Enclosure No:	**2**/AWMSG/0624
Agenda Item No:	6 – AWMSG Medicines Assessment Process for Licensed and Off-label Medicines
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Action for AWMSG:
AWMSG are asked to consider and endorse the update to the AWMSG medicine assessment routes outlined in the document 'AWMSG Medicines Assessment Processes for Licensed and Off-label Medicines'.

Members are also provided with the AWTTC Equality and Health Impact Assessment (EqHIA) form associated with the work – see Appendix 3

Purpose:
Following a shift in the medicines access landscape AWMSG will adapt to the changing needs of the service by refining and developing the current medicines assessment processes. The paper describes an updated AWMSG assessment process which meets the needs of the service and will support an 'All-Wales' approach to medicines access.

Process:
- March 2024: Draft document out for consultation with key stakeholders
- April 2024: Consultation comments and responses considered by AWTTC
- May 2024: Document presented to AWMSG Steering Committee
- *June 2024: Document presented to AWMSG for endorsement*

Consultees
Consultees include:
- Association of the British Pharmaceutical Industry (ABPI)
- All Wales Prescribing and Advisory Group (AWPAG)
- All Wales Medicine Strategy Group (AWMSG)
- AMWSG Steering Committee
- All Wales Therapeutics and Toxicology Centre (AWTTC) Industry Forum
- Chair of National Clinical Directors Group
- Chief Pharmacists
- Ethical Medicines Industry Group (EMIG)
- Formulary Network
- Joint Commissioning Committee (JCC)
- Medicines Value Unit (MVU)
- New Medicines Group (NMG)
- One Wales Medicines Advisory Group (OWMAG)
- Patient and Public Interest Group (PAPIG)

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AWMSG Medicines Assessment Process for Licensed and Off-label Medicines

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:	
Review date:	
Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) for the AWMSG Medicines Assessment Process for Licensed and Unlicensed Medicines has been completed and key actions have been identified.

Background

Since 2002, the All Wales Medicines Strategy Group (AWMSG) has provided health technology assessment (HTA):

- on medicines that have **not** been included in the National Institute for Health and Care Excellence (NICE) work programme; or
- if there might be a benefit in AWMSG assessing a medicine **before** NICE.

After assessment, AWMSG's recommendations are ratified by Welsh Government and published as 'AWMSG advice'.

In 2015, the One Wales Medicines process (previously known as the One Wales Interim Commissioning process) was introduced to give an alternative way to assess and allow access to medicines for clearly defined and specific cohorts (groups) of patients in the absence of HTA by NICE or AWMSG.

HTA is the gold standard for evaluating the clinical effectiveness and cost-effectiveness of a medicine. However, sometimes a medicine with a service benefit or patient need might fall outside the established scope for HTA, by NICE or by AWMSG, and the medicine does not meet the current criteria for assessment through the One Wales Medicines process. This may include medicines that are routinely available elsewhere in the UK through routes of access that do not apply in Wales AWMSG should provide timely advice on medicines that are of most value to patients and the NHS in Wales. Therefore, AWMSG will adapt and update their existing medicine assessment processes into one overarching process to achieve this aim.

Overview

The All Wales Therapeutics and Toxicology Centre (AWTTC) supports AWMSG in providing evidence-based assessment processes.

Medicines are identified for assessment through the AWTTC horizon scanning process, which includes engaging with key stakeholders:

- healthcare professionals;
- the pharmaceutical industry;
- patient organisations;
- patients, their families and carers; and
- the general public.

Once a licensed or an off-label medicine is identified, the AWMSG Scrutiny Panel will use pre-defined criteria to decide if the medicine is suitable for assessment by AWMSG. AWMSG's two sub-groups: the Licensed One Wales Medicines Assessment Group (LOWMAG), and the One Wales Medicines Assessment Group (OWMAG), will assess and recommend medicines for AWMSG to endorse and Welsh Government to ratify.

LOWMAG replaces the New Medicines Group (NMG), and considers and provides recommendations on medicines that are licensed. OWMAG considers and provides recommendations on off-label medicines. Once ratified by Welsh Government, these recommendations will ensure equitable and consistent funding of these medicines across the NHS in Wales.

For a visual representation of the intended process please see Appendix 1.

1.0 Identifying medicines for AWMSG assessment
AWTTC identifies licensed and off-label medicines that are likely to need assessment by AWMSG. This is done through direct evidence gathering by AWTTC, or by evidence submission or request for assessment from stakeholders including: the pharmaceutical industry, healthcare professionals, patient organisations and commissioning organisations. Sources of information include (but are not limited to): UK PharmaScan, Specialist Pharmacy Service prescribing outlook reports, National Institute for Health and Care Research (NIHR) Innovation Observatory evidence briefings, Individual Patient Funding Request (IPFR) database, NICE topic selection and NICE work programme and the NHS England (NHSE) work programme.

