Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

The AWMSG Off-label One Wales Medicines Assessment Process

Improving access to medicines where there is a clinical need or benefit to the NHS in Wales and the people it serves.

Approved by:	All Wales Medicines Strategy Group
Issued:	November 2015 (Revised February 2021, April 2023 December 2023 and March 2026)
Review date:	March 2029
Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be a positive impact. Key actions have been identified and these can be found in the Equality and Health Impact Assessment (EHIA) for the AWMSG Medicines Assessment Process for Licensed and Off-label Medicines.
Documents to read alongside this process	The AWMSG Licensed One Wales Medicines Assessment Process NHS Wales Policy Making Decisions on Individual Patient Funding Requests (IPFR). July 2025 AWMSG Medicines Assessment Process for Licensed and Off-label Medicines, June 2024 AWMSG Policy for appraising medicines for severe conditions Independent review process

The One Wales Medicines Process, (previously known as the One Wales Interim Commissioning process) was developed in 2015, following a review of the individual patient funding request (IPFR) process. It introduced an alternative route to access a medicine (or medicines) for a clearly defined and specific cohort of patients in the

absence of health technology appraisal advice. One Wales decisions are based on the available evidence of clinical effectiveness and cost-effectiveness. Once approved, these decisions ensure that there is equitable access to these medicines across NHS Wales. This document explains when this process may be used and how it works.

1. Background

The All Wales Medicines Strategy Group (AWMSG) and the National Institute for Health and Care Excellence (NICE) provide Health Technology Assessment (HTA) guidance on the introduction of new licensed medicines within NHS Wales. Whilst recognising that timely HTA is always the preferred means to routinely fund a medicine, in the absence of AWMSG/NICE advice, the IPFR process may be used by clinicians to access a licensed medicine when it is not routinely available in NHS Wales. Similarly, in the absence of a licensed medicine that will meet the patient's needs, a clinician may apply for funding of an off-label medicine (i.e. a medicine prescribed and used outside the terms of its UK Medicines and Healthcare products Regulatory Agency (MHRA) marketing authorisation) via the Health Board's IPFR panel. However, medicines will only be funded where it has been demonstrated that the medicine is considered to provide particular clinical benefit to the individual and provide value for money. Where several patients may benefit from the medicine (or medicines), the IPFR process (with its emphasis on the individual patient) may not be appropriate and may result in funding variation and differential access across Wales. To address this, the All Wales Therapeutics and Toxicology Centre (AWTTC) developed the One Wales Medicines process in conjunction with representatives from Welsh Health Specialised Services Committee (WHSSC), now the NHS Wales Joint Commissioning Committee (NWJCC) and IPFR panel co-ordinators. In the absence of health technology appraisal advice, the process enabled the means to access a medicine (or medicines) for a clearly defined and specific cohort of patients for an unmet need in accordance with specific criteria.

Following a comprehensive review of existing assessment processes in January 2025, the medicines assessment process for licensed and off label medicines was launched. The review was in response to the shift in the medicines access landscape and to ensure the AWMSG process meets the needs of the NHS in Wales and supports an 'All-Wales' approach to medicine access. This led to a change in the remit of the One Wales Medicines process to focus solely on the repurposing of off-label use of medicines. This mirrored more accurately the work being undertaken by the One Wales Medicines process. The licensed route was broadened, removing some of the previous exclusion criteria with the aim to eliminate any gaps still remaining in supporting access to treatments in Wales.

The Off-label One Wales Medicines Assessment process enables access to an off-label medicine where:

- the medicine has marketing authorisation in the UK but is not licensed for the indication of interest, or
- the requested use of the medicine is outside of the specification of the marketing authorisation, and
- there is no routinely available licensed medicine that will meet the patients' needs.

There are clinical situations when the use of an off-label medicine may be judged by the prescriber to be in the best interest of the patient based on available evidence. The assessment of an off-label medicine (or medicines) will take account of

nationally agreed criteria. The criteria include consideration of the suitability of any licensed medicine for the same patient cohort, and evaluation of the clinical efficacy versus the clinical risk of off-label medicines that may help patients with life-threatening, long lasting or seriously debilitating illnesses. Before prescribing a medicine that may not have a UK marketing authorisation for the use listed it is important that prescribers refer to relevant guidance on prescribing off-label/ unlicensed medicines.

