Enclosure No:	**4**/AWMSG/0226
Agenda Item No:	10. The AWMSG Licensed One Wales Medicines Assessment Process
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1.0 Action for AWMSG

AWMSG members are requested to endorse the enclosed document outlining the AWMSG process for the assessment of licensed medicines which is provided for information.

2.0 Purpose

This document has been developed to provide additional, more in-depth detail about the AWMSG assessment process for licensed medicines supplementary to the AWMSG process for licensed and off label medicines information already published on the AWTTC website (endorsed by AWMSG in June 2024).

3.0 Process

- February 2026: Draft document out for internal consultation
- April 2026: Draft document out for consultation with pharmaceutical industry
- May 2026: Consultation comments and responses considered by AWTTC
- June 2026: Document presented to AWMSG Steering Committee
- *June 2026: Document presented to AWMSG for endorsement*

4.0 Consultees

Consultees include:

- Association of the British Pharmaceutical Industry (ABPI)
- AMWSG Steering Committee
- All Wales Therapeutics and Toxicology Centre (AWTTC) Industry Forum

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

The AWMSG Licensed 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:	
Review date:	
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	AWMSG Medicines Assessment Process for Licensed and Off-label Medicines, January 2025 One Wales Medicines Process Policy AWMSG policy on appraising medicines for severe conditions AWMSG policy for appraising a medicine for a very rare disease

AWMSG and the National Institute for Health and Care Excellence (NICE) both produce guidance on new licensed medicines for NHS Wales. Typically, most licensed medicines undergo a Health Technology Assessment (HTA) by NICE, with its recommendations applying to NHS Wales. However, if NHS Wales has a clinical need or benefit and a medicine hasn't been prioritised or assessed by NICE - or if NICE's HTA process has terminated - AWMSG may evaluate the medicine. AWMSG also has the option to re-assess medicines that previously received negative

recommendations from either NICE or AWMSG, provided there is new evidence showing greater value or benefit to NHS Wales than what was considered initially.

The AWMSG Scrutiny Panel will determine whether AWMSG assessment is required and, if so, decide on the most appropriate route of assessment. For licensed medicines this can either be by full HTA, interim HTA or a more limited assessment. This document explains the process for the assessment of licensed medicines by AWMSG, when it may be used and how it works. A flow diagram illustrating the process is given in Appendix 1.

1. Background

Most newly licensed medicines undergo health technology assessment (HTA) by the National Institute for Health and Care Excellence (NICE). The HTA process carefully considers the clinical evidence, which shows how well the medicine works and how safe it is, and the cost-effectiveness evidence, which shows how well it works in relation to how much it costs the NHS compared with current standard treatments. NICE guidance determines if a medicine is recommended for NHS use in England and Wales. If NICE issue a positive recommendation, health boards in Wales and the NHS Wales Joint Commissioning Committee (NWJCC) are usually expected to make a medicine available for prescribing in Wales within 60-days of NICE publishing Final Draft Guidance.

Since 2002, AWMSG has assessed medicines not covered by the NICE work programme or when early assessment is beneficial. AWMSG's recommendations are ratified by Welsh Government and published as 'AWMSG advice'. Health boards in Wales and NWJCC are usually expected to make a medicine available for prescribing within 60-days of Welsh Government ratifying a positive AWMSG recommendation.

Following a comprehensive review, a revised process for AWMSG assessment of both licensed and off-label medicines started in January 2025. The process focuses on addressing the needs of NHS Wales and promoting an All-Wales approach to medicines access. The route for licensed medicines was expanded by removing several previous exclusion criteria to help close any remaining gaps in assessing treatments. Now, not only marketing authorisation holders (MAHs) but also healthcare professionals working in NHS Wales and patient organisations can submit requests for licensed medicines to be evaluated by AWMSG.

Once a licensed medicine or an off-label medicine has been identified, the AWMSG Scrutiny Panel will apply pre-defined criteria to determine its suitability 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) are responsible for evaluating the medicines and making recommendations for endorsement by AWMSG and subsequent ratification by Welsh Government.

