AWTTC

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

Access to medicines for patients in Wales

The All Wales Therapeutics & Toxicology Centre (AWTTC) developed this document in collaboration with the Association of British Pharmaceutical Industries (ABPI) and the Welsh Medicines Procurement and Logistics Advisory Group (WMPLAG).

October 2020

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Summary

This document explains how newly licensed prescription medicines reach patients in NHS Wales. It follows what happens after a medicine is granted a new licence, to how a patient can get hold of that medicine through a prescription.

We focus on:

- health technology assessment of medicines;
- types of financial agreements to supply medicines; and
- ways of procuring (buying or obtaining) medicines.

There are different routes that pharmaceutical companies may consider when planning market access for a newly licensed medicine in NHS Wales. The document summarises the work of the organisations that assess newly licensed medicines for their use in the NHS. It also describes how these medicines, if recommended for use, are funded and obtained in Wales.

The document describes the work of the Welsh Medicines Procurement and Logistics Advisory Group and the All Wales Drug Contracting Committee in making sure that all patients in Wales can get the medicines they need.

We will review this document every year.

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Glossary

Abbreviation	Definition
ABPI	Association of British Pharmaceutical Industries
AWDCC	All Wales Drug Contracting Committee
AWMSG	All Wales Medicines Strategy Group
AWTTC	All Wales Therapeutics & Toxicology Centre
BIT	Budget impact test
CAA	Commercial access agreement
CDF	Cancer Drugs Fund
EAMS	Early access to medicines scheme
EMA	European Medicines Agency
FAD	Final appraisal document
FED	Final evaluation document
FTA	Fast track appraisal
HST	Highly specialised technology
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
IPCG	Interim Pathway Commissioning Group
IPFR	Individual patient-funded request
KPI	Key performance indicators
MAA	Managed access agreement
MHRA	Medicines and Healthcare products Regulatory Agency
MTA	Multiple technology appraisal
NICE	National Institute for Health and Care Excellence
NTF	New Treatment Fund
NWSSP	NHS Wales Shared Services Partnership
PAS	Patient access scheme
PASWG	Patient Access Scheme Wales Group
PIM	Promising innovative medicine
QALY	Quality-adjusted life-year
SMC	Scottish Medicines Consortium
STA	Single technology appraisal
TA	Technology appraisal
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales patient access scheme
WMPLAG	Welsh Medicines Procurement and Logistics Advisory Group

1. Introduction

Regulatory authorities such as the UK's Medicines and Healthcare products Regulatory Agency (MHRA), or the European Medicines Agency (EMA) in the EU, usually have to grant a new medicine a marketing authorisation (a licence) before healthcare professionals in the UK can prescribe it for patients.

After getting a licence, a medicine may be prescribed for patients in the NHS, usually after it is recommended through a health technology assessment (HTA) by a recognised body. The National Institute for Health and Care Excellence (NICE) provides HTA for medicines for prescribing in the NHS in England and in the NHS in Wales. The All Wales Medicines Strategy Group (AWMSG) assesses medicines for use in NHS Wales only.

When NICE or AWMSG recommend that a medicine can be used in the NHS, the health boards in Wales must make sure the medicine is available for prescribing to patients within 60 days of the recommendation being published. The medicine's licence holder may make financial arrangements covering how it will supply the medicine to NHS Wales for prescribing. Several types of agreements and schemes may apply in England and Wales; these are described in Section 7.

The Welsh Medicines Procurement and Logistics Advisory Group (WMPLAG) focuses on getting medicines to patients in Wales. WMPLAG members represent finance, procurement, quality assurance, clinical pharmacists and chief pharmacists from across Wales. The group considers the issues around buying medicines and the logistics involved, so that people in Wales can get the medicines they need, as close to their home as possible.

2. Health technology assessment of medicines

In the NHS, patients can be prescribed medicines that have a positive recommendation after a health technology assessment (HTA) by a recognised body:

- National Institute for Health and Care Excellence (NICE) – for England and Wales;
- All Wales Medicines Strategy Group (AWMSG) – for Wales; and
- Scottish Medicines Consortium (SMC) – for Scotland.

The HTA bodies may assess all newly licensed medicines and also any marketed medicines that have had their licence extended, for example, to treat a different disease, or give to a different group of patients, such as children.

What is health technology assessment?

HTA of medicines involves conducting independent research about the effectiveness, costs and broader impact of a medicine for the people who plan, provide or receive care in the NHS.

A pharmaceutical company can begin the HTA process with NICE or AWMSG before the EMA or MHRA licenses a medicine. The medicine's licence holder usually sends the HTA body the main evidence about the clinical effectiveness and cost effectiveness of the new medicine.