2. How the Off-label One Wales Medicines Assessment process works

2.1 Identifying medicines and related potential patient cohorts and how to submit a request for consideration for assessment

Medicines and potential patient cohorts (clearly defined and specific) are identified by Health Board IPFR panels, NWJCC, Chief Pharmacists, formulary pharmacists, Drugs & Therapeutics committees or clinical experts (usually through their specialist group or network). These healthcare professionals can request that a medicine(s) be considered for One Wales by completing a medicines request form for healthcare professionals or emailing AWTTC at awttc@wales.nhs.uk.

AWTTC welcomes requests for medicines assessments from patient organisations; by contacting AWTTC at awttc@wales.nhs.uk.

AWTTC has a central co-ordinating role in the IPFR process, enabling the identification of potential patient cohorts at an early stage, by using All Wales IPFR data. The decision as to whether the One Wales Medicines Process should be initiated is proposed by AWTTC, approved by the AWMSG Scrutiny Panel and endorsed by the AWMSG Steering Committee.

2.2 The AWMSG Scrutiny Panel

The AWMSG Scrutiny Panel is responsible for deciding if AWMSG should proceed with the assessment of a licensed or an off-label medicine. The AWMSG Scrutiny Panel will decide on the route of assessment for off-label medicines by using pre-defined criteria as detailed in Section 1 above.

The AWMSG Scrutiny Panel considers a proforma compiled by AWTTC for each medicine. This summarises the rationale for the request for assessment and provides information on the extent of clinical and cost-effectiveness evidence available, how the medicine may fit in the treatment pathway including any available guidelines, the most likely comparators and an estimate of the potential budget and service impact should the medicine be made routinely available in NHS Wales. The Scrutiny Panel are also given the accompanying request form submitted by the healthcare professional, and any other information deemed relevant. The Scrutiny Panel will discuss the information presented and reach a consensus based on pre-defined criteria as to whether the medicine is suitable for assessment by the One Wales Medicines Assessment Group (OWMAG)

The Constitution and decision records of the AWMSG Scrutiny Panel are published on the AWTTC website.

The AWMSG Scrutiny Panel will notify the applicant – whether it be a healthcare professional or network, or patient organisation – of its decision before review by the AWMSG Steering Committee. If the applicant disagrees with the AWMSG Scrutiny Panel decision, they will have 10 working days to appeal. AWTTC will inform the AWMSG Steering Committee, who will make the final decision.

All endorsed Scrutiny Panel decisions will be published on the AWTTC website. If the AWMSG Steering Committee disagree with the AWMSG Scrutiny Panel decision, the AWMSG Steering Committee will provide their rationale to the AWMSG Scrutiny Panel. Any new information provided by the AWMSG Scrutiny Panel will be considered by the AWMSG Steering Committee and a final decision made.

2.3 Pharmaceutical company engagement

Once the need to initiate a One Wales assessment has been agreed for an off-label medicine, AWTTC contacts the marketing authorisation (MA) holder to inform them that an Evidence Summary Report (ESR) is being produced. AWTTC also invites them to submit any supportive information, including any evidence or experience of using the medicine to demonstrate its safety, efficacy, clinical and cost-effectiveness (see Appendix 1 One Wales Medicines Process flow diagram). For medicines that have a Patient Access Scheme (PAS) or commercial arrangement already in place, the MA holder is asked to confirm whether the existing arrangement can be extended to the medicine/indication under consideration. For medicines without a PAS or commercial arrangement, companies may be asked to consider submitting a commercial arrangement in the form of a simple discount. Commercial arrangements should be agreed prior to drafting the ESR. See Appendix 2 for details. The MA holder must inform AWTTC of any plans to license the medicine for the indicated cohort under consideration. There will be an obligation for the company to submit for HTA if marketing authorisation is granted.

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2.4 Gathering the evidence

The requesting clinician or organisation should provide supporting evidence with their request and further evidence will be gathered by AWTTC from all possible sources.

