PHARMAC
TE PĀTAKA WHAIORANGA

Pharmacology and Therapeutics
Advisory Committee
Objective advice to Pharmac

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Record of the Pharmacology and Therapeutics Advisory Committee Meeting

Held on 12 February & 13 February 2026

Table of Contents

1. Present:

PTAC members:
Rhiannon Braund (Acting Chair)
Brian Anderson
Bruce King
Elizabeth Dennett
Helen Evans
James Le Fevre
John Mottershead
Liza Lack
Matthew Dawes
Matthew Strother
Robyn Manuel
Stephen Munn

Observer / Guest:
Dr Peter Jamieson, Chair of Canadian Drug Expert Committee

2. The role of PTAC, Specialist Advisory Committees and meeting records

2.1. This meeting record of PTAC is published in accordance with the Pharmacology and Therapeutics Advisory Committee (PTAC) Terms of Reference 2021, and Specialist Advisory Committees Terms of Reference 2021.

2.2. The PTAC Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of PTAC and Specialist Advisory Committees.

2.3. Conflicts of Interest are described and managed in accordance with sections 6.4 of both the PTAC Terms of Reference and Specialist Advisory Committee Terms of Reference.

2.4. PTAC and Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. PTAC may therefore, at times, make recommendations that differ from Specialist Advisory Committees', including the priority assigned to recommendations, when considering the same evidence. Likewise, Specialist Advisory Committees may, at times, make recommendations that differ from PTAC's, or from other Specialist Advisory Committees', when considering the same evidence.

Pharmac considers the recommendations provided by both PTAC and Specialist Advisory Committees when assessing applications.

3. Record of PTAC meeting held 13 November & 14 November 2025

The Committee noted the record of the PTAC meeting held on 13 November & 14 November 2025 is not yet finalised and will be shared with members soon.

4. Action Points

There are no action points.

5. Summary of Recommendations

	Pharmaceutical and Indication	Provisional Recommendation
8.3	Aprepitant 40 mg tablet for people at high risk of post-operative nausea and vomiting (PONV)	Medium Priority
9.3	Abemaciclib for the treatment of people with hormone receptor positive, HER2 negative metastatic breast cancer	Cost Neutral
10.3	Pembrolizumab (with pemetrexed) for malignant pleural mesothelioma, unresected advanced, 1st line • non-epithelioid histological subtypes • all histological subtypes	 Unchanged – medium Unchanged – decline
10.4	Nivolumab + Ipilimumab for malignant pleural mesothelioma, unresected advanced, 1st line • non-epithelioid histological subtypes • all histological subtypes	 Unchanged – medium Decline
11.3	Testosterone cream (AndroFeme 1) for hypoactive sexual desire dysfunction (HSDD) in postmenopausal women	Low Priority
12.3	International Normalized Ratio (INR) testing equipment for people who require long-term anticoagulation management on warfarin	High Priority
13.6	Salbutamol dry powder inhaler for Chronic Obstructive Pulmonary Disease (COPD) and asthma	Cost Neutral
13.7	Whey Protein Concentrate (Unflavoured) as a protein supplement for protein losing enteropathy, high protein needs, or use as a component in a modular formula	Cost Neutral
13.8 – 13.9	Fortisip Plant Based for people who need oral nutrition support, vegan option	Cost Neutral
13.10 - 13.14	Tadalafil for the treatment of pulmonary arterial hypertension, Raynards syndrome and people undergoing cardiac surgery	Cost Neutral
13.15	Sodium chloride oral liquid 2mmol/mL for use in babies and children as a sodium replacement	Cost Neutral

6. Pharmac Update

6.1. The Committee noted the Pharmac Update.

6.2. The Committee acknowledged the introduction of new Pharmac staff.

6.3. The Committee noted an update about the organisation reset programme and acknowledged that more information can be found on the Pharmac Website. Members discussed and provided feedback to Pharmac staff on the following workstreams being progressed through the reset programme:

6.3.1. Draft organisational vision and strategy

6.3.2. Describing the current process consistently

6.3.3. Proposed advice & assessment milestones and timeframes

6.3.4. Identify core elements of the Pharmac model that should be retained

6.3.5. Input into the 4-year improvement programme blueprint

6.4. The Committee noted the update on expert advice planning for 2026, the updated approach to CTAC advisory meetings to increase capacity, and the ongoing focus work on reducing the backlog.

6.5. The Committee noted the medical devices update, including the establishment of new advisory groups.

6.6. The Committee noted the following updates and progress to the record processes:

6.6.1. 30-day provisional recommendation pilot – completed for 11 meetings to date (6 months). A review of the pilot is underway.

6.7. The Committee noted an update on a pilot Fast Track Assessment Process (FTAP) for assessments.

6.8. The Committee discussed initial plans for the review of the PTAC and Specialist Advisory Committee Terms of Reference. Members highlighted potential areas needing review or change and opportunities for improvement.

7. Specialist Advisory Committee Record

7.1. September 2025 Cancer Treatments Advisory Committee

7.1.1. PTAC reviewed the records of the Cancer Treatments Advisory Committee meeting held on 12 September 2025.

7.1.2. PTAC noted the record including the Advisory Committee's recommendations

7.2. October 2025 Cancer Treatments Advisory Committee

7.2.1. PTAC reviewed the records of the Cancer Treatments Advisory Committee meeting held on 09 October 2025.

7.2.2. PTAC noted the records including the Advisory Committee's recommendations

7.3. November 2025 (DRAFT) Cancer Treatments Advisory Committee (part record)

7.3.1. PTAC reviewed the draft record of the Cancer Treatments Advisory Committee meeting held on 20 November 2025 for one item, CDK4/6 inhibitors (abemaciclib and ribociclib) for the adjuvant treatment of HR positive, HER2 negative early breast cancer to support item 10 - Abemaciclib for metastatic breast cancer, HR positive, HER2 negative on this agenda.

7.3.2. PTAC noted the draft record including the Advisory Committee's recommendation.

8. Aprepitant 40 mg - People at high risk of post-operative nausea and vomiting (PONV) - new evidence

Application

8.1. The Committee reviewed the application for Aprepitant 40 mg - People at high risk of post-operative nausea and vomiting (PONV) - new evidence in the prevention of post-operative nausea and vomiting (PONV) in people at high risk of PONV.

