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

Individual Patient Funding Request (IPFR)

Annual Report 2018/2019

GIG CYMRU NHS WALES

PAMS
Patient Access to Medicines Service
Mynediad Claf at Wasanaeth Meddyginiaethau

Contents

AWTTC Clinical Director's statement

2018/2019 – A year of aiming for greater clarity, transparency and quality assurance of the Individual Patient Funding Request process.

Professor Philip Routledge
CBE MD FRCP FLSW

Clinical Director, All Wales Therapeutics and Toxicology Centre

The work during 2018/2019 has continued to focus on implementing the recommendations of the extremely valuable second independent review of the individual patient funding request (IPFR) process led by Andrew Blakeman and published in January 2017. Resources supporting the IPFR process can be found on a dedicated webpage at www.awttc.org/ipfr. These resources include a short animated video for patients and clinicians explaining the IPFR process, frequently-asked questions on the IPFR processes and the alternative commissioning routes of access to medicines and non-medicines in Wales, and previous IPFR annual reports.

The IPFR electronic e-submission system can now 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 resources to support applications for IPFRs. A help function is embedded in to the system to assist the clinician through the completion of the application. As of March 2019, this system has been in operation for nine months and the feedback has been that it is helping to reduce the administrative burden on clinicians and IPFR teams and improve the timely processing of IPFR applications.

The IPFR Quality Assurance Advisory Group has met quarterly since January 2018. The terms of reference of the group can be viewed on the AWTTC website at www.awttc.org/ipfr/ipfr-quality-assurance-advisory-group and it reports to the Head of Pharmacy and Prescribing at the Welsh Government. The group assesses sample IPFRs from across all panels in Wales to audit how well the panels are adhering to the nationally-agreed process. It has been encouraging to see how panels are seeking to meet these requirements in a clear and robust manner.

The One Wales Interim Pathways Commissioning Group (IPCG) is continuing to address major cohort commissioning issues in Wales. Between 1 April 2018 and 31 March 2019, one medicine was assessed through the One Wales Interim Commissioning Process, three medicines were reviewed 12 months after endorsement of the initial recommendation, and five medicines were reviewed for the second time since initial endorsement.

After 38 years working in NHS Wales, I retire this year. My sincere thanks go to all the highly dedicated IPFR administrative teams and IPFR Panel Chairs and members across Wales, the superb IPFR/One Wales team at AWTTC in University Hospital Llandough and members of the One Wales IPCG and IPFR Quality Assurance Advisory Group. I am grateful to the UHB Chief Executives for their continued support of the One Wales process, and Dr Sharon Hopkins, Chair of the One Wales IPCG (May 2016 to June 2019) and Ann-Marie Matthews, lead IPFR Coordinator for their wise advice and counsel.

2

Executive Summary

- There has been a continuing annual decline in the number of IPFRs across Wales. In 2018/2019, there were approximately 6% fewer IPFRs compared with the previous year (a decrease from 383 requests to 358 requests). This reduction was mainly due to a decline in medicine-related requests (from 153 requests in 2017/2018 to 101 requests in 2018/2019). The decline is likely to be multifactorial and may include greater awareness by the submitting clinicians of health technology assessment (HTA) advice, or 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 2018/2019 (68%) compared with the previous year (63%). The approval rate for medicines varied between IPFR panels. The overall approval rate for medicines was 71% in 2018/2019, this rate has increased annually over the last four years. The overall approval rate for non-medicines was 66% in 2018/2019, and has increased annually over the last three years. The increase in approval rate may be due to more thorough completion of the IPFR application form and fewer inappropriate IPFR submissions.
- Health boards approved a similar number of IPFRs for cancer medicines compared with previous years.
- Bevacizumab was the most commonly requested medicine via IPFR in Wales in 2018/2019. This medicine replaced pertuzumab as the most commonly requested medicine in 2017/2018.
- As in the previous year, the most common non-medicine requests were for positron emission tomography (PET) scans. The majority of these were for the detection or investigation of cancers.
- There has been an increase in outcome data provided from clinicians, however encouragement is still needed to improve reporting of outcome data to IPFR panels.
- The Quality Assurance Advisory Group continue to be impressed with the documentation and adherence to processes by IPFR panels in Wales. Recommendations have been shared to all panels to further improve the consistency of the process across the service.
- The recommendations of the 2017 independent review report have been implemented. AWTTC continues to support the work of IPFR panels in Wales.

Background

A comprehensive range of NHS healthcare services are routinely provided across health boards in Wales. The Welsh Health Specialised Services Committee (WHSSC), working on behalf of the seven health boards in Wales, commissions specialised services at a national level.

However, each year, 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.

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.

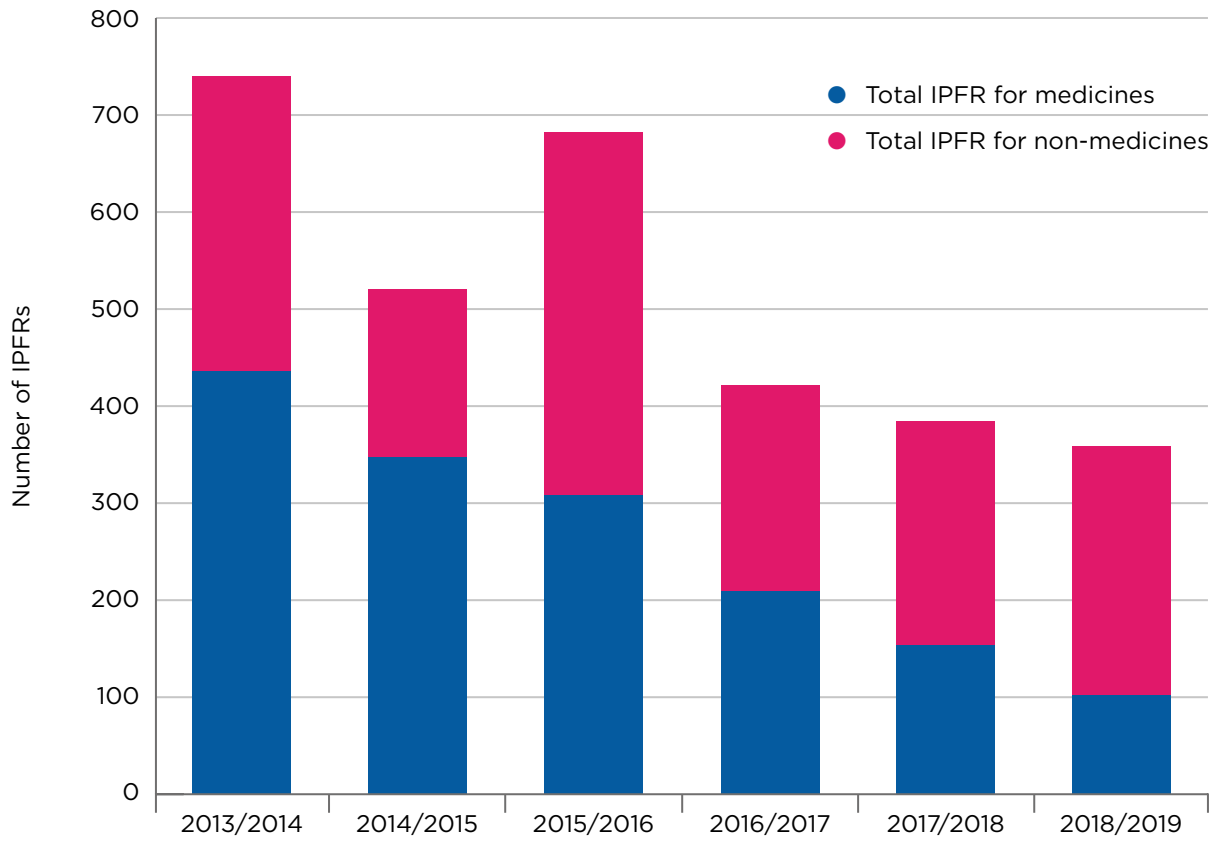
In September 2016, following a 2014 review and implementation of its recommendations, the Cabinet Secretary for Health and Social Services agreed the time was right for a new, independent review of the IPFR process. A panel, independent of the Welsh Government and encompassing a range of expertise and knowledge, was convened and published a report in January 2017. A copy of the report can be found at www.gweddill.gov.wales/docs/dhss/publications/170117ipfrreporten.pdf. The 2017/2018 IPFR annual report, found at www.awttc.org/ipfr, provides detail on the implementation of these recommendations. This work was completed in 2018/2019. AWTTC continues to support these recommendations through quality assurance, IPFR database updates and developments, monitoring of cohorts of medicines for One Wales and hosting the annual IPFR workshop.