AWTTC works closely with clinical networks, patient groups and IPFR panels in producing the ESR that supports decision-making. AWTTC is keen to build on good working relationships with colleagues in the pharmaceutical industry by maintaining a collaborative approach to ensure that the evidence base on which One Wales decisions are made is robust, comprehensive and clearly identifies the place of treatment in relation to alternative treatment strategies for the identified cohort of patients. To this end AWTTC will request any available additional clinical and cost-effectiveness evidence from the MA holder. Costs used in the report will aim to be reflective of those procured by NHS Wales and may be confidential. The draft ESR is circulated to the MA holder and clinicians identified through the process for comment before finalising.

Responsibilities:

- **AWTTC**: to carry out a comprehensive literature search and compile all available evidence into an ESR.
- **MA holder**: to provide clinical and cost-effectiveness evidence, budget impact and other relevant information where available and to make comment on the draft ESR.
- **Clinician**: to provide information on potential patient numbers and suitable comparators, to confirm unmet clinical need, to make comment on the draft ESR and respond to queries from the One Wales team compiling the report.
- **Patient organisations**: to provide a patient perspective on the unmet clinical need for the medicine, in particular the potential impact on quality of life for patients and their carers.

2.4.1 Commercially sensitive information

Commercially sensitive and academic in confidence information, will not be placed on the AWTTC website or in the public domain. However, such information may be shared in confidence with the Scrutiny Panel (in the medicine proforma) and OWMAG (in the ESR) to facilitate decision making. Confidential information is redacted from documents (such as the recommendation and decision rationale, ESR and Equality Health Impact Assessment [EHIA]) which are published on the AWTTC website following ratification of the recommendation. Any confidential commercial arrangements associated with comparator medicines will be redacted from documents shared with the applicant company during the assessment process and from all documents published on the AWTTC website.

Please refer to the AWTTC document, AWTTC use of pharmaceutical company data for further information.

2.5 One Wales Medicines Assessment Group (OWMAG)

The One Wales Medicines Assessment Group (OWMAG) considers and discusses the evidence presented in the ESR and provides a clear and robust recommendation, with rationale, to AWMSG. OWMAG is also provided with an Equality and Health Impact Assessment (EHIA) for the assessment of the medicine prepared by AWTTC, submissions from patients, carers or patient organisation (if available) and any completed clinical expert questionnaires (if available). AWMSG is asked to endorse the OWMAG recommendation which is then considered by Welsh Government for ratification. Additional considerations may be applicable to medicines which meet the eligibility criteria for assessment under the terms of the AWMSG policy for appraising medicines for severe conditions.

OWMAG reports to AWMSG and its membership is primarily drawn from IPFR Panels (see Constitution). Whenever possible, all of the health boards are represented at every meeting (with alternates [deputies] attending when the main member is unavailable). OWMAG convenes monthly or as needed for optimum timeliness. OWMAG makes recommendations in accordance with relevant guidance on unlicensed medicines[1].

The OWMAG recommendation, reached following a majority vote, may be either positive, positive with specific restrictions related to its use (restricted), or negative. OWMAG may defer a recommendation pending a request for further information. OWMAG will agree start/stop criteria for treatment as appropriate.

A clinical expert is invited to attend the OWMAG meeting to observe proceedings, answer questions and input into discussions to enable OWMAG members to gain a better understanding of the clinical context. Clinical experts are usually nominated by their specialist group or network and, therefore, should not express personal opinion or promote the use of a medicine.

A patient organisation representative is also invited to attend the OWMAG meetings to observe proceedings, answer questions and input into discussions to enable OWMAG members to gain a better understanding of the patient/carer perspective. Representatives are expected to relay broad views of the organisation rather than expressing a personal view. A lay member of OWMAG will verbally summarise the views of patients received by AWTTC.

Clinical expert and patient organisation representatives are asked to declare any personal or non-specific interests and will leave the meeting prior to the vote. In addition, if there is a confidential commercial arrangement associated with the

[1] Judicial treatment in Bayer Plc v NHS Darlington CCG and others, has clarified issues surrounding unlicensed treatment in preference to a licensed medicine, where clinical effectiveness is equivalent. OWMAG will continue to monitor jurisprudence relevant to medicines management.

medicine, the clinical expert and patient organisation representatives will be asked to leave the meeting before any discussions on cost-effectiveness and/or budget impact.