LOWMAG succeeds the New Medicines Group (NMG) and is tasked with providing recommendations on l**icensed medicines**.

OWMAG is tasked with providing recommendations on **off-label medicines**. Following ratification by the Welsh Government, these recommendations support the equitable and consistent funding of these medicines across NHS Wales.

2. How the Licensed One Wales Medicines Assessment Process works

2.1 Criteria for assessing licensed medicines and assessment routes

AWMSG will only consider a licensed medicine for assessment in Wales if there is a clear identified clinical need or benefit to NHS Wales and the people it serves. An unmet clinical need relates to a condition for which treatment or diagnosis is not addressed adequately by a routinely funded/available licensed medicine/therapy.

The available routes of AWMSG assessment for licensed medicines are health technology assessment (HTA), either full or interim, and limited assessment. The criteria for each are given in Sections 2.1.1 and 2.1.2.

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 technology appraisal (TA)/ highly specialised technology (HST) work programme, or there is anticipated to be a significant delay in the publication of NICE advice
- a medicine with terminated NICE advice or an AWMSG Statement of Advice (due to lack of a submission from the company)
- the commercial arrangement as part of the NICE advice is not applicable to the NHS in Wales.

Interim HTA may be considered for some licensed medicines or for some licence extensions which meet the above criteria and where there is:

- a need for data collection to reduce the uncertainty around comparative clinical and cost-effectiveness
- a commitment by the company to provide an updated submission (either to AWMSG or NICE) once data are collected, for post-interim full HTA advice to be issued.

A commercial arrangement to supply the medicine at a reduced cost would be required to ensure that the burden of risk is not entirely with NHS Wales. Should a medicine satisfy the criteria for interim HTA, AWMSG will assess the clinical and cost-effectiveness of the medicine using the best available evidence and produce an interim recommendation.

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 recommendations for the same indication. If the company fails to make an updated submission once data are collected for a full HTA assessment, the interim recommendation may be withdrawn. People having treatment may continue to do so until they and their NHS clinician decide it appropriate to stop. AWTTC will notify AWMSG that the interim recommendation has been withdrawn, and upon endorsement, this will be sent to the Welsh Government for ratification.

Additional considerations are applicable to medicines requiring HTA (full or interim) which meet the eligibility criteria for assessment under the terms of either the AWMSG policy for appraising medicines for severe conditions or the AWMSG policy for appraising a medicine for a very rare disease. The assessment process for medicines qualifying under either policy remains aligned to that for all medicines with the exception that a Clinician and Patient Involvement Group (CAPIG) meeting may be convened under the terms of the policy for the assessment of a medicine for a very rare disease in certain circumstances (see Section 2.8).

2.1.2 Limited Assessment

In some circumstances an assessment may be necessary; however, a review of the clinical evidence (if required), equity of access and budget impact may be sufficient. This more limited assessment may be appropriate for some licensed medicines or for extensions of a medicine's licence.

A limited assessment is likely if there is a clear need for all-Wales advice, if the medicine and its indication is not on the NICE work programme and there is no anticipated significant 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

2.2 Medicines with an existing negative recommendation for use

The reassessment of medicines that have previously received a negative recommendation from either NICE or AWMSG may be considered but only if it can be demonstrated that there are significant new factors showing added value and/or benefit to NHS Wales over and above that considered in the original assessment.

2.3 Identifying medicines and how to submit a request for consideration for assessment

AWTTC identifies licensed 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.

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 (usually through their specialist groups or networks) and NWJCC are invited to identify licensed medicines which may require AWMSG assessment. They are requested to complete a medicines request form for healthcare professionals or email AWTTC at awttc@wales.nhs.uk.

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

AWTTC may also identify medicines that may require all-Wales guidance without a stakeholder submission; sources of information for the identification of such medicines 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, the National Institute for Health and Care Excellence (NICE) topic selection and NICE work programme, the Scottish Medicines Consortium (SMC) work programme and the NHS England (NHSE) work programme. If a medicine is identified as a potential candidate for assessment, AWTTC will contact appropriate healthcare professionals and clinical networks to establish whether access to the medicine will address a clinical need or add benefit to the NHS in Wales.

