Record of the Reproductive and Sexual Health Advisory Committee Meeting held on 18 July 2022

Reproductive and Sexual Health Advisory Committee records are published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) Specialist Advisory Committees 2021.

Note that this document is not necessarily a complete record of the Reproductive and Sexual Health Advisory Committee meeting; only the relevant portions of the meeting record relating to Reproductive and Sexual Health Advisory Committee discussions about an Application or Pharmac staff proposal that contain a recommendation are generally published.

The Reproductive and Sexual Health Advisory Committee may:

(a) recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule and the priority it gives to such a listing;

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that Pharmac decline to list a pharmaceutical on the Pharmaceutical Schedule.

Pharmac Advisory Committees make recommendations, including priority, within their therapeutic groups of interest.

The record of this Advisory Committee meeting will be reviewed by PTAC at an upcoming meeting.

Specialist Advisory Committees and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of any one funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

1. Attendance

Present
Rhiannon Braund (Acting Chair)
Debbie Hughes
Jane Morgan
Helen Paterson
Christine Roke

Apologies:
Ian Page
Simon Wynn Thomas

2. The role of Specialist Advisory Committees and records of meetings

2.1. This meeting record of the Reproductive and Sexual Health Advisory Committee is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and Specialist Advisory Committees 2021, available on the Pharmac website at https://pharmac.govt.nz/assets/2021-Specialist-Advisory-Committee-Terms-of-Reference.pdf. The Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees and PTAC.

2.2. Conflicts of Interest are described and managed in accordance with section 7.2 of the PTAC Terms of Reference.

2.3. The Reproductive and Sexual Health Advisory Committee is a Specialist Advisory Committee of Pharmac. The Reproductive and Sexual Health Advisory Committee and PTAC and other Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. The Reproductive and Sexual Health Advisory Committee and other Specialist Advisory Committees may therefore, at times, make recommendations for treatments for Reproductive and Sexual Health that differ from PTAC's, including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for Reproductive and Sexual Health that differ from the Reproductive and Sexual Health Advisory Committee's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

Pharmac considers the recommendations provided by both the Reproductive and Sexual Health Advisory Committee and PTAC and any other relevant Specialist Advisory Committees when assessing applications for treatments for Reproductive and Sexual Health.

3. Discussion

3.1. The Committee noted the purpose of the meeting was to seek advice from the Advisory Committee on funding proposals previously assessed, to refresh and further develop Pharmac's economic analysis and understanding of the proposals.

Ring pessaries

3.2. The Committee noted Pharmac staff were considering the impact on co-administered pharmaceuticals should ring pessaries be funded in the community.

3.3. Members considered that a large proportion of the eligible population for ring pessaries are likely to be already using low dose oestrogen cream (ie. oestriol cream) for other indications. Members considered many patients not currently receiving oestriol cream would likely commence treatment with oestriol cream post-ring pessary insertion, unless contraindicated.

3.4. Members considered that while the overall use of oestriol cream would be unlikely to change as a result of ring pessaries being funded in the community, its use could increase to a small extent over time should clinical guidelines be further updated regarding best practice.

3.5. Members considered the currently funded oestriol cream products (1 mg per g, 15 g cream with applicator and 500 mcg pessaries) are appropriate for use in this setting.

3.6. The Committee considered it would be reasonable to assume that one ring pessary would be dispensed every two years for each patient on average, and that it was reasonable to assume patients using a ring pessary would also receive one tube of oestriol cream every three months. The Committee noted that ring pessaries may be dispensed to a patient more often than every two years if the fit of the pessary became suboptimal or the pessary changed texture due to normal wear and tear.

3.7. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for ring pessaries if these were to be funded in New Zealand. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

POPULATION	People with symptomatic pelvic prolapse
INTERVENTION	Ring pessaries (with or without low-dose oestrogen cream) • Ring pessaries to be replaced once every two years, on average
COMPARISON	No treatment
OUTCOME	Improvement in pelvic organ prolapse symptoms. • Cheung et al. Obstet Gynaecol. 2016;128: 73-80 reported that ring pessaries (in combination with PFMT) resulted in improvement in prolapse-related symptoms compared to PFMT alone RR 2.15 (95% CI, 1.58 to 2.94) Conservative management (no treatment) is not associated with an improvement in prolapse-related symptoms.

