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Access to new medicines in Wales

Research Briefing

December 2025

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This research briefing provides an overview of how patients in Wales access new medicines. The briefing:

- explains how medicines are licensed and assessed for clinical and cost-effectiveness by the Medicines and Healthcare Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE);
- examines the distinct role of the All Wales Medicines Strategy Group (AWMSG) in appraising medicines not assessed by NICE but where a clear benefit for NHS Wales has been identified;
- outlines the operation and impact of the New Treatment Fund in facilitating access to newly recommended medicines;
- sets out how spending on new medicines is regulated through commercial arrangements and UK-wide pricing schemes; and
- looks at the Individual Patient Funding Request (IPFR) process for medicines that are not routinely available, including trends in submissions and approvals.

Contents

1. Licensing and assessment by the National Institute for Health and Care Excellence (NICE)

Medicines must be licensed before they can be considered for use in Wales. Once licensed, medicines are assessed by the National Institute for Health and Care Excellence (NICE) on their clinical and cost-effectiveness to ensure they represent an appropriate use of NHS resources. Local Health Boards and Trusts in Wales are required to make medicines recommended by NICE available to patients within 60 days of a positive recommendation.

Licensing

Before a medicine can be legally sold or supplied in the UK it must first be licensed. The **Medicines and Healthcare Regulatory Agency (MHRA)** is the agency responsible for licensing medicines in the UK. It issues UK-wide licenses called 'marketing authorisations' to medicines it has assessed as **safe**, **effective** and of high **quality**.

The MHRA conducts its assessment based on a dossier of evidence and other materials submitted by the applicant (usually a pharmaceutical company). These are required by **law**. An **expedited route** is available for medicines that have been authorised by regulators in other countries, though the final assessment is still made by the MHRA.

If the MHRA concludes that the benefits of a medicine outweigh any risks then it will issue a marketing authorisation. This allows the medicine to be promoted for specific, approved uses. While a medicine can be prescribed for other uses in certain circumstances, this is considered an **unlicensed or 'off-label'** use of the medicine.

What is an indication?

An indication is a valid reason to use a medicine (or other medical intervention). Marketing authorisations issued by the MHRA specify the indications for which a medicine has been approved. A single medicine can have multiple indications. For example, **Adalimumab** is indicated for moderate to severe rheumatoid arthritis and moderate to severe Crohn's disease, among others.

The opposite of an indication is a contraindication, meaning a reason to avoid a treatment because the risks outweigh the benefits.

Assessment by NICE

Medicines that are expected to receive a marketing authorisation are assessed by the **National Institute for Health and Care Excellence (NICE)** to determine whether they should be made available in the NHS. To make this decision, NICE carries out a **Health Technology Assessment (HTA)** (referred to as a **'technology appraisal'** by NICE) which looks at the overall cost to the NHS of making the medicine available along with the health benefits it provides, measured in quality-adjusted life years (QALYs).

What is a QALY?

A QALY is a measure of health that combines the length and quality of life. One QALY equates to one year of life in perfect health. To calculate QALYs, the number of years a person is expected to live following treatment is estimated. Each year is weighted by a quality-of-life score ranging from 0 (equivalent to death) to 1 (perfect health). These scores reflect factors such as the ability to perform daily activities, along with freedom from pain or mental distress.

If a medicine is both more effective and less expensive than existing NHS treatments, NICE will usually recommend it for routine use in the NHS. If it is more effective but also more expensive, it must meet a **cost-effectiveness threshold**. Since NICE was established, this has typically been no more than £20,000 to £30,000 per QALY gained by the treatment compared with existing NHS treatments. From April 2026 however, this threshold will increase to £25,000 to £35,000 per QALY due to commitments made as part of the **UK–US Economic Prosperity Deal.**

Medicines that treat **ultra-rare diseases** (sometimes referred to as **ultra-orphan medicines** are routed through a separate **Highly Specialised Technologies (HST)** programme. In these cases, a higher threshold of £100,000 per additional QALY gained typically applies.

Are NICE's thresholds set at the right levels?

NICE's cost-effectiveness thresholds of £20,000 to £30,000 per additional QALY were **first referenced in official guidance in 2004,** though **analyses indicate they had been applied informally since 1999**. This led to criticism that the thresholds had not kept up with rising inflation and should be higher. Pharmaceutical company **Novartis described the thresholds as "outdated,"** while **Gilead Sciences refused to submit breast cancer drug Trodelvy to NICE for assessment**, arguing that NICE "undervalued medicines" and Britain offered no chance of an "appropriate profit."