1.1 Identifying licensed medicines for assessment
AWTTC's horizon scanning team routinely gathers information about new medicines, and new indications and formulations for currently available medicines, alongside those that are in development and are expected to be licensed and launched in the UK. More information about AWTTC's horizon scanning, including its role in supporting financial and health service planning, is available at https://awttc.nhs.wales/accessing-medicines/make-a-submission/pharmaceutical-industry-submissions/submit-horizon-scanning-information/

AWTTC invites pharmaceutical companies to complete and submit a medicine assessment form for licensed medicines that meet the criteria for assessment by AWMSG.

Healthcare professionals are also invited to identify when an AWMSG assessment is required for a licensed medicine. They may complete a form for a licensed medicine or email AWTTC at awttc@wales.nhs.uk.

AWTTC also welcomes requests for medicines assessments from patient organisations; please contact AWTTC at awttc@wales.nhs.uk

1.2. Identifying off-label medicines for assessment
The potential benefits of off-label medicines for clearly defined groups of patients are routinely identified by Health Board IPFR panels, the NHS Wales Joint Commissioning Committee, Health Board Chief Pharmacists, formulary pharmacists and local formulary committees, or by clinical experts, usually through their specialist

group or network. These healthcare professionals can ask for an off-label medicine(s) to be considered for assessment by contacting AWTTC directly at awttc@wales.nhs.uk or by completing a medicine request form. AWTTC plays a central co-ordinating role in the IPFR process, using All Wales IPFR data to also identify potential groups of patients.

The assessment of off-label medicines is driven by unmet clinical need identified by healthcare professionals in NHS Wales; requests from pharmaceutical companies are not accepted.

2.0 Routing medicines for assessment

AWTTC interprets and collates horizon scanning information and stakeholder submissions, requesting and sourcing additional information if needed; this is then provided to the AWMSG Scrutiny Panel for consideration.

The AWMSG Scrutiny Panel considers the information, which includes:

- the licence status of the medicine;
- its availability in the UK and internationally;
- views of expert healthcare professionals across Wales;
- views of patients, carers and patient organisations (if available);
- the current treatment pathway for the therapeutic indication and current NICE or AWMSG advice;
- information submitted by the pharmaceutical company (if available);
- AWTTC expert opinion; and
- an equality and health impact assessment.

Each medicine is considered on a case-by-case basis.

2.1 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 prioritise requests and decide on the route of assessment for medicines by using pre-defined criteria as detailed in Section 2.2. The Terms of Reference and decision records of the AWMSG Scrutiny Panel are published online and available from https://awttc.nhs.wales/scrutiny-panel.

The AWMSG Scrutiny Panel decisions will be communicated to the marketing authorisation holder and the person submitting the medicine request before review and endorsement by AWMSG Steering Committee. In the instance that the marketing authorisation holder or person submitting the medicine request disagree with the AWMSG Scrutiny Panel decision they will have 10 working days to respond to AWTTC. AWTTC will inform the AWMSG Steering Committee and they will make the final decision.

All endorsed 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.

2.2 AWMSG assessment criteria

AWMSG will consider a medicine for assessment in Wales **only if there is a clear identified clinical need or benefit to NHS Wales and the people it serves.**

2.2.1 Criteria for assessing licensed medicines

It is expected that most licensed medicines will process through HTA by NICE. However, when there is a clinical need or benefit to NHS Wales and a licensed medicine has not been prioritised or processed for HTA assessment by NICE, or the NICE HTA has been terminated, the AWMSG Scrutiny Panel will determine whether assessment is required and, if so, decide on the most appropriate route for assessment in Wales.

Available routes will either be full or interim HTA or a limited assessment all via the Licensed One Wales Medicine Assessment Group (LOWMAG). For a visual representation of the available routes please see Appendix 2.

2.2.1.1 Health Technology Assessment (HTA)

Medicines which require a clinical and cost-effectiveness assessment may meet the criteria for full HTA if they are likely to have a significant impact (service and/or budget) to the NHS in Wales and when one of the following apply:

- a new licensed medicine or licence extension not on the NICE TA/HST work programme;
- the commercial arrangement as part of the NICE advice is not applicable to the NHS in Wales.

Interim HTA may be suitable for some licensed medicines or for some license extensions if there is a delay in NICE advice and they are likely to have a significant impact (service and/or budget) to the NHS in Wales when one or more of the following apply:

- there is no suitable licensed medicine available that will meet the patient's needs;
- further evidence/data needs to be collected to strengthen a submission for full HTA;
- there is a commercial arrangement for the NHS in Wales.