8.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

8.3. The Committee **recommended** that aprepitant for the prevention of PONV in people at high risk of PONV be listed with a **medium priority**, subject to the following access criteria:

Indication – postoperative nausea and vomiting (PONV)
Both
1. Maximum of one 40 mg dose; and
2. Any of the following:
   2.1. Patient has a history of PONV refractory to at least three other antiemetic treatments; or
   2.2. Patient is at high risk of PONV, as identified by an Apfel score of 3 or more, and anticipated to remain at high risk of PONV regardless of using other appropriate risk reduction strategies; or
   2.3. Patient is undergoing high-risk surgery where PONV can cause significant morbidity or risk to the surgical site.

8.4. In making these recommendations, the Committee considered:

8.4.1. The patient-important outcome of PONV and impact on recovery from surgery.

8.4.2. That aprepitant would be used in addition to current treatment and there is a low unmet health need given currently available treatments.

8.4.3. There is good evidence of the effectiveness of aprepitant compared with placebo, however limited evidence is available assessing the effectiveness of aprepitant as an add-on to current management of PONV. The evidence available indicates reduced rate of PONV associated with the addition of aprepitant.

Discussion

Māori impact

8.5. The Committee discussed the impact of funding aprepitant for the prophylactic treatment of PONV on Māori health areas of focus | Hauora Arotahi and Māori health outcomes. The Committee noted that there is no data available indicating a difference in prevalence of this condition among Māori.

Populations with high health needs

8.6. The Committee discussed the health needs of PONV among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee discussed the impact of funding aprepitant and considered there is unlikely to be a difference in prevalence of this condition among any group with high health needs.

Background

8.7. The Committee noted that aprepitant 120 mg and 80 mg formulation (Emend Tri-Pak) is currently listed in Section B and Part II of Section H of the Pharmaceutical Schedule under Special Authority restrictions for people receiving highly emetogenic chemotherapies.

8.8. The Committee noted that Pharmac received an application from a clinician in November 2013 for funding of aprepitant in patients with a history of severe, prolonged or refractory postoperative nausea and vomiting. The application was reviewed by PTAC in February 2014 and aprepitant was recommended for funding with a low priority At the December 2014 Analgesic Subcommittee meeting, the Subcommittee "requested that PTAC reconsider the low priority recommendation given to aprepitant for the prevention of PONV as members considered there was a clinical need for another treatment option for patients at high risk of PONV". At the February 2015 PTAC meeting "the Committee considered this application should remain a low priority for funding but would be willing to review the priority should new evidence become available to support the efficacy of aprepitant in the prevention of PONV for the population targeted by the Special Authority criteria".

8.9. The Committee noted that Pharmac had received a further application in October 2023, and that Pharmac staff were seeking advice on the magnitude of benefit with aprepitant 40mg for PONV based on the more recent evidence; the draft Special Authority criteria; and aspects of the economic assessment.

Health need

8.10. The Committee noted that PONV is a patient-important outcome, and that patients often rate PONV as worse than postoperative pain (Macario A et al., Anesth Analg. 1999 Sep;89(3):652-8). The Committee considered that PONV can adversely impact patient recovery and cause psychological burden and physical distress. The Committee also noted that because the period of PONV is short, the overall health loss directly from PONV is low.

8.11. The Committee noted that the incidence of PONV varies with patient factors (eg female gender, prior PONV, nonsmoking, post operative opioids required); anaesthetic and analgesic choices (particularly the use of morphine); and the type of surgery. The estimated incidence of PONV is 30% in the general surgical population and may be as high as 80% in high-risk patients (Apfel CC, et al Anesthesiology. 1999 Sep;91(3):693-700). The Committee noted that improvements in surgical techniques have lowered the incidence of PONV.

8.12. The Committee noted that surgical procedures where PONV can cause significant morbidity and/or mechanical risk to the surgical site include maxillofacial surgery, bariatric surgery, intracranial procedures, ocular surgery, abdominal surgery, cardiothoracic surgery, and ENT (ear, nose and throat) surgery.

8.13. The Committee noted that interventions used to prevent PONV in New Zealand are dependent on patient risk; surgical type; and anaesthesia to be provided. The Committee noted the Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting recommend that people with more than two risk factors be administered three-four prophylactic agents, and people with one or two risk factors be administered two agents Gan TJ et al. Anesth Analg. 2020 Aug;131(2):411-448). These treatments

include dopamine (D2) antagonists, serotonin(5-HT3) antagonists, antihistamines (H1 blockers), anticholinergics, prokinetics, antispasmodics, and steroids. The Committee considered that most people get a minimum of two prophylactic agents.

8.14. The Committee considered that, given currently available treatments, there is unlikely to be a substantial unmet health need. The Committee considered there is a small proportion of patients who could benefit from an additional treatment, including people with intractable vomiting that leads to a delay in recovery or those already administered a NK1 receptor antagonist for other indications.

Health benefit

8.15. The Committee considered that aprepitant 40 mg would only be used as an add-on to existing antiemetics and would not replace any other agent.

8.16. The Committee noted the following post-2014 studies published on aprepitant for prevention of PONV:

8.16.1. Alam et al. BMC Anesthesiol. 2023 Dec 13;23(1):412

8.16.2. Grigio TR, et al. Clinics (Sao Paulo). 2020;75:e1688

8.16.3. Sinha AC, et al., Obes Surg. 2014 Feb;24(2):225-31

8.16.4. Kawano H, et al., 2015 Apr;81(4):362-8.

8.16.5. Ortiz E,et al., 2024 Apr;34(4):1316-1323.

8.16.6. Ham SY, et al.. Eur J Anaesthesiol. 2016 Feb;33(2):90-5

8.17. The Committee considered that these studies were of limited relevance to clinical practice as they used a comparator of placebo or a single other emetic; many used high dose (80 mg) aprepitant; they are of limited duration; and used various measures of effectiveness. The Committee noted that in clinical practice a multimodal approach including pharmacological and non-pharmacological strategies is used.

