fourth consecutive year in which medicine-related IPFRs have fallen in Wales so that the fall since 2013/14 has been 52%. 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 2015/16. The number of IPFRs for non-medicines fell by 43% in 2016/17 compared with the previous year.

FIGURE 1: Total number of Individual Patient Funding Requests (IPFRs) considered in Wales from 2013/2014 to 2016/2017



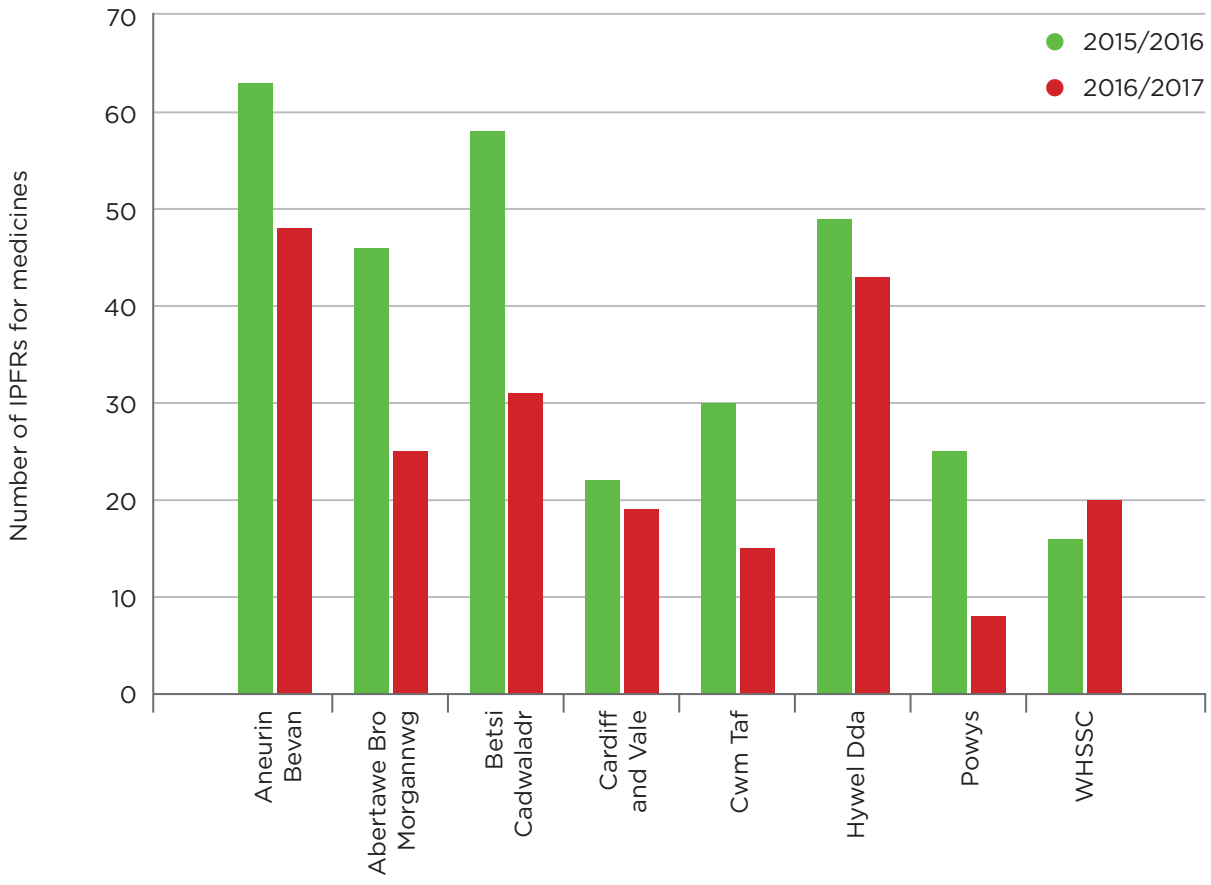
IPFRs for medicines by health board and WHSSC

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).

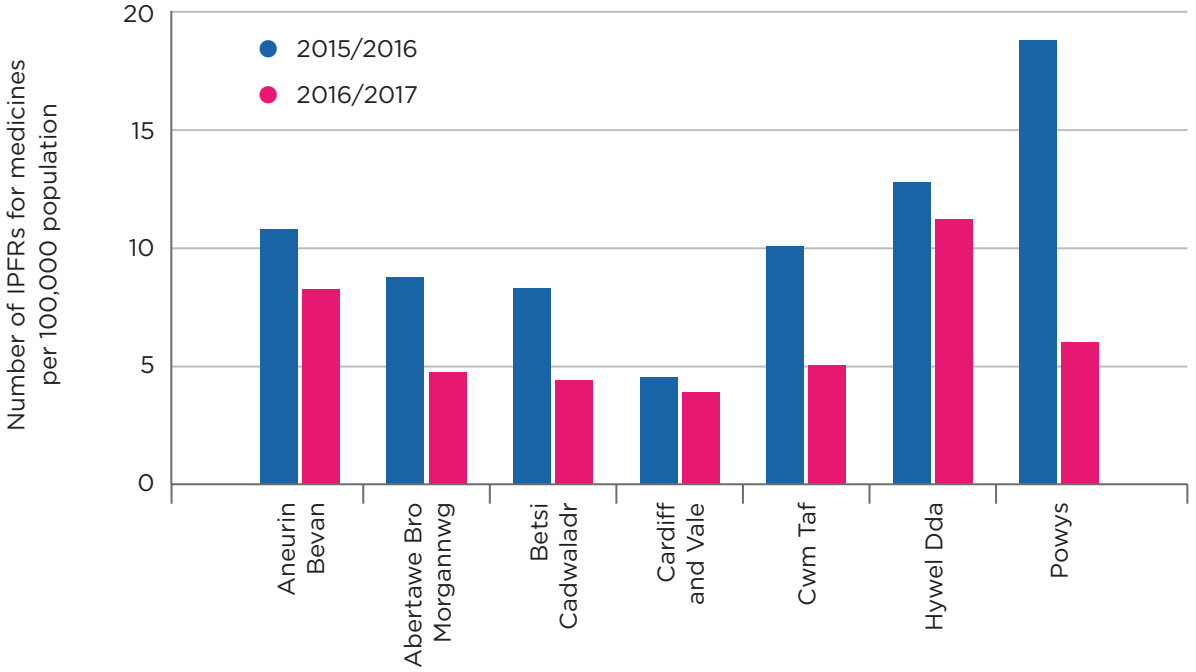
The highest absolute number of IPFRs for medicines in 2016/17 was considered by Aneurin Bevan University Health Board (n = 48), as shown in Figure 2. This is consistent with 2015/16. The fewest number of IPFRs was considered by Powys Teaching Local Health Board (n = 8) in 2016/17 and WHSSC (n = 16) in 2015/16, as shown in Figure 2. The number of IPFRs considered within each health board decreased from 2015/16 to 2016/17, with a small increase in IPFRs considered by WHSSC. In addition to these requests there were a further 15 'continued funding' IPFRs for medicines that had previously been approved and now required an extension to that treatment. Fourteen of these requests were approved.