2.4 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 licensed medicines by using pre-defined criteria as detailed in Section 2.1 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 either by an applicant company, or 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 AWMSG assessment, and if so, what type of assessment is appropriate.

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 company, 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.

The Scrutiny Panel is also responsible for deciding whether a medicine qualifies for assessment under the AWMSG policy for appraising a medicine for a very rare disease when it is unclear whether eligibility criteria are met following initial review of the evidence by AWTTC. Experts will be invited to join the Scrutiny Panel for these decisions to ensure relevant expertise informs the decision-making process. The applicant company will be notified of the Scrutiny Panel's decision within five working days and may challenge this decision within seven calendar days of notification. AWMSG Steering Committee will review any challenge and if accepted, will direct Scrutiny Panel to reconsider the evidence and the company response. No new evidence can be submitted at this point, and further challenges are not permitted. See Section 2.8 for information on the assessment of medicines for very rare diseases.

2.4.1 Pharmaceutical company engagement

For most medicines proposed for AWMSG assessment, AWTTC will contact the company holding the UK marketing authorisation before the Scrutiny Panel meeting; this is to inform them that the medicine is under consideration for assessment and to establish the position of any commercial arrangements offered to NHS Wales. The company is requested to inform AWTTC of the proposed price of the medicine to NHS Wales so that this can be considered by the Scrutiny Panel. However, formal discussions on discounts or commercial arrangements will only begin after the Scrutiny Panel has made the decision to proceed with an assessment.

AWTTC will communicate the endorsed Scrutiny Panel decision and, if assessment is necessary, specify the required assessment type.

If the initial request for assessment was made by an applicant company and the decision is to proceed with AWMSG assessment, AWTTC will request the applicant company to either complete the Submission for AWMSG HTA Assessment Form or the Submission for AWMSG Limited Assessment Form as appropriate. Applicant companies should refer to the relevant accompanying guidance notes to ensure that all the required information is included in their submission. The assessment will only proceed once a submission has been received, the scope and timelines have been agreed between AWTTC and the applicant company, and any commercial arrangements have been confirmed.

For medicines accepted for AWMSG assessment where the request for assessment was not made by an applicant company, AWTTC will invite the company to complete the relevant submission form or submit any written supportive information. If there are generic or biosimilar products available for a medicine under assessment, AWTTC will extend this invitation to all MA holders supplying the medicine to NHS Wales. Companies are under no obligation to make a submission or provide information to AWTTC as the assessment will proceed regardless of their involvement. Should the company choose not to engage and the medicine is

deemed a high priority for NHS Wales, the AWMSG Steering Committee may direct that the assessment proceed based on publicly available information.
The AWMSG Steering Committee may recommend issuing a Statement of Advice for medicines where a request for assessment was initiated by an applicant company and the AWMSG Scrutiny Panel deemed assessment appropriate but progress was halted due to subsequent non-engagement by the company. This Statement is notification that the medicine is not endorsed for routine use in NHS Wales. Statements of Advice are ratified by Welsh Government.

2.4.1.1 Commercial arrangements

For medicines with an existing commercial arrangement (including Patient Access Schemes or Commercial Access Arrangements), AWTTC will ask the company to confirm whether the arrangement can be extended to the medicine or indication under consideration. For medicines without a commercial arrangement, AWTTC may invite companies to consider offering a simple scheme. If a company wishes to propose a commercial arrangement, AWTTC will provide guidance on how to do this once the Scrutiny Panel confirms the decision to progress with an assessment. An assessment will only proceed, and timelines agreed once a commercial arrangement has been accepted by the Commercial Arrangement Scheme Wales Group (CASWG). See Appendix 2 for details on CASWG. If an interim HTA is proposed, there is an expectation that a commercial arrangement will be offered for this interim period.