2.6 All Wales Medicines Strategy Group (AWMSG)

The recommendation from OWMAG with the decision rationale will be provided to AWMSG members for consideration at the next AWMSG meeting. AWMSG will be asked to endorse the recommendation from OWMAG. AWMSG members may direct questions about the assessment to AWTTC before or during the meeting, and any feedback will be shared with the AWMSG Chair and presented at the meeting. AWMSG will be asked to endorse the recommendation and to confirm that the assessment was thorough and consistent.

If AWMSG endorses the recommendation, the Chair will confirm this at the meeting, and, allowing 10 working days (2 weeks) for any objections from the applicant, it will be sent to Welsh Government for ratification. If not endorsed, AWMSG must state their reasons clearly and submit them to OWMAG for review. This will allow for recommendations to be re-considered by AWMSG subject to further information being supplied by OWMAG. AWMSG will then make their final decision.

2.7 Ratification by Welsh Government

Following confirmation of AWMSG's endorsement, the One Wales recommendation will be sent to Welsh Government for ratification. If Welsh Government ratifies (approves) the recommendation this will be disseminated to the Service for implementation (see section 2.8). It is expected that health boards will fund the medicine in accordance with the recommendation.

2.8 Informing the service/stakeholders

AWTTC will inform NHS Wales, the company and any clinical experts and patient groups involved with the process of the final decision by email. All decisions are displayed on the AWTTC website. In the interests of transparency, the OWMAG decision rationale, ESR and meeting minutes are made available on the AWTTC website, alongside the Equality and Health Impact Assessment. Commercially sensitive information is redacted from all documents prior to publication (see section 2.4.1). Health boards should ensure the medicine or medicines is/are included on their formulary.

2.9 Independent Review

If the applicant wishes to raise a complaint about the way the assessment was conducted and/or how scientific information was interpreted, they have two weeks from the date of the AWMSG meeting to request an Independent Review. Ratification will be postponed until the appeal is investigated. Details of this process and the grounds that may qualify for triggering an Independent Review are given in the AWMSG Independent Review Process document.

2.10 Prescribing off-label medicines

For positive One Wales decisions relating to off-label medicines, the responsibility associated with prescribing the medicine falls on the prescriber. Prescribers should pay particular attention to the risks associated with using off-label medicines and must discuss the risks and benefits with individual patients, their families and carers. These risks may include adverse reactions or discrepant product information or labelling (e.g. potential confusion for patients or carers when the Patient Information Leaflet [PIL] is inconsistent with a medicine's off-label use). Prescribers should consult the relevant guidance on prescribing unlicensed medicines before any off-label medicines are prescribed.

2.11 Discontinuation and retirement of a One Wales decision

All One Wales decisions will be reviewed by AWTTC on an annual basis and by OWMAG every 1 to 3 years (refer to section 4). Decisions regarding off-label medicines may be discontinued if the medicine receives an MA for the indication or if an alternative licensed medicine becomes routinely available (funded) for the same cohort of patients. In the former circumstance the MA holder will be expected to progress the medicine through the usual HTA routes.

If the medicine becomes licensed for the indication under which it is available through One Wales and the MA holder fails to make a timely (usually within 12 months of licence) submission to either AWMSG or NICE for HTA, the One Wales decision will be withdrawn. People having treatment may continue to do so, until they and their NHS clinician consider it appropriate to stop. AWTTC will inform AWMSG that the One Wales decision is withdrawn. On agreement, they will forward to Welsh Government for ratification.

Similarly, the advice for a medicine may be retired. This may apply, for example, when national guidance endorses the routine use of this medicine for the same indication or specified patient cohort. Subsequent availability of this medicine within NHS Wales may not be affected by retirement of the One Wales decision. AWTTC will inform AWMSG of the medicine that is retired and will forward to Welsh Government for ratification.