IPFRs

Data for this annual report have been collated entirely from the national IPFR database which was launched on the 1 October 2016. In April 2019 a boundary change came into effect creating Swansea Bay University Health Board and Cwm Taf Morgannwg University Health Board. The data in this report are unaffected by this change; Abertawe Bro Morgannwg University Health Board and Cwm Taf University Health Board were still in effect up to the data cut off of 31 March 2019.

A total of 358 IPFRs were considered between 1 April 2018 and 31 March 2019; 100 were for medicines, 257 were for non-medicines and 1 was for a medicine and a non-medicine within the same application (Figure 1). The number of requests for medicines has continued to decrease annually since 2013/2014. The number of requests for medicines in 2018/2019 decreased by 34% compared with the previous year, and by 77% compared with 2013/2014, as shown by the blue bars in Figure 1.

FIGURE 1: Total number of Individual Patient Funding Requests (IPFRs) considered in Wales from 2013/2014 to 2018/2019

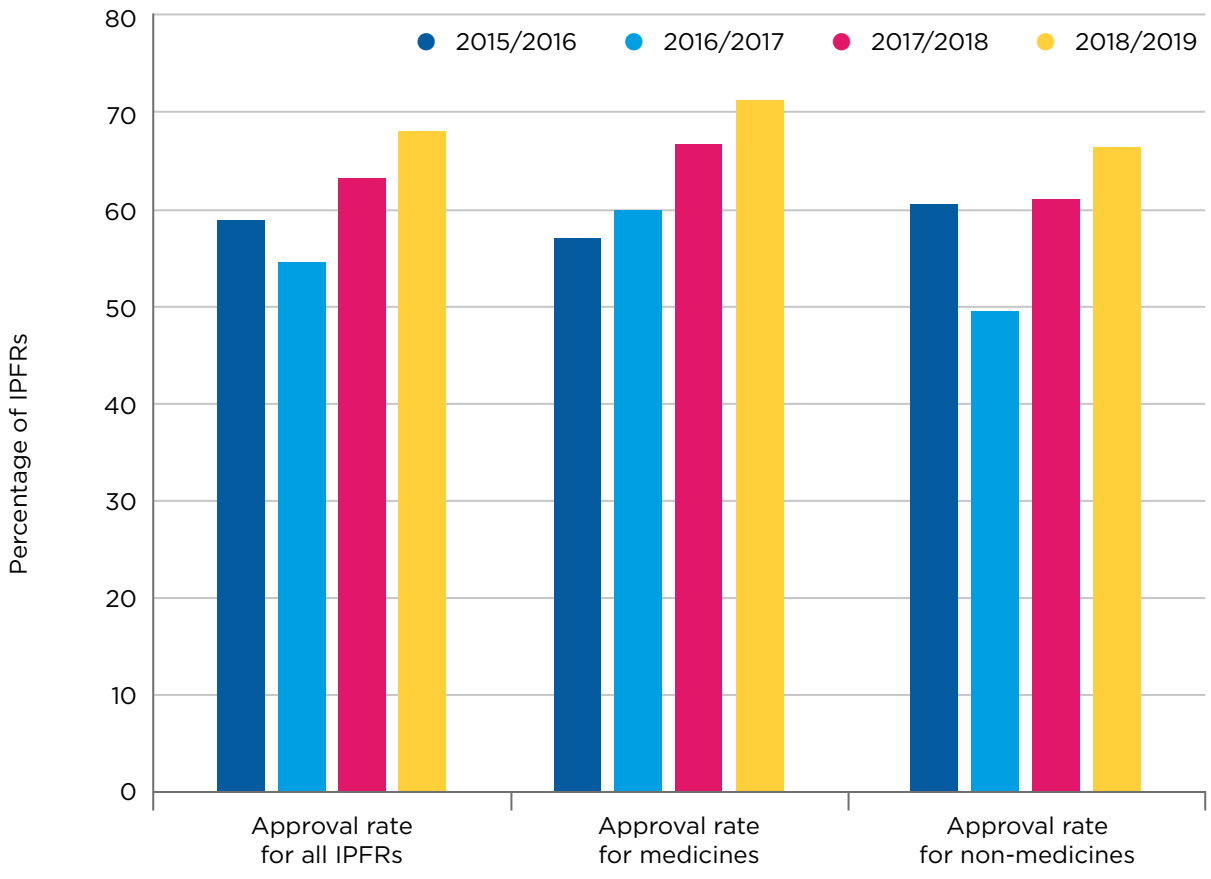


In contrast, the number of requests for non-medicines fluctuated over the same period, with the greatest number of requests occurring in 2015/2016 (n = 374; Figure 1). Over the past three years, the number of requests for non-medicines has gradually increased annually.

Overall, 68% of IPFRs were approved in 2018/2019 (Figure 2). The approval rate has continued to increase annually since 2016/2017. For medicines, the approval rate was 71% in 2018/2019 which has increased annually over the last four years (Figure 2). The approval rate for non-medicines was 66% in 2018/2019 which has increased annually since 2016/2017, as shown in Figure 2.

In addition to these requests, in 2018/2019 there were 28 continued funding requests for medicines and 6 requests for non-medicines. Continued funding requests are for medicines or non-medicines which had previously been approved and now require an extension to that treatment.

FIGURE 2: Percentage of Individual Patient Funding Requests (IPFRs) approved in Wales from 2015/2016 to 2018/2019



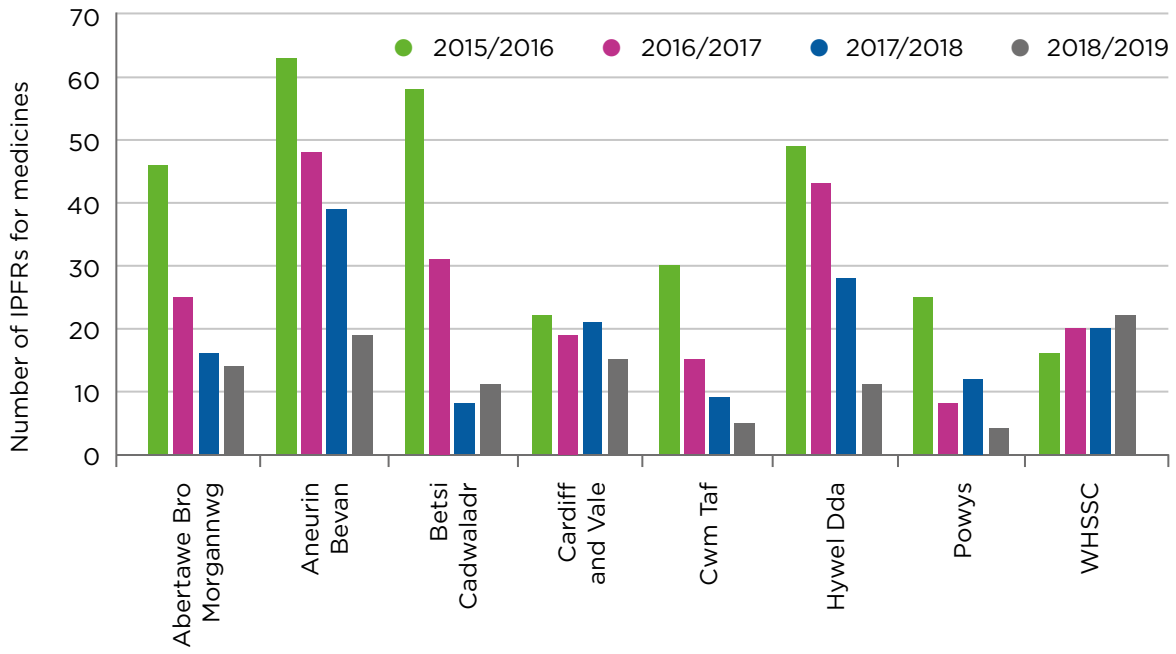
5 IPFRs for medicines by health board and WHSSC

