Progesterone for the prevention of preterm births: 24 month predicted versus actual analysis

Drug utilisation sub-committee (DUSC)

February 2024

Abstract

Purpose

At its November 2020 meeting the Pharmaceutical Benefits Advisory Committee (PBAC) considered that the estimated utilisation of progesterone for the prevention of preterm births was highly uncertain and considered that a utilisation review by the DUSC should be conducted two years after initial listing.

Date of listing on the Pharmaceutical Benefits Scheme (PBS)

Progesterone for the prevention of preterm was listed on the general schedule of the PBS with a streamlined authority.

Item 12465C, progesterone 200 mg pessary, 15 (Oripro) was listed on the PBS on 1 June 2021.

Item 12598C, progesterone 200 mg capsule, 42 (Utrogestan) was listed on 1 July 2021.

Data Source / methodology

Data extracted from the PBS database maintained by Department of Health and Aged Care, processed by Services Australia were used for the analyses.

Key Findings

- Utilisation of progesterone for the prevention of preterm birth has slowly increased since the initial increase upon listing on the PBS.
- Utilisation of Utrogestan (Item 12598C) has been more than double the utilisation of Oripro (Item 12465C) in the second and third quarters of 2023.
- Prescribing of progesterone for the prevention of preterm birth has been highest amongst obstetricians and gynaecologists, followed by vocationally registered general practitioners (GPs) and non-vocationally registered GPs.
- Despite the PBS listing of progesterone for the prevention of preterm birth allowing prescribing by nurse practitioners and midwives, actual prescribing from these prescriber types has been extremely low.
- Actual utilisation of progesterone for the prevention of preterm birth was different from estimated. The number of treated patients and prescriptions supplied is [redacted] than estimated.

Purpose of analysis

At its November 2020 meeting the PBAC considered that the estimated utilisation of progesterone for the prevention of preterm births was highly uncertain and considered that a utilisation review by DUSC should be conducted two years after initial listing.

Background

Clinical situation

Progesterone is used by women undergoing fertility treatment, for the treatment of unexplained threatened miscarriage, and for the prevention of preterm birth in women with a short cervix and/or history of spontaneous preterm birth.

The Australian Institute of Health and Welfare (AIHW)[1] data shows that in 2022 there were 264,341 births of which 22,053 were pre-term (20-36 weeks), which is a rate of 8.3%. Over the same period, the PBS data shows that 5,995 women initiated treatment with PBS progesterone for prevention of pre-term birth. If progesterone treatment for the prevention of preterm birth is effective and widely used, overtime the pre-term birth rate should decrease, however this has not happened yet as the pre-term birth rate is still 8.3%.

Pharmacology

Progesterone is a naturally occurring steroid hormone that is secreted by the ovary, placenta and adrenal gland. It acts on the endometrium by converting the proliferating phase to the secretory phase. Progesterone is necessary to increase endometrial receptivity for implantation of an embryo, and once an embryo is implanted, progesterone acts to maintain the pregnancy. As well as gestagenic actions, progesterone also has anti-estrogenic, slightly anti-androgenic and anti-aldosterone effects.

Therapeutic Goods Administration (TGA) approved indications

Progesterone is registered for the prevention of preterm birth in singleton pregnancies at risk due to:

- Shortened cervix (midtrimester sonographic cervix ≤25mm); and/or
- Where there is a history of spontaneous preterm birth.

Progesterone is also registered for:

- The treatment of unexplained threatened miscarriage in women with bleeding in the current pregnancy and a history of at least three or more previous miscarriages;
- Assisted reproductive technology (ART) treatment of infertile women with progesterone deficiency, requiring progesterone supplementation or replacement to support embryo implantation and maintain initial pregnancy, and for luteal phase support;
- Women with menstrual abnormalities or secondary amenorrhoea due to normogonadotrophic amenorrhoea; and

[1] https://www.aihw.gov.au/reports/mothers-babies/australias-mothers-babies/contents/summary

- In combination with estrogen in hormone replacement therapy.

Dosage and administration

Table 1: Dosage and administration of progesterone for the prevention of preterm birth

Brand name and sponsor	Product	Dose and frequency of administration
Oripro, Orion Laboratories Pty Ltd	Pessaries contain as active substance 100mg or 200mg of progesterone.	200 mg daily (at night)
Utrogestan, Besins Healthcare Australia Pty Ltd	Soft pessary capsule containing as active substance 200mg of progesterone.	200 mg/day, recommended at bedtime

Source: Product Information.

The current Product Information (PI) and Consumer Medicine Information (CMI) are available from the TGA (Product Information) and the TGA (Consumer Medicines Information).

PBS listing details (as at 23 October 2023)

Progesterone for the prevention of preterm was listed on the general schedule of the PBS with a streamlined authority.

Item 12465C, progesterone 200 mg pessary, 15 (Oripro) was listed on the PBS on 1 June 2021.

Item 12598C, progesterone 200 mg pessary capsule, 42 (Utrogestan) was listed on 1 July 2021.

The current PBS listings for progesterone for the prevention of preterm are presented in Table 2 below.