If a medicine meets the criteria for interim HTA, AWMSG will assess the clinical and cost-effectiveness of the medicine using the best available evidence and provide an interim recommendation. There is an expectation that the company holding the medicine's marketing authorisation (the MA holder) will offer NHS Wales a commercial arrangement for this interim period.

The outcome of AWMSG interim assessments for licensed medicines will be time limited and subject to regular review, especially if alternative licensed medicines are awarded positive HTA guidance for the same indication.

The AWMSG Scrutiny Panel may also consider medicines that have previously received a negative recommendation from NICE or if NICE HTA has been terminated. In these situations, the applicant company must submit additional evidence showing added value or benefit to NHS Wales over and above that considered by NICE. The company's application will be expected to include

additional information that may not have been submitted to NICE, for example, information specific to NHS Wales (highlighting a specific patient population or other societal benefit), a commercial arrangement (Wales Patient Access Scheme [WPAS] or a commercial access agreement [CAA]).

2.2.1.2 Limited Assessment

In some circumstances an assessment may be required but review of the clinical evidence and budget impact may be sufficient. This more limited assessment might be suitable for some licensed medicines or for extensions of a medicine's licence. A limited assessment is likely if there is a clear need for AWMSG advice, if the medicine and its indication is not on the NICE work programme and there is no anticipated service impact to NHS Wales and at least one of the following apply:

- the medicine has a small net budgetary impact, or is cost saving to NHS Wales;
- the medicine is included in national guidelines
- the medicine represents standard-of-care for a particular indication;
- there is national commissioning advice in another area of the UK;
- the medicine offers significant benefit to the NHS in Wales in terms of service delivery or patient experience.

2.2.2 Criteria for assessing off-label medicines

AWMSG will consider assessment of off-label medicines when;

- a clearly defined group of potential patients has been identified who may benefit from access to the medicine; **and**
- the medicine is not licensed for the indication of interest; **or**
- the requested use of the medicine is outside the specification of the marketing authorisation (for example a change in dosing to that authorised) **and**
- there is no suitable licensed medicine available that will meet the patient's needs.

The assessment of an off-label medicine (or medicine combination) considers nationally agreed criteria, including the suitability of any licensed medicine for the same patient group, 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 conditions.

All recommendations for off-label medicines after AWMSG assessment are interim and subject to regular review. See Section 9.2.

3.0 Assessment process

3.1 Information requested from marketing authorisation holder

AWTTC will inform the marketing authorisation (MA) holder which route will be used to assess their medicine, and will invite them to engage in the assessment process.

For licensed medicines, AWTTC will ask the MA holder to fill in a submission form and provide supportive information. Details of the information needed, including guidance notes and the forms to fill in, are available from https://awttc.nhs.wales/assessment-documents.

The AWMSG Steering Committee reserves the right to recommend that a Statement of Advice is issued for medicines that meet the criteria for assessment by AWMSG but are unable to progress due to non-engagement by the MA holder. This Statement is notification that the medicine is not endorsed for routine use in NHS Wales. Statements of Advice are ratified by Welsh Government.

The AWMSG also reserves the right to instruct that an assessment is conducted using information in the public domain if the MA holder does not engage in the assessment process and considers the medicine to be a high priority for NHS Wales.

For the assessment of medicines for off-label use, AWTTC will invite the MA holder to submit supportive information, including any evidence or experience of using the medicine that demonstrates its safety, efficacy, and clinical and cost-effectiveness in the indication or specified patient population.

The MA holder is expected to inform AWTTC of any plans to license the medicine for the indication/patient group under consideration by AWMSG. There will be an obligation for the company to submit for HTA by AWMSG or NICE if a marketing authorisation is granted.

3.2 Commercial arrangements

For medicines that already have a commercial arrangement (including PAS, CAA, WPAS) AWTTC will ask the MA holder to confirm the existing arrangement can be extended to the medicine or indication under consideration.

For medicines without a commercial arrangement, AWTTC will ask companies to consider submitting a simple discount.

Sometimes, AWMSG may endorse an interim positive recommendation while further evidence is collected to support a later full HTA, on the expectation that the MA holder will offer a commercial arrangement for this interim period.

Commercial arrangements should be agreed by the Commercial Arrangement Scheme Wales Group (CASWG) before an assessment proceeds. Any decisions will involve the Medicines Value Unit (MVU) and will be considered by the AWMSG Scrutiny Panel. For more information contact AWTTC at awttc@wales.nhs.uk

3.3 Preparing the assessment report

3.3.1 Assessment report for licensed medicines

AWTTC produces an assessment report summarising and critiquing the clinical and cost-effectiveness evidence and the budget and societal impact submitted by the company. If the MA holder has not engaged with the assessment, this report is written from information in the public domain gathered by AWTTC.

AWTTC asks clinicians to provide additional information, such as: potential patient numbers; place in therapy; and suitable comparators. AWTTC invites 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 families and carers.