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

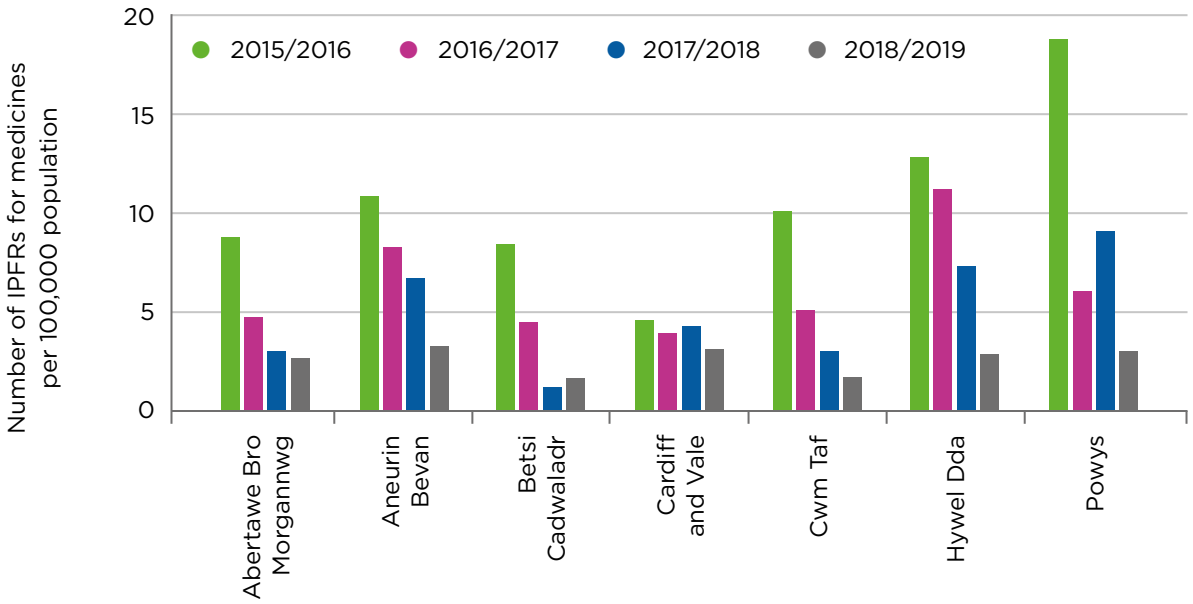
The highest absolute number of IPFRs for medicines in 2018/2019 were considered by WHSSC (n = 22) and the fewest were considered by Powys Teaching Health Board (n = 4), as shown in Figure 3. In the previous year, Aneurin Bevan University Health Board considered the highest number of IPFRs for medicines (n = 39), and Betsi Cadwaladr University Health Board considered the fewest (n = 8; Figure 3). The number of IPFRs considered by four health boards has decreased annually over the last four years. Betsi Cadwaladr University Health Board had an increase in the number of IPFRs for medicines considered in 2018/2019 compared to the previous year. The number of IPFRs for medicines considered by WHSSC has increased over the last four years.

FIGURE 3: Number of Individual Patient Funding Requests (IPFRs) for medicines within each health board in Wales, including the Welsh Health Specialised Services Committee (WHSSC), from 2015/2016 to 2018/2019



To acknowledge the different population sizes within each health board, these data were expressed as IPFRs 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 2018/2019

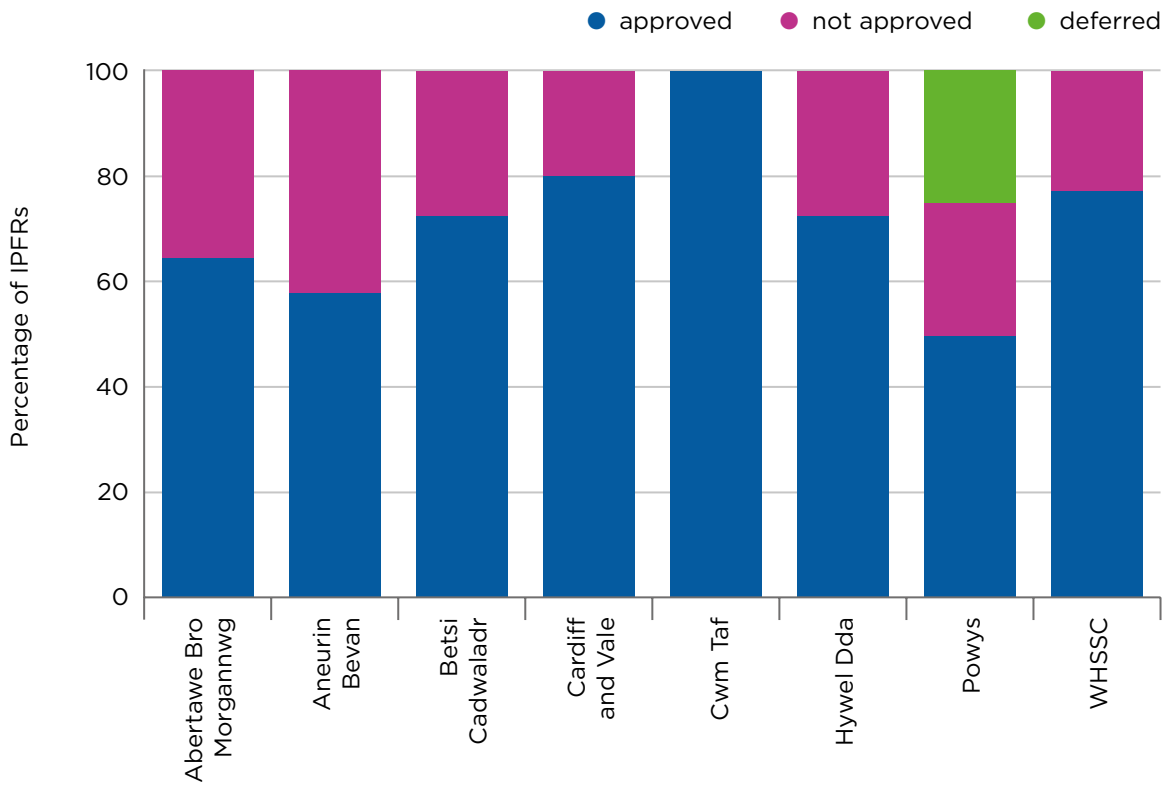


In 2018/2019, the number of IPFRs for medicines per head of population were similar across all health boards. Abertawe Bro Morgannwg, Aneurin Bevan, Cardiff and Vale, Hywel Dda and Powys Health Boards received the highest number of IPFRs for medicines per head of population (3 per 100,000 population). Betsi Cadwaladr and Cwm Taf Health Boards received 2 IPFRs for medicines per 100,000 population. In the previous years, the number of IPFRs for medicines per head of population varied widely between health boards. In 2017/2018, Powys Teaching Health Board received the highest number of IPFRs for medicines per head of population (9 per 100,000 population) and Betsi Cadwaladr considered the fewest number of IPFRs (1 per 100,000 population).

The outcome of IPFRs for medicines considered by each health board and WHSSC in 2018/2019 are shown in Figure 5. Over the last four years, the percentage of IPFRs for medicines approved by Cwm Taf University Health Board has increased annually, concurrent with an annual decrease in the total number of IPFRs. The percentage of IPFRs for medicines approved by the other health boards and WHSSC have fluctuated over the last four years. Abertawe Bro Morgannwg and Cardiff and Vale University Health Boards had an increase in the percentage of IPFRs approved for medicines in 2018/2019 compared with the previous year. The remaining four health boards and WHSSC had a decline (ranging from 1% to 16%) in the percentage of IPFRs approved for medicines in 2018/2019 compared with the previous year.

The 'deferred' 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. One (25%) IPFR was deferred by Powys Teaching Health Board panel.

FIGURE 5: Percentage of Individual Patient Funding Requests (IPFRs) for medicines approved, not approved, or deferred within each health board in Wales and the Welsh Health Specialised Services Committee (WHSSC) from 1 April 2018 to 31 March 2019



The medicines most frequently considered annually between 1 April 2013 and 31 March 2019 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. This is the case for pertuzumab, which was a frequently requested medicine from 2015/2016 to 2017/2018, and since publication of NICE guidance in March 2018, pertuzumab was not a commonly requested medicine via IPFR (Table 1). Additionally, since the launch of the One Wales Interim Commissioning Process in 2016, suitable medicines/indications have been assessed via this route and the IPFR route was therefore 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 (Table 1). The advent of the One Wales Interim Commissioning Process may also in part explain why only three medicines were requested more than five times in 2018/2019, 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**	**2018/2019**
Bevacizumab	Bevacizumab	Bevacizumab	Bevacizumab	Pertuzumab	Bevacizumab
Cetuximab	Axitinib	Cetuximab	Rituximab	Rituximab	Rituximab
Rituximab	Brentuximab	Adalimumab	Adalimumab*	Bevacizumab*	Abiraterone
Axitinib	Bendamustine	Pertuzumab	Omalizumab*	Ibrutinib*	NR
Adalimumab*	Cetuximab	Rituximab*	Pertuzumab	Daratumumab	NR
Eribulin*	NR	Bendamustine*	Infliximab*	NR	NR
Infliximab*	NR	Trastuzumab emtansine	Nivolumab*	NR	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

Annually, rituximab has been one of the most commonly approved, and bevacizumab one of the most commonly not approved, medicines since 2015/2016.