2.4.1.2 Commercially sensitive information

Commercially sensitive and academic in confidence information, received from the company and identified accordingly, will not be placed on the AWTTC website or in the public domain. However, such information may be shared in confidence with Scrutiny Panel (in the medicine proforma) and LOWMAG (in the evidence summary report [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. Applicant company representatives attending the LOWMAG meeting will be asked to leave prior to discussions on confidential comparative costs.

Please refer to the AWTTC document, AWTTC use of pharmaceutical company data for further information (*link to be added on publication*).

2.5 Gathering the evidence, preparing and finalising the evidence summary report

AWTTC produces an evidence summary report (ESR) summarising and critiquing the available evidence. This may include the clinical and cost-effectiveness evidence and the budget impact, health and care resource, and societal impact submitted by the applicant company, or, for assessments initiated by clinician or patient organisation submission, from information in the public domain gathered by AWTTC.

For all assessments, AWTTC requests clinicians/clinical networks to provide additional information on 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. AWTTC will also gather and include further appropriate evidence from various sources.

Costs used in the report will be those expected to be incurred by NHS Wales and may be confidential. The draft evidence summary report is circulated to the applicant company and clinicians identified through the process for comment before finalising.

If the assessment has not been initiated through a company submission, the marketing authorisation holder(s) will be invited to provide a short summary response to the draft ESR. If the company has provided a submission, they will be invited to complete a company response to ESR (CR-ESR) table. In the table AWTTC may raise queries relating to specific sections in the ESR which the company is asked to respond to; the company may also identify any factual inaccuracies or typographical errors. No additional clinical or health economic evidence is to be included at this stage unless previously agreed with AWTTC. The summary response or CR-ESR table will form part of the LOWMAG assessment documentation along with the ESR itself (see Section 2.6). Companies are given 10 working days to respond to the draft ESR. Failure to provide a response will not delay the process.

Responsibilities:

- **AWTTC**: to carry out a comprehensive literature search and compile all available evidence into an ESR.
- **Applicant company (providing either limited or HTA submission):** to provide clinical and cost-effectiveness evidence, budget impact and other relevant information where applicable as part of their submission and submit a response to the draft ESR.
- **Company (not providing a limited or HTA submission)**: 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 comparators, confirm unmet clinical need, submit comments on the draft ESR and respond to queries from the AWTTC 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 carer/s and/or family.

2.6 Licensed One Wales Medicines Assessment Group (LOWMAG)

The Licensed One Wales Medicines Assessment Group (LOWMAG) reviews and discusses the evidence presented in the ESR and makes a clear and robust recommendation, with rationale, to AWMSG. LOWMAG is also provided with the submission form completed by the applicant company (if available), an Equality and Health Impact Assessment (EHIA) for the assessment of the medicine prepared by AWTTC, the company response to the ESR or CR-ESR table (if available),

submissions from patients, carers or patient organisation (if available) and any completed clinical expert questionnaires (if available).
LOWMAG reports to AWMSG and its membership comprises of a Chair plus healthcare professionals working in NHS Wales, representatives from key stakeholders including the pharmaceutical industry and lay members (see the LOWMAG Constitution). LOWMAG convenes in private on a monthly basis or as needed for optimum timeliness. Members agree to follow the AWMSG code of conduct and complete declaration of interest forms.

The LOWMAG recommendation, reached following a consensus decision or majority vote, may be either positive, positive with specific restrictions related to use (restricted), positive interim or negative. LOWMAG may defer a recommendation pending a request for further information. LOWMAG will provide a full written rationale for every recommendation it makes. If the evidence is insufficient for full HTA advice, LOWMAG reserves the right to propose an interim positive recommendation. The applicant company will be given opportunity to respond to this proposal and will need to agree to an interim recommendation being issued before it is submitted to AWMSG for endorsement and then to Welsh Government for ratification.

