



AWTTC

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

Enclosure No:	3/AWMSG/0526
Agenda Item No:	7 – Progesterone (Prometrium®) for the prevention of miscarriage in women presenting with bleeding in the first trimester of pregnancy and have a history of recurrent miscarriages (6820)
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Action for AWMSG:

Members are asked to consider the decision rationale and endorse the recommendation made by the Licensed One Wales Medicines Assessment Group (LOWMAG) to confirm that the decision-making process has been completed robustly and consistently.

Purpose:

Licensed medicines may be assessed by the AWMSG limited assessment route if the AWMSG Scrutiny Panel determines that specific criteria have been met which justify that the review of clinical evidence (if appropriate), budget impact, equity of access and wider societal issues is sufficient to make a robust recommendation on access to the medicine in NHS Wales. LOWMAG has considered and discussed the evidence presented in an Evidence Summary Report (ESR) compiled by AWTTC, the views of clinicians and patients, and comments from the Marketing Authorisation holder, and has provided a recommendation with rationale to the All Wales Medicines Strategy Group (AWMSG). AWMSG is being asked to endorse the LOWMAG recommendation which will then be forwarded to Welsh Government for ratification.

Overview:

The AWMSG Scrutiny Panel decided that progesterone (Prometrium®) was suitable for a limited assessment via the Licensed One Wales Medicines Assessment Group (LOWMAG) as national clinical guidance from NICE and the Royal College of Obstetricians and Gynaecologists recommend use of vaginal progesterone products for this indication, Prometrium® is the first licensed progesterone product for this patient group and will replace off-label preparations used in NHS Wales, and is expected to be cost-saving, and it is available to patients in both England and Scotland. The AWMSG Scrutiny Panel agreed that the case for clinical effectiveness was established and did not warrant further review and so the limited assessment considered current use, equity of access and budget impact only.

Attached is the LOWMAG recommendation and accompanying rationale for:

Progesterone (Prometrium®) 400 mg soft vaginal capsules for the prevention of miscarriage in women presenting with bleeding in the first trimester of pregnancy and have a history of recurrent miscarriages.

The ESR has been provided separately for information.

If you have any questions regarding the ESR, LOWMAG recommendation or decision rationale, please email awttc@wales.nhs.uk by 13th of May 2026.

The assessment lead will respond to your query by email ahead of the meeting and will also provide a verbal summary at the meeting of any significant issues raised. It is anticipated that there will be no discussion required on the day, however, there will be opportunity to clarify any outstanding issues.

Once the LOWMAG recommendation has been endorsed by AWMSG, it will be forwarded to Welsh Government for ratification. In exceptional circumstances, where AWMSG is unable to endorse the recommendation by LOWMAG, the reasons for non-endorsement must be fully justified and will be raised with LOWMAG for further consideration. This will allow for recommendations to be re-considered by AWMSG subject to further information being supplied by LOWMAG.

Licensed One Wales Medicines Assessment Group Recommendation
Progesterone (Prometrium®) 400 mg soft vaginal capsules

Date of advice: April 2026

AWTTC reference number: 6820

Recommendation to the All Wales Medicines Strategy Group (AWMSG)

Progesterone (Prometrium®) is recommended for use in NHS Wales for the prevention of miscarriage in women presenting with bleeding in the first trimester of pregnancy and have a history of recurrent miscarriages.

This recommendation applies only in circumstances where the approved Welsh Patient Access Scheme (WPAS) is utilised or where the list / contract price is equivalent to or lower than the WPAS price.

This recommendation will be reviewed if there is new evidence that is likely to change it.

Licensed One Wales Medicine Assessment Group summary of decision rationale

Medicine: **Progesterone (Prometrium®)**

Assessment type: **Limited**

Indication: **For the prevention of miscarriage in women presenting with bleeding in the first trimester of pregnancy and have a history of recurrent miscarriages.**

Meeting date: **15 April 2026**

Criteria	LOWMAG opinion
Clinical effectiveness	The scrutiny panel acknowledged that clinical effectiveness is already established and therefore no clinical effectiveness evidence was presented to or considered by LOWMAG.
Cost-effectiveness	As this is a limited assessment cost effectiveness is not considered.
Budget impact	<p>LOWMAG considers the estimates of patient numbers to be reasonable.</p> <p>LOWMAG agrees that the most appropriate comparators are the other micronised vaginal progesterone products, Utrogestan® and Cyclogest® which are not licensed for the prevention of miscarriage and are used off label.</p> <p>LOWMAG considers that the base case ranges provided in the report are reasonable estimates of the costs associated with the use of Prometrium® to NHS Wales.</p> <p>LOWMAG acknowledges that the budget impact estimates consider medicine acquisition costs only; administration costs, monitoring costs and costs associated with adverse events have not been included. However, LOWMAG considers that these costs will be virtually the same for all micronised vaginal progesterone products.</p> <p>LOWMAG considers that treatment with Prometrium® is likely to be cost-saving in comparison to off-label comparators although think likely that cost-savings associated with Prometrium® will be modest as the less costly off-label progesterone product is the one most likely being used currently and hence displaced.</p>
Resource use	LOWMAG notes that treatment with Prometrium® is unlikely to be associated with significant additional resource use compared with off-label comparator progesterone products. No additional monitoring is required for the use of Prometrium® in comparison to currently used

	<p>off-label progesterone products above that routinely offered to women presenting with bleeding and with a history of recurrent miscarriage.</p>
Other factors	<p>LOWMAG notes that micronised vaginal progesterone treatment is recommended in NICE, Royal College of Obstetricians and Gynaecologists and European Society of Human Reproduction and Embryology guidelines for the prevention of miscarriage in pregnant women in their first trimester with bleeding and history of miscarriage.</p> <p>LOWMAG notes that Prometrium® is the first licensed progesterone product for this indication and is available in England through local commissioning and in Scotland following an abbreviated assessment by SMC.</p> <p>LOWMAG acknowledges that miscarriage is associated with a significant burden of disease and can have a substantial impact on patient quality of life; there may also be wider socio-economic impacts resulting from time off work, reduced productivity and social withdrawal, with a corresponding increased utilisation of healthcare services including fertility and mental health support.</p> <p>LOWMAG notes the view of the applicant company that recurrent miscarriage is inconsistently treated due to the uneven application of, and access to, guidance and treatment options and that access to a licensed progesterone treatment option will address these issues.</p> <p>LOWMAG also notes that clinicians in Wales would welcome a licensed progesterone product, which may be cost-saving, as an alternative to the off-label products currently used.</p>
Final recommendation	<p>LOWMAG recommends the use of progesterone (Prometrium®), for the prevention of miscarriage in women presenting with bleeding in the first trimester of pregnancy and have a history of recurrent miscarriages.</p> <p>This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list / contract price is equivalent or lower than the WPAS price.</p>
Summary of rationale	<p>LOWMAG notes that micronised vaginal progesterone treatment is recommended in NICE and Royal College of Obstetricians and Gynaecologists guidelines for the prevention of miscarriage in women presenting with</p>

	<p>bleeding in the first trimester of pregnancy and have a history of miscarriage.</p> <p>LOWMAG recognises that Prometrium® is the first licensed progesterone product for this indication and is available in England and in Scotland.</p> <p>LOWMAG consider that making Prometrium routinely available throughout NHS Wales will be modestly cost-saving compared to off-label progesterone products currently used.</p>
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