Responsibilities:

- **AWTTC**: to monitor NICE and AWMSG guidance, monitor off-label medicines for MA, monitor new medicines for the same indications.
- **MA holder**: to inform AWTTC of new evidence or of plans to license an off-label medicine.

3. Monitoring Outcomes

It is crucial that appropriate patient outcomes are monitored for all One Wales decisions. Outcome data, including patient numbers, are an important part of the review process and are used by AWTTC to inform the review report (see section 4). Clinicians are responsible for providing patient numbers and outcome data to

AWTTC. Clinicians in Wales may be required to complete a Blueteq form on initiation of treatment and at subsequent review.

Responsibilities:

- **AWTTC**: to liaise with clinicians to ensure patient numbers and outcome data are collected.
- **Clinicians**: to monitor and record outcomes and patient numbers and provide data to AWTTC in a timely manner.

4. Review process

4.1 Context

For all One Wales decisions a review by OWMAG is scheduled at 12 months from the date of advice and thereafter every 1 to 3 years. The principle of the initial review is to ensure that any new evidence is considered and that outcome data are in line with expectations from both a clinical and budgetary perspective. A decision may be reviewed earlier than 12 months if significant new evidence becomes available which may change the decision. Following initial review, for those medicines that have a review date that is longer than 12 months, AWTTC will conduct a literature search annually from the date of the last decision and may contact clinicians to request outcome data. If new significant information is found, a full review will be undertaken (see sections 4.2 to 4.4).

4.2 Preparing the review report

Approximately two to three months prior to the review date AWTTC will gather evidence including:

- a literature search for any literature published since the first assessment or last review;
- any changes to current clinical guidelines including starting and stopping criteria;
- new HTA advice from NICE or AWMSG for the same medicine or for a different medicine for the same indication;
- consultation with clinical experts on new information and clinical need;
- consultation with MA holders to inform them of the review and request information on updates to licence status and any new evidence they are aware of;
- outcome and usage data from clinicians collected as a pre-requisite for medicines supported by the One Wales Medicines process (see section 3).

The above evidence is collated by AWTTC to produce a summary review report.

4.3 Consideration by OWMAG

The review report is considered by OWMAG. For a review, OWMAG is not required to meet and may be consulted via email and submit votes electronically.

The recommendation from OWMAG, reached by majority vote, may be either: to renew the One Wales decision for up to 3 years; renew with restrictions or amendments; discontinue or retire the One Wales recommendation; or fully re-assess the One Wales decision using newly available information. If OWMAG recommend that a full re-assessment is warranted, the full One Wales Medicines Assessment process is followed as per section 2.0 above. If OWMAG renew, discontinue or retire the recommendation, the decision will be forwarded to AWMSG for noting. There is no requirement to send the decision to WG for ratification if the advice remains the same. In all other cases, the advice will be sent to WG for ratification.

4.4 Ratification and informing the service

Following ratification by Welsh Government the final review decision is disseminated to the service and displayed on the AWTTC website.

4.5 Static list

For those One Wales decisions where a full review is unlikely to lead to any changes to the recommendation, entry on to a static list may be considered. After a medicine has been through the initial One Wales Medicines Assessment process and the decision has been reviewed externally three times or has been on the work programme for a minimum of five years since the initial assessment (whichever comes first), the option to include that medicine on the static list would become available. The list has a robust set of inclusion criteria that will be assessed by the AWTTC team. AWTTC staff would present entry on to the static list as an option to OWMAG members after review if the medicine meets the inclusion criteria. If members decide not to endorse the request to place the medicine on the static list, then OWMAG will consider the other options currently available to them in accordance with the review process (continue with recommendation, amend recommendation, or remove recommendation).

When a medicine is moved to the static list it is no longer externally reviewed by OWMAG but will still undergo annual internal review by the AWTTC team to identify any new information that could affect the current decision. The medicine would remain on the static list unless the internal review process suggested that a review and discussion at an OWMAG meeting was required. AWTTC would flag this to OWMAG who may ask for the treatment to be taken off the static list and to be externally reviewed.

Entry on to the static list would not affect access to the treatment in Wales and the treatment would remain on the One Wales Medicines Assessment process work programme without a review date.