Low Sensitivity Pregnancy tests

3.8. The Committee noted that Pharmac has received a funding application for low sensitivity pregnancy tests (1000 mIU/ml) for use in confirmation of termination of pregnancy following early medical abortion (EMA) – in line with the recently published New Zealand Aotearoa Abortion Clinical Guideline (Ministry of Health, 2021).

3.9. The Committee considered that if low sensitivity pregnancy tests were funded the only indication would be following early medical abortion.

3.10. Members noted that currently around half of people may not complete follow up testing post-EMA, although noted this proportion is likely to vary by region. Members considered, based on experience, post-EMA testing for patients receiving treatment via telehealth occurs less often compared than those receiving in-clinic treatment.

3.11. Members noted that currently, clinicians extensively attempt to contact and follow up those patients who have not completed serum hCG testing following EMA (ie. two hCG tests: on day 0 and day 7-10). Members considered this to be a staff and time resource intensive process and the resulting gaps in follow-up were not consistent with best practice care for patients post-EMA. An estimate of once-weekly contact and follow-up attempts for up to four weeks post-EMA was considered a reasonable estimate of the resource use associated with this issue.

3.12. The Committee noted that low sensitivity pregnancy tests represented a more accessible hCG testing method compared to serum testing, that could be performed by patients at home. Members considered that this would improve post-EMA testing rates and potentially reduce the burden on clinicians associated with following up patients who do not access serum testing.

3.13. Members considered that if funded, one low sensitivity pregnancy test would be dispensed with every patient's treatment pack but noted however that this would not fully replace serum hCG testing in this setting. Members considered that the availability of low sensitivity pregnancy tests would be particularly suitable for those receiving treatment via telehealth and anticipated it would increase the number of patients completing testing post-EMA.

3.14. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for low sensitivity pregnancy tests if they were to be funded in New Zealand. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

POPULATION	Patients who have received an early medical abortion (EMA) (<10 weeks gestation), and require testing to confirm EMA is complete and to exclude ongoing pregnancy.
INTERVENTION	A urine β-hCG test (low sensitivity pregnancy test) at 3 or 4 weeks after mifepristone administration in line with the Ministry of Health's Abortion Clinical Guideline (New Zealand Aotearoa Abortion Clinical Guideline, 2021).

	If the test is positive, further investigation and management would be required.	
COMPARISON	Serum β-hCG testing • performed in line with the Ministry of Health's Abortion Clinical Guideline (New Zealand Aotearoa Abortion Clinical Guideline, 2021), which recommends serum β-hCG testing: • once on the day of mifepristone administration • once again at 7–14 days after mifepristone administration. If the reduction in β-hCG is less than 80%, further investigation and management will be required.	No testing post-abortion (approximately 50% of current patients may not access testing)
OUTCOME	No evidence of a difference in safety or effectiveness between urine and serum β-hCG testing to confirm the termination of a pregnancy and inform further medical management (Baiju et al. BJOG. 2019;13: 1536-1544; Schmidt-Hansen et al. A J Obstet Gynaecol. 2020;6: 551-563)	

Non-latex condoms and internal condoms

Non-latex condoms

3.15. The Committee noted the previous estimates of condom use of one per week was based on figures across the adult heterosexual population. Members considered that for the heterosexual individuals who would use condoms for STI protection (for example people engaging in casual sex or a new relationship), frequency of condom use was likely to be higher and considered it appropriate to assume that approximately 3 to 4 condoms would be used per week per individual. Members noted that there is limited literature on patterns of condom use for men who have sex with men, however anecdotal evidence and small studies suggest that the frequency of use per week could be up to double that of their heterosexual counterparts.

3.16. The Committee noted that currently, a dispensing limit of 60 condoms per dispensing is in place for latex condoms, members considered that it would be appropriate for the same dispensing volumes to apply to non-latex condoms should they be funded.