8.18. The Committee noted the 2020 Cochrane meta-analysis that compared different prophylactic treatment against placebo or each other. The results of the meta-analysis indicate that five single treatments (aprepitant, ramosetron, granisetron, dexamethasone, and ondansetron) reduce vomiting with high certainty compared with placebo, and that combinations of drugs were generally more effective than the corresponding single treatment in preventing vomiting.

8.19. The Committee considered that current evidence indicates that aprepitant reduces the absolute risk of PONV by approximately 20-30% compared to placebo (or the absence of intervention).

8.20. The Committee noted a randomised controlled trial that was powered to evaluate the interactions of up to three antiemetic treatments (Apfel CC, et al., N Engl J Med. 2004 Jun 10;350(24):2441-51). The trial reported that the risk of PONV with three antiemetic treatments reduced from 60% to 24%. The Committee noted that ondansetron, dexamethasone and droperidol each reduce the relative risk of PONV by approximately 25-26%, and the use of propofol-based anaesthesia instead of volatile anaesthesia reduces PONV risk by approximately 19%.

8.21. The Committee noted that there is little evidence assessing the effectiveness of aprepitant as an add-on to current management of PONV. The Committee noted de Morais et al. assessed the efficacy of 80 mg aprepitant (in additional to dexamethasone, ondansetron and propofol) compared with dexamethasone plus ondansetron and propofol alone, in 66

patients with a Apfel-score three or four scheduled for laparoscopic procedures. The study reported a large reduction in vomiting in the first 24 hours with the addition of aprepitant (2.9% aprepitant 80 mg versus 40.6% control group).

8.22. The Committee noted that ondansetron, droperidol and haloperidol are associated with QT prolongation (Nachimuthu S et al., Therapeutic Advances in Drug Safety. 2012;3(5):241-253) but that there does not appear to be a harm in QT prolongation with aprepitant (Marbury TC, et al. Anesth Analg. 2009 Aug;109(2):418-25). The Committee noted that the risk of QT prolongation increases with antiemetic dose for treatment such as ondansetron, droperidol and haloperidol (Charbit B et al., Anesthesiology 109(2):p 206-212).

8.23. The Committee noted that although PONV has an impact on immediate quality of life, due to the relatively short duration and current treatments available, the overall quality-adjusted life year (QALY) gain is likely to be very small.

Suitability

8.24. The Committee noted that aprepitant is a single 40 mg capsule taken orally as part of multiple pharmaceutical therapy. The Committee noted that it is recommended it be administered 2-3 hours prior to surgery, which is not always practical. The Committee considered that it would likely be still appropriate if administered 1 hour before therapy.

Cost and savings

8.25. The Committee considered that there is likely to be a small reduction in the risk of additional surgical or other intervention required in the case of mechanical damage to the surgical site resulting from PONV. This includes neurosurgery where PONV can cause a risk in intracranial pressure; bariatric surgery where mechanical strain can pose a risk to the gastric or intestinal surgical anastomoses; orthognathic surgery where there is a mechanical risk to the jaw; and intra-abdominal pressure after abdominal surgery straining suture lines potentially leading to wound dehiscence, bleeding, or hernia formation. The Committee considered that the addition of aprepitant to the existing package of antiemetics may reduce the need for medical care to address these problems in a small proportion of surgeries.

8.26. The Committee considered that there are many other factors that influence time in hospital therefore the impact of a single antiemetic agent is uncertain. However, it was considered that treatment with aprepitant would likely have a small impact on the length of hospital stay, particularly for those patients who receive day surgery and subsequently require hospital admission.

8.27. The Committee considered that reduced rates of PONV are unlikely to be associated with reduced need for intravenous fluids as intravenous fluids are given as part of ERAS (enhanced recovery after surgery) irrespective of PONV.

8.28. The Committee considered that most patients would only receive one capsule of 40 mg aprepitant pre-operatively, and that the access criteria should limit access to one 40 mg dose.

8.29. The Committee considered that there is likely to be a very high uptake of aprepitant if funded for high-risk PONV.

Funding criteria

8.30. The Committee noted that high risk patients are identified by a combination of factors including risk assessment scores such as the Apfel score, anaesthetic choice, and surgery type. The Committee noted that the Apfel PONV Risk Score has some limitations. It is validated in adults but not children, it does not include anaesthetic technique (e.g.

TIVA vs volatile gases), and it is intended for baseline risk estimation rather than precise prediction.

Summary for assessment

8.31. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for aprepitant if it were to be funded in New Zealand for the prevention of PONV in high-risk people. 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 at high risk of post-operative nausea and vomiting (PONV), defined as any of the following: 1. Patient has a history of PONV refractory to at least three other antiemetic treatments; or 2. Patient at high-risk of PONV, as identified by an Apfel score of 3 or more, and anticipated to remain at high risk of PONV regardless of using other appropriate risk reduction strategies; or 3. Patient is undergoing high-risk surgery where PONV can cause significant morbidity or risk to the surgical site.
Intervention	Aprepitant: one 40 mg capsule prior to the surgery, in addition to other agents listed below in the comparator section.
Comparator(s) (NZ context)	At least two agents chosen from different classes: Dopamine (D2) antagonists (e.g. prochlorperazine, haloperidol) Serotonin (5-HT3) antagonists (e.g. ondansetron) Antihistamines (H1 blockers) (e.g. cyclizine, meclizine) Anticholinergics (e.g. scopolamine patches) Prokinetics (e.g. metoclopramide, domperidone) Antispasmodics (e.g. hyoscine butylbromide) Steroids (e.g. dexamethasone)
Outcome(s)	Reduced nausea and vomiting in the days following the surgery Reduced risk of disruption of the surgery site (for some procedures)

Table definitions:

Population: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup)

Intervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation).

Comparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation).

Outcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.

9. Abemaciclib - Metastatic breast cancer, HR positive, HER2 negative

Application

9.1. The Committee reviewed the application for abemaciclib for the treatment of hormone receptor (HR) positive, human epidermal growth factor receptor (HER2) negative metastatic breast cancer.