Table 2: PBS listing of Progesterone for the prevention of short term birth

Item	Name, form & strength, pack size	Max qty packs	Max qty units	Rpts	DPMQ	Brand name and manufacturer
12465C	Progesterone 200 mg pessary, 15	3	45	3	$127.89	Oripro, Orion Laboratories Pty. Ltd.
12598C	Progesterone 200 mg pessary capsule, 42	1	42	3	$94.20	Utrogestan, Besins Healthcare Australia Pty Ltd

Source: the PBS website.

Restriction

Prevention of preterm birth clinical criteria:

- Patient must have a singleton pregnancy, AND
- Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth, AND
- The treatment must be administered no earlier than at 16 weeks gestation.

Authority required (STREAMLINED).

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
For details of the current PBS listing refer to the PBS website.

Relevant aspects of consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)

Progesterone (Utrogestan® and Oripro®) was first considered by PBAC for the prevention of preterm birth in November 2020. The PBAC recommended listing for the prevention of preterm birth in women with singleton pregnancies and a short cervix (≤25 mm) and/or a history of preterm birth. The PBAC considered that the estimated utilisation of progesterone was highly uncertain and that a utilisation review by DUSC should be conducted two years after initial listing.

For further details refer to the Public Summary Document for Utrogestan® and Oripro® from the November 2020 PBAC meeting.

Previous reviews by the DUSC

No previous DUSC reviews have been undertaken for progesterone.

Methods

PBS and RPBS (R/PBS) prescription data for PBS-listed progesterone for prevention of premature birth (PBS item codes 12465C and 12598C) were extracted from the supplied prescriptions database maintained by the Department of Health and Aged Care and processed by Services Australia for the period June 2021 to September 2023 inclusive, based on the date that the prescription was supplied. Data for this period includes all R/PBS supplies regardless of whether a subsidy was paid; i.e. both over co-payment and under co-payment. These item codes are specific to the “prevention of premature birth “ indication, so there was no need to have regard to the Streamlined Authority code to determine indication.

The item 12465C, progesterone 200 mg pessary, 15 (Oripro) was listed on the PBS on 1 June 2021. The item 12598C, progesterone 200 mg capsule, 42 (Utrogestan) was listed one month later on 1 July 2021. This item was described as a capsule when listed, but in the current PBS schedule is described as a pessary (the same as item 12465C). It should be noted that the PBS maximum quantity for 12465C is 3 packs, giving 45 pessaries in a standard supply and the PBS maximum quantity for 12598C is 1 pack, giving 42 pessaries in a standard supply.

The R/PBS prescription data were used to determine the number of prescriptions supplied, R/PBS expenditure, patient age, gender and prescriber type. These prescription data were also used to count the number of patients, both incident (new to treatment with progesterone for this indication) and prevalent (number treated) in each time period. There were two types of initiations calculated, initiation to a particular PBS item (see Figures 3 and 6) and initiation to progesterone therapy (see Figures 2, 4, 5 and 7 and Table 4). For both types of initiation, the initiation date was defined as the date of supply of the first PBS or RPBS prescription.

The number of prevalent people was determined by counting the number of people supplied at least one PBS prescription using person-specific numbers (non-identifying) in the data for the specified time periods.

As these analyses use date of supply prescription data, there may be differences compared with publicly available Services Australia Medicare date of processing data.