The HTA body will also seek evidence from several sources and prepare a report reviewing **all** the evidence about the medicine, for their committee to discuss.

An independent committee of healthcare professionals, health economists, pharmaceutical industry representatives and lay members, meets to discuss the research findings. Meetings are usually held in public. The committee considers:

- how well a medicine works, compared with current treatments;
- whether the benefits of a medicine outweigh any extra costs; and
- which patients it will benefit most.

The committee will recommend that a medicine may be used, or not used, in the NHS. The recommendation is then formally approved or ratified, and published. If the recommendation is positive, the medicine can be prescribed for patients as soon as the NHS can buy and supply it.

How do committees decide?

The committees talk about the potential benefits that a new medicine is expected to bring to patients and whether those benefits would outweigh any extra costs associated with using the new medicine. For example, does the new medicine cost more or less than the medicines currently used, or would using the new medicine have other advantages, such as fewer hospital visits for patients.

The incremental cost-effectiveness ratio (ICER) measures value for money: expressing the extra costs and health benefits of using a new medicine, over a currently used medicine. HTA bodies measure ICERs in quality-adjusted life-years (QALY), which estimate a medicine's benefits to patients: length of life, and their quality of life.

3. Health technology assessments for England and Wales

The National Institute for Health and Care Excellence (NICE) assesses medicines for use in the NHS in England and Wales.

Types of NICE assessment

Single technology appraisal

NICE's single technology appraisal (STA) process covers one medicine for treating a single disease (or indication). An STA is usually used for new medicines or for licence extensions.

Fast track appraisal

NICE introduced a fast track appraisal (FTA) for medicines that may offer exceptional value for money. It's a type of STA with a quicker assessment process, aiming to get the most cost-effective medicines to patients faster.

NICE uses three criteria to decide whether to review a medicine by FTA.

- The company estimates the most realistic ICER is less than £10,000 per QALY gained.
- NICE estimates the most realistic ICER is likely to be less than £20,000 per QALY gained, and unlikely to be over £30,000 per QALY gained.
- The medicine is likely to give similar or greater health benefits at a similar or lower cost than medicines already recommended to treat the same disease.

NICE's FTA process is around 10 weeks shorter than for a medicine assessed under the usual STA process. NICE publishes a final appraisal document (FAD) after one committee meeting, with no consultation step.

Highly specialised technologies

A highly specialised technology (HST) is a type of STA that covers one specialised medicine for treating one very rare disease. The National Institute for Health Research Innovation Observatory identifies most of the medicines for NICE's HST programme. The Department of Health and Social Care aims to refer these to NICE **before** the EMA or MHRA license them, usually at:

- 20 months before licensing for new medicines; or
- 15 months before licensing for licence extensions.

Multiple technology appraisal

NICE uses a multiple technology appraisal (MTA) to assess several medicines for treating a single disease (or indication), and also for reviews of published appraisals.

NICE guidance

After assessing a medicine, NICE's committee makes one of five recommendations. (Table 1). NICE publishes its recommendation about a medicine in a FAD or a final evaluation document (FED) for each assessment. Its technology appraisal (TA) guidance for NHS England and NHS Wales is usually published around two months later.

NHS England and NHS Wales follow all NICE's TA guidance. If NICE recommends a medicine for use, health boards in Wales must fund it within 60 days of NICE publishing the FAD or FED (unless stated otherwise).

Table 1 NICE's assessment results for medicines

NICE decision	Result for patients
Recommended	NICE recommends that healthcare professionals in NHS England and NHS Wales can routinely prescribe the medicine to treat the disease considered.
Optimised	NICE recommends that healthcare professionals in NHS England and NHS Wales can prescribe a medicine only for use in a smaller group of patients than stated in the medicine's licence. For example, the medicine's use may only be cost-effective when given to a specific group of people, if other medicines aren't suitable for them.
Not recommended	NICE may decide not to recommend a medicine. This might happen if there is little evidence of its clinical effectiveness (how well it works), or it's not considered a cost-effective use of NHS resources. Healthcare professionals in NHS England and NHS Wales will not routinely prescribe the medicine for patients.
Only in research	NICE may decide to recommend a medicine is only used in research studies, such as a clinical study. This may be because there isn't enough clinical evidence to recommend its use in the NHS at the time of the appraisal. NICE may recommend that further research is conducted if: • the medicine is likely to be cost effective; • research will help to develop future NICE guidance; • research is realistic, already planned, or in progress; and • the benefits and costs of the research are favourable. Healthcare professionals in NHS England and NHS Wales will not routinely prescribe the medicine for patients.
Cancer Drugs Fund	NICE can recommend that a medicine to treat cancer is only available through the Cancer Drugs Fund for patients in NHS England and NHS Wales (see Medicines for treating cancer).