The draft report is provided to the MA holder and clinicians for comment before finalising for consideration by the Licensed One Wales Medicines Assessment Group (LOWMAG).

3.3.2 Assessment report for off-label medicines

AWTTC will carry out a comprehensive literature search and compile all available evidence into an evidence summary report. The clinicians who requested the assessment will be asked for additional information, such as potential patient numbers, place in therapy and suitable comparators.

AWTTC will invite the MA holder to provide clinical and cost-effectiveness evidence and budget impact information if available. Patient organisations will be invited 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 families and carers

The draft report is provided to the MA holder and clinicians for comment before finalising for consideration by the One Wales Medicines Assessment Group (OWMAG).

4.0 AWMSG sub-groups

4.1 Licensed One Wales Medicines Assessment Group (LOWMAG)

The Licensed One Wales Medicines Assessment Group (LOWMAG) replaces the former New Medicines Group (NMG) and provides recommendations to AWMSG on new and existing licensed medicines. LOWMAG considers evidence of cost-effectiveness, clinical effectiveness, and the budget impact presented in AWTTC's assessment report. LOWMAG also takes into account any wider societal issues, equity of access and considers the views given by clinicians and patients. LOWMAG provides a clear and robust recommendation, with rationale, to AWMSG. AWMSG is asked to endorse the LOWMAG recommendation, which is then considered by Welsh Government for ratification.

Representatives from the MA holder are invited to attend the LOWMAG meeting to observe proceedings and answer any questions that members may have about the evidence submitted.

Clinical experts are invited to attend the LOWMAG meeting to observe proceedings, answer questions and join in discussions to help group members to better understand the clinical context. Clinical experts are usually nominated by their specialist group or network and are not expected to express their personal opinion or promote the use of a medicine.

A patient organisation representative is also invited to attend the LOWMAG meeting to observe proceedings, answer questions and join in discussions to help group members gain a better understanding of the patient and carer perspective. A lay member of LOWMAG will verbally summarise the views of patients received by AWTTC.

Clinical experts and patient organisation representatives are asked to declare any personal or non-specific interests. They and the MA holder representatives will leave the meeting before LOWMAG makes its decision.

A LOWMAG recommendation may be:

- positive;
- positive with specific restrictions related to its use (known as 'restricted use');
- positive interim, or
- negative.

LOWMAG may defer a recommendation pending a request for further information. LOWMAG will agree start and stop criteria for treatment, if appropriate.

LOWMAG may issue an interim positive recommendation on condition that outcome data are collected to inform a full HTA at the end of the interim period.

The LOWMAG recommendation and decision rationale is shared with the MA holder for comment before being tabled at a subsequent AWMSG meeting.

LOWMAG meets monthly or as needed for optimum timeliness. LOWMAG members include representatives from Health Boards and Trusts in NHS Wales, the pharmaceutical industry and the public ('lay' members). The LOWMAG Constitution, including current membership, and meeting minutes are available from https://awttc.nhs.wales/LOWMAG.

4.2 One Wales Medicines Assessment Group (OWMAG)

The One Wales Medicines Assessment Group (OWMAG), provides recommendations to AWMSG on off-label medicines. OWMAG considers the available evidence of cost-effectiveness, clinical effectiveness, and the budget impact presented in AWTTC's assessment report. OWMAG also takes into account any wider societal issues, equity of access and considers the views given by clinicians and patients. OWMAG provides a clear and robust recommendation, with rationale, to AWMSG. AWMSG is asked to endorse the OWMAG recommendation, which is then considered by Welsh Government for ratification.

Clinical experts are invited to attend the OWMAG meeting to observe proceedings, answer questions and join in discussions to help group members to better understand the clinical context. Clinical experts are usually nominated by their specialist group or network and are not expected to express their personal opinion or promote the use of a medicine.

AWTTC will invite a representative of a patient organisation to attend the OWMAG meeting to observe proceedings, answer questions and join in discussions to help group members gain a better understanding of the patient and carer perspective. 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 before OWMAG makes its recommendation.

OWMAG makes interim recommendations in accordance with relevant guidance on off-label medicines. These recommendations may be:

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

OWMAG may defer a recommendation pending a request for further information. OWMAG will agree start and stop criteria for treatment, if appropriate.

The OWMAG recommendation and decision rationale is shared with the MA holder for comment before being tabled at a subsequent AWMSG meeting.

Because OWMAG recommendations are interim, OWMAG reviews all recommendations after the first 12 months, and then every 1 to 3 years. See Section 9.2 for information.