9.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

9.3. The Committee recommended that **abemaciclib** be funding only if **cost neutral** to other funded cyclin dependent kinase 4/6 inhibitors (CDK4/6i) subject to the following Special Authority criteria:

Initiation – [HR+ HER2- unresectable locally advanced or metastatic breast cancer] Abemaciclib

From any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1. All of the following:
    - 1.1. Patient has unresectable locally advanced or metastatic breast cancer; and
    - 1.2. There is documentation confirming disease is hormone-receptor positive and HER2; and
    - 1.3. Patient has an ECOG performance score of 0-2; and
    - 1.4. Either:
        - 1.4.1. Disease has relapsed or progressed during prior endocrine therapy; or
        - 1.4.2. Both:
            - 1.4.2.1. Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state; and
            - 1.4.2.2. Patient has not received prior systemic endocrine treatment for metastatic disease; and
    - 1.5. Treatment must be used in combination with an endocrine partner; and
    - 1.6. Patient has not received prior funded treatment with a CDK4/6 inhibitor; or
2. All of the following:
    - 2.1. Patient has an active Special Authority approval for ribociclib or palbociclib; and
    - 2.2. Patient has experienced a grade 3 or 4 adverse reaction to ribociclib or palbociclib that cannot be managed by dose reductions and requires treatment discontinuation; and
    - 2.3. Treatment must be used in combination with an endocrine partner; and
    - 2.4. There is no evidence of progressive disease since initiation of ribociclib or palbociclib.

Renewal – [HR+ HER2- unresectable locally advanced or metastatic breast cancer] Abemaciclib

From any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both

1. Treatment to be used in combination with an endocrine partner; and
2. There is no evidence of progressive disease since initiation of abemaciclib.

9.4. In making this recommendation the Committee considered that there is:

9.4.1. A similar health benefit and safety profile between abemaciclib and the funded CDK4/6i (ribociclib and palbociclib)

9.4.2. Clinically meaningful overall survival benefit from abemaciclib in combination with either aromatase inhibitors or fulvestrant

Discussion

Māori impact

9.5. The Committee discussed the impact of funding abemaciclib for the treatment of hormone receptor (HR) positive, human epidermal growth factor receptor (HER2) negative metastatic breast cancer on Māori health areas of focus | Hauora Arotahi and Māori health outcomes.

9.6. The Committee noted that three quarters of wāhine Māori had oestrogen receptor (ER) positive /HER2 negative breast tumours however were also more likely to be diagnosed with HER2 positive cancers than European women (Te Rēhita Mate Ūtaetae - Breast Cancer Foundation National Register 2003-2020 report).

9.7. The Committee noted Māori had similar uptake of endocrine therapies compared with other ethnicities (Te Rēhita Mate Ūtaetae - Breast Cancer Foundation National Register 2003-2020 report).

Populations with high health needs

9.8. The Committee discussed the health need(s) of HR positive, HER2 negative metastatic breast cancer among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee discussed the impact of funding abemaciclib and considered:

9.8.1. Whilst HR positive, HER2 negative tumours account for 70% of all breast cancers overall, Pacific peoples are more likely than other ethnicities to be diagnosed with HER2 positive disease, which is considered to have a worse prognosis, and therefore this treatment would not benefit these individuals with HER2 positive disease (Te Rēhita Mate Ūtaetae - Breast Cancer Foundation National Register 2003-2020 report).

9.8.2. Pacific people have similar uptake of endocrine therapies compared with other ethnicities (Te Rēhita Mate Ūtaetae - Breast Cancer Foundation National Register 2003-2020 report).

Background

9.9. The Committee noted ribociclib and palbociclib, both CDK4/6i, are funded for this indication.

9.10. The Committee noted that abemaciclib for early breast cancer was considered by the Cancer Treatments Advisory Committee (CTAC) in November 2025 and recommended with a high priority.

Health need

9.11. The Committee noted the health need of individuals with HR positive, HER2 negative metastatic breast cancer has been considered by CTAC in September 2018.

9.12. The Committee considered that whilst HR positive, HER2 negative tumours account for 70% of all breast cancers, Pacific Peoples are more likely to be diagnosed with HER2 positive disease which is considered to have a worse prognosis.

9.12.1. The Committee noted that three quarters of wāhine Māori had ER positive /HER2 negative breast tumours however were also more likely to be diagnosed with HER2 positive cancers than European women (Te Rēhita Mate Ūtaetae - Breast Cancer Foundation National Register 2003-2020 report).

9.12.2. The Committee noted both Māori and Pacific Peoples had similar uptake of endocrine therapies compared with other ethnicities (Te Rēhita Mate Ūtaetae - Breast Cancer Foundation National Register 2003-2020 report).

9.13. The Committee noted Pharmac staff reached out to the New Zealand Breast Cancer Special Interest Group (SIG) to receive feedback on a range of applications. The SIG noted that '*both ribociclib and abemaciclib have the strongest evidence in the metastatic setting. For those younger women who cannot tolerate ribociclib, having abemaciclib as an alternative option would be clinically useful'.*

Health benefit

9.14. The Committee noted results from the MONARCH3 study; A double-blind, randomised phase III study that compared abemaciclib compared to placebo in combination with a nonsteroidal aromatase inhibitor in individuals with no prior systemic therapy. The Committee noted:

9.14.1. Goetz et al. Ann Oncol. 2024;35:718-27 that reported the final overall survival (OS) results with a median follow-up of 8.1 years, at 198 OS events (60.4%) abemaciclib vs 116 (70.3%) placebo arm (hazard ratio (HR), 0.804; 95% confidence interval (CI) 0.637-1.015; P = 0.0664, non-significant). Median OS was 66.8 vs 53.7 months for abemaciclib compared to placebo.

9.14.2. Johnston et al. NPJ Breast Cancer.2019:5:5 that reported the final progression free survival (PFS) results from the MONARCH3 study. Abemaciclib had a significantly longer median PFS compared to placebo (28.18 versus 14.76 months; HR [95% CI, 0.540 [0.418-0.698]; p =0.000002).