Medicines for treating cancer

NICE assesses all medicines to treat cancer that it expects will get a licence. NICE's guidance applies in England and Wales. For medicines to treat cancer, NICE's committee makes one of three recommendations (Table 2).

NICE may recommend that a medicine to treat cancer is only available to patients through the Cancer Drugs Fund (CDF). This happens if NICE thinks the medicine is likely to meet the criteria for routine commissioning, but is uncertain about its benefits to patients and wants more data to be collected in the NHS or in clinical studies.

The CDF is a source of funding for cancer medicines in England. The medicine's licence holder needs to agree a managed access agreement (MAA) with NHS England, and is encouraged to share the details with NHS Wales through the National Procurement Lead Pharmacist for Wales. Sometimes, the licence holder may need to agree an alternative MAA or commercial access agreement (CAA) with NHS Wales, which offers equivalent value during the managed access period.

Table 2. NICE's assessment results for medicines to treat cancer

NICE decision	Result for patients in Wales
Recommended for routine commissioning	A medicine should be available for prescribing to patients within 60 days of the publication date of NICE's FAD.
Not recommended	A medicine will not be routinely prescribed for patients.
Recommended for use only through the Cancer Drugs Fund (CDF)	A medicine will only be available for prescribing to patients after the medicine's licence holder has signed a managed access agreement (MAA) or commercial access agreement (CAA) with the NHS in Wales.

Budget impact test

NICE introduced a budget impact test (BIT) in 2017 for all medicines assessed in its health technology appraisals. The BIT assesses the impact on NHS resources and finances that a medicine is expected to make during the first three years that it's used in NHS England.

If NICE estimates that the budget impact will be over £20 million in any of the first three years, NHS England may suggest a commercial access agreement (CAA) with the medicine's licence holder. The aim is to reduce the impact of funding the medicine on NHS England's budget.

If a CAA is signed with NHS England, the medicine's licence holder is responsible for sharing the details of the CAA with NHS Wales.

4. Health technology assessment for Wales

NICE's guidance applies in Wales: NHS Wales must follow NICE's decisions about newly licensed medicines and medicines with new licence extensions. If NICE recommends a medicine, healthcare professionals in Wales must be able to prescribe it for patients within 60 days of NICE publishing a FAD or FED.

NICE will assess all medicines to treat cancer and most new medicines.

AWMSG will generally only assess a medicine for use in NHS Wales if:

- NICE doesn't expect to publish guidance within 12 months of a new medicine being licensed;
- the medicine's licence is extended, for example, to treat a different group of patients, such as children; or
- a new formulation of a medicine is licensed.

AWMSG's recommendations about medicines will be funded in NHS Wales after Welsh Government has ratified them. Full details of AWMSG's appraisal process are on its website: http://awmsg.nhs.wales/

All published AWMSG recommendations include a review date. A team at AWTTC reviews the evidence for each recommendation every three years after its publication.

An AWMSG assessment allows NHS Wales to fund and use a medicine if NICE is not going to assess it, or **before** NICE's guidance is published. Once NICE publishes guidance for a medicine, NICE's guidance applies in Wales and replaces AWMSG's.

Types of AWMSG assessment

Form A

The All Wales Therapeutics & Toxicology Centre (AWTTC) provides secretarial and administrative support to AWMSG. Pharmaceutical companies should fill in a company submission, called a Form A, for **all** new licensed medicines and new licence extensions, and send this to AWTTC. This includes any medicines for which the company has already sent evidence to NICE or SMC.

After assessing the Form A, AWMSG's Steering Committee will decide which type of submission it needs, if any, to assess the medicine.

Full submission

If AWMSG asks for a full submission, the medicine's licence holder should submit comprehensive evidence of its clinical effectiveness, cost effectiveness and budget impact. AWTTC will seek evidence from additional sources to produce an assessment report for each medicine, for the AWMSG to discuss.

Limited submission

AWMSG may ask for a limited submission from the licence holder in some cases.

- The medicine is a new formulation costing the same or less per treatment, for example, a slow-release tablet, or new chemical salt of an existing medicine.
- The medicine's licence is extended to treat a different group of patients.
- AWMSG expects that using the medicine in NHS Wales would have a minimal impact on the NHS Wales budget.
- AWMSG estimates a small difference in cost between the new medicine and a medicine currently used to treat the same disease.

When AWMSG asks for a limited submission, the licence holder may submit less information than for a full submission. But it should include sufficient evidence of the medicine's clinical effectiveness or equivalence to a medicine currently used to treat the same disease. The company should also show evidence of expected impact of the new medicine on the NHS Wales budget, compared with the treatments currently used in Wales.

AWMSG may ask for a full submission for a medicine at any time during its assessment process. AWMSG's Steering Committee decides about submission type; its decision is final and binding.