Others have argued they should be lower. **Analysis published in The Lancet** estimated that between 2000 and 2020 in England, new medicines provided 3.75 million additional QALYs at a cost of £75 billion, but the same funding could have delivered 5 million additional QALYs if it had been spent on existing services.

From April 2026, NICE will apply new cost-effectiveness thresholds of £25,000 to £35,000 per additional QALY. This increase was agreed as part of the **UK–US Economic Prosperity Deal**, which secured zero tariffs on pharmaceutical exports to the United States for at least three years in return for increased NHS spending on medicines. **NICE expects** these changes to enable the recommendation of between three and five additional medicines or indications each year.

How NICE guidance applies in Wales

Local Health Boards and Trusts in Wales have a **statutory obligation** to make medicines recommended by NICE available to patients within 60 days of the publication of **Final Draft Guidance** (or Final Evaluation Determination in the case of HSTs).

The requirement to make medicines available within 60 days of a positive recommendation applies without the need for ratification by the Welsh Government. This timeframe can be **extended** however if either the Welsh Government or NICE determine that a longer implementation period is necessary. This can occur where significant service changes or long lead times are needed to make a medicine available.

2. The All Wales Medicines Strategy Group (AWMSG)

Although NICE guidance is implemented in Wales, Wales has its own process to ensure patients can access new medicines promptly and fairly. The All Wales Medicines Strategy Group (AWMSG) assesses medicines that NICE has not appraised but where a clear clinical need or other benefit for NHS Wales has been identified.

The role of AWMSG

The **All Wales Medicines Strategy Group (AWMSG)** assesses medicines that NICE has not appraised and that also:

- treat conditions that are not sufficiently addressed by any routinely funded or licensed medicine currently available in NHS Wales; or
- provide another benefit to NHS Wales in terms of cost, service delivery or patient experience.

The **AWMSG constitution** states that the group's role is to 'complement and support' the work of NICE and that it avoids duplication of NICE's work programme. AWMSG may appraise medicines ahead of NICE in cases where there is a clear benefit in doing so. However, it will not usually appraise a medicine if NICE is expected to publish its final guidance within a year of the medicine receiving marketing authorisation. When AWMSG does issue advice, it serves as interim guidance and is superseded by NICE recommendations once they are published.

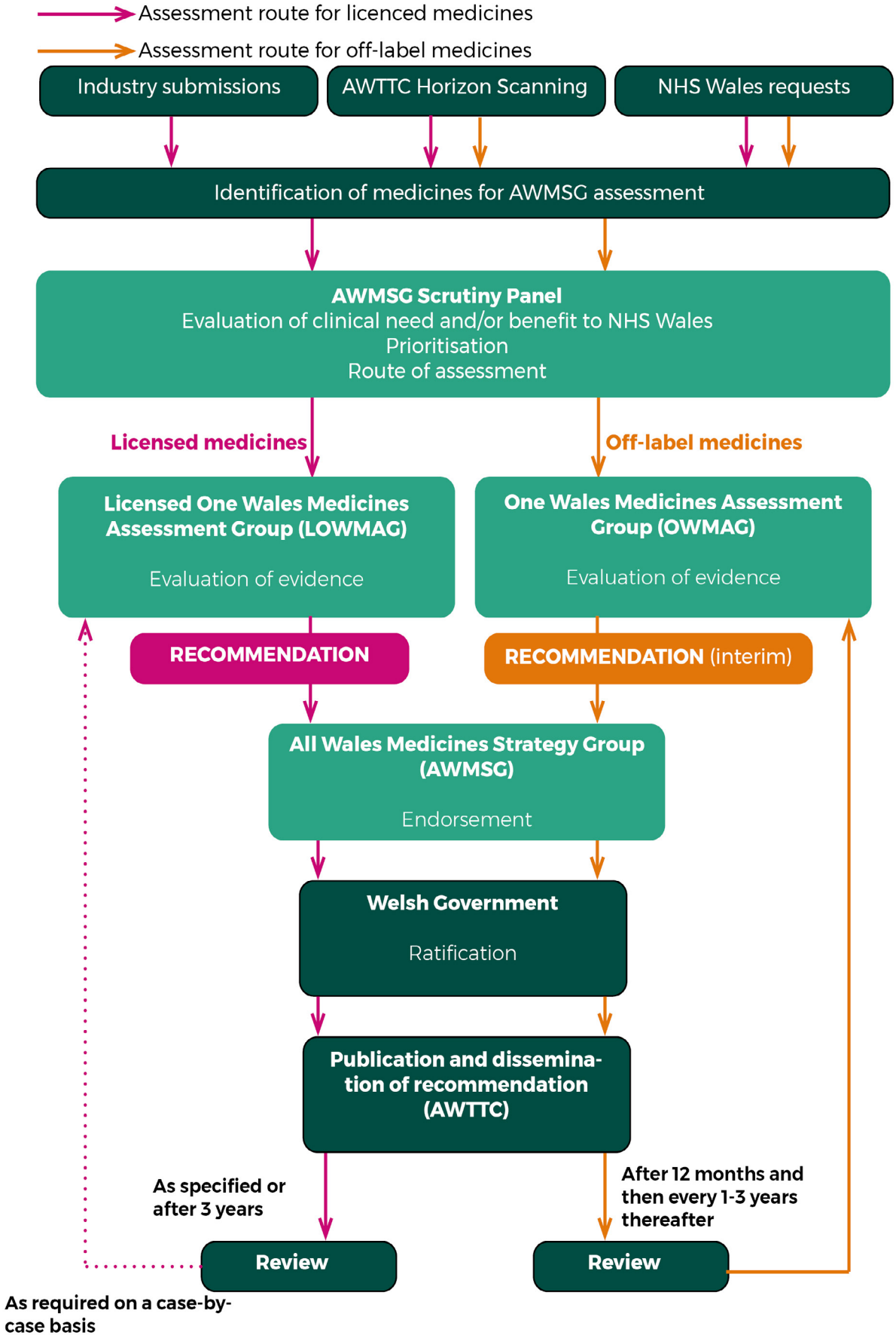
AWMSG can also appraise medicines that have received a negative recommendation from NICE or had a recommendation from NICE terminated. In these cases, the applicant must provide additional evidence demonstrating added value or benefit to NHS Wales beyond what was considered by NICE.