OWMAG meets monthly or as needed for optimum timeliness. OWMAG members are representatives from all IPFR panels in Wales (if possible), the public ('lay' members) and the pharmaceutical industry. The OWMAG Constitution, including current membership and meeting minutes, are available at: https://awttc.nhs.wales/OWMAG

5.0 All Wales Medicines Strategy Group (AWMSG)

Recommendations made by LOWMAG and OWMAG, with their decision rationale, are shared with AWMSG members for consideration at their next meeting. AWMSG members are asked to endorse each recommendation and confirm that the assessment process followed was appropriate and completed robustly and consistently. AWMSG members may raise any queries they have about the assessment with AWTTC before the meeting. Queries and responses are shared with the Chair of AWMSG and are verbally presented at the meeting.

If AWMSG is unable to endorse a recommendation, their rationale for non-endorsement must be stated and returned to LOWMAG or OWMAG (whichever is appropriate) for further consideration. This allows AWMSG to re-consider LOWMAG and OWMAG recommendations if further information is supplied after which AWMSG will make their final decision.

AWMSG meets monthly or as needed for optimum timeliness. Meetings are open to the public for anyone to attend; however, discussions involving confidential pricing arrangements will be conducted in private. AWMSG meeting dates, the minutes of previous meetings and information on how meetings are conducted are available from https://awttc.nhs.wales/AWMSG-meetings. More information about the role of AWMSG, including the Constitution and current membership is available at: https://awttc.nhs.wales/about-us1/our-committees/#AWMSG.

6.0 AWMSG advice

After AWMSG endorsement, AWTTC sends the recommendation to Welsh Government for ratification.

6.1 Recommendations for licensed medicines

Welsh Government decides if a medicine should be funded in NHS Wales. If Welsh Government ratifies (approves) AWMSG's positive (including positive with restrictions) recommendation and the medicine is launched in the UK and any commercial arrangements are in place, the medicine should be available no later than 60 calendar days after ratification of the recommendation by the Welsh Government. Health Boards and NHS Wales Joint Commissioning Committee are expected to fund the medicine according to the recommendation. Funding variations may be agreed by exception and in specified circumstances (Details to follow).

AWMSG recommendations for licensed medicines will usually be superseded by any NICE HTA guidance published for the same licensed medicine and indication(s). If NICE subsequently terminates an HTA, then the AWMSG advice will continue to stand.

6.2 Recommendations for off-label medicines

After Welsh Government has ratified recommendations for off-label medicines, the decision is disseminated to appropriate organisations and individuals in NHS Wales for implementation. Health Boards and the NHS Wales Joint Commissioning Committee are expected to fund the medicine according to the recommendation.

7.0 Informing all stakeholders

AWTTC informs NHS Wales, the MA holder and any clinical experts and patient groups involved with the assessment process, about the final decision. Ratified recommendations are also disseminated to NHS Wales colleagues through established internal communications channels.

All AWMSG advice for licensed and off-label medicines is published on the AWTTC website. The decision rationale and the assessment report are also made available, as well as the Equality and Health Impact Assessment for each medicine assessed.

8.0 Prescribing

8.1 Licensed medicines

In accordance with the New Treatment Fund, launched by Welsh Government in January 2017, the NHS in Wales must fund the medicine and make sure it’s available for prescribing to patients no later than 60 calendar days after ratification of the AWMSG recommendation or publication of NICE FAD/FDG. In order for Welsh Government to monitor compliance with the New treatment Fund, health boards regularly report the time taken to put the new medicines onto their prescribing lists. If the MA holder has offered a commercial arrangement this must be in place before the medicine can be routinely prescribed in NHS Wales.

8.2 Off-label medicines

If Welsh Government ratifies a positive (including positive with restrictions) recommendation, the off-label medicine can be routinely prescribed for patients who meet the starting criteria as set out in the recommendation.

The responsibility associated with prescribing an off-label 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 problems with the medicine's information or labelling, for example, potential confusion for a patient or their carers when the Patient Information Leaflet is inconsistent with the licensed use of the medicine. Healthcare professionals should consult their relevant professional guidance on prescribing off-label medicines before they prescribe any off-label or unlicensed medicines.

8.3 Patients receiving treatment outside Wales

Licensed and off-label medicines ratified by Welsh Government are available to all eligible patients who are registered with a GP practice in Wales, even if they need to receive their treatment outside Wales.

9.0 Review of recommendations

9.1 Recommendations for licensed medicines

AWTTC usually reviews positive (including positive with restrictions) recommendations for licensed medicines 3 years after publication. The review looks for any significant new evidence or information published that is likely to affect the current AWMSG advice. If any is found, further investigation or reassessment of the recommendation may be appropriate. After their first review, recommendations may be assigned:

- to a 'static list' - if it appears that no new future significant evidence that would affect the advice is likely to be published; or
- for a repeat review after a specified time.