9.14.3. Goetz et al. J Clin Oncol. 2017;35:3638-46 that reported the PFS interim analysis after 189 events.

9.14.4. The Committee considered that while the OS benefit was not statistically significant, the improvement in OS of approximately 13 months compared to placebo was clinically meaningful.

9.15. The Committee noted results from the MONARCH2 study. A double-blind, randomised phase III study that compared abemaciclib compared to placebo in combination with a fulvestrant in individuals who had progressed on prior endocrine therapy. The Committee noted:

9.15.1. Neven et al. JCO Oncol Adv 2, e2500052(2025) that reported the final OS results with a median follow-up of 80 months. A median OS of 45.8 and 37.3 months with abemaciclib treatment and placebo, respectively were reported (HR, 0.784 [95% CI, 0.644 to 0.955, *P=0.0156*]).

9.15.2. Sledge et al. JAMA Oncol 2020;6:116-24 that reported the interim OS results with a median OS of 46.7 months for abemaciclib plus fulvestrant and 37.3 months for placebo plus fulvestrant (HR, 0.757; 95% CI, 0.606-0.945; *P* = 0.01).

9.15.3. Sledge et al. J Clin Oncol.2017 35, 2875-84 that reported primary PFS results of abemaciclib plus fulvestrant versus placebo plus fulvestrant (median, 16.4 *v* 9.3 months; HR, 0.553; 95% CI, 0.449 to 0.681; *P* <0.001).

9.15.4. The Committee noted that there was a protocol amendment to reduce the starting dose. The Committee considered it was unclear when this protocol change occurred however a sensitivity analysis on the impact of the dose reduction noted no difference following the reduction in dosing.

9.16. The Committee considered that the MONARCH2 trial more accurately reflected clinical practice in New Zealand as it included pre, peri and post-menopausal women. The Committee noted individuals who were pre or peri menopausal would receive goserelin in New Zealand.

9.17. The Committee noted Kalinsky et al. J Clin Oncol. 2025;43:1101-12 that reported results from the postMONARCH trial, that evaluated the effect of switching endocrine therapy with/without CDK4/6 inhibition with abemaciclib after disease progression on a different CDK4/6i. The trial reported the following results:

9.17.1. The primary analysis (258 events) reported a HR of 0.73 (95% CI, 0.57 to 0.95; nominal *P* = .017), with median PFS 6.0 (95% CI, 5.6 to 8.6) versus 5.3 (95% CI, 3.7 to 5.6) months and 6-month PFS rates of 50% and 37% in the abemaciclib and fulvestrant compared to the placebo and fulvestrant arms, respectively. These results were supported by blinded independent central review (BICR)-assessed PFS (HR, 0.55 [95% CI, 0.39 to 0.77]; nominal *P* < 0.001).

9.18. The Committee considered that whilst the PFS was statistically significant it was not clinically significant.

9.19. The Committee considered that there was evolving evidence that changing the class of endocrine therapy can create a more durable response in combination with a CDK4/6i.

9.20. The Committee noted the following meta-analyses:

- Petrelli et al. Breast Cancer Res Treat. 201;174:597-604
- Liu et al. BMC Cancer. 2023;23:816
- Liu et al. BMC Cancer. 2025;25:1535
- Leung et al. Aging (Albany NY) 2025;17:1313-27
- Harbeck et al. Front Oncol. 2025 :15:1530391
- Harbeck et al. Front Oncol. 2025:15:1577075.
- Qureshi et al. Am J Clin Oncol. 2025;48:6-15.
- Messina et al. Breast Cancer Res Treat. 2018;172:9-21.
- Kassem et al. Breast Cancer. 2018;25:17-27
- Ramos-Esquivel et al. Cancer Treat Res Commun. 2020:23:100175

9.20.1. The Committee considered that the meta-analysis studies were comparable in their outcomes, with each CDK4/6i providing similar OS benefit and being well tolerated with different safety profiles.

9.21. The Committee considered overall the MONARCH trials were of high quality and well designed. The Committee considered that while the results were generalisable to European or Asian populations, due to the enrolled populations in the study there was uncertainty on the generalisability of the results to other groups.

9.22. The Committee considered overall there was a class effect for abemaciclib, palbociclib and ribociclib in the metastatic setting, in combination with either aromatase inhibitors or fulvestrant.

Suitability

9.23. The Committee considered that as abemaciclib is an oral tablet, it would have similar suitability benefits to other CDK4/6i.

9.24. The Committee noted the dosing regimen of abemaciclib would result in a higher pill burden to individuals, with twice daily administration compared to once daily for ribociclib.

9.25. The Committee noted that abemaciclib did not need to be refrigerated, unlike ribociclib, which would be a suitability advantage in clinical practice.

Cost and savings

9.26. The Committee considered that abemaciclib would not be the preferred first-line CDK4/6i in the metastatic setting.

9.27. The Committee considered that the predominant patient group for abemaciclib would be those who had experienced a grade 3 or 4 adverse reaction to ribociclib or palbociclib.

9.28. The Committee considered that patients would most likely trial palbociclib and then receive either abemaciclib or ribociclib if grade 3 or 4 adverse reactions were experienced with palbociclib.

Summary for assessment

9.29. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for abemaciclib if it were to be funded in New Zealand for people with HR positive, HER2 negative unresectable locally advanced or metastatic breast cancer. 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 HR positive, HER2 negative unresectable locally advanced or metastatic breast cancer.
Intervention	Abemaciclib: 150 mg orally twice daily until disease progression, death or unacceptable toxicity used in combination with endocrine therapy (including aromatase inhibitors or fulvestrant).
Comparator(s) (NZ context)	Ribociclib: 600 mg per day orally once daily for 21 days, followed by 7 days off treatment, until disease progression, death or unacceptable toxicity. Ribociclib is used in combination with endocrine therapy. OR Palbociclib: 125 mg per day orally once daily for 21 days, followed by 7 days off treatment, until disease progression, death or unacceptable toxicity. Palbociclib is used in combination with endocrine therapy.
Outcome(s)	Similar benefits and risks to palbociclib and ribociclib.
Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the patient population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data.	