FIGURE 2: 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 2016/2017



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 the population-corrected data are shown in Figure 3.

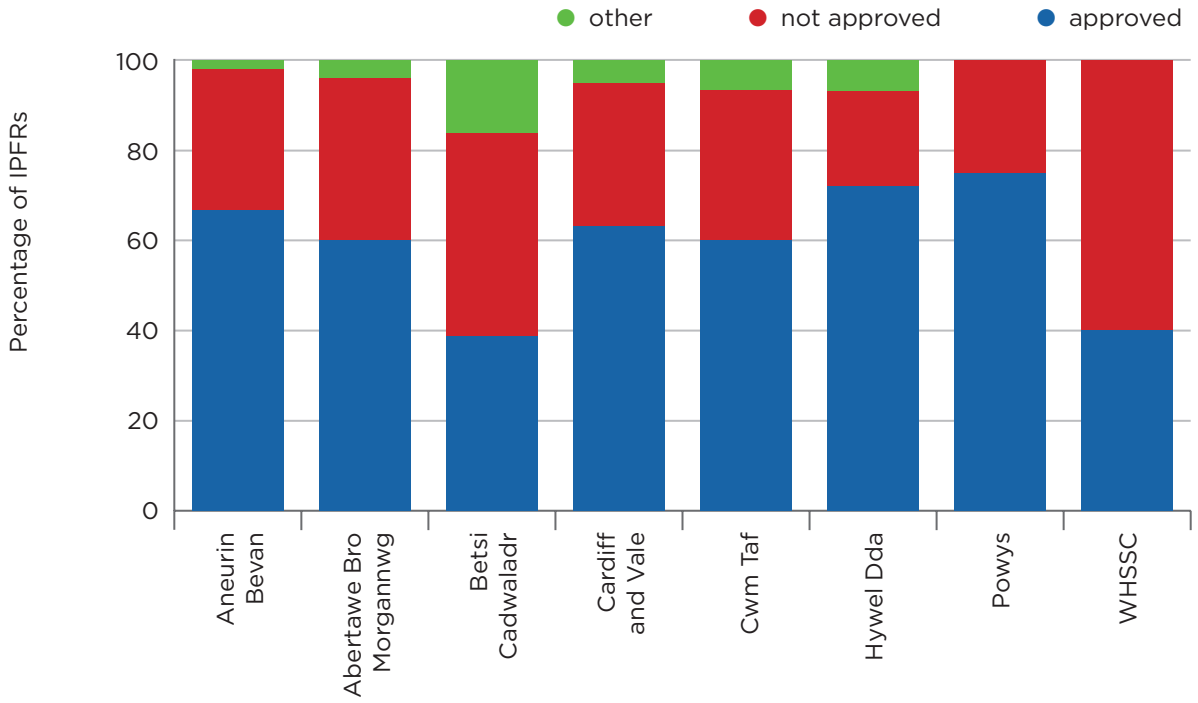
FIGURE 3: Number of Individual Patient Funding Requests (IPFRs) per 100,000 population within each health board in Wales from 2015/2016 to 2016/2017



In 2016/17 Hywel Dda University Health Board received the highest number of IPFR applications for medicines per head of population (11 per 100,000 population) compared to Powys Teaching Local Health Board (19 per 100,000 population) in the previous year. The fewest number of applications was considered by Cardiff & Vale University Health Board over the last 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 are shown in Figure 4. Compared with 2015/16; the percentage of IPFRs approved has increased or stayed the same for all health boards with the exception of Betsi Cadwaladr University Health Board. The percentage of IPFRs approved within Betsi Cadwaladr University Health Board decreased from 64% in 2015/16 to 39% in 2016/17. Recognition of the unusually high disparity between these figures has been noted. This decrease may be due to the inclusion of non-contracted activities (NCAs) in the IPFR results for the previous year but not in 2016/17, contributing to the higher approval rate in 2015/16, and the subsequent fall. Further investigation may be required to establish if there are any other reasons as to why the approval rate for this health board has fallen. The 'other' outcomes 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 4: Percentage of Individual Patient Funding Requests (IPFRs) 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 2016 to 31 March 2017



The medicines most frequently considered annually between 1 April 2013 and 31 March 2017 are shown in Table 1. Bevacizumab has been the most frequently requested medicine each year since 2013/14. 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.

Table 1: The most commonly requested medicines in rank order

2013/2014	2014/2015	2015/2016	2016/2017
Bevacizumab	Bevacizumab	Bevacizumab	Bevacizumab
Cetuximab	Axitinib	Cetuximab	Rituximab
Rituximab	Brentuximab	Adalimumab	Adalimumab*
Axitinib	Bendamustine	Pertuzumab	Omalizumab*
Adalimumab*	Cetuximab	Rituximab*	Pertuzumab
Eribulin*	NR	Bendamustine*	Infliximab*
Infliximab*	NR	Trastuzumab emtansine	Nivolumab*

** 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

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. Table 2 shows the medicines most frequently approved or not approved by IPFR panels from 1 April 2015 to 31 March 2017.

Table 2: The medicines most frequently approved or not approved in 2015/2016 and 2016/2017 in rank order

2015/2016		2016/2017	
Approved	**Not approved**	**Approved**	**Not approved**
Bevacizumab	Bevacizumab	Rituximab	Bevacizumab
Adalimumab	Cetuximab	Adalimumab	Pertuzumab
Rituximab	Pertuzumab	Infliximab	NR
Apremilast	Trastuzumab emtansine	Bevacizumab*	NR
Bendamustine	NR	Omalizumab*	NR
Ibrutinib*	NR	Bendamustine	NR
Ruxolitinib*	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 four indications for which the most commonly requested medicines were considered are outlined in Table 3 below.