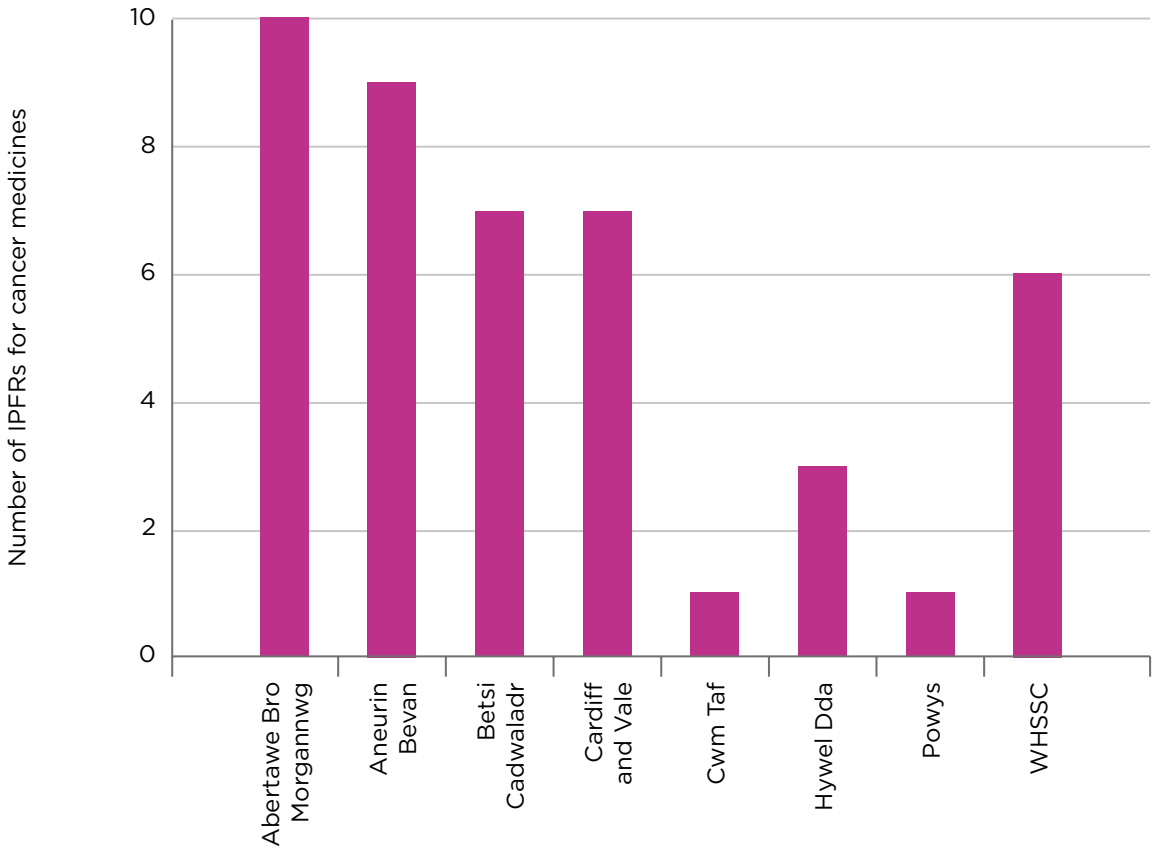
6

IPFRs for medicines for the treatment of cancer

As per the previous year, almost half (44%) of the medicines requested via IPFR in 2018/2019 were for the treatment of cancer.

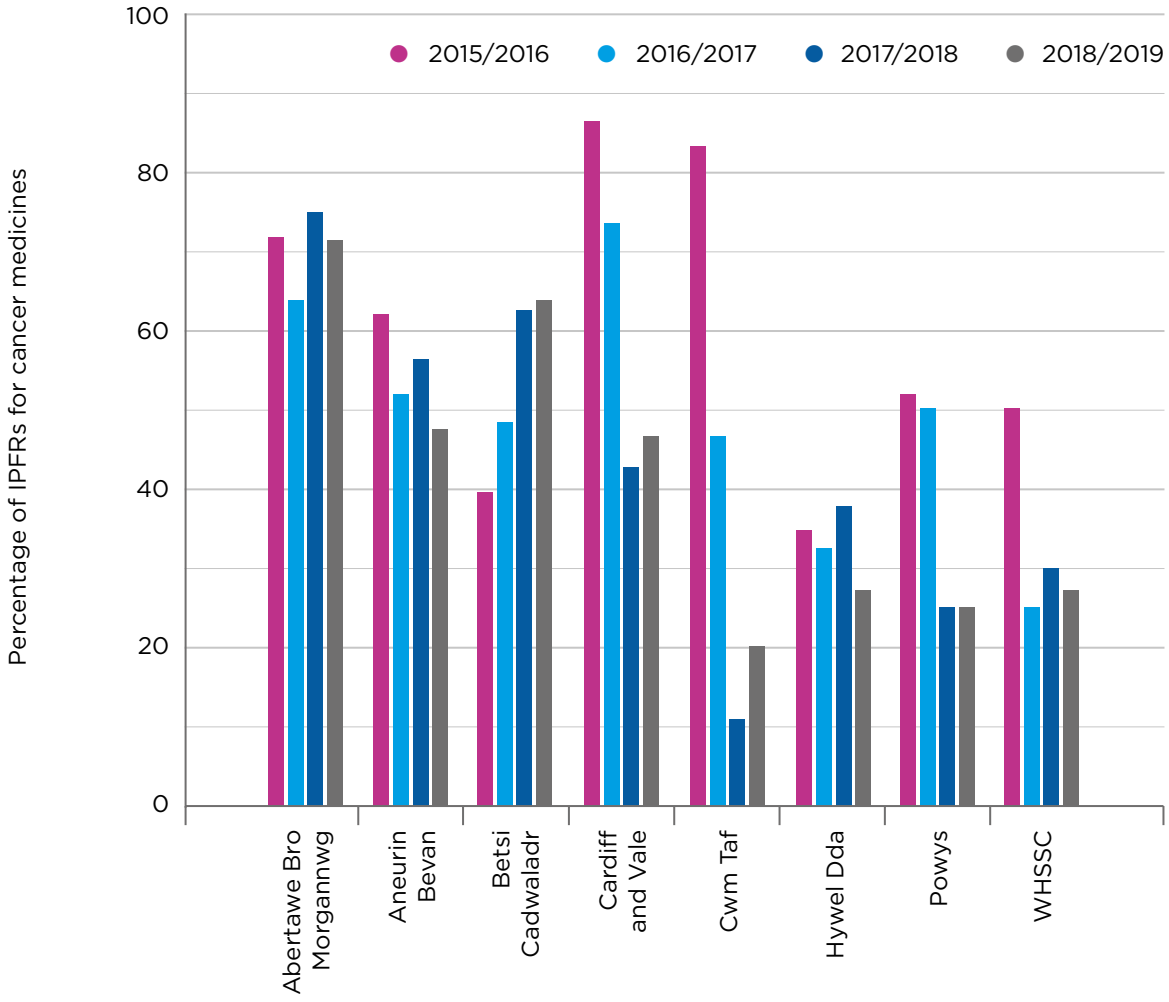
The greatest number of IPFRs for medicines for the treatment of cancer were received by Abertawe Bro Morgannwg University Health Board (n = 10) and the fewest were submitted in Cwm Taf University and Powys Teaching Health Boards (n = 1), as shown in Figure 6.