Medicines suitable for AWMSG assessment are typically identified by the **All Wales Therapeutics and Toxicology Centre (AWTTC)** but can also be identified by other stakeholders. Each case is reviewed by the AWMSG Scrutiny Panel, which decides whether an appraisal should proceed and determines the most appropriate

assessment route. The **appraisal process** varies depending on whether the medicine is licensed or used off-label.

AWTTC provides detailed information on medicines AWMSG has appraised and recommended through its **medicine recommendations portal**. The portal also includes details of medicines excluded from AWMSG appraisal, as well as those where advice has been superseded by NICE guidance.

Figure 1. Overview of AWMSG medicine assessment process in Wales



Source: **All Wales Therapeutics and Toxicology Centre**

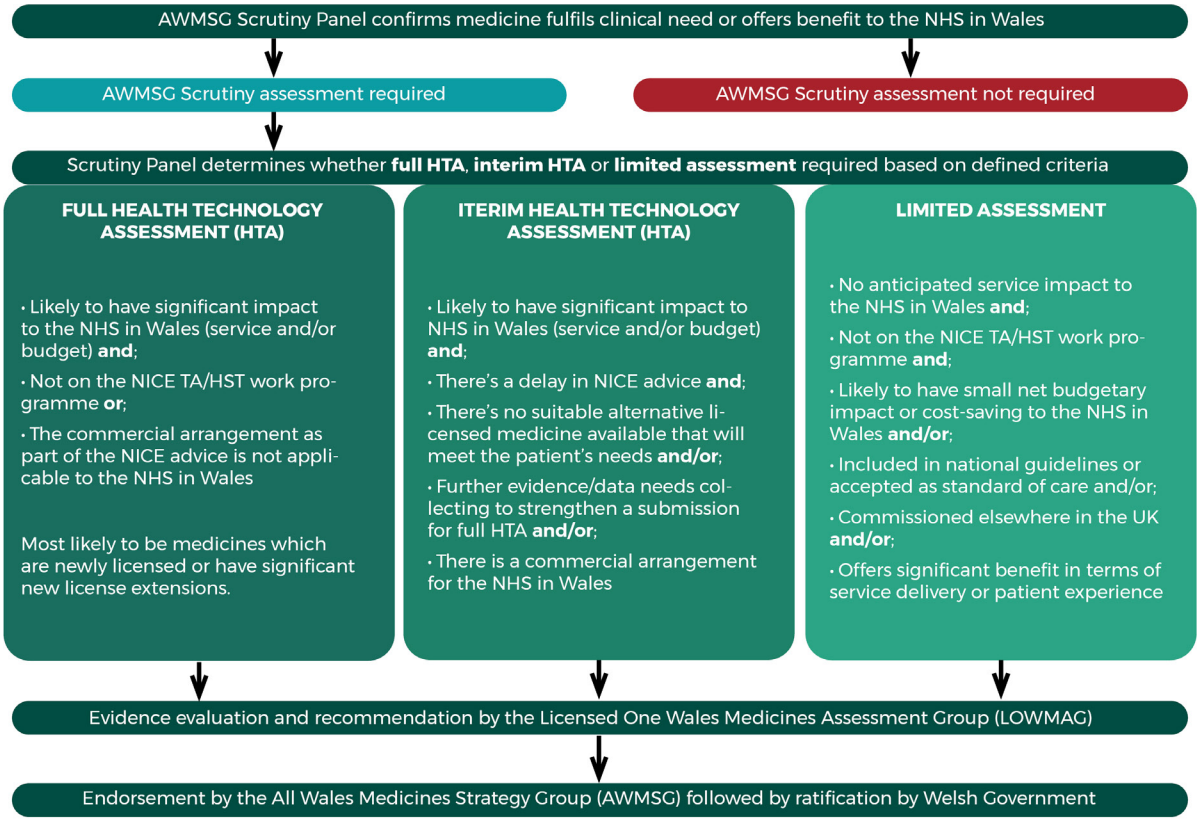
Licensed medicines

Licensed medicines suitable for assessment are identified by AWTTC's horizon scanning team. The team routinely collects information on new medicines, indications and formulations expected to receive a license in the following year. They also monitor the development of **Advanced Therapy Medicinal Products** that may become available over the next three to five years.

In addition to its own horizon scanning, AWTTC invites pharmaceutical companies, healthcare professionals and patient organisations to propose licensed medicines that may be suitable for assessment by AWMSG.

AWTTC compiles this information and provides it to the AWMSG Scrutiny Panel for consideration. The AWMSG Scrutiny Panel then determines whether an assessment should proceed and on the most appropriate route for assessment. This can be either a full Health Technology Assessment (HTA), an interim HTA or a limited assessment. Figure 2 shows the criteria for each of these routes.

Figure 2. Overview of available assessment routes for licensed medicines



Source: **All Wales Therapeutics and Toxicology Centre**

AWMSG's HTA methods are broadly aligned with NICE and based on the incremental cost per QALY gained from the medicine. Interim HTAs are based on the best available evidence and result in an interim recommendation. These are time-limited and reviewed regularly, particularly if other licensed medicines receive positive HTA guidance for the same indication. Limited assessments involve a high-level review of clinical evidence and basic cost considerations only.

Regardless of the assessment route, AWTTC prepares a report using evidence provided by the marketing authorisation holder. If the marketing authorisation holder does not participate, the report is compiled from publicly available information gathered by AWTTC.