Table 3: Top four medicine-indication combinations considered by IPFR panels in 2016/2017

Medicine	Indication	License Status
Pertuzumab*	First-line treatment of metastatic advanced breast cancer	Licensed
Bevacizumab 7.5 mg†	First-line treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer	Off-label
Trastuzumab emtansine§	Metastatic breast cancer	Licensed
Nivolumab¶	Metastatic renal cell carcinoma	Licensed

**HTA in process, †Not supported for use by One Wales, §HTA negative recommendation, ¶IPFR requests prior to HTA advice becoming available*

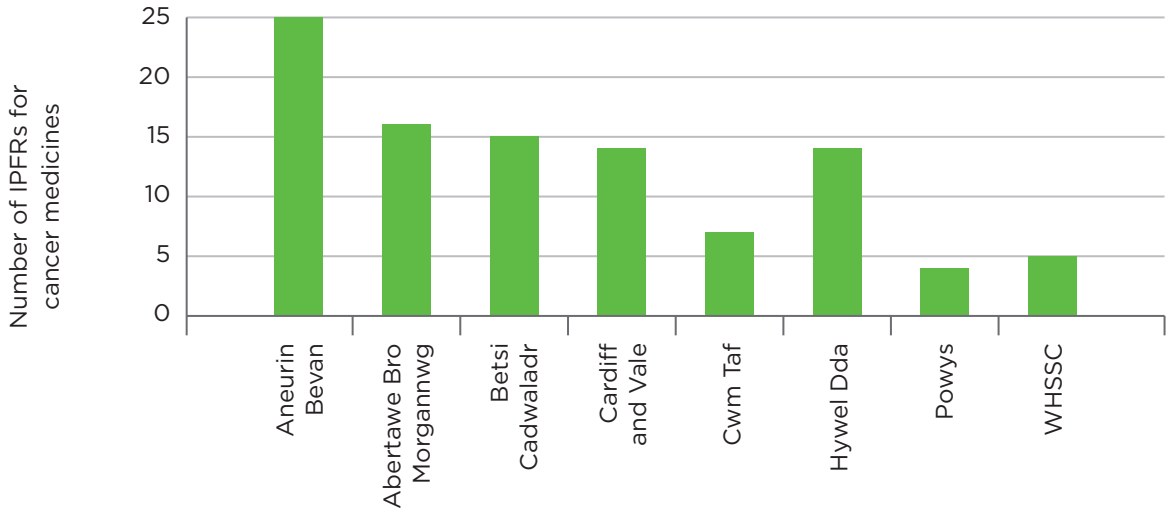
For one indication, health technology appraisal (HTA) is in progress. The off label medicine (bevacizumab 7.5 mg/kg daily) has been assessed by the One Wales Interim Pathways Commissioning process but its use was not supported in NHS Wales (see page 19). For the year 2016/17 trastuzumab emtansine had negative HTA advice from NICE. Therefore, IPFR would be considered the only route for access to these medicines. Requests for nivolumab were made prior to positive HTA advice by NICE.

IPFRs for medicines for the treatment of cancer

Almost half (48%) of the medicines requested via IPFR in 2016/17 were for the treatment of cancer.

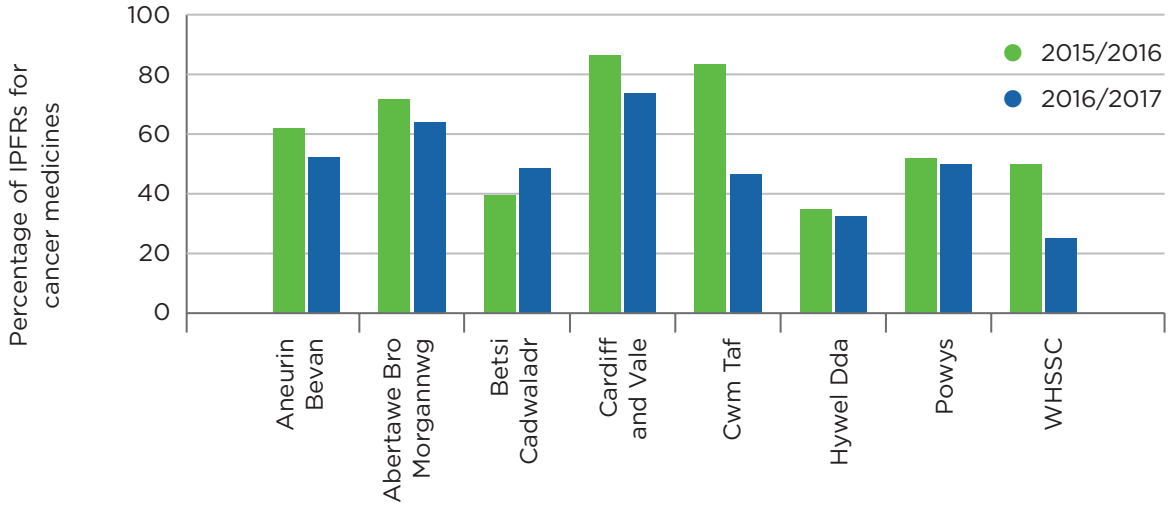
The greatest number of IPFRs for medicines for the treatment of cancer was received by Aneurin Bevan University Health Board (n = 25) and the fewest were submitted in Powys Teaching Local Health Board (n = 4), as shown in Figure 5.

FIGURE 5: 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 2016 to 31 March 2017



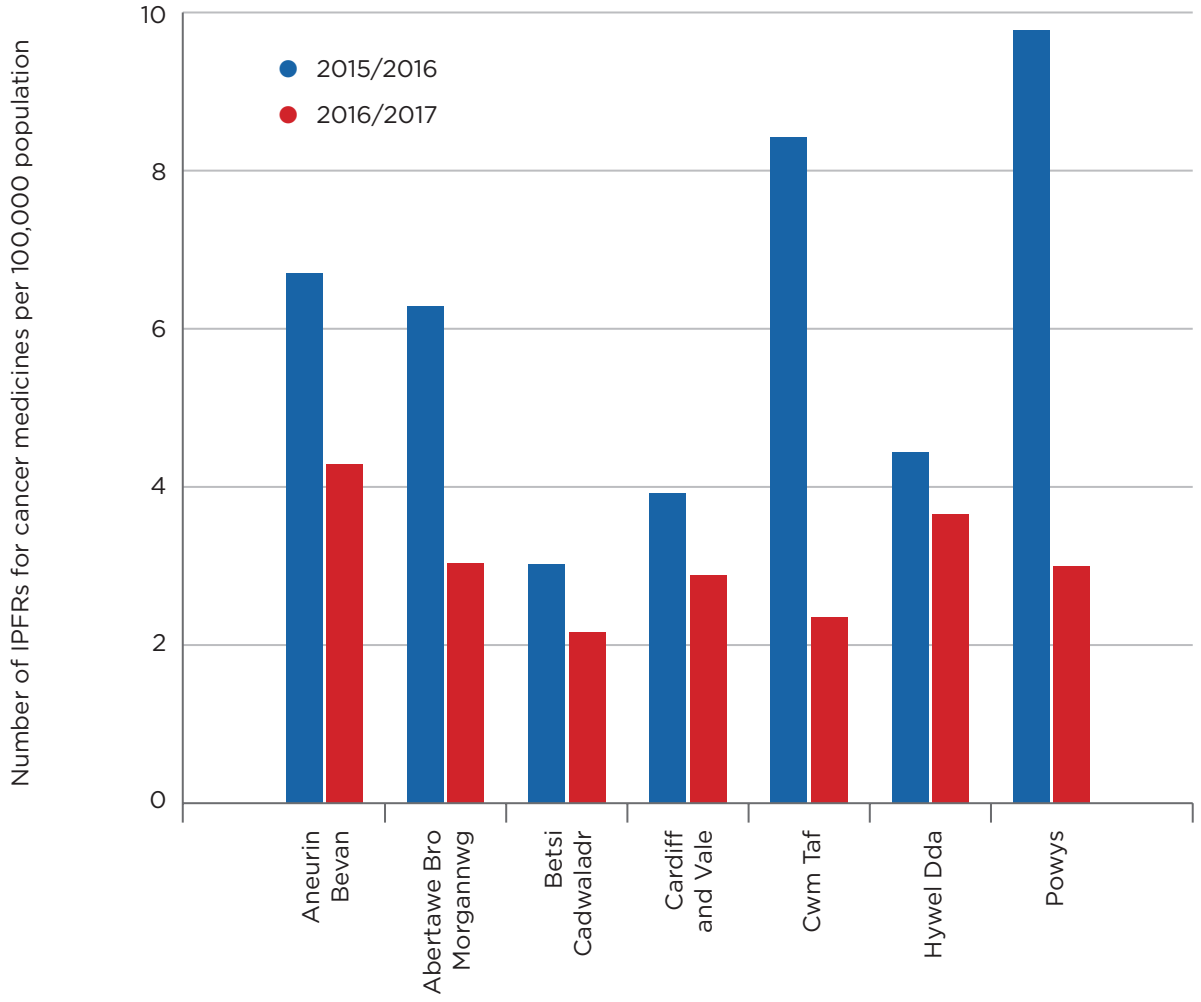
The percentage of IPFRs for cancer medicines has decreased in 2016/17 compared with the previous year in six of the seven health boards and also in WHSSC. Figure 6 shows that WHSSC and Cwm Taf received 50% and 43% fewer IPFRs for cancer medicines, respectively.