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

For assessments initiated by a company submission, representatives from the company (typically two people; one with clinical knowledge of the medicine, the other with cost-effectiveness knowledge) are invited to attend the LOWMAG meeting to observe proceedings, input into discussions and answer any questions that members may have about the evidence submitted. The Chair will ask the submitting applicant company representative(s) in attendance to confirm whether or not they are satisfied that all relevant issues have been addressed prior to concluding the assessment. For assessments not initiated by an applicant company submission, representatives from the marketing authorisation holder(s) are invited to attend the meeting to observe proceedings and answer any questions.

Clinical expert and patient organisation representatives must declare any personal or non-specific interests and, along with the company representatives, must leave the meeting before LOWMAG makes its decision. In addition, if there is a confidential commercial arrangement associated with the 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. If there are any confidential

commercial arrangements associated with comparator medicines, the company representatives will also be asked to leave the meeting before any discussions involving comparative costs.

The decision of LOWMAG will remain confidential until it is tabled for endorsement at a subsequent AWMSG meeting except in the following circumstances:

- For assessments initiated by an applicant company submission, the LOWMAG recommendation and decision rationale is shared with the applicant company for comment.
- For assessments of medicines to treat very rare diseases when LOWMAG makes a negative recommendation and a Clinician and Patient Involvement Group (CAPIG) meeting is convened (see Section 2.8).

2.7 All Wales Medicines Strategy Group (AWMSG)

LOWMAG's recommendation, the decision rationale and the company response to the decision (if available) will be provided to AWMSG members for consideration at the next AWMSG meeting. 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.

For assessments initiated by a company submission, representatives from the company are invited to attend the AWMSG meeting to observe proceedings and answer any questions that members may have. Before the recommendation is considered for endorsement, the AWMSG Chair will ask the submitting applicant company representative(s) in attendance to confirm whether or not they are satisfied that all relevant issues highlighted in the company response to the recommendation by LOWMAG have been considered.t. For assessments not initiated by an applicant company submission, representatives from the marketing authorisation holder(s) are invited to attend the meeting to observe proceedings but will not be permitted to participate.

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

For assessments initiated by **an applicant company submission**, the applicant company will be officially informed by email that the recommendation has been endorsed by AWMSG and, unless any concerns are raised within 10 days of the meeting, it will be sent to Welsh Government for ratification.

For assessments initiated by request from either **healthcare professionals/clinical networks** in NHS Wales or from **patient organisations**, the submitter of the request for assessment will be officially informed by email that the recommendation has been endorsed by AWMSG and, unless any concerns are raised within 10 days of the meeting, it will be sent to Welsh Government for ratification.

The assessment originator has the right to appeal on how the assessment was conducted and/or how scientific information was interpreted and has ten days from the AWMSG meeting date 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.

2.8 Medicines for very rare diseases

A medicine may be assessed under the AWMSG Policy for appraising a medicine for a very rare disease if it satisfies the specific eligibility criteria defined by the policy. The appraisal process for medicines intended to treat very rare diseases follows AWMSG's standard assessment process. However, an additional step is included to further evaluate the benefits of the medicine from both clinical and patient perspectives, facilitated by the Clinician and Patient Involvement Group (CAPIG).

A CAPIG meeting may be convened when a medicine to treat a very rare disease receives a negative recommendation from LOWMAG. Patient organisation representatives or designated individual patient experts, clinical experts, a public representative, a lay member from an AWMSG committee or sub-group and a representative from AWMSG's Patient and Public Interest Group (PAPIG) are invited to participate. Representatives from the applicant company are also invited and permitted to present a brief statement and contribute to discussions but must leave prior to the conclusion and final agreement of the statement. All attendees are required to declare any conflicts of interest and sign a confidentiality agreement.

Information from the CAPIG meeting will be shared with LOWMAG, which will then review it and make a new decision - either confirming or changing the original recommendation. This updated recommendation will be sent to AWMSG for endorsement.

2.9 Ratification by Welsh Government

Following confirmation of AWMSG's endorsement, the recommendation will be sent to Welsh Government for ratification. 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 made available no later than 60 calendar days after ratification of the recommendation by the Welsh Government. Health Boards, NHS Trusts 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. Once ratified, the recommendation will be disseminated to the Service for implementation (see section 2.10).