All interim positive recommendations for licensed medicines will have a specified end date. In advance of this, it is likely that the MA holder will be asked to submit evidence to support a full HTA by NICE or AWMSG, so that a final recommendation on whether the treatment should continue to be routinely funded in NHS Wales can be made.

If the MA holder fails to make a timely submission to AWMSG or NICE for HTA, the interim positive recommendation may 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 when the interim recommendation is withdrawn. On endorsement by AWMSG, AWTTC will forward this information to Welsh Government for ratification.

9.2 Recommendations for off-label medicines

OWMAG reviews all recommendations for off-label medicines 12 months after they are first published, and then every 1 to 3 years thereafter. The reviews consider any new evidence and patient outcome data (if available).

After the review, OWMAG may decide to:

- renew the recommendation for up to 3 years;
- renew it with restrictions or amendments;
- discontinue or retire the recommendation; or
- fully re-assess the recommendation using newly available information.

If OWMAG recommend that a re-assessment is needed, the full process for assessing an off-label medicine is followed (see Section 3.0). If OWMAG renew, discontinue or retire the recommendation, the decision will be forwarded to AWMSG for noting, and then sent to Welsh Government for ratification.

AWTTC conducts a short internal review for recommendations in years where no OWMAG review is scheduled. If new evidence is identified that may affect the current recommendation, AWTTC advises OWMAG that a full review should be prioritised ahead of the planned schedule.

Recommendations may be discontinued if the medicine has received UK marketing authorisation (MA) for the indication, or if an alternative licensed medicine becomes routinely available (funded) for the same group of patients. If an MA is granted the MA holder will be expected to progress the medicine through the usual routes for licensed medicines.

If the medicine receives marketing authorisation for the indication under which it is recommended and the MA holder fails to make a timely (usually within 12 months of licence) submission to AWMSG or NICE for HTA, the interim recommendation for off-label use may be withdrawn. People receiving treatment may continue to do so, until they and their NHS clinician consider it appropriate to stop. AWTTC will inform AWMSG that the recommendation is withdrawn and will forward this information to Welsh Government for ratification.

Advice for an off-label medicine may also be retired if, for example, national guidance endorses the routine off-label use of the medicine for the same indication or specified patient group. The availability of this medicine in NHS Wales will not be affected by retirement of the recommendation. AWTTC will inform AWMSG that the recommendation is retired and will forward the information to Welsh Government for ratification.

10.0 Monitoring outcomes

10.1 Licensed medicines

There may be a need to monitor the outcomes of patients being treated with the medicine. If this is needed, it will be stated in the AWMSG recommendation. Clinicians may be asked to support AWTTC data collation and analysis e.g. patient numbers and outcome data. AWTTC will discuss with clinicians and MA holder the most appropriate data to collect, the methods for collection and how such data will be reported and shared.

10.2 Off-label medicines

It is **crucial** that appropriate patient outcomes are monitored when off-label medicines are prescribed. 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 9.2). Clinicians are responsible for providing AWTTC with patient numbers and outcome data. AWTTC will discuss with clinicians the most appropriate data to collect, the methods for collection and how such data will be reported and shared.

Glossary

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 prioritising requests and 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. The Centre 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.

Benefit to NHS Wales
In this context, benefit denotes that having AWMSG or NICE advice on a medicine will have a positive impact on NHS Wales in terms of cost, service delivery or patient experience.

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.

Horizon scanning
The gathering of information by AWTTC about new medicines, new indications and new formulations of medicines that are in development and are expected to be licensed and made available in the UK in the next financial year. Medicines likely to need assessment by AWMSG are also identified.

IPFR – Individual Patient Funding Request
Requests made to a Health Board or JCC to fund NHS healthcare for an individual patient who falls outside the range of services and treatments that a Health Board has arranged to routinely provide or commission.

JCC - Joint Commissioning Committee
NHS Wales Joint Commissioning Committee (JCC) established on the 1st April 2024 following the merger of the former Emergency Ambulance Services Committee (EASC) the National Collaborative Commissioning Unit (NCCU) and the Welsh Health Specialised Services Committee (WHSSC).
The role of JCC is to make sure that the population of Wales has fair and equitable access to the full range of specialised services. JCC is responsible for the joint

planning of Specialised and Tertiary Services on behalf of Local Health Boards in Wales.

Licensed medicine
A medicine that has a marketing authorisation from the UK Medicines & Healthcare products Regulatory Agency (MHRA), meaning that it can be prescribed in the UK

LOWMAG – Licensed One Wales Medicines Assessment Group
LOWMAG advises NHS Wales about the routine use of licensed medicines and is a sub-group of AWMSG. LOWMAG decides whether to recommend the use of a licensed medicine after assessing all available evidence collated by AWTTC, including that submitted by the MA holder and the views of clinicians and patient organisations. The group comprises representatives from Health Boards and Trusts in NHS Wales, lay members, industry representatives, finance representatives, a clinical pharmacologist and a health economist. LOWMAG's recommendations about licensed medicines are sent to AWMSG for endorsement and then to Welsh Government for ratification. LOWMAG replaces the former New Medicines Group (NMG).