This is then assessed by the **Licensed One Wales Medicines Assessment Group (LOWMAG)**, which makes a recommendation based on the evidence. A LOWMAG recommendation may be:

- positive;
- positive with restrictions on its use (known as 'restricted use');

- positive interim; or
- negative.

Recommendations are shared with AWMSG. If AWMSG endorses a recommendation, it is sent to the Welsh Government. The Welsh Government makes the final decision on whether a medicine should be funded. If the recommendation is ratified by the Welsh Government, the medicine must be made available by Local Health Boards and Trusts within 60 days of ratification.

Which licensed medicines have been appraised by AWMSG?

AWMSG appraised five licensed medicines in 2024-2025. Of these, four received positive recommendations. These were **trifarotene**; **opicapone**; **cytisinicline**; and **galsulfase**. The recommendations for trifarotene and opicapone have since been ratified by the Welsh Government.

AWMSG also appraised **emtricitabine/tenofovir alafenamide fumarate (Descovy®)** for use as pre-exposure prophylaxis to reduce the risk of sexually-acquired HIV-1 infection in at-risk men who have sex with men. AWMSG concluded that the case for its cost-effectiveness had not been proven.

The **Welsh Government chose not to ratify this recommendation** however, citing commitments made in its **HIV Action Plan for Wales** and concerns that its availability in other parts of the UK—and through Individual Patient Funding Requests (IPFRs) in some Welsh health boards—could lead to inequitable access. Descovy® is therefore available for use within NHS Wales, though it is restricted to certain patient cohorts.

The number of medicines appraised in 2024-2025 increased from just one medicine in **2023-2024**. Prior to this, AWMSG appraised significantly more medicines. In **2022-2023** it appraised 17 medicines and in **2015-2016** it made 45 positive recommendations out of 47 medicines appraised.

The reason for this drop was a **new approach to technology appraisals** introduced by NICE in 2022. This sped up NICE's technology appraisals process by 45% and increased its capacity for guidance on more complex treatments, significantly reducing the number of medicines needing assessment by AWMSG.

Off-label medicines

A Welsh Government review of the **Individual Patient Funding Request (IPFR)** process in 2014 found that access to certain medicines varied within specific patient groups—some individuals were able to obtain treatments through IPFRs while others in the same group were not.