3.17. The Committee considered it appropriate to assume that people who use other forms of contraception and STI prophylaxis would continue to do so if non-latex condoms were funded.

3.18. The Committee considered that roughly 1% of the New Zealand population has a latex allergy, and that the prevalence of latex sensitivity was roughly 5%. Members considered that, due to the different manifestations and severity of latex allergy and sensitivity, some people with a latex sensitivity may be using latex condoms currently and would switch to non-latex condoms if they were funded.

3.19. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for non-latex condoms if they were to be funded in New Zealand. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

POPULATION	People with a confirmed latex allergy who require a barrier method of STI prophylaxis or contraception.
INTERVENTION	Three to four non-latex condoms per person per week. People are assumed not to discontinue their current contraception (ie. non-latex condoms are assumed to be used in addition to current contraception options) and STI prophylaxis
COMPARISON	Non-barrier methods of STI prophylaxis or contraception.
OUTCOME	Reduced risk of acquiring STIs • Lower protection with non-latex condoms than from latex condoms due to higher risk of clinical breakage (OR 2.64, 95% CI 1.63 to 4.95) (Gallo et al. Cochrane database Syst Rev. 2006;1: CD0035500) Reduced risk of unintended pregnancy with non-latex condoms assumed to be of the same magnitude as for latex condoms (Gallo et al. Cochrane database Syst Rev. 2006;1: CD0035500)

Internal condoms

3.20. The Committee considered that if internal condoms were funded without restriction, three main populations would likely use them: men who have sex with men, females living with HIV, and sex workers.

3.21. The Committee noted that the prevalence of consistent condom use in men who have sex with men has substantially reduced in recent years, with similar rates of condom use to heterosexual individuals now observed. Members considered this was in most part due to changes in the availability of HIV preventative treatments. As such, members considered that an assumption that 5% of men who have sex with men would use internal condoms was particularly high. The Committee considered 5% would be a maximum proportion and that the likely uptake of internal condoms should they be funded would likely be lower than this.

3.22. The Committee considered that an uptake of three to four internal condoms per week would be an appropriate estimate for females living with HIV, and men who have sex with men, should they be funded.

3.23. The Committee noted that HIV treatments have evolved recently and concerns regarding medicine interactions are now relatively minimal, meaning that systemic contraceptives can be widely utilised by females living with HIV. The Committee therefore considered that the uptake of internal condoms in females living with HIV would likely be lower than previously assumed and would likely be around 10% of this group.

3.24. The Committee noted that male latex condom use among sex workers in New Zealand is very high, noting that condom use is a legislative requirement for clients of sex workers. On that basis, members considered that uptake of internal condoms among sex workers would be very low. Members considered that it would be appropriate to assume that for sex workers anticipated to use internal condoms, a frequency of use of approximately 16 per person per week; however, noted that the Aotearoa New Zealand Sex Workers Collective would be well placed to further advise on this.

3.25. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for internal condoms if they were funded in New Zealand. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

<table>
<tr><td>POPULATION</td><td>People living with HIV, requiring suitable contraception and/or STI prophylaxis.</td><td>People requiring alternative STI prophylaxis for anal sex (primarily MSM).</td><td>People working in the sex industry using currently funded non-barrier contraception methods.</td></tr>
<tr><td rowspan="2">INTERVENTION</td><td colspan="2">Three to four internal condoms per week per patient.</td><td>16 internal condoms per week per person on average, based on clients per week reported in Sex Worker Health Surveillance report, UNSW (2016).</td></tr>
<tr><td colspan="3">Internal condoms are assumed to be used in addition to peoples' current non-barrier contraception and STI prophylaxis.</td></tr>
<tr><td>COMPARISON</td><td colspan="3">Non-barrier methods of STI prophylaxis and/or contraception methods.</td></tr>
<tr><td>OUTCOME</td><td colspan="3">Reduced risk of acquiring STIs – assumed to be the same as for non-latex condoms.

Reduced risk of unintended pregnancy assumed to be of the same magnitude as for male latex and non-latex condoms (Gallo et al. Cochrane database Syst Rev. 2006;1: CD0035500).</td></tr>
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