Results

Analysis of drug utilisation

Overall utilisation

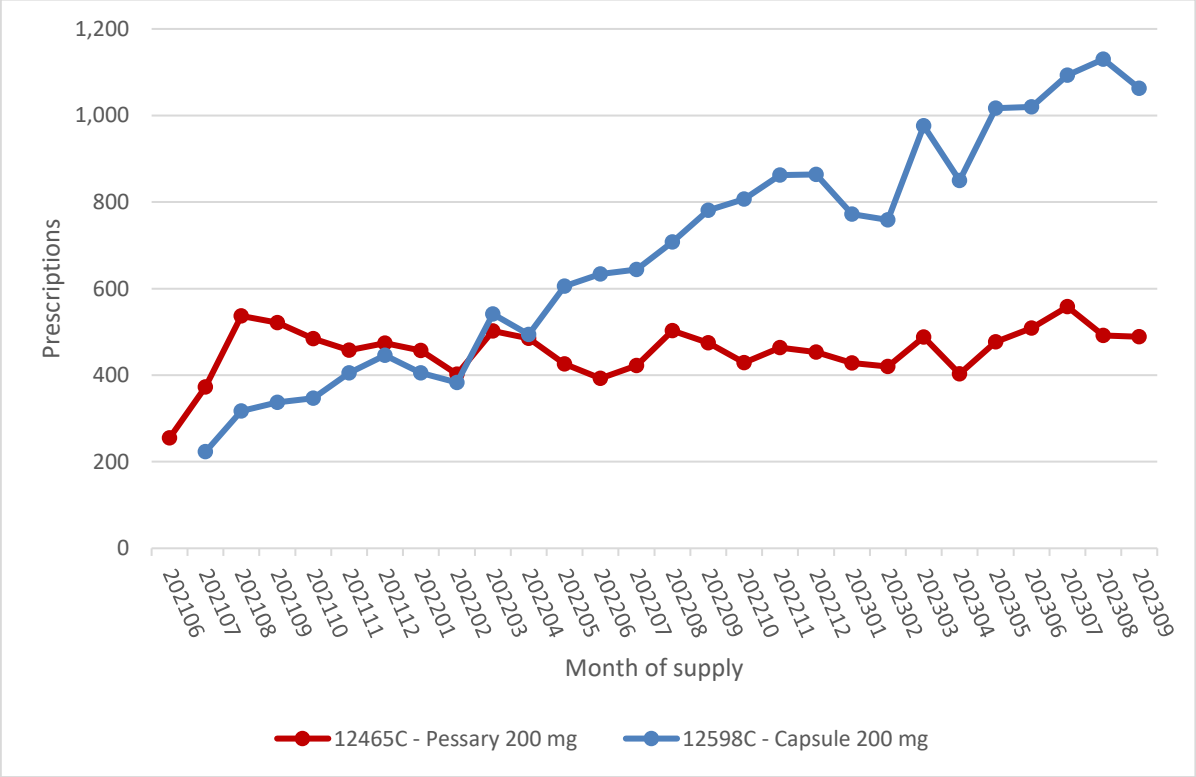

Figure 1: Number of PBS/RPBS progesterone prescriptions (items 12598C and 12465C) for prevention of preterm birth by month since listing

Note: Item 12465C is Oripro (pessary) and item 12598C is Utrogestan (pessary capsule)

Since listing on the PBS, overall prescriptions of progesterone for the prevention of preterm birth have increased. However, when looking at the two separate medicines (Figure 1 and Table 3) it is evident that overall prescriptions of Utrogestan are higher than Oripro.

Figure 1 and Table 3 show that since listing on 1 July 2021, the prescription count of Utrogestan continues to increase, whereas following the initial increase in prescribing of Oripro (on 1 June 2021) the prescribing rate appears to be levelling out.

Table 3: Number of PBS/RPBS progesterone prescriptions for prevention of preterm birth (items 12598C and 12465C) by quarter since listing

Quarter	Oripro Pessary 200 mg (Item 12465C) Listed 1 June 2021	Utrogestan Pessary Capsule 200 mg (Item 12598C) Listed 1 July 2021	Total
2021Q2	255	-	255
2021Q3	1,431	877	2,308
2021Q4	1,416	1,198	2,614
2022Q1	1,361	1,329	2,690
2022Q2	1,304	1,734	3,038
2022Q3	1,400	2,133	3,533
2022Q4	1,346	2,533	3,879
2023Q1	1,336	2,507	3,843
2023Q2	1,389	2,887	4,276
2023Q3	1,539	3,286	4,825
Grand Total	**12,777**	**18,484**	**31,261**

Note: Data for 2021Q2 is incomplete.

Patients initiating and prevalent to progesterone for the prevention of preterm birth

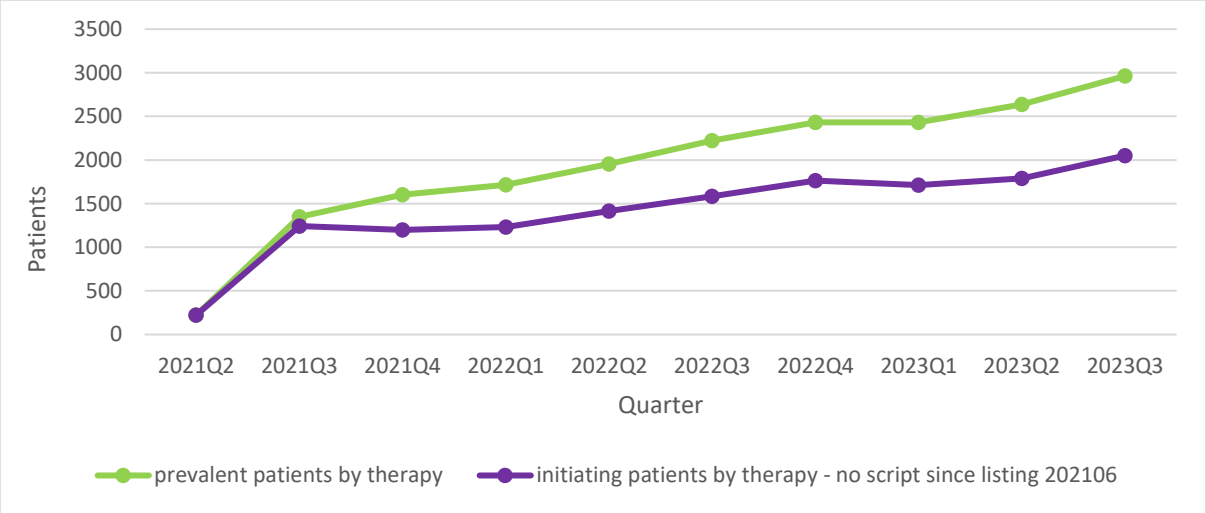

Figure 2: Total prevalent and initiating patients receiving progesterone for the prevention of preterm birth per quarter

Note: Data for 2021Q2 is incomplete.