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, the AWMSG advice will continue to stand.

2.10 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 LOWMAG 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 2.4.1.2)

2.11 Prescribing licensed medicines

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 a NICE Final Appraisal Determination (FAD) or Final Draft Guidance (FDG).

For Welsh Government to monitor compliance, 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.

Licensed 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.

3. Monitoring outcomes

LOWMAG may identify that patient numbers and specified patient outcomes are monitored for some licensed medicines with positive recommendations, especially those with interim HTA positive recommendations. The company, in collaboration with clinicians, may develop outcome(s) or data collection tools to gather relevant data (including health-related quality of life). This real world data can support submissions to NICE or AWMSG, particularly when current clinical or economic evidence is limited. In some cases when an assessment has been initiated by clinician request, clinicians may be required to provide patient numbers, outcome data and resource use 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 and the company (if applicable) 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.
- **Company:** to develop and use a data collection tool and liaise with clinicians to implement data collection, and to collate outcome data for AWTTC.

4. Review process

Recommendations issued by AWMSG will be reviewed if there is significant new evidence that may have a material effect on the published recommendation; positive, restricted-positive and negative recommendations may all be reviewed. The outcome of the review will be presented to LOWMAG who will be asked to decide whether:

- reassessment is required to take into account the new information and the type of assessment most appropriate or,
- the recommendation can remain as it stands but a subsequent review within a specified timescale is stipulated.
- the recommendation can remain as it stands and further review is required only if significant new information becomes available.

Any reassessment will follow the AWMSG assessment process for licensed medicines as outlined in this document. The MA holder of the medicine will be invited to provide an updated submission if reassessment is recommended although they are under no obligation to do so as the assessment will proceed without MA holder engagement if necessary.

The AWMSG Scrutiny Panel, LOWMAG, AWMSG or the All Wales Prescribing Advisory Group (AWPAG) may ask AWTTC to review a recommendation at any time. Healthcare professionals can also request a review if new factors arise which means that the recommendation no longer aligns with the clinical pathway followed in NHS Wales. For negative or positive restricted recommendations, the company may submit new evidence at any time to AWTTC to support a potential reassessment. All such requests will be considered by the AWMSG Scrutiny Panel following the process outlined in section 2.4.

If AWMSG has not assessed a medicine due to the absence of a company submission and its use is not endorsed in NHS Wales (i.e. a Statement of Advice [SOA] has been issued by AWMSG), healthcare professionals may request a review of the non-endorsement if it can be demonstrated that an unmet clinical need for all-Wales advice exists. AWTTC may recommend a medicines request form for healthcare professionals is completed so that the request can be considered by the AWMSG Scrutiny Panel as outlined in section 2.4.

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.

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.

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.

Company
The pharmaceutical company which is a market authorisation holder of the medicine for the indication being assessed. If the company seeks assessment by submitting a medicine information form and engages with AWMSG by providing the requested submission (limited or HTA) it is referred to as the ‘applicant company’.

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 NWJCC 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.

NWJCC – NHS Wales Joint Commissioning Committee
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.

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 company 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 aims to improve population health and to drive greater value for the Welsh NHS through a value-based approach to medicines procurement. MVU works 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.