FIGURE 6: Percentage of Individual Patient Funding Requests (IPFRs) for cancer medicines within each health board in Wales and the Welsh Specialised Services Committee (WHSSC) from 2015/2016 to 2016/2017



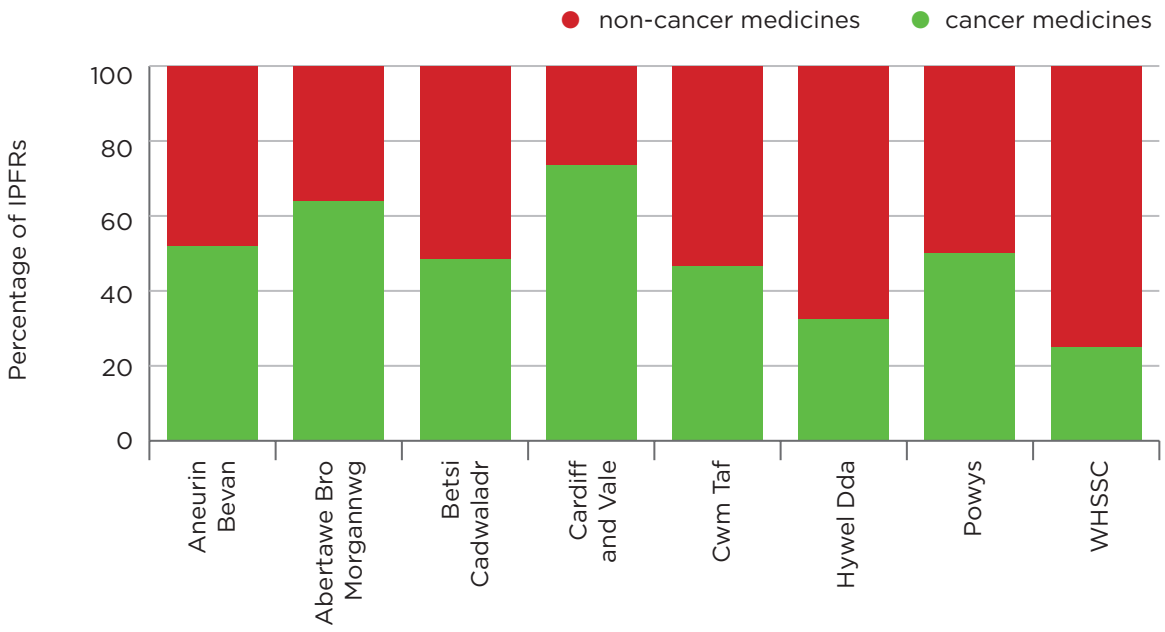
The data were also expressed as the number per 100,000 population in each health board and are shown in Figure 7. Aneurin Bevan University Health Board received the greatest number of IPFRs for cancer medicines per 100,000 population (n = 4.3) and Betsi Cadwaladr University Health Board received the fewest (n = 2.2).

FIGURE 7: Number of Individual Patient Funding Requests (IPFRs) for cancer medicines per 100,000 population within each health board in Wales from 2015/2016 to 2016/2017



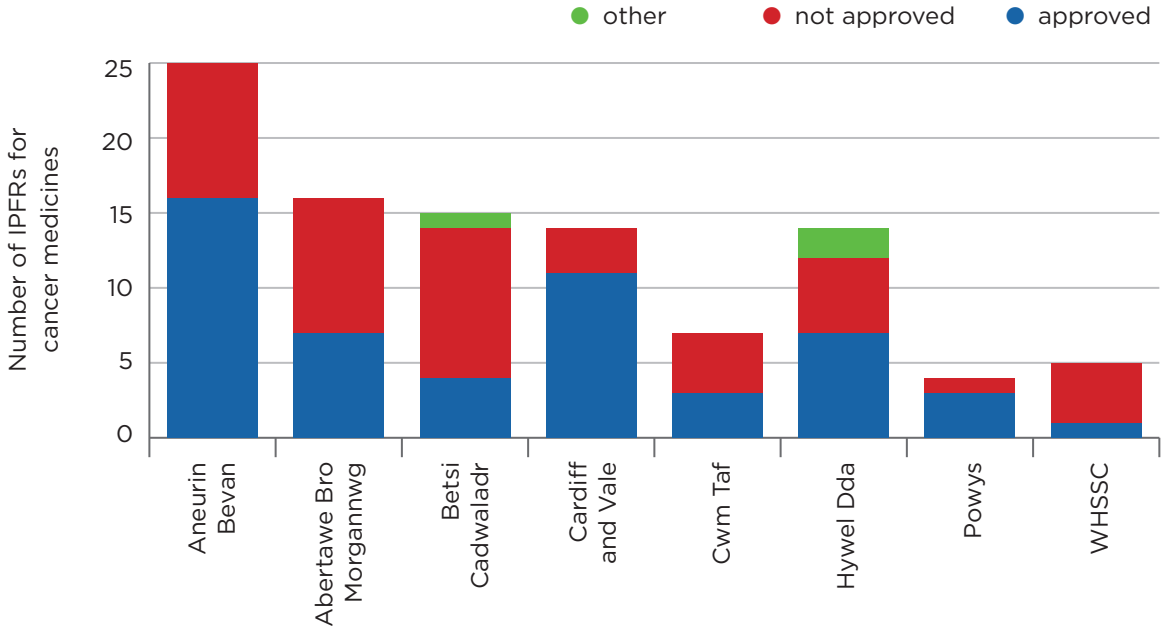
The percentage of IPFRs for cancer medicines within each health board and WHSSC are shown in Figure 8. More than 50% of IPFRs considered by Aneurin Bevan (n = 25) and Abertawe Bro Morgannwg (n = 16), and more than 70% of IPFRs considered by Cardiff and Vale (n = 14) were for cancer medicines. In contrast, fewer than 30% of IPFRs considered by WHSSC (n = 5) were for cancer medicines. Possible reasons for the variation in the percentages of IPFRs for cancer medicines between the health boards may be differences in commissioning arrangements and in the delivery of cancer treatment services. There may also be differences in local policies or treatment pathways and the presence of a minimum cost threshold before a medicine goes to IPFR.