10. Review of recommendations regarding immune checkpoint inhibitors for the treatment of malignant pleural mesothelioma

Application

10.1. The Committee reviewed the following applications:

10.1.1. Pembrolizumab with pemetrexed for the treatment of malignant pleural mesothelioma.

10.1.2. Nivolumab plus ipilimumab for the treatment of surgically unresectable malignant mesothelioma.

10.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

10.3. Regarding nivolumab plus ipilimumab:

10.3.1. The Committee **recommended** the proposal to fund nivolumab plus ipilimumab for the treatment of all histological subtypes of malignant pleural mesothelioma be **declined.**

10.3.2. The Committee upheld its prior determination, which **recommended** that nivolumab plus ipilimumab for the treatment of non-epithelioid (sarcomatoid or biphasic) malignant pleural mesothelioma be listed with a **medium** priority.

10.4. Regarding pembrolizumab with pemetrexed and platinum-based chemotherapy:

10.4.1. The Committee upheld its prior determination, which **recommended** that the application for funding pembrolizumab with pemetrexed and platinum-based chemotherapy for people with all subtypes of malignant pleural mesothelioma be **declined**.

10.4.2. The Committee upheld its prior determination, which **recommended** that pembrolizumab with pemetrexed and platinum-based chemotherapy be funded with a **medium** priority for non-epithelioid subtypes of malignant pleural mesothelioma, subject to Special Authority criteria.

10.5. In making these recommendations, the Committee considered:

10.5.1. The available evidence indicating a comparable treatment effect between nivolumab plus ipilimumab and pembrolizumab (with pemetrexed and chemotherapy) warrants aligned funding recommendation stratified by histological subtype.

10.5.2. The marginal health benefit compared to the standard of care associated with either regimen for people with epithelioid histology.

10.5.3. The survival advantage associated with either regimen in people with non-epithelioid histology appears to drive the significant survival advantage demonstrated in populations with all histological subtypes of mesothelioma.

Discussion

Background

10.6. The Committee noted it's prior consideration of nivolumab plus ipilimumab for unresectable malignant pleural mesothelioma (MPM) at its February 2025 meeting (02/2025 PTAC Meeting Record). Members noted the discussion yielded two funding recommendations, stratified by histological subtype:

10.6.1. The Committee **recommended** that nivolumab plus ipilimumab for the treatment of malignant pleural mesothelioma of the sarcomatoid or biphasic subtypes be listed with a **medium** priority, subject Special Authority criteria.

10.6.2. The Committee **recommended** that nivolumab plus ipilimumab for the treatment of malignant pleural mesothelioma (any subtype) be listed with a **low** priority, subject to Special Authority criteria.

10.7. The Committee noted it's prior consideration of pembrolizumab with pemetrexed and platinum-based chemotherapy for unresectable malignant pleural mesothelioma at its meeting in August 2025 (08/2025 PTAC Meeting Record). The Committee noted that the discussion yielded two funding recommendations stratified by histological subtype. As stated in the meeting record:

10.7.1. The Committee **recommended** that pembrolizumab with pemetrexed and platinum-based chemotherapy be funded with a **medium** priority for non-epithelioid subtypes of malignant pleural mesothelioma, subject to Special Authority criteria.

10.7.2. The Committee **recommended** that the application for funding pembrolizumab with pemetrexed and platinum-based chemotherapy for people with all subtypes of malignant pleural mesothelioma be **declined**.

10.8. The Committee noted it previously discussed the two immune checkpoint inhibitor regimens for the treatment of MPM and the consistency of their recommendations in this setting in August 2025.

10.8.1. The Committee previously acknowledged that their recommendation to decline funding pembrolizumab (with chemotherapy) for people with all subtypes of malignant pleural mesothelioma may not align with their previous recommendations regarding other treatments for this population. Members also suggested it would be appropriate to discuss this at a future meeting (08/2025 PTAC Meeting Record).

10.9. The Committee noted that the purpose of the current discussion was to review the previous recommendations made for nivolumab plus ipilimumab and for pembrolizumab with pemetrexed and chemotherapy in the treatment of MPM.

Health need

10.10. The Committee noted the health need for people with malignant pleural mesothelioma to be covered in the 02/2025 PTAC Meeting Record & 08/2025 PTAC Meeting Record.

10.11. The Committee discussed the three main histological variants of MPM, and noted that approximately 60% of cases are epithelioid, 20% are biphasic, and 20% are sarcomatoid (Taso et al. Semin Oncol. 2019;46:145-54).

10.12. The Committee noted that for MPM, histological subtype more reliably predicts clinical outcomes compared to disease stage and people with non-epithelioid mesotheliomas (sarcomatoid & biphasic) have worse prognosis than people with the epithelioid subtype (Meyerhoff et al. J Surg Res. 2015;196:23-32).

10.13. The Committee discussed that the understanding of epithelioid and non-epithelioid MPM is evolving, and considered the molecular differences observed in Fennell et al. Nat Rev Dis Primers. 2025;11:56 support the idea that histological subtypes may have different natural histories and different responses to therapy.

Health benefit

10.14. The Committee noted the findings of the following studies as key evidence:

10.14.1. **CHECKMATE-743** was a multicentre, open label, phase III, randomised controlled trial comparing nivolumab plus ipilimumab to platinum-based chemotherapy in surgically unresectable MPM (Peters et al. Ann Oncol. 2022;33:488-99).

10.14.2. **KEYNOTE-483** was an international, phase III, randomised controlled trial which investigated pemetrexed + platinum-based chemotherapy (n=218) versus those who received pembrolizumab in addition to pemetrexed + platinum-based chemotherapy (n=222) in people with MPM with no prior treatment (Chu et al. Lancet 2023;402: 2295-306).

10.15. The Committee discussed the methodology of both trials and considered there to be no substantive differences in inclusion and exclusion criteria, participant characteristics (including disease stage and histological subtype), or the statistical design of either study.

10.16. The Committee discussed the similarities between CHECKMATE-743 and KEYNOTE-483 and agreed with its previous consideration, that indirect comparison of the trial results was reasonable although such observations were regarded as hypothesis-generating rather than confirmatory (08/2025 PTAC Meeting Record).