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

MVU - Medicines Value Unit
The Medicines Value Unit was set up in September 2023 and aims to improve population health and to drive greater value for the Welsh NHS through a Value-Based approach to medicines procurement. The unit will work with NHS Wales bodies to gather, measure, and improve both patient outcomes and experience.

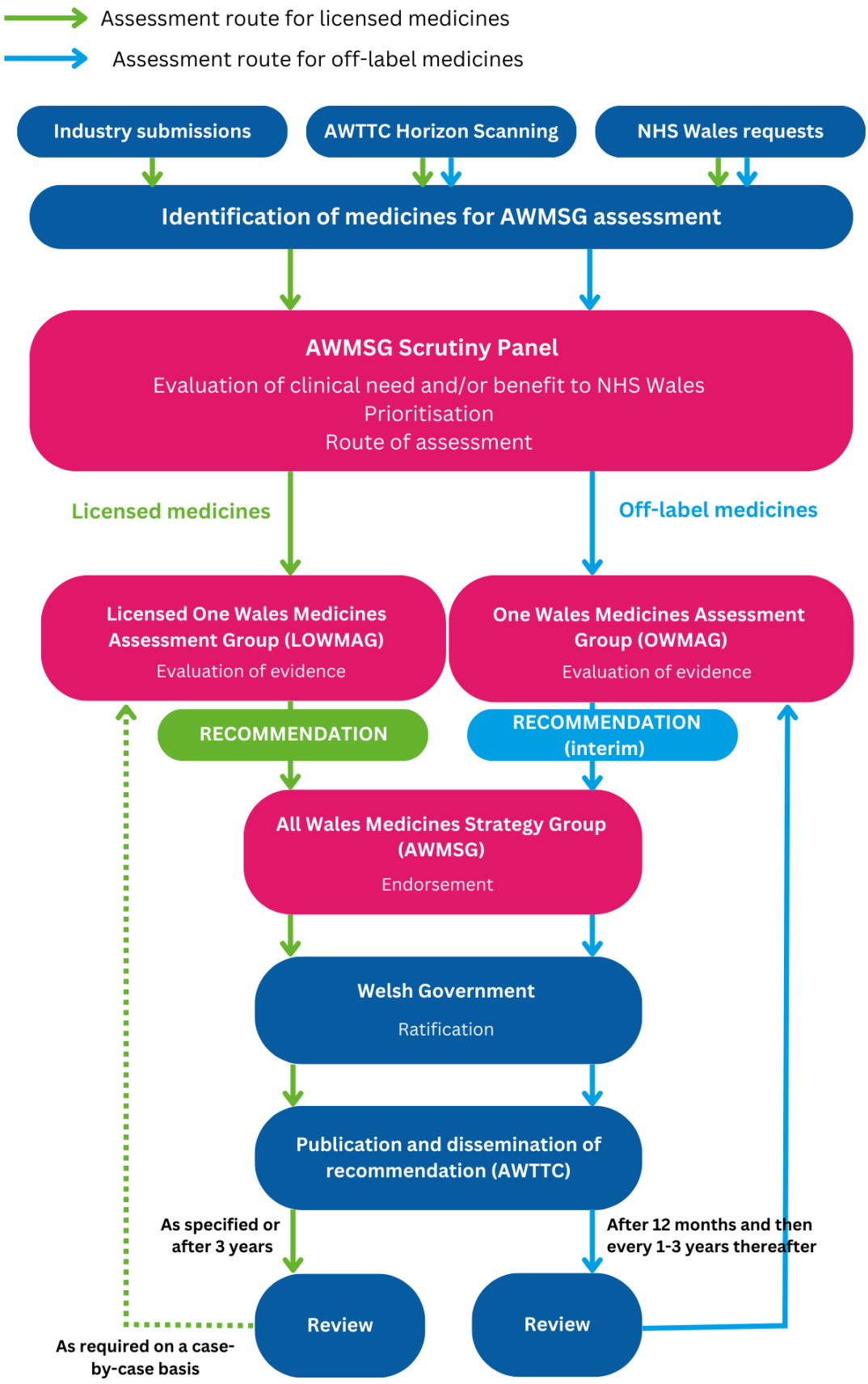
NICE - National Institute for Health and Care Excellence
Established in 1998, NICE is an independent NHS organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. NICE provides guidance and advice to the NHS in England and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