In response to this review, AWTTC along with partners developed the **One Wales Medicines process**. The process aims to enable national decisions on medicine availability and reduce the need for multiple IPFRs. It is used in cases where an off-label medicine:

- could benefit a specific patient group;
- is not licensed for the intended condition or use; and
- no suitable licensed alternatives are available.

AWTTC reviews data from IPFRs to identify groups of patients who might benefit from a medicine used off-label. Certain healthcare professionals can also suggest medicines for consideration. Unlike the process for licensed medicines, submissions from pharmaceutical companies are not accepted.

AWTTC compiles a report based on the available evidence and additional information requested from the marketing authorisation holder or the healthcare professionals who submitted the request. Patient organisations are also invited to share their views on the unmet clinical need for the medicine, particularly its potential impact on patients' quality of life and that of their families and carers.

The report is then assessed by the **One Wales Medicines Assessment Group (OWMAG),** which makes a recommendation based on the evidence received. An OWMAG recommendation may be:

- positive;
- positive with restrictions on its use (known as 'restricted use'); or
- negative.

If a recommendation from OWMAG is endorsed by AWMSG and ratified by the Welsh Government, Local Health Boards and Trusts are expected to make the medicine available in accordance with the recommendation.

All One Wales decisions are reviewed after a year and then every one to three years after. One Wales decisions for off-label uses of licensed medicines usually last a year

or until NICE or AWMSG guidance is published. Decisions on unlicensed medicines may end if the medicine receives a licence or an alternative licensed option becomes available, after which the marketing authorisation holder must follow the standard assessment process for licensed medicines.

Which off-label medicines have been appraised by AWMSG?

Off-label uses of three medicines received positive recommendations in 2024-2025. These were **dabrafenib and trametinib** (used in combination); **infliximab**; and **vedolizumab**.

Nivolumab was also assessed as a first-line treatment for certain cancers of the stomach and oesophagus. However, a decision was made not to recommend the treatment. This was made on the basis that it was unlikely to be cost-effective and that there was not enough evidence demonstrating it to be more effective than other available treatments.

The number of live One Wales recommendations has steadily increased since the process was introduced in November 2015—from 6 in **2016-2017**, to 11 in **2021-2022**, to a high of **21 current recommendations**.

3. The New Treatment Fund

The New Treatment Fund provides dedicated funding to enable Local Health Boards and Trusts to make newly recommended medicines available within 60 days of approval by NICE or AWMSG.

What the fund is used for

Before 2017, Local Health Boards and Trusts in Wales were required to make medicines recommended by NICE or AWMSG available within 90 days—a standard that **still applies in England** for medicines approved by NICE.

In 2017, the Welsh Government **shortened this timeframe to 60 days** and introduced the New Treatment Fund to support faster implementation. The fund provides £16 million each year to Local Health Boards and Trusts and is ring-fenced for the purpose of mitigating the financial pressures associated with making new treatments available.

In practice, making a medicine 'available' means that:

- the Local Health Board or Trust has allocated sufficient funding to cover the cost of the medicine and any associated service requirements;
- the medicine is stocked in hospital pharmacies or enabled for dispensing via community pharmacy prescribing routes; and
- the medicine has been added to the Local Health Board or Trust's formulary, which is the official list of approved medicines for prescribing within that area.

While Local Health Boards and Trusts must make newly recommended medicines available, the decision to prescribe them ultimately rests with clinicians, who consider individual patient needs and exercise their own clinical judgment.

How the fund has performed

Since its introduction, the New Treatment Fund has significantly reduced the amount of time it takes for newly recommended medicines to become available. By 2020, the average amount of time it took to make a medicine available had fallen by 85% from 90 days to **13 days**. The average amount of time it currently takes is **16 days**.

In order to monitor compliance with the New Treatment Fund, Local Health Boards and Trusts report on how quickly they have added medicines recommended by NICE and AWMSG to their prescribing lists. These are compiled into **formulary status reports** by AWTTC.

The latest report for **2024-2025** shows a total of 81 medicines on the New Treatment Fund. The vast majority of these had been added to formularies within the required timescale.

However, there is some variation between Local Health Boards and Trusts. Aneurin Bevan University Health Board, Cardiff and Vale University Health Board and Velindre University NHS Trust missed the required timescale for a total of 15 medicines:

- Aneurin Bevan University Health Board missed the required timescale for 10 medicines;
- Cardiff and Vale University Health Board missed the required timescale for 5 medicines; and
- Velindre University NHS Trust missed the required timescale for 6 medicines.

Among these, several medicines—relugolix, pembrolizumab, tebentafusp, durvalumab and osimertinib—were not added to multiple formularies within the required timescale. All of these medicines are used in cancer treatment.