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 2018 to 31 March 2019



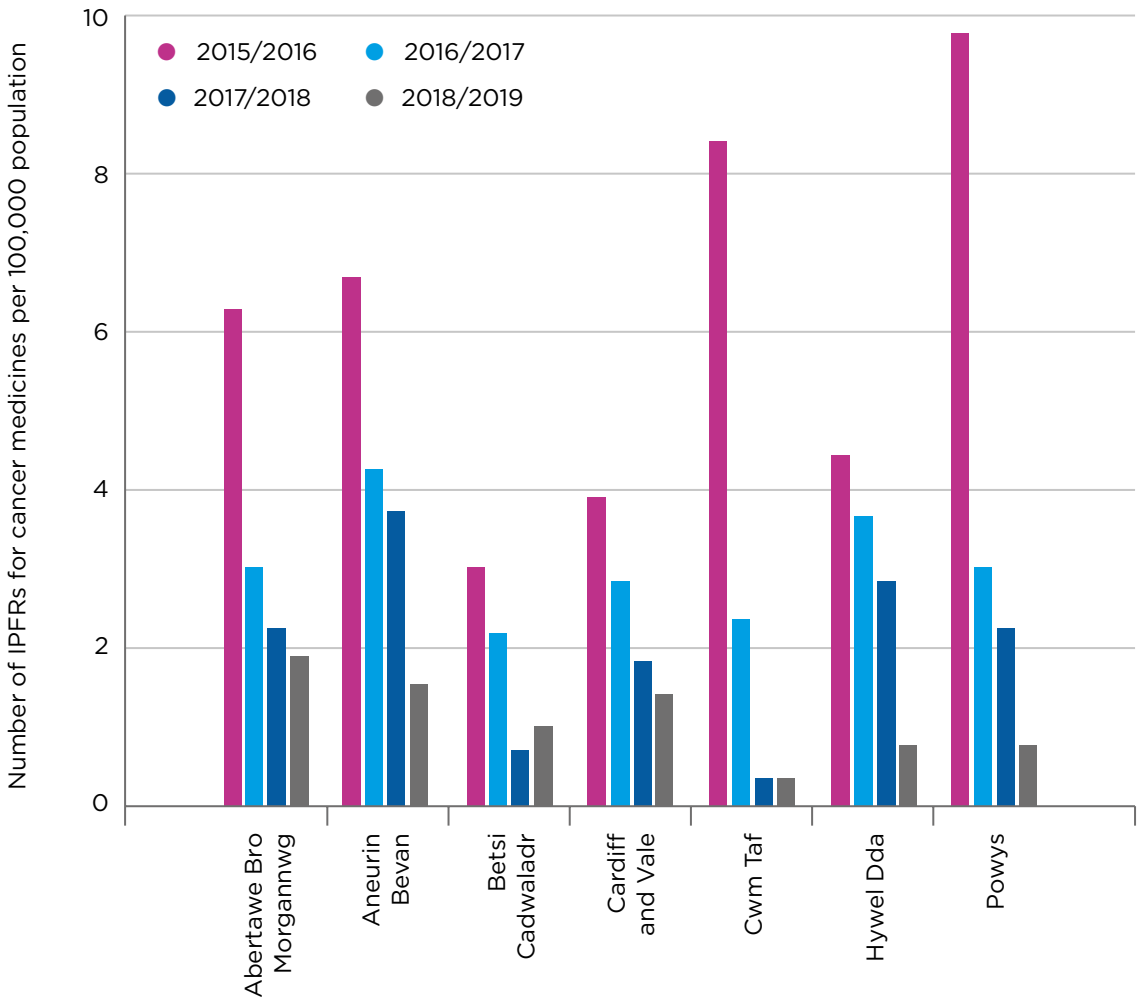
The percentage of IPFRs for cancer medicines slightly increased in 2018/2019 compared with the previous year in three health boards, as shown in Figure 7. The greatest increase was in Cwm Taf University Health Board, an approximate 10% increase compared with the previous year. However, it is important to note that the number of IPFRs considered by this Health Board has almost halved, from nine in 2017/2018 to five in 2018/2019. Therefore 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 Betsi Cadwaladr University Health Board since 2015/2016. Abertawe Bro Morgannwg, Aneurin Bevan and Hywel Dda Health Boards and WHSSC received between 3% and 11% fewer IPFRs for cancer medicines in 2018/2019 compared with the previous year. Although Powys Teaching Health Board had the same percentage of IPFRs for cancer medicines in 2018/2019 as in the previous year, the total number of IPFRs for medicines considered by this Health Board has decreased by a third, from 12 in 2017/2018 to 4 in 2018/2019.

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 2018/2019



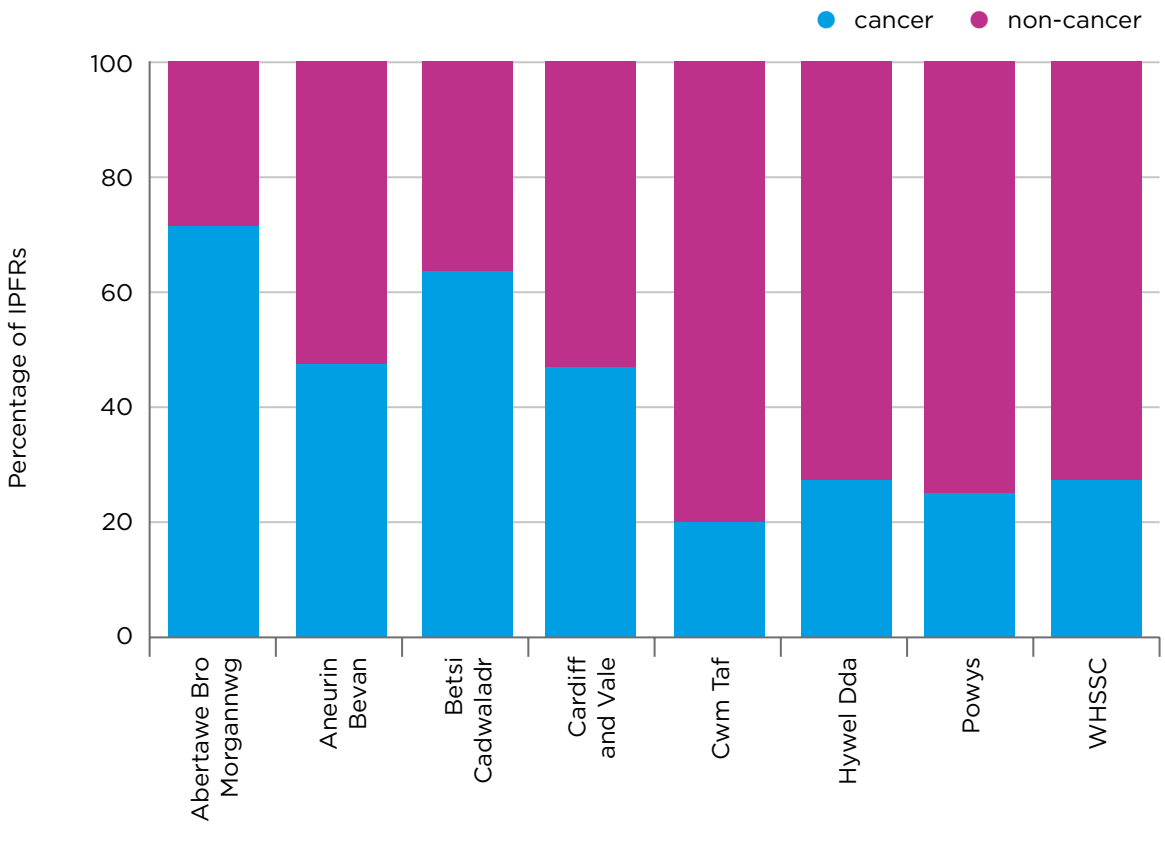
The data were also expressed as the number per 100,000 population in each health board and are shown in Figure 8. In 2018/2019, all health boards had fewer than 2 IPFRs for cancer medicines per 100,000 population. Abertawe Bro Morgannwg University Health board received the greatest number of IPFRs for cancer medicines per 100,000 people (n = 1.9) and Cwm Taf University Health Board received the fewest (n = 0.3). The number of IPFRs for cancer medicines per 100,000 people has decreased annually in five health boards since 2015/2016. Since January 2017 medicines added to the Cancer Drugs Fund list are funded in Wales through the New Treatment Fund which may explain this reduction in requests. Cwm Taf University Health Board had the same number of IPFRs for cancer medicines per 100,000 people in 2018/2019 compared with the previous year, and Betsi Cadwaladr University Health Board had a small increase.