Since listing the number of prevalent and initiating patients utilising progesterone for the prevention of preterm births have increased (Figure 2).

Figure 3 shows that both prevalent and initiating patients supplied Utrogestan are increasing, and that prevalent and initiating patients supplied Oripro appear to be stabilising.

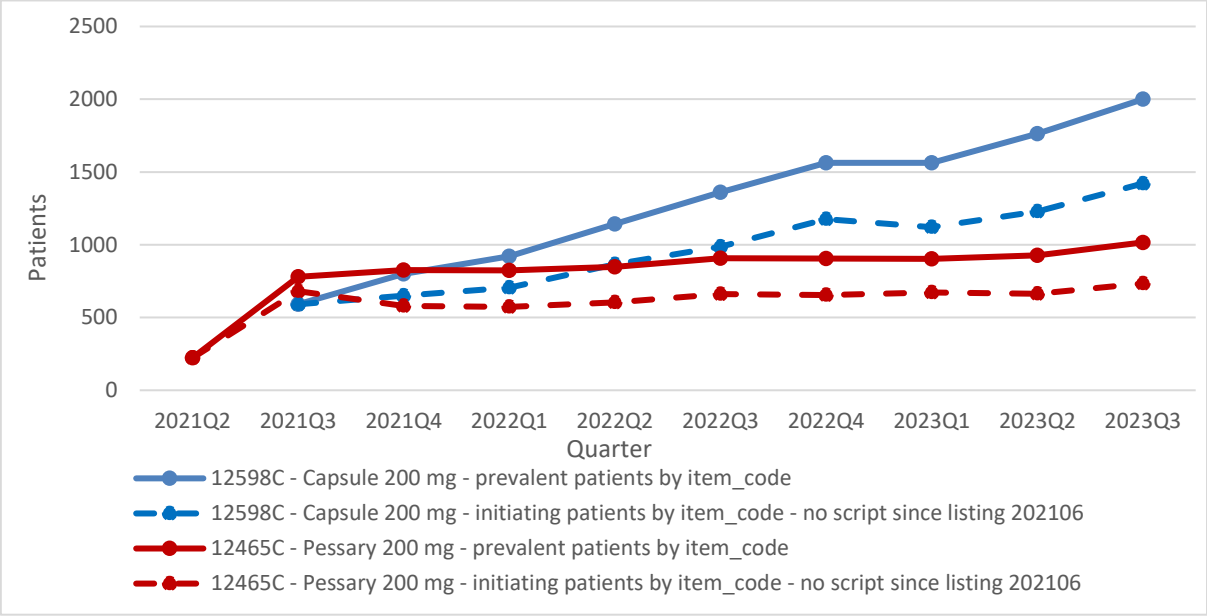

Figure 3: Prevalent and initiating patients receiving progesterone (items 12598C and 12465C) for the prevention of preterm birth per quarter

Note: Data for 2021Q2 is incomplete.
Note: Item 12598C is Utrogestan (pessary capsule) and item 12465C is Oripro (pessary)

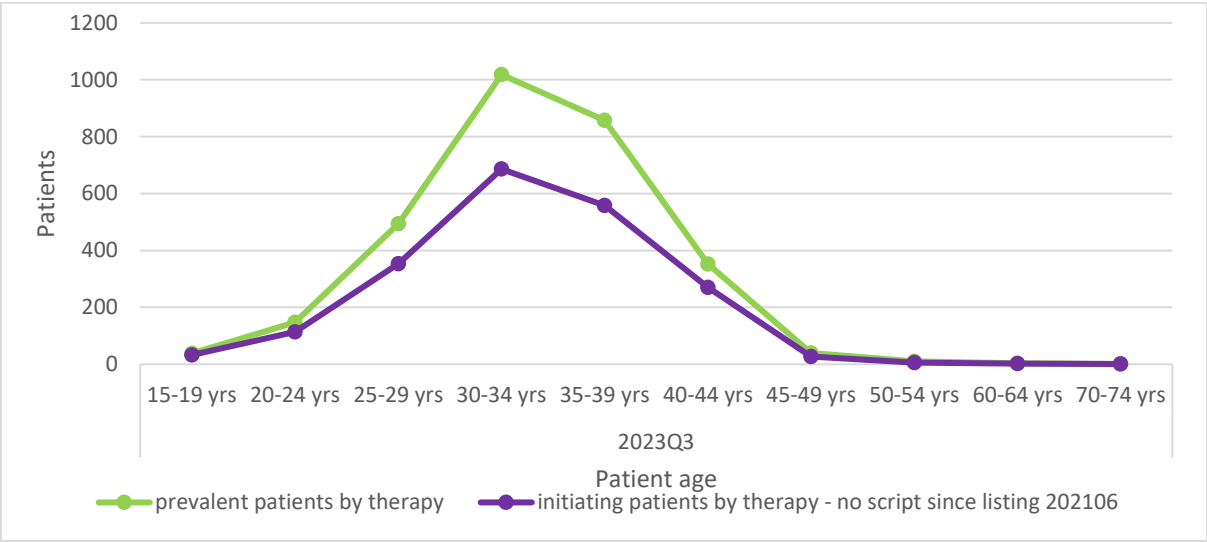

Figure 4: Prevalent and initiating patients receiving progesterone (items 12598C and 12465C) for the prevention of preterm birth by age group in 2023Q3

Figure 4 shows the age distribution of patients using progesterone to prevent preterm birth in Quarter 3 of 2023. The highest use in the quarter was in the 30-34 year old age group, with 1,018 prevalent patients and 686 initiating patients.