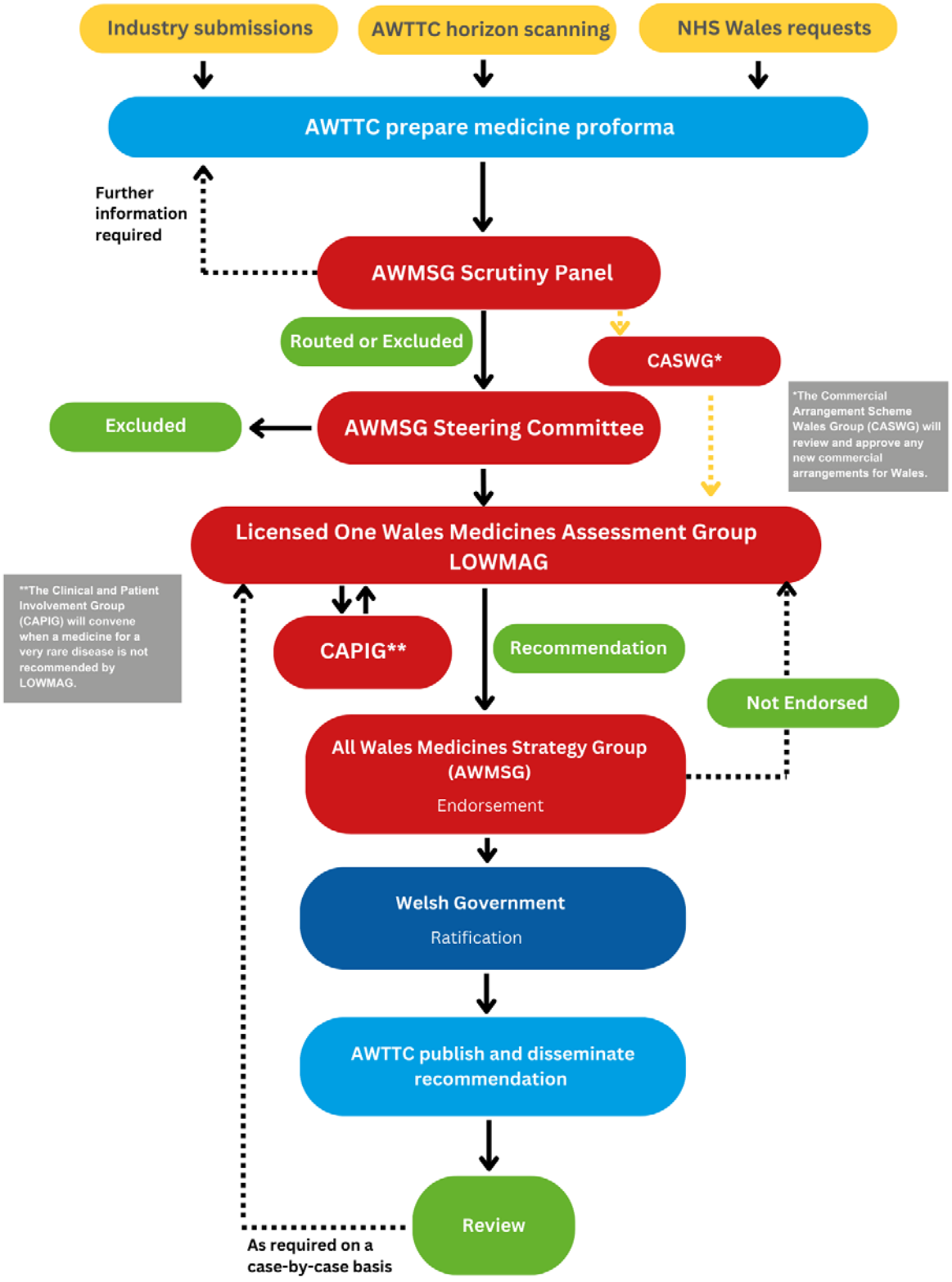
OWMAG – One Wales Medicines Assessment Group
OWMAG advises NHS Wales about the use of off-label medicines for specific and defined patient populations (cohorts, or groups) and is a sub-group of AWMSG.

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 approved by the Commercial Arrangement Scheme Wales Group (CASWG) as part of the AWMSG assessment process.

Appendix 1

Licensed One Wales Medicines Assessment Route



Appendix 2

COMMERCIAL ARRANGEMENTS FOR THE LICENSED ONE WALES MEDICINES PROCESS

As part of the Licensed One Wales Medicines Assessment process, 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.

Licensed One Wales Medicines Process

- 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.
- The completed commercial arrangement proposal template should be submitted to CMAT via the email NHSWales.CA@wales.nhs.uk
- 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