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 2018/2019



The percentage of IPFRs for cancer medicines within each health board and WHSSC are compared to non-cancer medicines in Figure 9. More than half of IPFRs considered by Abertawe Bro Morgannwg (71%) and Betsi Cadwaladr (64%) University Health Boards were for cancer medicines. In contrast, 30% or fewer IPFRs considered by Cwm Taf University, Hywel Dda University and Powys Teaching Health Boards, and WHSSC 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 and the presence of a minimum cost threshold before a medicine goes to IPFR.

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 2018 and 31 March 2019



In 2018/2019, at least 50% of IPFRs for cancer medicines were approved by all health boards and WHSSC, with the exception of Powys Teaching Health Board which only considered one cancer medicine and for which the decision was deferred. 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.

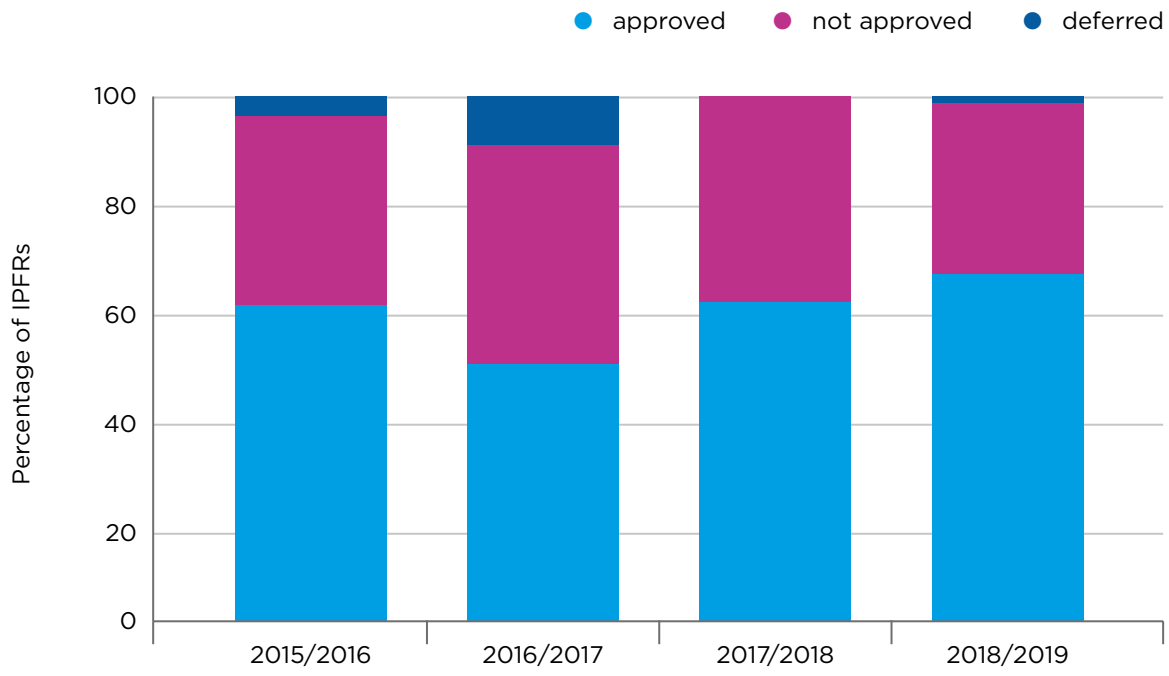
7

IPFRs for non-medicines by health board and WHSSC

The number of non-medicine IPFRs increased slightly in 2018/2019 (n = 258) compared with the previous year (n = 230; Figure 1). The number of requests has fluctuated over the last five years ranging from 173 requests in 2014/2015 to 374 requests in 2015/2016. Over the last three years, the number of requests has steadily increased annually.

The outcomes of non-medicine IPFRs considered between 2015/2016 and 2018/2019 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 considered in 2018/2019 (n = 258), 171 (66%) were approved, 84 (33%) were not approved and 3 (1%) were deferred. Deferred outcomes 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 the required information. In 2018/2019, the percentage of IPFRs approved increased by 5% compared with 2017/2018. The percentage of IPFRs approved has increased annually over the last three years (Figure 10).

FIGURE 10: Percentage of non-medicine Individual Patient Funding Requests (IPFRs) approved, not approved, or deferred from 2015/2016 to 2018/2019



In 2018/2019, the highest number of non-medicine IPFRs were considered by WHSSC (n = 185; Figure 11). The number of non-medicine IPFRs considered by WHSSC has more than doubled since 2015/2016 (n = 76). In contrast, in 2018/2019 the number of non-medicine IPFRs considered by the health boards is less than 10, with the exception of Aneurin Bevan University Health Board which was 45. The numbers considered by the health boards remained relatively consistent with the previous year (Figure 11).

FIGURE 11: Number of Individual Patient Funding Requests (IPFRs) for non-medicines within each health board in Wales, including the Welsh Health Specialised Services Committee (WHSSC) from 2015/2016 to 2018/2019