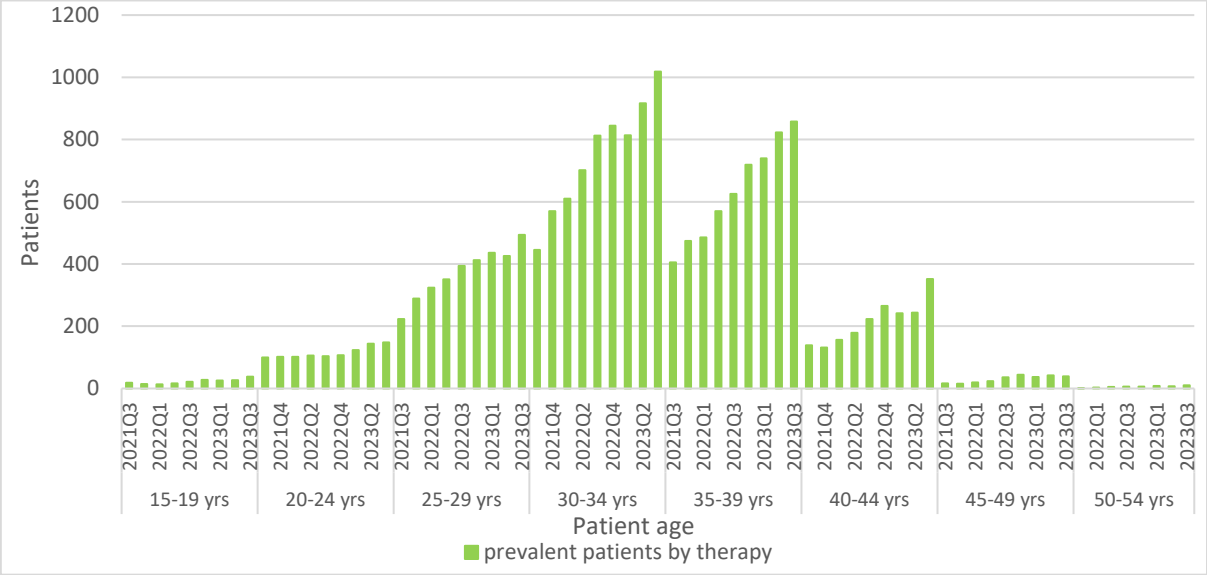

Figure 5: Prevalent patients by age group and quarter treated with progesterone

Figure 5 shows the utilisation of progesterone by prevalent patients, age group and quarter. An increased use over time can be observed for the majority of age groups.

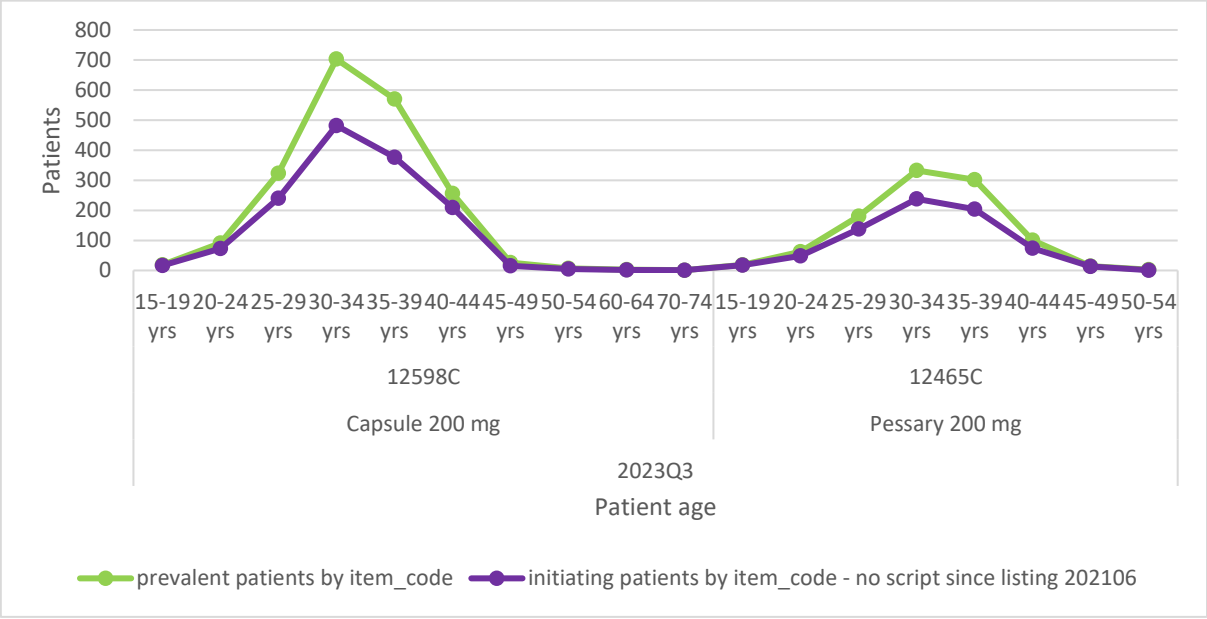

Figure 6: Age distribution of prevalent and initiating patients in 2023Q3 taking progesterone for items 12598C and 12465C