Glossary and abbreviations

AWMSG - All Wales Medicines Strategy Group
A statutory advisory public body sponsored by the Senedd that provides advice to the Welsh Government on the managed introduction of new medicines into NHS Wales and on the appropriate use of existing medicines.

AWMSG Scrutiny Panel
The AWMSG Scrutiny Panel is responsible for determining if a medicine, licensed or off-label, is suitable for assessment by AWMSG. The Panel is responsible for deciding on the route of assessment for each medicine by using pre-defined criteria.

AWTTC - All Wales Therapeutics and Toxicology Centre
An NHS organisation providing advice and services in therapeutics and toxicology in Wales. AWTTC liaises with, informs and helps healthcare professionals in Wales, engages with the pharmaceutical industry, involves patients and the general public in its work, and advises Welsh Government.

CASWG – Commercial Arrangement Scheme Wales Group
A group that considers the feasibility and implementation of commercial arrangements associated with the medicines access processes of AWMSG.

Clinical need
Clinical need, in this context, relates to a condition for which treatment is not addressed adequately by a routinely funded or licensed medicine available in NHS Wales.

CMAT – Commercial Medicines Access Team
A collaborative multi-organisational team comprised of colleagues from AWTTC, NHS Wales Shared Services Partnership (NWSSP) and the Medicines Value Unit (MVU). The role and responsibility of CMAT is to support and monitor the implementation of AWMSG and NICE recommended medicines associated with a commercial arrangement within the NHS in Wales.

IPFR – Individual Patient Funding Requests
IPFRs are defined as requests to a Health Board or NHS Wales Joint Commissioning Committee (NWJCC) 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 or commission.

MA Holder – Marketing Authorisation Holder
The company or other legal entity that has the authorisation to market a medicine in the UK.

NHS Wales Joint Commissioning Committee (NWJCC)
NWJCC is responsible for the joint planning of Specialised and Tertiary Services on behalf of Local Health Boards in Wales. It commissions and funds some medicines delivered by specialist and tertiary services.

NICE - National Institute for Health and Care Excellence
Established in 1998, it is an independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. NICE provides guidance and advice to the NHS in England and Wales on a wide range of topics relevant to healthcare. NICE guidance includes technology appraisals on the use of medicines.

Off-label medicine
A medicine prescribed and used outside the terms of its UK Medicines and Healthcare products Regulatory Agency (MHRA) marketing authorisation

OWMAG – One Wales Medicines Assessment Group
OWMAG advises NHS Wales about the use of off-label medicines for specific and defined patient populations (cohorts, or groups) and is a sub-group of AWMSG. The group comprises representatives from all IPFR panels, a lay member, industry representative, finance representative, a clinical pharmacologist and a health economist. OWMAG's recommendations about off-label medicines are sent to AWMSG for endorsement and then to Welsh Government for ratification.