10.17. The Committee noted that it previously considered the nivolumab plus ipilimumab regimen appeared to have a more favourable overall survival (OS) hazard ratio compared with the pembrolizumab (with pemetrexed and chemotherapy) regimen in the full study population (all histological subtypes) (08/2025 PTAC Meeting Record). Upon review, members considered that the observed differences in survival between agents may not represent a clinically important difference and may be secondary to differences in follow-up time. The Committee considered the median OS (full study population) reported for both regimens to be numerically similar.

10.18. The Committee noted that both trials included preplanned analyses by histological subtype which were not powered to provide definitive comparative findings but were considered informative as descriptive statistics. The Committee discussed the limitations of unpowered subgroup analyses and considered the evidence to be sufficient to stratify funding decisions by histological sub type.

10.18.1. The Committee noted that in KEYNOTE-483, the non-epithelioid subgroup was reported to have a more pronounced benefit in median OS compared to the control arm (Hazard ratio (HR): 0.57; 95% CI: 0.36–0.89) than was observed in the full study population (HR: 0.79, 95%CI 0.64-0.98; p=0.0324). Members noted that participants with epithelioid histology appeared to derive marginal or no benefit in median OS from pembrolizumab compared to the control arm (HR: 0.89; 95% CI: 0.70–1.13).

10.18.2. The Committee noted in CHECKMATE-743, the findings were similar to those in KEYNOTE-483, where the non-epithelioid subgroup demonstrated a more pronounced benefit in median OS compared to the control arm (HR: 0.48; 95%CI: 0.34-0.69) than was observed in the full study population (HR: 0.73; 95%CI: 0.61-0.87). Members noted that the epithelioid group appeared to derive marginal or no benefit in median OS compared to the control arm (HR: 0.85; 95%CI: 0.69-1.04).

10.18.3. Overall, the Committee considered the evidence suggests the additional health benefit conferred by either regimen, relative to standard care, is dependent on disease histology. Although a statistically significant improvement in median OS was reported irrespective of histological subtype, the Committee considered that the observed survival advantage appeared to be driven by the treatment effect in participants with non-epithelioid histology for both regimens in their respective trials. Members noted that when non-epithelioid participants were excluded from the analysis in either trial, the survival advantage over standard care in epithelioid subtypes appeared to be small to non-existent.

10.19. The Committee previously considered the pembrolizumab regimen appeared generally less well tolerated than nivolumab plus ipilimumab (08/2025 PTAC Meeting Record). The Committee considered that the type of toxicity associated with chemotherapy differs from that of immunotherapy, and that the toxicity of immunological agents is generally more long-term and may not be as well captured by trial measurements. Overall, members agreed with their previous considerations; that the risk profiles of each regimen differ but remain generally manageable, and that either treatment may require complex and prolonged management of immune-related adverse events.

11. Testosterone cream (AndroFeme 1) for hypoactive sexual desire dysfunction (HSDD) in postmenopausal women – new information

Application

11.1. The Committee reviewed new information regarding the application from Alchemy Health Limited for the use of testosterone cream (AndroFeme 1) for the treatment of hypoactive sexual desire dysfunction (HSDD) in postmenopausal women.

11.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

11.3. The Committee **recommended** that testosterone cream (AndroFeme 1) be funded for postmenopausal women with HSDD with a **low priority**, subject to the following Special Authority criteria:

> **Initial application** – hypoactive sexual desire dysfunction
> Applications from any relevant practitioner. Approvals valid for 6 months.
>
> All of the following:
> 1. Patient has hypoactive sexual desire dysfunction; and
> 2. Patient has experienced natural or iatrogenic menopause; and
> 3. Patient has received insufficient health benefit from addressing modifiable biopsychosocial factors
>
> **Renewal** – hypoactive sexual desire dysfunction
> Applications from any relevant practitioner. Approvals valid for 12 months.
>
> All of the following:
> 1. Patient has experienced a clinically significant improvement in sexual desire dysfunction outcomes.

11.4. In making this recommendation, the Committee:

11.4.1. Noted that Medsafe has now approved AndroFeme 1, which is only indicated for HSDD in post-menopausal women

11.4.2. Noted the published evidence of meaningful, small to moderate improvements in quality of life (QOL) with the use of AndroFeme 1 for post-menopausal women with HSDD. The Committee noted some consumers who provided input to Pharmac also reported improvements in libido and associated quality of life with topical testosterone.

11.4.3. Noted that the long-term safety of testosterone administration for women is unknown

11.4.4. Acknowledged clinical stakeholder input regarding evidence-based use of testosterone for women, and thanked the consumers who provided personal feedback to Pharmac regarding their experience using testosterone (Testogel

and/or AndroFeme 1), including their experience of other benefits (eg impact on fatigue and "brain fog") that are outside the Medsafe approved indication of post-menopausal HSDD

11.4.4.1. The Committee noted that AndroFeme 1 use in other indications (ie use beyond Medsafe's approval for HSDD in post-menopausal women) would be considered "off-label" and there was no support for use outside of the approved indication from any of the clinicians that provided feedback. Pharmac consideration of these other reported benefits for other indications would require a separate funding application supported by relevant clinical trial evidence and, ideally, Medsafe approval of the corresponding clinical indication.

11.5. The Committee considered that Pharmac could seek further advice from the Reproductive and Sexual Health Advisory Committee regarding eligibility criteria for funded access, monitoring, uptake, and healthcare utilisation whilst on treatment with AndroFeme 1.

Discussion

Māori impact

11.6. The Committee noted that it had previously discussed the health needs of post-menopausal women with HSDD, and the potential impact of funding AndroFeme 1 for the treatment of HSDD in post-menopausal women, on Māori health areas of focus | Hauora Arotahi and Māori health outcomes. The Committee had no new comments to make at this time.

Populations with high health needs

11.7. The Committee noted that it had previously discussed the health needs of post-menopausal women with HSDD among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee had no new comments to make at this time.