Note: Item 12598C is Utrogestan (pessary capsule) and item 12465C is Oripro (pessary)

Figure 6 shows the age distribution of prevalent and initiating patients across the two progesterone medicines for the prevention of preterm birth in the third quarter of 2023.

Utilisation of Utrogestan is higher than Oripro, with Utrogestan having a clear peak of use in patients aged 30-34, whereas Oripro has similar use within 30-34 year olds and 35-39 year olds.

Prescribers

Obstetricians and gynaecologists are the most common prescribers of Oripro and Utrogestan for the prevention of preterm birth. Vocationally registered GPs and non-vocationally registered GPs are the next highest common prescribers and together the three prescriber types make up 87% of prescribers of Oripro and 93% of prescribers of Utrogestan.

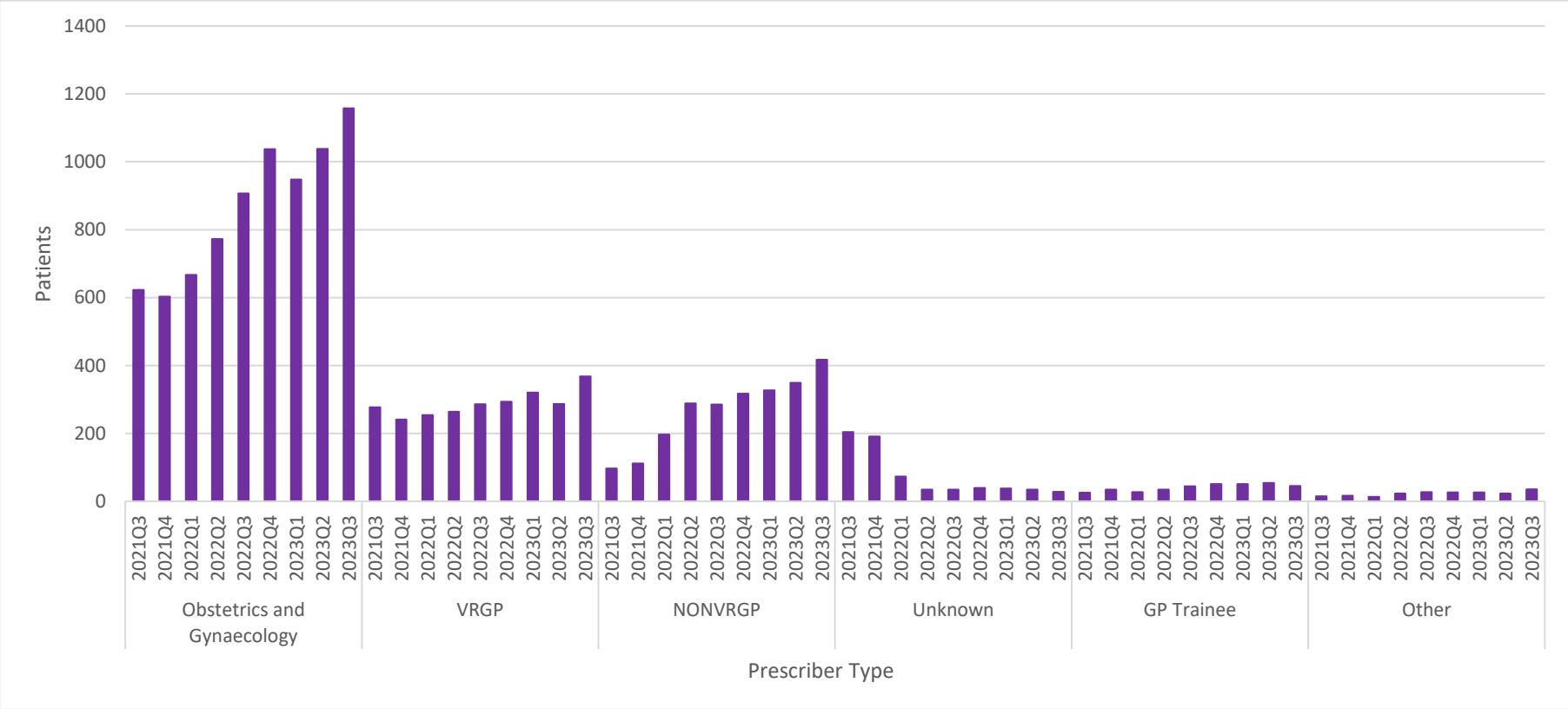

Figure 7: Prescriber type for patients initiating treatment with progesterone

Note: VRGP refers to vocational register general practitioner

Note "Other" includes nurse practitioners, midwives and endocrinologists. A full list of prescriber types included under "Other" can be found in Appendix A.