AWMSG guidance

For **all** submissions, AWMSG makes one of three recommendations about a medicine (Table 3). Welsh Government must ratify AWMSG's recommendations before they can be published. Once published, all seven health boards and the Velindre NHS Trust in Wales must make sure the medicine is available for prescribing to patients within 60 days of the publication date.

Table 3. AWMSG's assessment results for medicines

AWMSG decision	Results for patients in NHS Wales
Recommended	AWMSG recommends a medicine can be routinely prescribed to treat the disease (or indication) assessed. NHS Wales must fund and resource the medicine and make sure it's available for prescribing to patients in Wales within **60 days** of AWMSG publishing the recommendation.
Recommended with restrictions	AWMSG recommends a medicine for use only in a smaller group of patients than stated in the medicine's licence. For example, the medicine's use may only be cost effective when given to a specific group of people, if other medicines aren't suitable for them. NHS Wales must fund and resource the medicine, and make sure it's available for prescribing to those patients in Wales within **60 days** of AWMSG publishing the recommendation.
Not recommended	AWMSG may decide not to recommend a medicine, usually if there is little evidence of its clinical effectiveness, or if it's not considered a cost-effective use of NHS Wales' resources. The medicine will not be routinely available for prescribing to patients in NHS Wales.

AWMSG applies broader considerations for all medicines that treat rare diseases or medicines that may be life-extending for patients who have a short life expectancy.

Medicines for rare diseases

AWMSG considers additional factors for medicines developed to treat rare diseases, and recognises the potential higher costs of developing these medicines. The evidence for clinical and cost effectiveness is often based on small numbers of patients, and is therefore associated with greater uncertainty than for other medicines.

AWMSG acknowledges that the rarity of a disease is likely to affect the evidence available and the medicine's cost, and appreciates the need for innovation and research to meet the clinical needs of patients with a rare disease.

Patients with a rare disease should have the same opportunity to access medicines as other patients. Equity of access to medicines is an important consideration when appraising a medicine for a rare disease.

AWMSG considers medicines to treat rare diseases as:

- **Orphan medicines** (or equivalent): developed to treat a disease affecting at most 1 in 2,000 people in Wales, and meets the European Commission's criteria for "orphan status". It may have European Commission "orphan status".
- **Ultra-orphan medicines** (or equivalent): developed to treat a disease affecting at most 1 in 50,000 people in Wales. It may have European Commission "orphan status".

These definitions must apply to the **full population** of people with the disease, or diseases, stated in the medicine's licence.

The medicine's licence holder sends AWMSG additional information about the medicine if it's going to be assessed under the process for medicines for rare diseases.

AWMSG assesses medicines developed to treat rare diseases using the same process as for all other medicines. However, an additional meeting of a Clinician and Patient Involvement Group (CAPIG) may be included to further assess the benefits of the medicine from the perspective of clinicians and patients.

Broader considerations

For medicines developed to treat rare diseases, AWTTC's assessment report will include the incremental cost per QALY, to show relative cost-effectiveness, when possible. But the cost per QALY is only part of a wider decision AWMSG may make about the new medicine's value; AWMSG will also consider societal aspects.

When the cost per QALY is higher than the usual thresholds, AWMSG considers additional factors when assessing these medicines.

- How severe is the disease when treated with currently available medicines, in terms of survival and the quality of life of patients and their carers?
- Does the medicine address an unmet need (for example, no other licensed medicine treats the disease)?
- Does the medicine cure, or reverse, the disease, rather than stabilise it?
- Does the medicine bridge a gap to a definitive treatment, for example, a gene therapy; and is this treatment currently being developed?
- Is the medicine innovative?
- How much will the medicine improve a person's symptoms compared with current treatments?

AWMSG will also think about the broader societal impact: whether the medicine brings added value that isn't reflected in the QALY, such as:

- quality of life, for example, being able to continue working or studying; and
- added value to a patient's family, such as effects on carers or on family life.

Medicines for patients at the end-of-life

AWMSG assesses these medicines using the same process as all other medicines. But they will consider additional factors when assessing:

- medicines that may extend the life of a patient who may have a short life expectancy; and
- medicines licensed to treat incurable diseases affecting small numbers of patients.

AWMSG will assess these medicines using additional criteria.

- If they estimate the most realistic ICER to be over £30,000 per QALY gained.
- If the medicine treats patients who have a short life-expectancy, usually less than 24 months. For example, estimated from the median survival of patients in a control group of a clinical study.
- If evidence shows that the medicine extends life, usually by at least three extra months, compared with current NHS treatments.

Estimates of how long a medicine can extend life should be robust and shown, or inferred, by results of progression-free survival or overall survival of patients in a clinical study.