The remaining five Local Health Boards added all recommended medicines to their formularies within the required timescale.

4. Regulation of spending on new medicines

To manage the financial impact of new medicines on the NHS, a range of mechanisms—including commercial agreements and national pricing schemes—are used to control spending and ensure value for money.

Managing the cost of new medicines

New medicines can be expensive. Pharmaceutical companies **attribute** this to the complexity, high expense and low success rate of development. To protect companies' investments, governments **issue patents** which give companies the exclusive right to make and sell new medicines they have developed.

Once a patent expires, other companies can sell generic versions of the medicine (medicines with the same active ingredient) or **biosimilar versions**. Once these enter the market, prices are usually **driven down** by competition.

Various mechanisms serve to regulate prices and spending on new, branded medicines. These include:

- NICE's cost-effectiveness thresholds;
- commercial arrangements agreed between pharmaceutical companies and the NHS; and
- voluntary and statutory schemes that cap spending on branded medicines.

Commercial arrangements

NICE's cost-effectiveness thresholds play a role in determining how much is paid for branded medicines. If a pharmaceutical company sets the price of a medicine too high, they risk exceeding NICE's thresholds and not having the medicine recommended for routine use. For this reason, **companies often prefer** to set lower prices to make some revenue from the NHS rather than make no revenue from the NHS at all.

To secure a positive recommendation from NICE, pharmaceutical companies can enter into commercial arrangements with the NHS that reduce the effective prices of medicines. Arrangements of this kind are often necessary for medicines to be considered cost-effective by NICE. **Analysis from 2019** found that over half of

medicines approved by NICE had either a Patient Access Scheme or a Commercial Access Agreement attached.

Patient Access Scheme

A Patient Access Scheme (PAS) is the NHS's preferred means of providing a cost-effective price. PAS can be either 'simple' or 'complex,' with a simple PAS being the preferred approach.

- A simple PAS provides a confidential discount at the point of sale. These schemes are easier to manage and require minimal monitoring.
- A complex PAS involves more detailed reimbursement arrangements (for example, free upfront stock or rebate schemes) and are non-confidential to ensure transparency.

Commercial Access Agreement

In cases where a medicine is expected to deliver value at or below the lower end of NICE's cost-effectiveness threshold and a simple PAS would not be practical or commercially viable, a tailored Commercial Access Agreement (CAA) can be negotiated. Unlike a complex PAS, a CAA remains confidential.

Managed Access Agreement

If there is uncertainty about a medicine's clinical and cost-effectiveness, but the medicine is expected to be approved for routine use, NICE can recommend a Managed Access Agreement (MAA). This is a temporary arrangement that allows the medicine to be supplied at a cost-effective price while additional data is collected. MAA are often associated with HSTs and medicines in NHS England's Cancer Drugs Fund (CDF) and Innovative Medicines Fund (IMF).

NHS Wales usually aligns with commercial arrangements agreed with NHS England but expects companies to **share details and sign equivalent agreements** with NHS Wales before medicines are made available.

For medicines with a MAA, NHS Wales will sometimes require an alternative

arrangement that offers equivalent value to NHS Wales. This also applies to certain CAAs.

For medicines undergoing assessment by AWMSG, companies can propose a Wales Patient Access Scheme (WPAS) that apply only in Wales. These are agreed with the Welsh Government following input from the Patient Access Scheme Wales Group (PASWG). As with PAS, WPAS can be simple or complex.

Voluntary scheme

The **2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG)** is the current voluntary scheme and will last until 2029. It was negotiated between the UK Government, NHS England and the pharmaceutical industry and applies across the UK.

VPAG sets 'allowed growth' rates for spending on branded medicines, starting at 2% in 2024 and rising to 4% per annum by 2028. If actual NHS spend exceeds these growth limits, companies in the scheme must repay a share of their eligible sales revenue in the form of rebates.

Rebates paid by companies in the scheme are collected by the UK Government and reallocated to the devolved nations based on the amount each nation spends on branded medicines. The **majority of these payments** (around 81%) are made to England, with around 6% being paid to Wales.

Wales also receives a share of £400 million of funding over five years from the **VPAG Investment Programme**, which forms part of the agreement. This funding is ring-fenced for investment in clinical trials infrastructure, **sustainable medicines manufacturing** and health technology assessment processes. Funding has already been used to establish a **Commercial Research Delivery Centre in Wales** and to **support AWTTC deliver a range of initiatives**.

What is the headline payment rate?

The headline payment rate is the percentage of eligible sales revenue that pharmaceutical companies must repay to the NHS when spending on newer medicines exceeds the agreed budget cap. The rate rose to 22.9% in 2025—an increase of almost 8% from 2024. This increase was mainly driven by **higher than expected purchases** of newer medicines in the previous year.