Prior to the PBS listing of progesterone for preterm births the PBAC advised that progesterone would be suitable for prescribing by nurse practitioners and midwives, noting that this would support access to treatment for women in regional and remote areas.

Table 4 shows the numbers of patients who initiated treatment on Oripro and Utrogestan for the prevention of preterm birth. As can be seen in Table 4, the numbers of nurse practitioner and midwife prescribers have been low, the reasons for this are unclear.

Table 4: Initiating patients by prescriber type and item for the progesterone therapy initiating script, 1 June 2021 to 30 September 2023

Prescriber Type	Oripro Pessary 200mg (Item 12465C)	Utrogestan Pessary Capsule 200mg (Item 12598C)	Total
Obstetrics and Gynaecology	2,714	5,129	7,843
VRGP	1,027	1,605	2,632
NONVRGP	1,308	1,097	2,405
Unknown	490	250	740
GP Trainee	140	229	369
Endocrinology	33	6	39
Midwife	≤5	19	22
Intensive Care	7	13	20
Urogynaecology	17	≤5	18
Nurse Practitioner	9	9	18
Other	43	49	92
Total	≤5,793	≤8,411	≤14,204

Note: VRGP refers to vocational register general practitioner
Note: A full list of prescriber types included under "Other" can be found in Appendix A.

Table 4 shows that overall prescribing of Utrogestan is higher than Oripro, however this increased prescribing of Utrogestan is mainly seen in obstetrics and gynaecology and vocationally registered GPs. Oripro has increased rates of prescribing in non-vocationally registered GPs and "unknown" prescribers.

Time on treatment

Time on treatment was difficult to estimate due to the short timeframes of use involved and a lack of data. The data indicates that the mean number of scripts per patient are 2.17 and the median number of scripts per patient are 2. The expected length of treatment for 2.17 scripts, using one pessary per day, is over 2 months and shorter than the amount anticipated to be used. There is evidence to suggest that some patients are using several pessaries per day, however the data is unable to ascertain the amount used.

Table 5 shows that 98% of patients have less than 6 scripts of progesterone for the prevention of preterm birth filled. It is of interest to note that 209 patients have had 7 or more prescriptions filled, which is higher than allowed according to the restrictions.

Table 5: Number of prescriptions filled in the first 6 months after initiation

Number of scripts	1	2	3	4	5	6	7	8	9	10+	Total
Patients	4,781	2,416	1,569	875	334	186	68	64	15	62	**10,370**
% Patients	46.1%	23.3%	15.1%	8.4%	3.2%	1.8%	0.7%	0.6%	0.1%	0.6%	**100%**
% Patients cumulative	46.1%	69.4%	84.5%	93.0%	96.2%	98.0%	98.6%	99.3%	99.4%	100.0%	**100.0%**

Approach taken to estimate utilisation

The utilisation and financial estimates presented in the November 2020 submissions for Oripro and Utrogestan were considered by DUSC and the PBAC. The submissions for Oripro and Utrogestan applied an epidemiological approach to develop the financial estimates.

Commercial-in-confidence

[redacted]

For further details about the methods used to estimate the eligible patient population, refer to the Public Summary Documents for Oripro® and Utrogestan® from the November 2020 PBAC meeting.

Table 6: Predicted versus actual utilisation of progesterone for the prevention of preterm birth

		Year 1 June 2021 - May 2022	Year 2 June 2022 – May 2023
Patients	Predicted	[redacted]	[redacted]
	Actual	4,841	7,424
	Difference	[redacted]	[redacted]
Prescriptions	Predicted	[redacted]	[redacted]
	Actual	9,878	15,029
	Difference	[redacted]	[redacted]
Net Cost PBS/RPBS	Predicted	[redacted]	[redacted]
	Actual	$521,688	$1,004,448
	Difference	[redacted]	[redacted]

Note: The predicted and actual figures include both Oripro and Utrogestan

Table 6 presents a comparison of the predicted versus actual utilisation and expenditure of progesterone treatment for the prevention of preterm birth since listing in June 2021.

In the first year of listing the number of patients utilising progesterone for the prevention of preterm birth was 4,841 which is [redacted] than what was predicted. The number of patients in Year 2 was 7,424 which is [redacted] than what was predicted.

The number of prescriptions dispensed in the first year of listing was 9,878, which was [redacted] than what was predicted. The number of prescriptions in the second year of listing was 15,029, which was [redacted] than what was predicted.

The cost to the PBS/RPBS are [redacted] than what was predicted, [redacted] in the first year of listing, and [redacted] in the second.

End commercial-in-confidence

Discussion

The utilisation of progesterone for the prevention of preterm birth has been [redacted] than predicted. The reasons for this are unclear and may include; lack of knowledge and awareness of the medicine; the medicine not working as intended and not preventing preterm births; and specialists and medical practitioners in the field preferring to use different methods such as bed rest and/or a cervical stitch (cerclage).

Since listing on the PBS, overall prescriptions of progesterone for the prevention of preterm birth have increased, with utilisation of Utrogestan being higher than Oripro (Figure 1 and Table 3).