AWMSG should also agree that the medicine's licence holder has made realistic, objective and robust assumptions in the economic model submitted.

If the medicine meets the criteria, AWMSG will consider:

- giving greater weight to QALYs achieved in the later stages of terminal diseases, assuming that the extended life is experienced at the full quality of life expected for a healthy person of the same age; and
- how much additional weight to assign to the QALY benefits in this patient group for the medicine to be cost effective within the current threshold range.

5. Welsh Government policy to fund new medicines

New Treatment Fund

Welsh Government established the New Treatment Fund (NTF) in 2017, to help NHS Wales resource new medicines in Wales. The fund speeds up access to medicines that NICE or AWMSG recommend for use by reducing the time taken to make the medicines available.

All new medicines that NICE or AWMSG recommend for use in the NHS must be available for prescribing to patients in Wales within:

- 60 days of Welsh Government ratifying AWMSG's guidance; or
- 60 days of the date that NICE publishes its FAD or FED.

Table 4 shows an overview of HTA in England and Wales, with the expected times for the medicines to be available for prescribing to patients in NHS Wales.

Table 4. HTA results in England and Wales

<table>
<tr><th colspan="2">Health technology assessment</th><th>Guidance issued</th><th>Routinely available in NHS Wales</th></tr>
<tr><td rowspan="4">NICE</td><td rowspan="4">• Single technology appraisal
• Fast track appraisal
• HST appraisal
• Multiple technology appraisal</td><td>Recommended</td><td rowspan="3">within 60 days months of NICE's FAD or FED published</td></tr>
<tr><td>Optimised</td></tr>
<tr><td>Recommended for use in the Cancer Drugs Fund*</td></tr>
<tr><td>Only in research</td><td>n/a</td></tr>
<tr><td rowspan="3">AWMSG</td><td rowspan="3">• Full submission
• Limited submission</td><td>Not recommended</td><td>No</td></tr>
<tr><td>Recommended</td><td rowspan="2">within 60 days of Welsh Government's ratification</td></tr>
<tr><td>Recommended with restrictions</td></tr>
<tr><td colspan="4">* Only for medicines to treat cancer
n/a = not applicable</td></tr>
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6. Access to medicines before they are licensed

Early Access to Medicines Scheme

Sometimes patients can be prescribed medicines that the EMA or MHRA has not yet licensed. The Early Access to Medicines Scheme (EAMS) aims to get new medicines that don't yet have a licence to patients who have life-threatening or seriously debilitating diseases, but **only if there is a clear, unmet medical need**. The access scheme applies in England and Wales.

Under EAMS, the MHRA gives a scientific opinion about the balance of a medicine's benefits and its risks. The MHRA bases its opinion on the data available when a pharmaceutical company submits a medicine for the scheme.

The MHRA conducts a two-step evaluation and gives:

- promising innovative medicine (PIM) designation; and
- early access to medicines scientific opinion.

The scientific opinion lasts for one year and can be renewed. It will expire on the day that the EMA licenses the medicine. EAMS is voluntary and the MHRA's scientific opinion doesn't replace the usual licensing procedures for medicines.

Individual Patient Funding Requests

Sometimes a health board may not routinely provide a medicine, for example, a medicine that the EMA, or MHRA, has not yet licensed for treating a particular condition. Requests may also be made for licensed medicines.

If a patient and their clinician agree that a medicine that isn't routinely available would benefit the patient, the clinician can submit an Individual Patient Funding Request (IPFR), asking the health board or trust, or the Welsh Health Specialised Services Committee (WHSSC), to fund the medicine.

An independent panel of healthcare professionals and lay members meets to consider the IPFR and the clinical evidence. The patient's personal details are always kept confidential.

The panel will decide to fund a medicine if the information provided shows:

- significant clinical benefit is expected for that particular patient; and
- the medicine's cost is in balance with the expected clinical benefit.

AWTTC works with IPFR panels and WHSSC to ensure the IPFR process in Wales is fair and consistent.

One Wales process

When a group of patients might benefit from a medicine that isn't routinely available, AWTTC co-ordinates the One Wales medicines process.

One Wales can be used for medicines when:

- the medicine's licence holder commits to a future HTA of a licensed medicine;
- the EMA or MHRA have not licensed a medicine;
- the EMA or MHRA have licensed a medicine only to treat a different condition(s); or
- a medicine isn't included in current treatment guidelines and no other suitable medicine is licensed to treat the condition.

The process results in a decision that applies to all of Wales. If a medicine gets a positive One Wales recommendation, if considered appropriate, it can then be prescribed for patients across Wales.

