



**Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group**

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

Submission by Besins Healthcare SA
Date of advice: May 2026
AWTTC reference number: 6820

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 has been endorsed by the All Wales Medicines Strategy Group (AWMSG) and ratified by Welsh Government.

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

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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 off-label progesterone products above that routinely offered to women presenting with bleeding and with a history of recurrent miscarriage.
Other factors	LOWMAG notes that micronised vaginal progesterone treatment is recommended in NICE, Royal College of Obstetricians and Gynaecologists and European Society of

	<p>Human Reproduction and Embryology guidelines for the prevention of miscarriage in pregnant women in their first trimester with bleeding and history of miscarriage. 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>
<p>Final recommendation</p>	<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>
<p>Summary of rationale</p>	<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 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>