FIGURE 8: 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) from 1 April 2016 to 31 March 2017



The outcome of IPFRs for cancer medicines considered by health boards and WHSSC are shown in Figure 9. At least 50% of IPFRs for cancer medicines were approved by four of the health boards, similar to the previous year.

FIGURE 9: Number of Individual Patient Funding Requests (IPFRs) approved, not approved or with another (other) outcome for cancer medicines within each health board in Wales and the Welsh Health Specialised Services Committee (WHSSC) from 1 April 2016 to 31 March 2017



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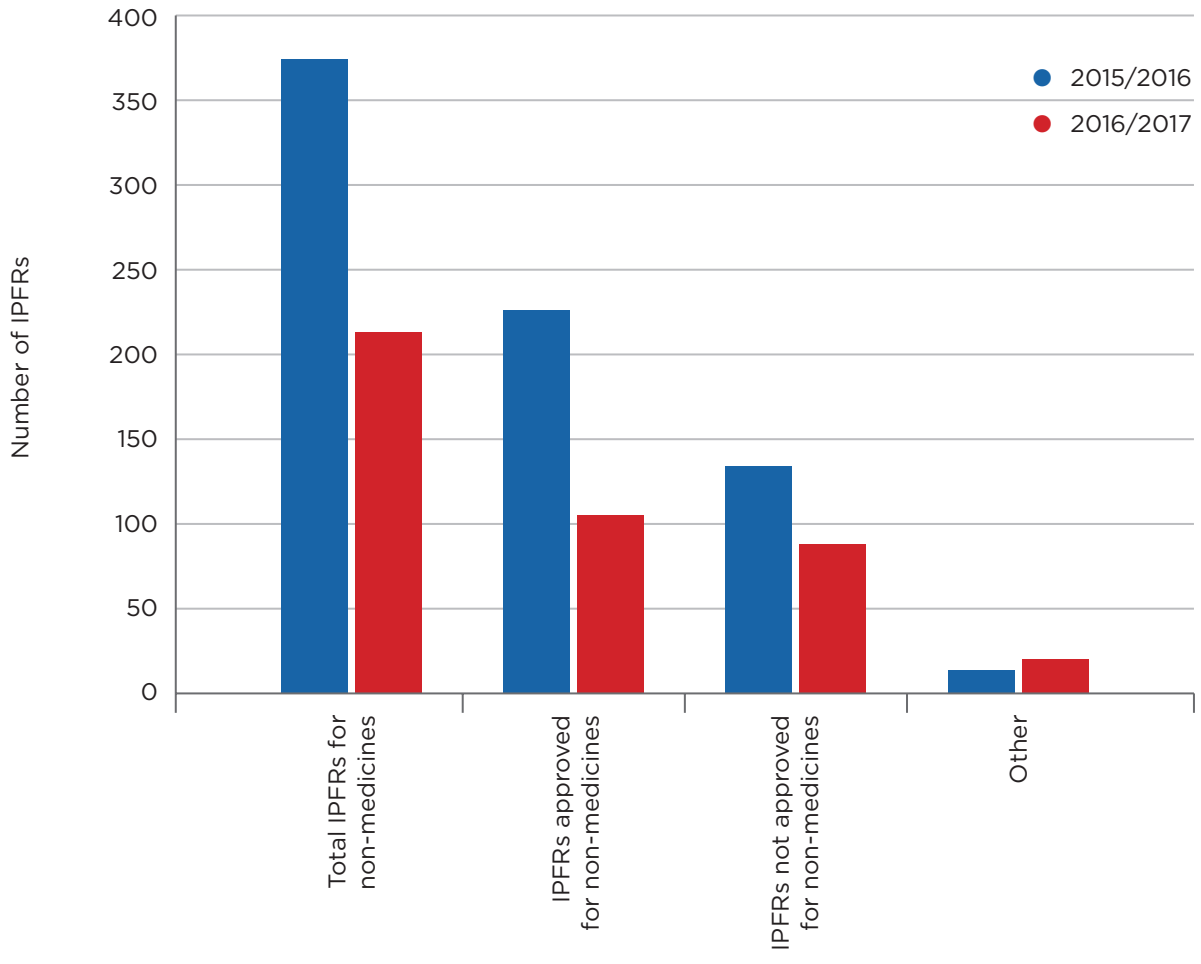
IPFRs for non-medicines by health board and WHSSC