AWTTC regularly collects and analyses data from IPFRs across Wales to look for potential groups of patients for a particular medicine and condition. As well as finding groups of patients from IPFR panels, clinicians, chief pharmacists or medicines and therapeutics committees in Wales can ask AWTTC to consider medicines for the One Wales process.

AWTTC considers each medicine against agreed criteria and also asks clinical experts whether it is suitable for the One Wales process. AWMSG Steering Committee decides whether a medicine will be assessed by the One Wales process.

An Interim Pathways Commissioning Group (IPCG) assesses the evidence and recommends the use of the medicine to the health board chief executives. If they endorse the recommendation, the decision applies across NHS Wales.

Health boards are responsible for implementing One Wales decisions and making sure that clinical outcomes are monitored. Clinicians who have requested access to use a medicine through the One Wales process must monitor and collect patient outcomes. AWTTC reviews each One Wales decision after 12 months, or earlier if new evidence becomes available, and considers all the clinical outcome data collected.

For licensed medicines, One Wales advice is interim to health technology assessment guidance from AWMSG or NICE.

7. Commercial agreements for newly licensed medicines

Before, during and after the HTA process, a medicine's licence holder may agree financial arrangements about a medicine's cost to NHS England and NHS Wales. These agreements affect the availability of new medicines for patients in Wales.

For all agreements applying to NHS England, the licence holder should share the details and sign an equivalent agreement with NHS Wales. Patient access schemes (PAS) apply in England and Wales; Wales patient access schemes (WPAS) only apply in Wales.

Patient access schemes and Wales patient access schemes

Patient access scheme

A patient access scheme (PAS) is a pricing agreement between the medicine's licence holder and the Department of Health and Social Care, to help NHS patients receive high-cost medicines. The medicine's licence holder may propose a PAS for a new medicine when NICE assesses that its value is unlikely to support the proposed list price, based on the current evidence. Only the medicine's licence holder can propose a PAS, which may be simple or complex.

Wales patient access scheme

A Wales patient access scheme (WPAS) is a pricing agreement between the medicine's licence holder and Welsh Government to help NHS patients in Wales receive high-cost medicines. The medicine's licence holder may propose a WPAS before AWMSG's HTA process. The Patient Access Scheme Wales Group (PASWG) advises Welsh Government on whether the simple or complex scheme will be workable within NHS Wales.

Simple PAS and WPAS

A simple PAS is usually the preferred option and offers a simple discount at the point of invoice. It must meet the simple discount criteria, which make sure that a PAS imposes no ongoing additional burden on the NHS and will remain in place until the next review of the guidance.

An approved simple discount PAS applies to all NICE-recommended indications and use of the same medicine. It will also apply to use of that medicine in NHS Wales. The medicine's licence holder shares the details of the PAS with the National Procurement Lead Pharmacist for Wales and AWTTC. A single point of contact for all the commercial arrangements in NHS Wales is managed through a central team on email: NHSWales.CA@wales.nhs.uk

For a simple PAS or WPAS, the licence holder must offer a lower price than the list price. This lower price applies:

- for all supplies of that medicine, for all diseases the medicines is licensed to treat and any licence extensions in the future, during the life of the PAS or WPAS;
- to the original invoice;
- without administration cost; and
- until or after AWMSG's three-year HTA review of the medicine.

The details of a simple PAS or WPAS are usually confidential.

Complex PAS and WPAS
All other types of PAS are complex. These include: rebates; free stock; dose capping; and schemes based on the results seen in patients treated with the medicine.

The licence holder may consider a complex PAS or WPAS if their scheme doesn't meet the criteria for a simple one. Any proposed scheme for use in primary care would be considered complex. The details of a complex PAS or WPAS are usually confidential.

Managed access agreements

A managed access agreement (MAA) is agreed between NICE and NHS England, as part of the HTA process. Under an MAA, patients may receive a new medicine while long-term data on it are still being collected. The medicine's licence holder will provide the new medicine at a discounted cost, and before final funding decisions.

Agreements with NHS Wales
In Wales, the medicine's licence holder is encouraged to share the details of an agreed MAA through the National Procurement Lead Pharmacist for Wales. Sometimes, the licence holder may need to agree an alternative MAA with NHS Wales, which offers equivalent value during the managed access period.

Cancer Drugs Fund managed access agreements

For medicines licensed to treat cancer, the licence holder agrees a commercial access arrangement with NHS England, which is considered in NICE's technology appraisal.

The CDF MAA has two parts.

- A data collection arrangement, stating what data to collect during the managed access period to resolve the most important areas of uncertainty.
- A CDF commercial access agreement (CAA), determining how much the NHS will pay for the new medicine during the managed access period.

Highly specialised technology managed access agreements

For medicines recommended under NICE's HST program, the medicine's licence holder may agree an MAA with NICE and NHS England.

An HST MAA may specify several items.