Concerns were raised by the Association of the British Pharmaceutical Industry (ABPI) early in the year over the higher than expected rate, which it argued was

harming UK competitiveness and could have meant companies launching fewer medicines in the UK. In April 2025, the UK Government agreed to bring forward the mid-term review of VPAG to address these concerns, but **discussions with ABPI collapsed in August.**

In December 2025 however, the UK Government agreed to cut the rate to 15% and keep it at or below this level for the remainder of the scheme (up until 2029). This commitment was made as part of the **UK-US Economic Prosperity Deal**, which secured zero tariffs on pharmaceutical exports to the United States for at least three years.

The 15% cap will not apply in 2026 however because NHS demand for newer medicines grew more slowly in 2025. Consequently, the **headline payment rate** under the existing VPAG formula will be set at 14.5% for 2026.

Statutory scheme

Pharmaceutical companies that have not joined VPAG are subject to the statutory scheme. This is set out in the **Branded Health Service Medicines (Costs) Regulations 2018.**

The statutory scheme, like VPAG, controls NHS spending on branded medicines by requiring companies to pay a percentage of their sales revenue back to the UK Government. Its terms are regularly reviewed to keep them broadly aligned with VPAG.

Under the **current terms**, companies must repay 23.4% of their eligible sales revenue and this is set to increase to 24.3% in 2026. As with VPAG, payments made by companies under the statutory scheme are redistributed to the devolved nations on an agreed basis each year.

5. Individual Patient Funding Requests

If a medicine is not routinely available, it may still be funded on an individual basis via an Individual Patient Funding Request.

How the process works

An **Individual Patient Funding Request (IPFR)** can be made for medicines or other interventions that are not routinely available. IPFRs for medicines are usually made when:

- advice from NICE or AWMSG on the medicine is not available;
- NICE or AWMSG has recommended not to use the medicine; or
- there is no One Wales advice available for a medicine used off-label.

IPFRs are submitted by a patient's clinician and considered by an independent panel appointed by the patient's Local Health Board. If the condition to be treated falls within a **specialised service** commissioned by the **NHS Wales Joint Commissioning Committee (NWJCC)**, the request is considered by NWJCC instead.

Each request is assessed on its individual merits in line with the **All Wales IPFR Policy**. For an IPFR to be approved, the patient's clinician must demonstrate that:

- the patient is likely to gain significant clinical benefit; and
- the value for money of the medicine is likely to be reasonable.

Clinical benefit is assessed by comparing the medicine's expected outcomes to the next best routinely funded alternative (which in some cases may be supportive care). Value for money is assessed in terms of the incremental cost per QALY gained, following the approach used by NICE and AWMSG. Non-clinical factors, such as a patient's caring responsibilities, are not considered by IPFR panels.

AWTTC has **published** an FAQ and a video explainer on the IPFR process.

Clinical exceptionality

Prior to 2017, the patient's clinician would have to demonstrate 'clinical exceptionality' for an IPFR to be approved. This meant having to prove that the patient differed significantly from other patients with the same condition.

An **independent review** of the IPFR process in 2016 found that this principle was poorly understood and had not been applied consistently. It recommended replacing it with evaluations based on clinical benefit and cost-effectiveness. This recommendation was accepted by the Welsh Government in **March 2017**, with new guidance issued in **June 2017**.

The principle of clinical exceptionality is still used however in cases where NICE or AWMSG have recommended that a medicine should not be used. In these cases, the patient's clinician must demonstrate that:

- the patient's circumstances differ significantly from others with the same condition;
- the patient is likely to gain substantially greater benefit than would normally be expected of others with the same condition; and
- the value for money of the intervention is likely to be reasonable.