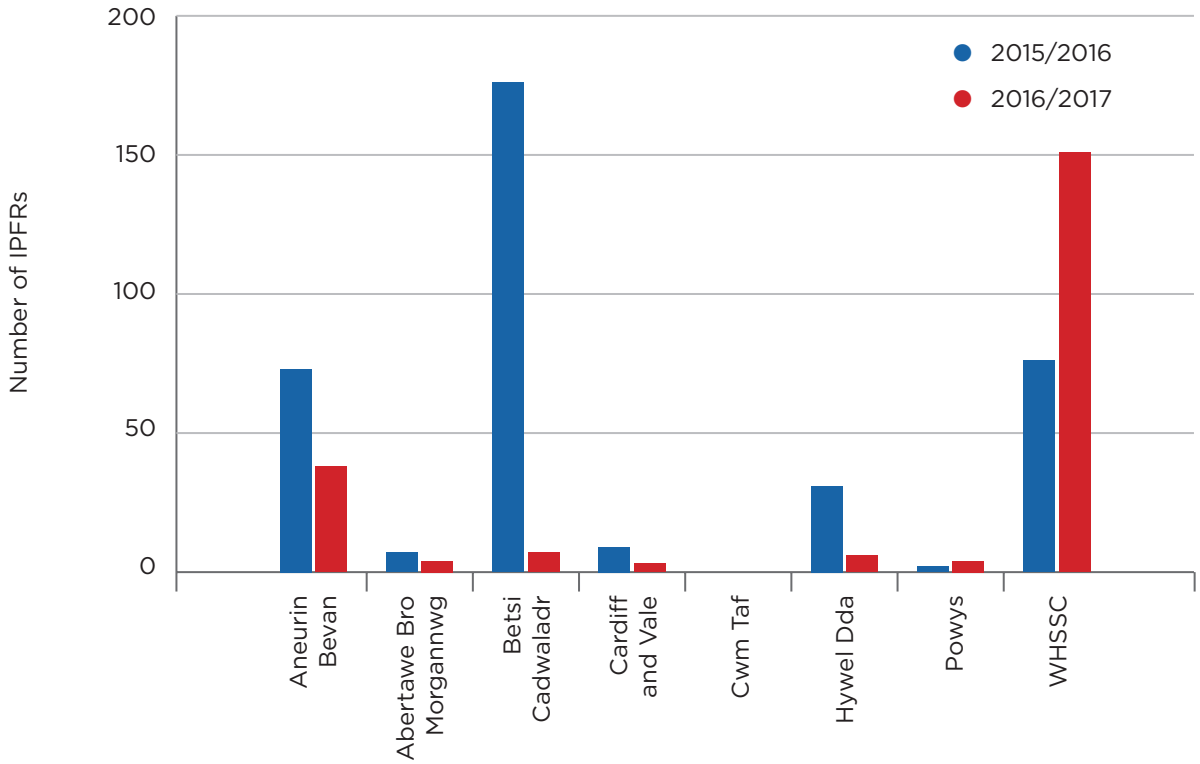
The outcomes of non-medicine IPFRs considered in 2015/16 and 2016/17 are illustrated in Figure 10 below. Of the total IPFRs for non-medicines (n = 213) considered in 2016/17, 105 (49%) were approved and 88 (41%) were not approved. The 'other' outcomes (n = 20; 9%) include IPFRs for non-medicines that 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. These data show a decrease in the number of non-medicine IPFRs from a total of 374 in the previous year. This is partly due to the way that some health boards recorded the IPFR requests; in the previous year some NCAs had been included in the IPFR totals resulting in a misleadingly high number. This has been rectified in 2016/17 and numbers now represent true IPFR requests only. If this discrepancy is taken into account then the data suggest a slight increase in non-medicine IPFRs in 2016/17. Data were not available for 2013/14 and 2014/15 for comparison.

FIGURE 10: Number of Individual Patient Funding Requests (IPFRs) considered for non-medicines in Wales from 2015/2016 to 2016/2017



The highest number of non-medicine IPFRs was considered by WHSSC and none were considered by Cwm Taf Health Board, as shown in Figure 11. The numbers considered by the health board panels in 2016/2017 were relatively low and had decreased compared to the previous year. WHSSC considered the majority (70%) of non-medicine IPFRs in Wales.

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



The number of non-medicine IPFRs considered by WHSSC has increased considerably in 2016/17 compared with the previous year (from 76 to 146 requests). This has been driven by a rise in the number of requests for positron emission tomography (PET) scans which have become an increasingly important investigative tool in the assessment of cancer and non-cancer medical conditions. The service in Wales is commissioned by WHSSC. More information is available on the WHSSC website (**www.whssc.wales.nhs.uk/home**).

In September 2016, WHSSC convened an All Wales PET Advisory Group (AWPET) which includes clinical experts from across Wales. One of its functions is to advise WHSSC on the introduction of new PET indications within the WHSSC commissioning policy ensuring that all decisions are made following a systematic review of the available evidence. This Group has subsequently recommended a list of new PET indications to WHSSC for funding within their 2017/18 Integrated Commissioning Plan due in May 2017.

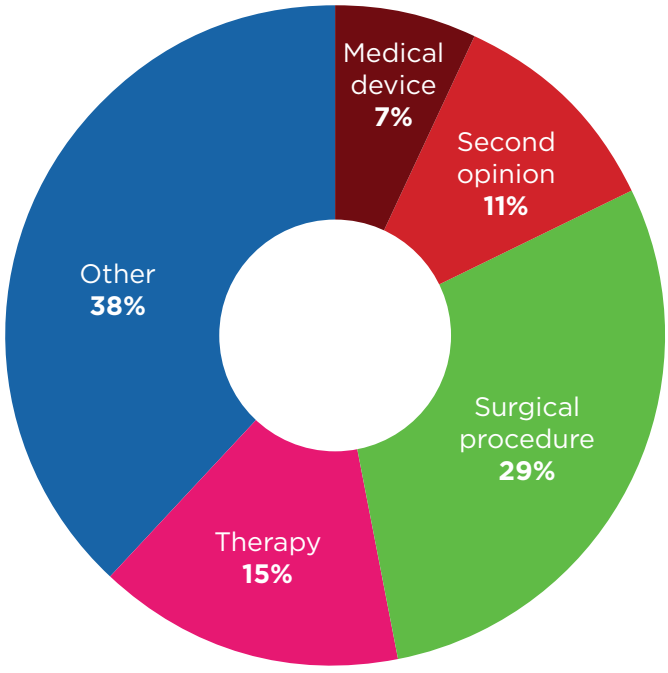
The outcome of this process will determine the extent of new PET indications that are affordable within the funding available for next year. If supported, a revised WHSSC policy will then be issued for consultation and ratification. Subsequent to the ratification of the revised policy and the inclusion of any new indications, we anticipate that the number of IPFRs considered by WHSSC for PET scans will fall.

In addition to this work, Welsh Government, WHSSC and AWPET are now considering the future provision of PET-computerised tomography across Wales, including the resilience of the South Wales service and future demands and capacity.