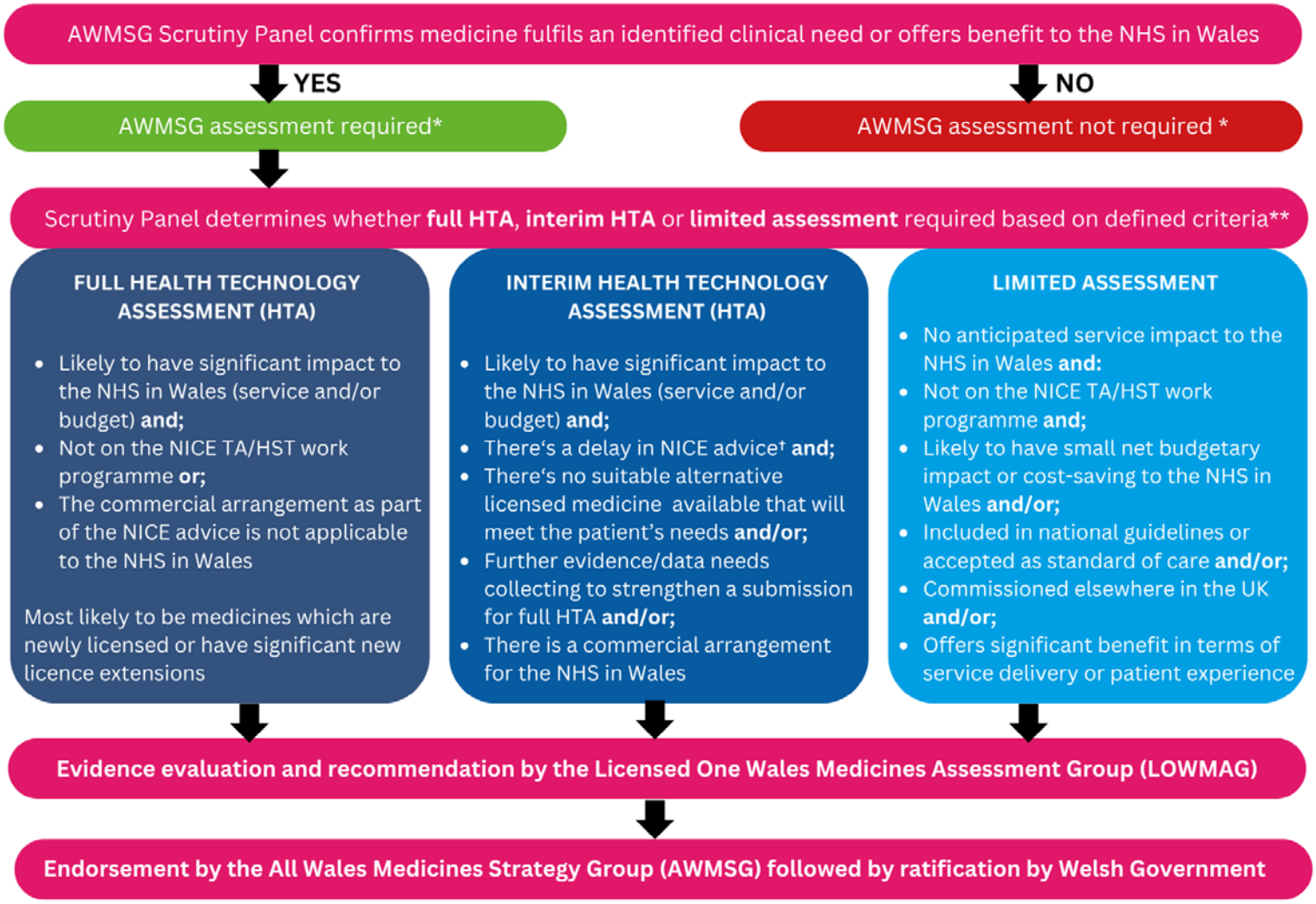
OWMAG – One Wales Medicines Assessment Group
OWMAG advises NHS Wales about the use of off-label medicines for specific and defined patient populations (cohorts, or groups) and is a sub-group of AWMSG. OWMAG decides whether to recommend the use of an off-label medicine after assessing all available evidence collated by AWTTC, including the views of clinicians and patient organisations. 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 considered by Welsh Government on advice from the Commercial Arrangement Scheme Wales Group (CASWG) as part of the AWMSG HTA process.

Appendix 1: Overview of AWMSG Medicine Assessment Process in Wales



Appendix 2: Overview of the available routes of AWMSG assessment for licensed medicines



*Scrutiny Panel decisions will be communicated back to the submitter who will have 10 working days to raise any objections regarding the decision
** The Scrutiny Panel may instruct that an assessment is conducted using information in the public domain if the MA holder does not engage
† There maybe occasions when AWMSG will consider a medicine with NICE terminated appraisal status or a NICE negative recommendation