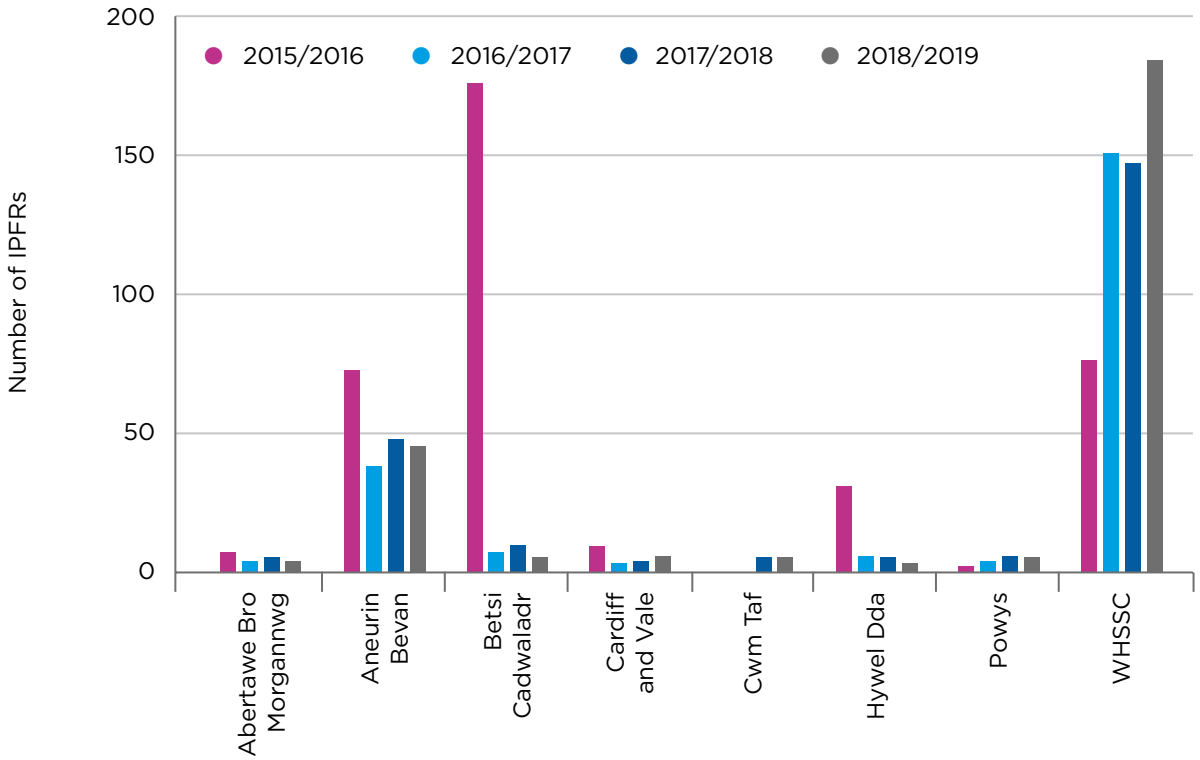


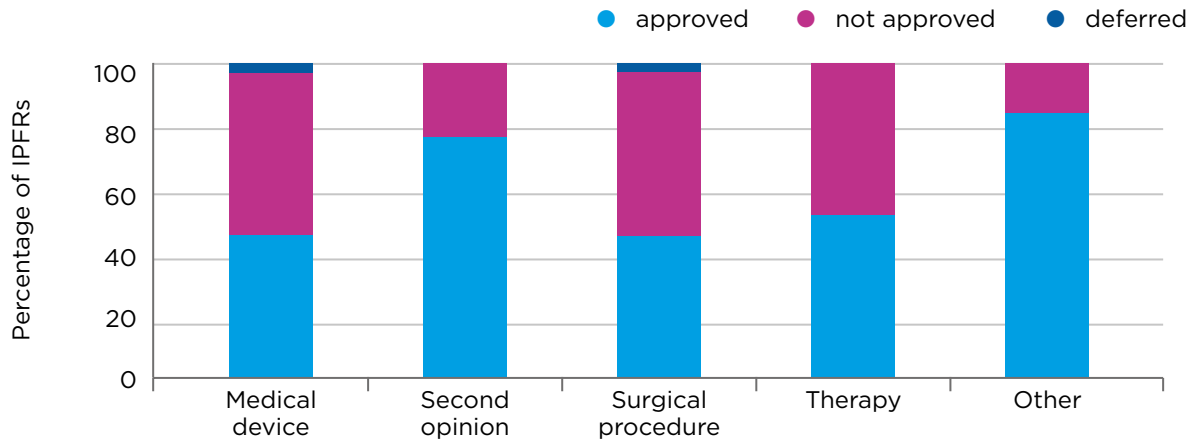
Figure 12 shows the percentage of requests for each type of intervention for the period April 2018 to March 2019. The largest number of non-medicine IPFRs were for 'other' interventions (43%). Of these interventions classed as 'other', the majority (80%) are for PET scans. This reflects a small number of commissioned PET indications in Wales compared with elsewhere in the UK. WHSSC has recently reviewed and updated their PET-Computed Tomography policy and it was published on 3 June 2019. The revised policy includes several newly funded indications and it is anticipated that the number of IPFRs for PET will now fall considerably. 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 the Welsh Health Specialised Services Committee (WHSSC), between 1 April 2018 and 31 March 2019

- Medical device **12%**
- Second opinion **8%**
- Surgical procedure **26%**
- Therapy **11%**
- Other **43%**

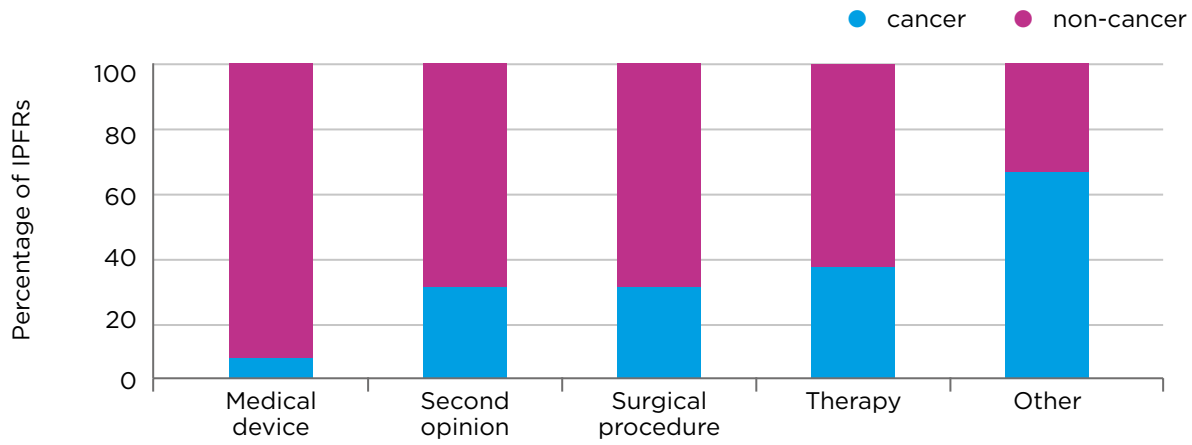
The outcomes of the IPFRs for the different types of non-medicines considered by health boards and WHSSC are shown in Figure 13. The approval rate for the different types of non-medicines ranged from 45% to 84%.

FIGURE 13: Percentage of Individual Patient Funding Requests (IPFRs) for types of non-medicines approved, not approved or deferred within each health board in Wales, including the Welsh Health Specialised Services Committee (WHSSC), between 1 April 2018 and 31 March 2019



Of the 258 non-medicine IPFRs considered by health boards and WHSSC between 1 April 2018 and 31 March 2019, a total of 109 (42%) requests were for interventions to diagnose or treat cancer. The majority (69%) of these were for PET (diagnostic) scans, of which 80% 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 which include requests 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 2018 to 31 March 2019



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.

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

Medicines and patient cohorts are identified for the One Wales Interim Pathways Commissioning process by signals from activity in the IPFR panels, from WHSSC, the Committee of Chief Pharmacists or clinician groups. In 2018/2019 a total of four medicines were considered for the One Wales Interim Pathways Commissioning process. Of the four medicines, three were excluded by AWMSG Steering Committee as they were not considered suitable for One Wales Interim Pathways Commissioning. In one case the medicine was considered suitable for standard HTA and the market authorisation holder has been duly contacted by AWTTC to encourage engagement with AWMSG's HTA process. The second was for a licensed medicine, which met the exclusion criteria for HTA and was referred back to local health boards for consideration. The third medicine was highlighted by a single centre in Wales and there was no evidence to suggest a national need.

In 2018/2019, one new medicine was assessed through the One Wales Interim Pathways Commissioning process. One decision was partially superseded by HTA. Three medicines were reviewed 12 months after endorsement and a further five were reviewed for the second time since endorsement. For one medicine IPCG recommended that its use should no longer be supported, since the previous review a new licensed medicine for the same indication had become available. The other seven decisions remain unchanged for a further 12 months. Table 2 shows the One Wales Interim Pathways Commissioning decisions which were endorsed, reviewed or superseded in 2018/2019.

Table 2: One Wales Interim Pathways Commissioning Decisions endorsed in 2018/2019					
Medicine	**Indication**	**One Wales Interim Decision**	**Chief Executive endorsement date**	**Review decision**	**Chief Executive endorsement date of review decision**
Adalimumab	Treatment of paediatric patients with severe refractory non-infectious uveitis	Supported - partially superseded by AWMSG advice 08/12/2017	11/10/2016	Interim decision to continue for 12 months	26/11/2018
Arsenic trioxide	Acute promyelocytic leukaemia - 1st line therapy in patients unsuitable for anthracycline-based therapy	Supported	24/10/2016	Interim decision to continue for 12 months – partially superseded by NICE advice 04/05/2018	25/02/2019
Axitinib	Treatment of advanced renal cell carcinoma after failure of prior treatment with pazopanib	Supported	03/08/2016	Use no longer supported	26/11/2018
Bevacizumab	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	28/01/2019
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	24/09/2018

Medicine	Indication	Not supported	Chief Executive endorsement date	Review decision	Chief Executive endorsement date of review decision
Opicapone	Adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations	Supported	26/02/2019	—	—
Rituximab	Treatment of pemphigus and pemphigoid disease in adults and children where steroids and steroid sparing treatments have failed	Supported	20/07/2017	Interim decision to continue for 12 months	23/07/2018
Rituximab + bendamustine	Treatment of indolent lymphomas, first line and relapsed. To include follicular lymphoma, Waldenstrom's and marginal zone lymphoma	Supported	28/04/2017	Interim decision to continue for 12 months	30/04/2018
Rituximab + bendamustine	Treatment of mantle cell lymphoma, first line and relapsed	Supported	28/04/2017	Interim decision to continue for 12 months	30/04/2018

Along with the steady decrease in IPFRs for medicines, emerging cohorts of IPFRs have decreased since the inception of the One Wales Interim Pathways Commissioning process. This may be due to:

- the implementation of the New Treatment Fund in 2017 which promotes the rapid availability of medicines following published HTA recommendations
- earlier guidance from NICE around the time of licence
- medicines on the Cancer Drugs Fund are now appraised by NICE and recommendations apply in Wales
- clearance of the backlog of cohorts identified at the beginning of the process; the number of emerging cohorts is expected to remain stable in the future.

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

Since December 2018 a medicine request form has been made available on the AWTTC website. IPFR panels, WHSSC, clinical networks, chief pharmacists, formulary pharmacists and medicines and therapeutics committees may all request medicines to be considered for the One Wales Interim Pathways Commissioning process using this form when any unmet clinical need is identified. More information on the process is available on the AWTTC website (www.awttc.org/pams/one-wales-interim-commissioning-process).