Non-medicine IPFRs from 1st October 2016 to 31st March 2017

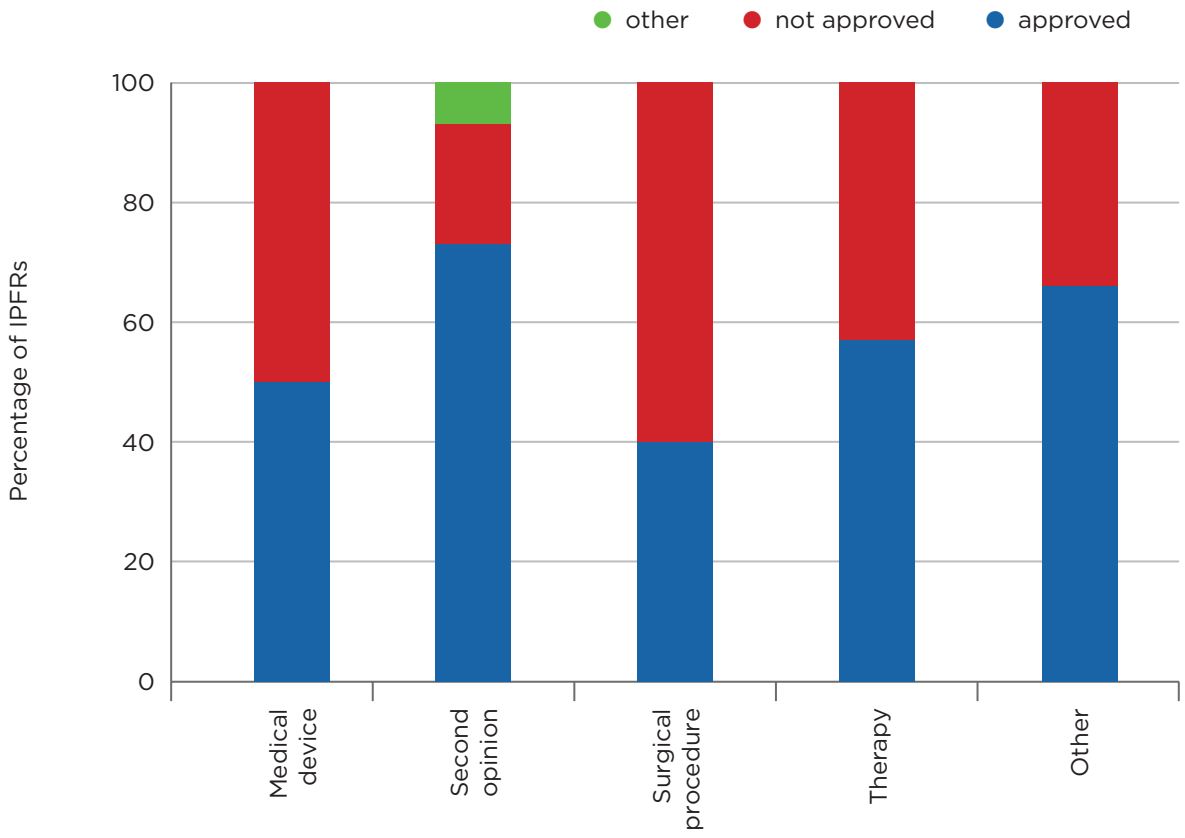
More detailed data are available for the latter half of the 2016/17 report period due to the launch of the national IPFR database on 1st October 2016 which captures information for non-medicines as well as medicine IPFRs. These data enable us to report in more detail than previously on the types of non–medicine IPFR applications considered by panels in Wales. During this six-month period a total of 117 IPFRs were considered for non-medicines of which 67 (57%) were approved, 48 (41%) not approved and 2 (2%) were deferred. Figure 12 shows the percentage of requests for each type of intervention for the period October 2016 to March 2017. The largest number of non-medicine IPFRs were for 'other' interventions (38%). Of these interventions classed as 'other', the majority (76%) 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 and the Welsh Specialised Services Committee (WHSSC) from 1 October 2016 to 31 March 2017



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 second opinions, therapies and 'other' interventions were approved in Wales.

FIGURE 13: Percentage of Individual Patient Funding Requests (IPFRs) for types of non-medicines approved, not approved or with another (other) outcome within each health board in Wales and the Welsh Specialised Services Committee (WHSSC) from 1 October 2016 to 31 March 2017



Of the 117 non-medicine IPFRs considered by health boards and WHSSC between 1st October 2016 and 31st March 2017, a total of 49 (42%) requests were for interventions to diagnose or treat cancer. The majority (55%) of these were for PET (diagnostic) scans, of which 64% were approved.

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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 new One Wales Interim Pathways Commissioning process.

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. The main aim of the One Wales Interim Pathways Commissioning process is to ensure equity of access to medicines not routinely available in NHS Wales for a patient cohort.

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, which 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. A total of 37 medicines covering 50 indications have been considered for the One Wales process. The majority (39 indications) were identified by compiling IPFR data which provided early intelligence of emerging cohorts. In the year 2016/17 seven medicines have been assessed through the One Wales Interim Pathways Commissioning process, with a further two in progress. All decisions will be reviewed 12 months post endorsement. Table 4 shows the One Wales Interim Pathways Commissioning decisions which were endorsed in 2016/17.

Table 4: Current One Wales Interim Pathways Commissioning Decisions			
Medicine	**Indication**	**One Wales Interim Decision**	**Chief Executive endorsement date**
Adalimumab (Humira®)	Treatment of paediatric patients with severe refractory non-infectious uveitis	Supported	11/10/2016
Adalimumab (Humira®)	Treatment of adult patients with severe refractory non-infectious uveitis	Supported	11/10/2016
Arsenic trioxide (TRISENOX®)	Acute promyelocytic leukaemia - 1st line therapy in patients unsuitable for anthracycline-based therapy	Supported	24/10/2016
Axitinib (Inlyta®)	Treatment of advanced renal cell carcinoma after failure of prior treatment with pazopanib	Supported	03/08/2016
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
Denosumab (Prolia®)	Treatment of osteoporosis in men at increased risk of fractures	Supported	06/03/2017
Docetaxel	In combination with androgen deprivation therapy for the treatment of hormone-naive metastatic prostate cancer	Supported	03/08/2016

Of the 50 indications identified, 41 were excluded by AWMSG Steering Committee as they were not considered suitable for One Wales Interim Pathways Commissioning. The rationale for which varied; Table 5 overleaf shows the most common reasons for excluding medicines.

Table 5: Reasons for patient cohorts identified between 1 April 2016 and 31 March 2017 not being considered appropriate for One Wales Interim Pathways Commissioning	
Number of medicines excluded	**Reasons not considered appropriate for One Wales Interim Pathways Commissioning**
14	The medicine was already on either the NICE or AWMSG HTA work programmes
8	NICE or AWMSG positive recommendation published (IPFR requests made before HTA advice had been published)
5	Negative NICE or AWMSG advice published
4	Uncertainty over cohorts, or clinical experts did not identify unmet need
2	Suitable licensed alternative(s) to an off-label medicine available.

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. AWTTC contacted the marketing authorisation holder of two medicines (bevacizumab and Duodopa® [carbidopa monohydrate/levodopa]) and highlighted the clinical need. Both companies then made a commitment to engage with AWMSG's HTA process.

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.