Since listing on 1 July 2021, the number of patients using Utrogestan continues to increase, whereas following the initial increase of patients using Oripro (on 1 June 2021) the number of patients using Oripro appears to be stabilising (Figure 3).

The age distribution of patients using progesterone to prevent preterm birth in Quarter 3 of 2023 was highest in the 30-34 year old age group, with 1018 prevalent patients and 686 initiating patients (Figure 4). An increased use over time can be observed for the majority of age groups (Figure 5).

Prior to the PBS listing of progesterone for preterm births the PBAC advised that progesterone would be suitable for prescribing by nurse practitioners and midwives, noting that this would support access to treatment for women in regional and remote areas. Table 4 shows that the prescribing of progesterone for reducing preterm birth by nurse practitioners and midwives has been very low in practice.

Table 4 and Figure 7 show that the most common prescriber for progesterone for the prevention of preterm birth are obstetricians and gynaecologists, followed by vocationally registered GPs and non-vocationally registered GPs.

Clinical guidelines recommend starting progesterone at 20-24 weeks until 34 weeks' gestation to reduce preterm birth risk (American College of Obstetricians and Gynecologists 2022; RANZCOG Clinical Statement November 2023). The mean and median number of prescriptions supplied per patient was 2.17 and 2, respectively. This suggests that most patients are supplied progesterone for a shorter time compared to recommended use.

AIHW[1] data shows that in 2022 there were 264,341 births of which 22,053 were pre-term (20-36 weeks), which is a rate of 8.3%. Over the same period, the PBS data shows that 5,995 women initiated treatment with PBS progesterone for prevention of pre-term birth. If progesterone treatment for the prevention of preterm birth is effective and widely used, overtime the pre-term birth rate should decrease, however this has not happened yet as the pre-term birth rate is still 8.3%.

DUSC consideration

DUSC noted:

- The data might be too immature for a reduction in preterm births to be observed.
- The population includes new women having first births, and thus they would not have the history of preterm births that forms part of the restriction and would not be taking progesterone as a preventative measure.
    - DUSC commented that this might form part of the reasons behind why the number of preterm births has not decreased.
- The higher utilisation of Utrogestan may be due to it being less oily than Oripro, and as such being easier for women to use.
- The mean number of scripts suggests that progesterone was being used for a shorter amount of time than predicted. DUSC commented that the guidelines recommend starting treatment at 20-24 weeks compared to the 16 weeks of the submission.
- That perhaps women are not using the medication for long enough.
- Nurse practitioner and midwife prescribing was low. DUSC commented that nurse practitioner numbers are low and that midwives may be less inclined to prescribe

progesterone as part of their care model where the guidelines direct care to be referred to a doctor/specialist.

- Pregnancy care standards are evolving. DUSC commented that in the near future, detection of early cervical shortening (through cervical length measurement) will form part of routine care for pregnant women. DUSC considered that utilisation of progesterone for the prevention of preterm birth may increase as part of this change.

DUSC commented that:

- A future review should only be undertaken once the data has had time to mature, and changes in birthing practices and patient care models have had time to flow through to be represented in the data.
- Reviewing use in high-risk population groups (i.e. smokers, via linking with smoking cessation medicines) would be beneficial. DUSC suggested incorporating geographical data in future analyses.
- A breakdown of utilisation for the Indigenous population through the S100 RAS program could be useful, noting that Indigenous women mostly receive care through midwives. DUSC discussed if this model of care was appropriate for Indigenous women.
- There might be leakage into the IVF market for women who have increased numbers of scripts or are using higher doses.

Actions undertaken by the DUSC Secretariat

DUSC requested the report be provided to the PBAC for consideration.

Context for analysis

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

Sponsors' comments

Besins Healthcare Australia Pty Ltd: The sponsor has no comment.

Orion Laboratories PTY Ltd: The sponsor has no comment.

Disclaimer

The information provided in this report does not constitute medical advice and is not intended to take the place of professional medical advice or care. It is not intended to define what constitutes reasonable, appropriate or best care for any individual for any given health issue. The information should not be used as a substitute for the judgement and skill of a medical practitioner.

The Department of Health and Aged Care has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up-to-date when it was considered by the Drug Utilisation Sub-committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

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Utrogestan PBAC Public Summary Documents – November 2020. Available from https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2020-11/progesterone-capsule-200-mg-utrogestan

Appendix A: Prescriber types included in the "Other" category.

Endocrinology,
Midwife
Intensive Care
Urogynaecology
Nurse Practitioner
Anaesthetics
Nephrology
Paediatric Medicine
Surgery
Internal Medicine
Maternal-foetal Medicine
Respiratory and Sleep Medicine
Ophthalmology
Ear, Nose and Throat
Oral and Maxillofacial Surgery
Palliative Medicine
Psychiatry
GP Unclassified
Occupational & Environmental Medicine
Rehabilitation Medicine
Geriatric Medicine
Cardiology
Medical Oncology
Gastroenterology and Hepatology
Neurology
Rheumatology
Dermatology
Social Worker
Pathology