Patient outcomes

Of the data collected during 2018/2019 patient outcome information was available for 55 people, 45 following applications where the intervention was approved and 10 which were not approved.

Eight were following continued funding of medicines which had previously been approved. Of the 45 patients for whom treatment was approved: 16 reported evidence of clinical benefit; 7 were awaiting treatment or had treatment delayed; 2 patients showed no improvement and 1 patient was too early in the treatment pathway to assess. Seven outcomes were related to second opinions, assessments or scans. Four patients discontinued treatment, one due to disease progression, one due to treatment–related toxicity and two were the patients' choice. For eight patients only basic outcome information was provided, seven were reported to have not deceased, one had died.

Of the ten patients for whom treatment was not approved all were reported as not deceased; four had improved, one had stable condition and there was no further detail provided for the remaining five patients.

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 cases for which outcome data are available in 2018/2019 has increased since 2017/2018 although it remains a small proportion (approximately 15%) of all IPFRs considered. 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.

10

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 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 1 April 2018 to 31 March 2019, one request for a review of the IPFR process followed was submitted. The panel did not uphold the grounds of the review and the decision of the original IPFR panel stood.

Quality Assurance Advisory Group

The IPFR Quality Assurance Advisory Group was established in January 2018 to address variation between panels in relation to consistency in decision-making processes.

The objectives of the group are to monitor and support all IPFR panels to ensure quality in decision making and consistency across Wales. The group meets on a quarterly basis to assess a randomly selected IPFR application from each panel in relation to completeness, timeliness and efficiency of communication.

The IPFR reports are considered in relation to the criteria shown in Table 3 in line with the NHS Wales IPFR policy process.

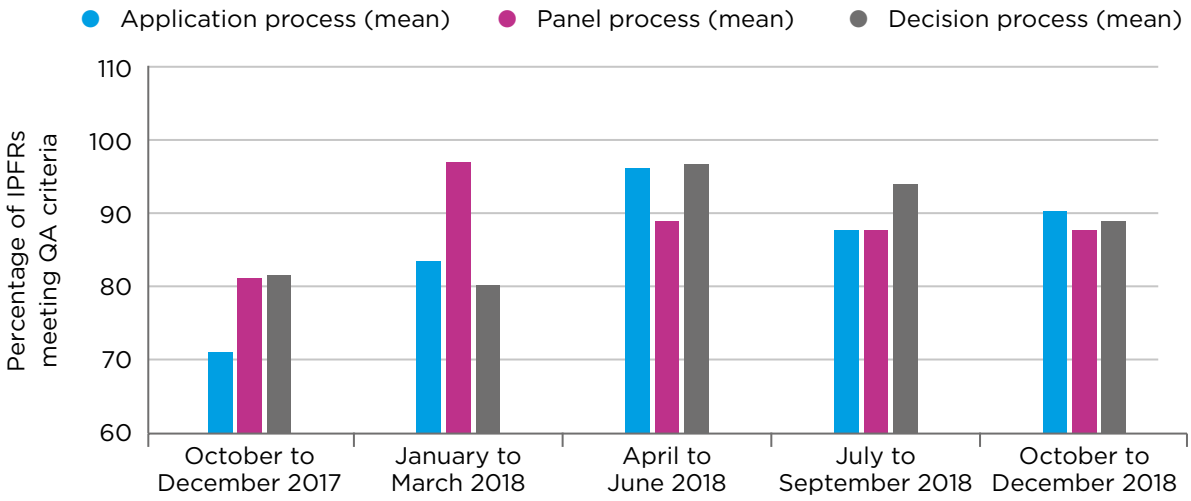
Table 3 Criteria considered by the IPFR Quality Assurance Advisory Group

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 fully completed 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 each meeting individual detailed reports are 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 are shared across the panels. A combined report is sent to the Deputy Chief Medical Officer and the Head of Pharmacy and Prescribing Policy at the Welsh Government bi-annually.

In the period 2018/2019 a total of 31 IPFRs were reviewed by the group and all areas have shown improvement between October to December 2017 and October to December 2018, shown in Figure 15.

FIGURE 15: Percentage of Individual Patient Funding Requests (IPFRs) assessed meeting the Quality Assurance (QA) process criteria



Since the first meeting particular improvement has been seen in communication with patients with a patient letter sent within five days of a panel decision in 87.5% of cases in the last quarter of 2018 compared with just 50% in the same period in 2017.

Suggestions for improvement in all three areas of the process have arisen from the findings of the Quality Assurance Advisory Group:

Application process

- Although overall the application process was found to be robust it was noted that the statement in support of the application in the IPFR form was poorly completed in several cases.

  Action: AWTTC has updated the guidance notes for clinicians completing applications to provide further clarity.

- IPFRs were falling outside of the stipulated urgency timelines. On further investigation it was found there was on occasion a discrepancy between when an application was fully completed and could be assessed and the original submission date.

  Action: the date an application is considered complete and ready for panel should be captured on the IPFR database as 'date completed', this will be used to calculate time to panel. In addition provided there is clear communication and agreement from the applicant clinician then the urgency may be revised to take into account this change.

Panel process

- A checklist used by one of the panels to ensure all paperwork for the panel was completed before and after the meeting was highlighted as good practice

  Action: this checklist has been shared to all panels.

- Panel meeting minutes were identified as needing better clarity when recording value for money discussions.

  Action: the group have fed back to all panels that minutes should ensure value for money discussions are captured and if not discussed (for example if clinical effectiveness is not proven) this should be highlighted. The IPFR workshop in May 2018 included a value for money teaching session.

- Reference to past cases as part of the panel discussion was noted in some cases and raised as a concern.

  Action: the Quality Assurance Advisory Group have stressed that each case must be considered on its own merits and circumstances at that time with no reference to previous decisions.

- The group have found it difficult to determine if decisions have been reached through Chair's action or a virtual panel.

  Action: the group have highlighted to the panels that it should be made clear in the documentation if a decision has been made as a Chair's action or as a virtual panel. All panel decisions should follow the IPFR policy guidelines and virtual panel discussions should be minuted to ensure transparency of the process followed.

Decision process

- The decision process was followed well overall. In some cases a patient letter had not been sent following consideration at panel.

  Action: the panels have been instructed to send a patient letter in all cases irrespective of urgency to ensure agreed processes are followed and the patient has been informed that they would be hearing from the clinician.

The Quality Assurance Advisory Group consider that overall the IPFR process is being followed as per the IPFR policy. The implementation of a universal template for IPFR meeting minutes across the panels has aided clarity of decision making discussions. IPFRs meeting urgency deadlines is expected to continue to improve as there is now an agreed process for recording re-negotiated urgency with the applicant clinician.

In 2019 there will be an internal review of the IPFR quality assurance role and process to reflect on progress since January 2018 and make any improvements as necessary.

12

IPFR workshop

In May 2018, AWTTC held its third IPFR workshop. This annual event was open to IPFR panel members, clinicians who write applications and those with an interest in learning more about the work of IPFR. Areas covered during the morning session included:

- an update on the progress made with the 2016 review recommendations
- an introduction to IPFR e-submissions
- an introduction to the IPFR quality assurance process
- legal and ethical considerations on the new IPFR policy criteria: clinically significant benefit and value for money
- methods to evaluate value for money.

In the afternoon, delegates formed into mock IPFR panels and considered example IPFR cases. The aim of this session 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.

Sixty-two delegates attended the workshop, with IPFR panel representatives from all of the health boards in Wales and WHSSC. Representatives from Public Health Wales were also in attendance. The presentations from the 2018 workshop can be accessed on the AWTTC website (www.awttc.org/ipfr).

Summary of the data

Overall the data for 2018/2019 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 a greater awareness by the submitting clinicians of HTA advice, or a better understanding of the most appropriate route(s) for accessing a medicine on behalf of patients.
- This decline is associated with a reduction in requests for medicines rather than non-medicines.
- Overall, 68% of IPFRs were approved compared with 63% in 2017/2018.
- For medicines, the approval rate was 71% in 2018/2019 and the rate has increased annually over the last four years, from 57% in 2015/2016.
- The approval rate for non-medicines was 66% in 2018/2019 and this has increased over the last three years, from 49% in 2016/2017.
- Pertuzumab was one of the most commonly requested medicines by IPFR from 2015/2016 to 2017/2018. Since publication of NICE guidance in March 2018, pertuzumab was not a commonly requested medicine by IPFR in 2018/2019.
- As in the previous year the most common non-medicine requests were for PET scans; 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.