Positive feedback from the clinicians who have engaged in the One Wales Interim Pathways Commissioning process has been received, including the following:

"I am pleased Wales are showing the way, thank you on behalf of our patients." Professor Andrew Dick, Professor of Opthalmology, Moorfields Eye Hospital and Expert Advisor to the IPFR process.

"Please thank the wider One Wales team for so effectively facilitating our participation in your commissioning process it has been great working with you." Dr Richard Lee, Lead for experimental Medicine, Moorfields Eye hospital and Expert Advisor to the IPFR process.

"I was very impressed with how efficiently it [the One Wales process] worked and with the level of interactions in the meeting." Dr Stephen Knapper, Senior Lecturer and Honorary Consultant Haematologist, Cardiff and Vale NHS Trust and Expert Advisor to the IPFR process.

It is noteworthy that the NHS England interim commissioning policy statement 'Adalimumab for severe refractory uveitis', which was published in March 2017, cites the One Wales Interim Pathways Commissioning decision for adalimumab in this indication as a document which has informed the policy in England.

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

Grounds for approval

In developing a common dataset as part of the review recommendations, AWTTC can report that, of the 125 IPFR cases for medicines approved in 2016/17, "exceptionality" (the criterion required at that time) was recorded to have been demonstrated in 105 cases and not demonstrated in 20 cases.

The reasons for approving an IPFR varied but there were common rationales which are shown in Table 6.

Table 6: Reasons for approval of Individual Patient Funding Requests for medicines between 1 April 2016 and 31 March 2017 in rank order
The patient had demonstrated a lack of response or refractory disease to the standard available treatment options/pathway
The patient had an unusual variant of the disease
There are no standard available treatment options or no licensed treatment options for the condition
The patient's condition is more severe or had progressed more quickly than is usual in the general population
Co-morbidity contraindicated the usual recommended treatment for a condition
The patient had experienced a severe adverse reaction to the normally recommended treatment for the condition
The patient had demonstrated an unusually good response to this treatment/efficacy greater than in the general population

In cases where exceptionality had not been proven and treatment was approved, access had been granted on grounds of:

- good governance
- treatment recommended by national centre of excellence
- treatment is an accepted choice by professional body guidelines
- continuation of treatment previously approved
- treatment is in line with NHS England commissioning policy.

Common reasons for not approving an IPFR are shown in Table 7 overleaf.

Table 7: Reasons for not approving Individual Patient Funding Requests for medicines between 1 April 2016 and 31 March 2017 in rank order
Patient presented with normal disease progression
There was a lack of sufficient evidence for exceptionality provided in the application form
Lack of evidence for use of the treatment in the particular presentation
Patient had not exhausted the alternative treatments available
Conflicting evidence on whether the treatment might do more harm than good
Patient had adherence (compliance) issues with existing treatment

IPFR workshop

In the past 12 months AWTTC has held two full day IPFR workshops. The days were open to IPFR panel members and clinicians with an interest in learning more about the work of IPFR. Areas covered in the workshop included:

- critical appraisal, in particular health economics looking at costs and quality-adjusted life years
- legal issues in relation to IPFR and the impact of the 2016 review recommendations on the IPFR policy
- ethical consideration of moving from the term 'exceptional' to 'significant clinical benefit' and 'value for money'
- an update on the progress made with the 2014 review recommendations
- an update on the One Wales Interim Pathways Commissioning process.

The afternoon sessions of both workshops enabled attendees to group into mock IPFR panels and consider example IPFR cases. The aim of these sessions was to encourage panel members to share experiences across health boards, develop good practices and demonstrate consistency of decision making. It also provided the opportunity for panel members to network and develop links across health boards.

In response to feedback from the April 2016 workshop, in March 2017 delegates were sent the cases for the mock IPFR panels prior to the day. This was well received and the panels felt they had sufficient time to evaluate cases in the afternoon.

In total approximately 120 delegates attended the two workshops with IPFR panel representatives from all of the Health Boards in Wales and WHSSC. Representatives from the Welsh Government and Public Health Wales were also in attendance. The presentations from the 2017 workshop can be accessed on the AWTTC website (**www.awttc.org/pams/individual-patient-funding-request-ipfr-0**).

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Patient outcomes

Of the data collected during 2016/17 patient outcome information was available for only 16 people, 8 associated with medicine IPFRs and 8 with non-medicines. These outcomes are summarised below:

- Seven individuals improved in association with the approved treatment
- Three individuals did not improve
- Three people died (it should be noted that no delays in treatment were recorded for any person)
- Three outcomes were recorded as "not deceased" with either no further information or that outcome feedback was too early to assess

The collection of outcome data is very important in order to monitor and analyse whether or not a treatment has been effective. It will be a mandatory (essential) part of the IPFR reporting process in the future. In addition, the IPFR policy has been updated to reflect the requirement for (and obtain a commitment from) the requesting clinician to provide outcome data as part of the IPFR application process. AWTTC will continue to work with IPFR panels to encourage capture of reported outcomes.

13 Independent review of an IPFR decision

For IPFRs that are declined 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 the following grounds:

- the Health Board has failed to act fairly and in accordance with the All Wales Policy on making decision 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 the 1st April 2016 to 31st March 2017 three requests for a review of the IPFR process followed were referred to review panels. Two requests for a review were received for the same application. The review panel did not uphold the grounds of the review and concluded that the process had been followed correctly and in accordance with the IPFR policy. In the third case the review panel upheld the grounds of the review and asked the original panel to reconsider the request. The application was later approved for funding by the IPFR panel.

Summary of the data

Overall the data for 2016/17 indicate:

- a decline in the number of IPFRs across Wales compared with previous years

Possible reasons for the decline in requests for medicines may be a greater awareness of HTA advice, or a better understanding of the most appropriate routes for accessing a medicine. In addition, following publication of positive One Wales Interim Pathways Commissioning decisions, IPFR applications were no longer submitted for these indications.

- Health boards approved a similar number of IPFRs for cancer medicines in 2015/16 compared with previous years.
- The most commonly requested medicines were for the treatment of cancer and in that group of medicines, bevacizumab remains the most commonly requested cancer medicine via IPFR.
- The most common non-medicine requests were for PET scans of which the majority were for patients with cancer-related circumstances.

In compiling this 2016/17 report, from April to September 2016 health boards have submitted information to AWTTC on a regular basis. In October 2016 the new IPFR database was launched and AWTTC can access all non-patient-identifiable data for all health boards and WHSSC centrally. This was combined with the first six months of data to produce this report. For the 2017/18 report all of the data will be captured on the new IPFR database.

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Glossary and additional note

AWMSG	All Wales Medicines Strategy Group
AWPET	All Wales PET Advisory Group
AWTTC	All Wales Therapeutics and Toxicology Centre
CHC	Community Health Council
HTA	Health Technology Appraisal
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
NCAs	Non-contracted activities
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NWIS	NHS Wales Informatics Service
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.