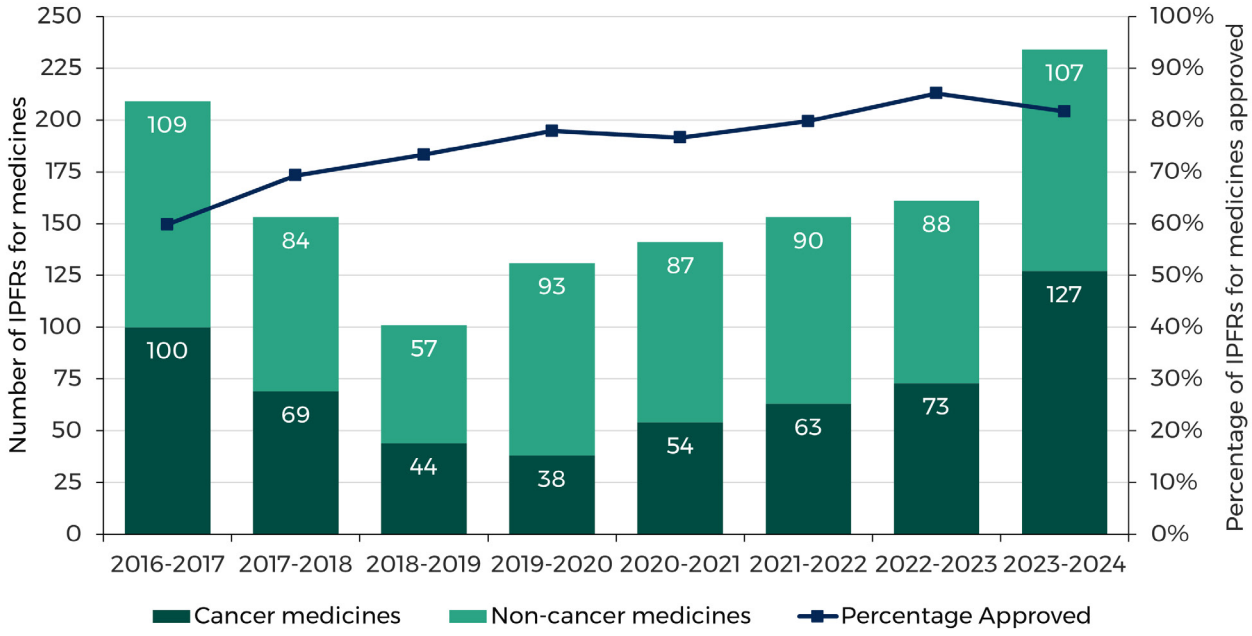
Trends in submissions and approvals

Since 2016, AWTTC has published **annual reports** on IPFR activity in Wales. These include data on the number of requests considered and approved, patient outcomes, emerging trends and other relevant updates. Expenditure relating to IPFRs is not routinely reported, however.

These reports show that the number of IPFRs for medicines fell sharply from 209 in **2016–2017** to just 100 in **2018-2019**. Since then, the number has risen each year, reaching 234 in **2023–2024**. A significant number of these are for medicines to treat cancer. In 2023-2024 there were 127 IPFRs for medicines to treat cancer—54% of the total number.

The approval rate for IPFRs has also increased steadily from 60% in **2016-17** to a high of 86% in **2022-2023**. This was followed by a slight dip in the approval rate to 81% in **2023-2024**.

Figure 3. Number of IPFRs for medicines considered in Wales from 2016-2024 and the percentage approved



Source: **All Wales Therapeutics and Toxicology Centre**

In its latest **IPFR annual report**, AWTTC attribute the decline in requests from their peak in 2016–2017 to an increased awareness of the most appropriate routes for accessing medicines in Wales. AWTTC also point to the impact of the One Wales Medicines process, which has reduced the need for IPFR submissions for approved medicines. AWTTC's **ongoing monitoring** of IPFR data has shown that once a positive One Wales decision is published, IPFRs for the relevant medicine and indication are no longer submitted.

The modest rise in requests in 2019–2020 has been linked by AWTTC to the COVID-19 pandemic, namely efforts to reduce hospital visits for routine drug administration (especially among immunosuppressed patients) by using non-routinely commissioned oral treatments or less immunosuppressive alternatives. Reasons for the year-on-year rise in requests since the pandemic have not yet been identified by AWTTC.

Patient outcomes

Patient outcome data is not available in the majority of cases. In **2023-2024**, data was available for only 57 patients (14.5% of all IPFRs). All of these were in relation to IPFRs for medicines. None were reported in relation to requests for other interventions.

Among those who provided feedback in 2023-2024, 32 out of 48 patients (67%) experienced either a complete or partial response to treatment, while 28 out of 42 patients (67%) reported an improvement in their quality of life. Comparable rates of clinical benefit and improvements in quality of life have been observed in previous years.

The availability of patient outcome data has been consistently low and never exceeded 17% of all IPFRs (in **2022–2023**). This is despite AWTCC **emphasising in 2016** that the collection of patient outcome data would be crucial for monitoring and assessing treatment effectiveness, and that it would become a mandatory part of the IPFR reporting process in future.

In its latest **IPFR annual report**, AWTTC note that most patient outcome data is submitted alongside requests for continued treatment funding and, as a result, largely reflects patients who are benefiting from an approved medicine. There is also a lack of outcome information for one-off treatments and outcomes are missing in cases where treatment requests were declined.

An update to the IPFR database was set to be implemented this year to prompt IPFR coordinators to request patient outcome data, with the aim of improving reporting rates.