- A proposal to address any uncertainty in the HTA evidence that NICE identifies. For example, a plan to generate more evidence for a group of patients covered by the licence but who were not represented in clinical studies.
- How long the arrangement will last, with a reason; agreed between the licence holder, NHS England and patient groups.
- Defined rules for starting, continuing and stopping treatment with the medicine; and clear starting and stopping points in the treatment pathway.
- Outcomes to measure, and how to collect and analyse the data.
- How often to review the outcomes in the MAA.
- Funding arrangements.
- What will happen to patients receiving treatment who may no longer be eligible if NICE issues a more restricted, or negative, recommendation after reviewing its guidance using the data collected.

- Financial risk management plans agreed between NHS England and the licence holder, including risk-sharing during the agreement.
- The roles and responsibilities of patient groups.

NICE's evaluation committee may recommend that a medicine is used only in research, or recommend it as an option, but that data are formally collected during its use. This may happen if evidence of clinical effectiveness or impact of an HST on other health outcomes is missing, weak or uncertain. Before recommending this, the committee will consider several factors.

- The need and potential value to the NHS of collecting additional evidence to inform future NICE guidance and use of the medicine in clinical practice.
- Uncertainty in the analysis and how to reconsider based on the research results.
- Whether it's possible to collect the data needed.
- Reducing the costs of introducing the medicine.
- How likely the research needed will give results.
- When results are likely to be available to inform future NICE guidance and clinical practice.
- Other factors affecting data generation, such as other research planned, under way or likely to be completed.

To form the guidance, NICE's evaluation committee will consider commercial agreements.

Agreements with NHS Wales
The medicine will be funded, but NHS Wales expects the licence holder to share the details of the HST MAA or equivalent through the Chair of the AWDCC, and agree this with NHS Wales before implementing the recommendation.

Commercial access agreements

A commercial access agreement (CAA) is proposed by a medicine's licence holder to NHS England to manage the cost of a medicine to the NHS. A simple PAS is considered a type, or component, of a CAA.

A CAA is the pricing part of a complete MAA, where the other part is a data collection agreement. Details of these arrangements are confidential. The medicine's licence holder is responsible for sharing details of the agreement with the relevant NHS organisations.

Cancer Drugs Fund commercial access agreements

When NICE recommends a medicine for use only within the CDF, it invites the medicine's licence holder to propose a CAA, or to amend an already proposed arrangement. They agree a price for the medicine to be available to the NHS during the CDF term.

For a medicine to be recommended for use within the CDF, it must show likely potential to satisfy the criteria for routine use, considering end-of-life criteria when appropriate. Licence holders should ask NICE for advice about how the appraisal committee will consider clinical and cost effectiveness, on which they must base their proposal for a CDF CAA.

Agreements with NHS Wales
In Wales, the medicine's licence holder is responsible for telling NHS Wales about the details of a CAA.

Highly specialised technology commercial access agreements

NICE's HST evaluation process has a reconsideration step at specific points. The step gives an opportunity to develop new, or enhance existing managed access proposals and for NICE to talk to the licence holder and NHS England. These discussions would cover:

- identifying sub-groups of patients for treatment;
- clinical tests;
- criteria for starting and stopping treatment;
- patient access schemes;
- conditions for collecting data;
- commercial agreements between the licence holder and NHS England.

Agreements with NHS Wales
In Wales, the medicine's licence holder is responsible for telling NHS Wales about the details of a HST CAA.

Budget impact test commercial agreements

NHS England will offer commercial discussions with licence holders whose medicines NICE appraised when the BIT was engaged before asking for a change to the funding. These discussions happen in parallel with the HTA or evaluation.

NHS England must give NICE a progress update at least five working days before NICE's first appraisal or evaluation committee meeting. Any commercial agreements at this point are only to manage the net budget impact of the medicine; NICE's appraisal committee or HST committee will not consider them when determining the cost effectiveness of the technology.

Agreements with NHS Wales
In Wales, the medicine's licence holder is expected to share the results of commercial discussions about the BIT through the Chair of the AWDCC. Sometimes, an alternative CAA may be agreed with NHS Wales, which offers the same value for the length of NICE's recommendation.

Pharmaceutical rebate schemes in England and Wales

A medicine's licence holder, or a third party company, may offer a rebate scheme to primary care organisations in England and to health boards in Wales, on the prescribing of their medicine. These schemes are contractual arrangements to lessen prescribing costs of licensed, branded, medicines.

Licence holders should supply medicines to the NHS using transparent pricing, creating no additional administrative costs for the NHS.

Rebate schemes should only be agreed if a medicine is believed to be appropriate for a defined group of patients. All patients should continue to be treated as individuals. Accepting a rebate scheme should not restrict local decision-making or formulary development.