WPAS - Wales Patient Access Scheme
A way for pharmaceutical companies to make high-cost medicines affordable for NHS Wales. The scheme is proposed by a pharmaceutical company and approved by the Commercial Arrangement Scheme Wales Group (CASWG) as part of the AWMSG assessment process.
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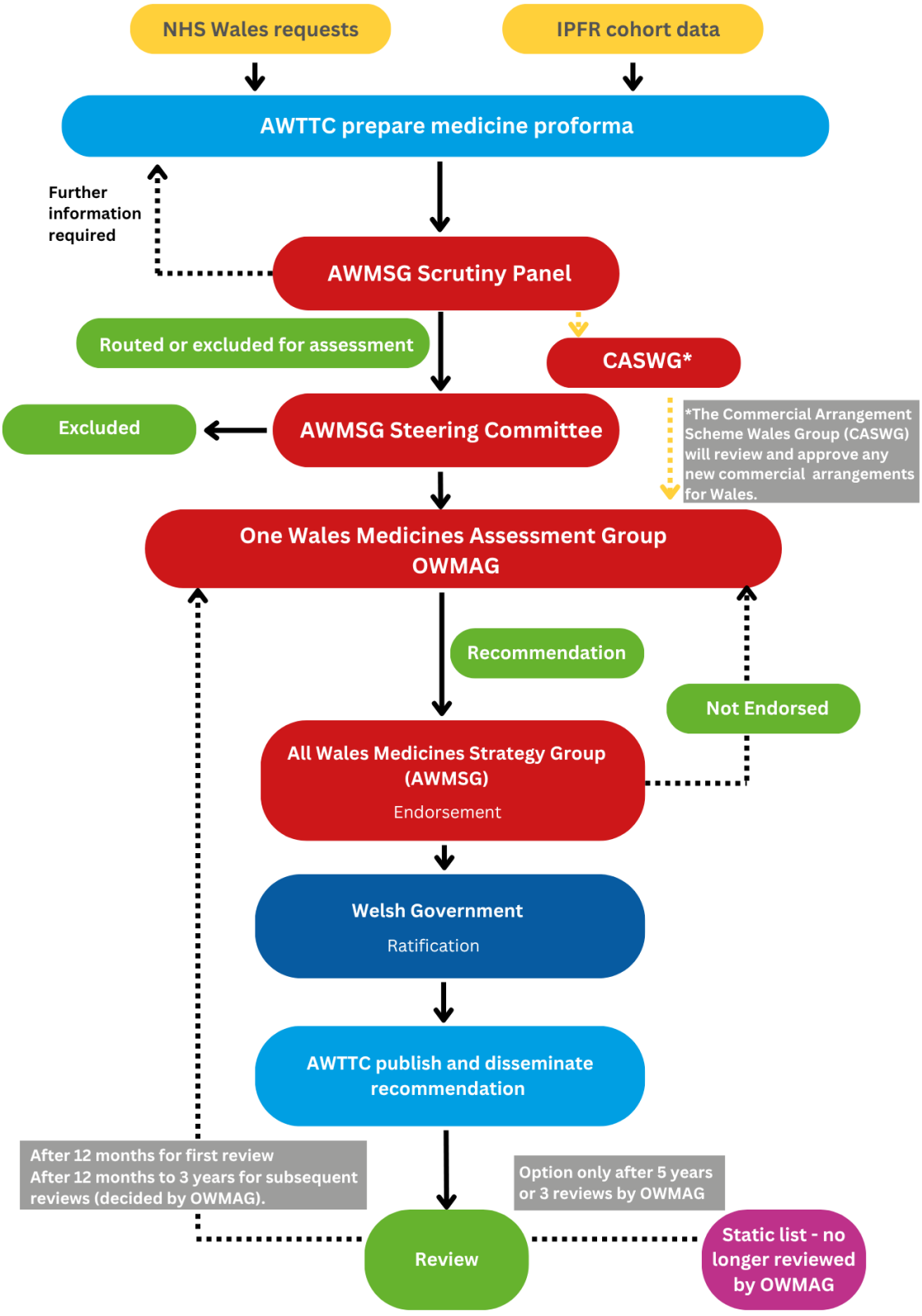
Appendix 1

One Wales Medicines Assessment Route for Off-Label Medicines



Appendix 2

COMMERCIAL ARRANGEMENTS FOR THE OFF LABEL ONE WALES MEDICINES PROCESS

As part of the process, the MA holders may be asked to consider submitting a commercial arrangement which would allow a price that is lower than the list price of the medicine (or a previously agreed commercial arrangement) to be considered as part of the assessment. The commercial arrangement proposals will be reviewed by the Commercial Arrangement Scheme Wales Group (CASWG) to assess the feasibility of implementation.

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- AWTTC confirm with the MA holder that they wish to submit a commercial arrangement and inform the Commercial Medicines Access Team (CMAT) who can provide the MA holder with submission instructions.

- Any contractual arrangements will be discussed between CMAT and the MA holder ahead of consideration by CASWG.

- CASWG will review the feasibility of implementing the proposed commercial arrangement in relation to the NHS in Wales.

- The MA holder will be informed of the decision by CASWG.

- Should a medicine become licensed for the indication, the commercial arrangement will expire on subsequent receipt of ministerial ratification of AWMSG advice or publication of the NICE final appraisal document (FAD). The MA holder shall be notified by AWTTC one month prior to the expected date of expiry. All future arrangements should be in place on receipt of HTA advice.