A rebate scheme must be compatible with the effective, efficient and economic use of NHS resources.

8. How NHS Wales obtains medicines

Through the integrated health service structure in NHS Wales, Chief Pharmacists are accountable for:

- safety of patients related to the supply of medicines;
- spending on medicines; and
- pharmacy services in the managed sector and in primary care.

NHS Wales shared services partnership (NWSSP) invites and manages all medicines procurement contracts and services for the Velindre NHS Trust and all seven health boards in Wales. They are supported by the National Procurement Lead Pharmacist for Wales who leads the clinical procurement (obtaining) of medicines.

The All Wales Drug Contracting Committee

The All Wales Drug Contracting Committee (AWDCC) awards all the hospital medicines contracts in Wales. They make sure that the contracts meet all legal and governance requirements under the public procurement regulations.

AWDCC's work also includes commercial agreements for new medicines, or medicines licensed for new indications, that NICE or AWMSG have assessed. The AWDCC Chair will agree any commercial agreements that are part of an HTA, including agreements under an MAA, and make sure the agreements meet all governance requirements.

The AWDCC Chair also makes sure that all organisations in NHS Wales can obtain the medicine for their local population at the same time and at the same cost.

The AWDCC includes:

- the National Procurement Lead Pharmacist for Wales (Chair)
- health board medicine procurement lead pharmacists;
- the National Quality Assurance Lead Pharmacist for Wales;
- a Chief Pharmacist;
- a finance director;
- the medicines procurement category manager; and
- a representative from AWTTC.

Medicines homecare services

All health boards in Wales and the Velindre NHS Trust collaborate to deliver medicines under the NHS Wales 'care closer to home' strategy: *A Healthier Wales: our plan for Health and Social Care*.

The collaboration works as a virtual team to standardise practice, share experience and apply a “once-for-Wales” philosophy for homecare services. There are several examples of its work.

- Adhering to NHS Wales’ terms and conditions for providing services and goods.
- A standard service level agreement for NHS Wales to share with homecare providers to make sure all parties are aligned.
- Patient care and experience drive the medicines homecare service.
- An NHS Wales supplier engagement process to improve performance through regular supplier review meetings, including an NHS standard set of key performance indicators (KPI) for homecare services.

- NHS Wales is a member of the National Homecare Medicines Committee to contribute to these services in an equitable manner across the UK, making sure the needs of the Welsh population are considered and included.

Once-for-Wales primary care rebate schemes

All primary care rebate schemes in Wales must meet ethical, financial and governance requirements, and working with suppliers to minimise administrative burden to both parties. Several health boards are likely to implement individual schemes, so a "once-for-Wales" approach works best, giving a single point of access and administration.

The AWDCC advises the Chief Pharmacists, on behalf of all health boards, if an individual proposal is suitable as "once-for-Wales". Developing this strategy and standard process to assess and implement any primary care rebate scheme has several benefits.

- No need to assess or approve schemes offered to individual health boards.
- Ensuring fair and equal access to medicines for patients in Wales across all health boards.
- A standard way to govern and manage schemes across NHS Wales.
- Helping to find ways to automatically calculate and monitor all rebate agreements with minimal administrative costs.

Free-of-charge medicines

NICE or AWMSG's HTA is the best way to advise on the clinical effectiveness and cost effectiveness of newly licensed medicines. However, if there is no HTA advice, or it's waiting to be published or ratified, some licence holders may want to offer NHS Wales a free-of-charge medicine supply agreement. This would give patients and clinicians early access to a medicine at no cost to the NHS.

Health board Chief Pharmacists and the National Procurement Lead Pharmacist for Wales co-ordinate the free-of-charge medicine supply agreements on behalf of NHS Wales, supported by AWTTC. The free-of-charge medicine policy only applies to newly licensed medicines, where the licence holder has engaged in HTA with AWMSG or NICE, but there is no guidance published.

Each licence holder's offer should meet certain conditions.

- The licence holder has submitted the medicine to NICE or AWMSG for HTA, but expects a delay of over six months before guidance is published or ratified.
- The medicine is not associated with significant additional administration costs, such as testing or monitoring.
- The medicine is fully free-of-charge and the offer is not a partial price discount.
- The licence holder commits, in writing, to supply the medicine for the specified indication free-of-charge:
    - until 60 days after AWMSG publishes positive HTA guidance;
    - until 60 days after NICE publishes a positive FAD or FED, and, when appropriate, with an agreed CAA or PAS; or
    - if the medicine is not recommended for use after HTA but patients who are already taking it still need to continue their treatment.

The Chief Pharmacists will prioritise medicines they expect to help patients with life-threatening, long-lasting or seriously debilitating diseases, when no suitable licensed medicine is available.