Background

11.8. The Committee noted that Pharmac listed testosterone gel, brand name Testogel, on the Pharmaceutical schedule in April 2024 without funding restrictions. Testogel has Medsafe approval and is indicated in adults as testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed. The Medsafe datasheet for Testogel specifically states that "*this medicine should not be used by women due to possibly virilising effects*."

11.9. The Committee noted that Pharmac received an application from a supplier, Alchemy Health, for the funding of testosterone cream (AndroFeme 1) for the treatment of HSDD in postmenopausal women in July 2024. This indication aligns with the Medsafe registration of AndroFeme 1. The application was first considered by PTAC in November 2024, who recommended it be declined based on consideration of the following:

11.9.1. Uncertainties regarding diagnostic requirements, appropriate diagnosis and treatment, and potential barriers to access for the target population as proposed

11.9.2. Uncertainty regarding the health benefits of AndroFeme 1 compared with off-label Testogel

11.9.3. Potential suitability issues in administering appropriate doses of Testogel for women, noting increased used of Testogel by women, and lack of evidence to suggest significant bioavailability differences between Testogel and AndroFeme 1 at equivalent dosages.

11.9.4. Uncertainty regarding long-term safety of testosterone use in women.

11.10. The Committee noted the following new information had become available since the application was previously reviewed by PTAC:

11.10.1. Advice from the Reproductive and Sexual Health Committee meeting in March 2025. This Committee agreed with PTAC's recommendation to decline the application, however considered that the potential safety risk with Testogel use in women could be a reason to recommend funding of AndroFeme 1 and indicated it would be useful to fund a female-specific formulation for postmenopausal women with HSDD given that this is where there is evidence to support efficacy and short term safety.

11.10.2. Additional information provided by the supplier in April 2025 in response to PTAC's November 2024 meeting record, and further updates provided in August 2025 and December 2025.

11.10.3. Medsafe approval of AndroFeme 1 for postmenopausal women with HSDD. The approved indication is as follows (Source: AndroFeme 1 Data Sheet, June 2025): "*AndroFeme 1 is indicated for the treatment of hypoactive sexual desire dysfunction (HSDD) in postmenopausal women.*
Therapeutic intervention with AndroFeme 1 should only be initiated in women following failure of appropriate education and correction of modifiable biopsychosocial factors (which may include neuroendocrine imbalance, physical ill health or disease, interpersonal difficulties, psychological distress or specific cultural or religious beliefs), according to the International Society for the Study of Women's Sexual Health (ISSWSH) process of care."

11.10.4. Further information about potential harms from Testogel/AndroFeme 1 use in women in New Zealand, and views and comments from consumers and clinical stakeholders regarding experience with, and suitability of, both Testogel and AndroFeme 1.

Clinical stakeholder input and consumer input

11.11. The Committee acknowledged the consumer input received in response to Pharmac's website survey, which was shared by menopause support Facebook groups, and noted the petition to fund AndroFeme 1 with over 5,000 signatures to date.

11.12. The Committee noted Pharmac staff had sought information, via the survey, on personal experience and ease of use of Testogel and/or AndroFeme 1 by women who had used either or both products. PTAC and Pharmac staff thanked consumers for sharing these personal comments and experiences.

11.13. The Committee noted some consumers who provided input to Pharmac reported improvements in libido and associated quality of life with topical testosterone. The Committee noted the consumer feedback spoke to a range of themes including the impact of HSDD on individuals and their partners (as applicable); that some women sought testosterone for indications other than postmenopausal HSDD (eg for menopause symptoms without HSDD); and that some reported anecdotal evidence of a range of benefits (eg impact on fatigue and "brain fog"). The Committee also noted themes of gender equity in feedback and members considered this touched on broader societal issues of insufficiently recognising and supporting women's health including menopause.

11.13.1. However, the Committee noted that the only Medsafe-approved indication for AndroFeme 1 is the treatment of HSDD for post-menopausal women which is the indication requested in the supplier's application.

11.13.2. The Committee noted that AndroFeme 1 use in other indications (ie use beyond Medsafe's approval for HSDD in post-menopausal women) would be considered "off-label". Pharmac consideration of other reported benefits for other indications would require a separate funding application supported by relevant clinical trial evidence and, ideally, Medsafe approval of the corresponding clinical indication.

11.14. The Committee acknowledged the views and input provided by clinical stakeholders including the Menopause Society of Australia and New Zealand. The Committee noted that clinical specialists provided recommendations for testosterone in postmenopausal HSDD only (ie there was no support for use outside of the registered indication) and endorsed the funding of a female-appropriate formulation. The Committee noted this view was due to the evidence base for safety and efficacy for HSDD in postmenopausal women only.

Health need

11.15. The Committee noted that although menopause is a natural part of life for women, about 70% experience troublesome symptoms and 40% will see a GP about their symptoms (Healthify, 2024). The Committee noted that HSDD is a defined, multifactorial condition that does not only occur during menopause and can have a profound effect on an individual's quality of life. The Committee noted that the effect of HSDD on post-menopausal women with this condition, their families and partners (as applicable), had been noted by PTAC in November 2024.

11.16. The Committee noted it had previously reviewed evidence for the prevalence of HSDD in postmenopausal women which suggested the prevalence was relatively low, however, the New Zealand Menodoctor survey suggests it might be higher (Menodoctor Survey Report, 2023). Members noted that this survey was conducted online through a menopause clinic in Tauranga and that it did not meet the expected standards for level of evidence for prevalence estimation. The Committee further considered that the survey may not be representative of all individuals in New Zealand given it came from a select group of respondents in one region.

11.17. The Committee noted a previous concern around the accurate diagnosis of HSDD in the Medsafe-approved indication. The Committee noted that the supplier had highlighted that the tool for diagnosis of HSDD, the Decreased Sexual Desire Screener (DSDS) was validated, as reported by Clayton et al. (J Sex Marital Ther. 2013;39:132-43).

11.17.1. The Committee noted the authors compared diagnoses of generalised acquired HSDD made by clinicians (who were not trained or specialised in the diagnosis of female sexual dysfunction) using the decreased sexual desire screener with diagnoses made by expert clinicians after an extensive diagnostic interview, which occurred during the screening visits of two clinical trials. Members considered this indicated that the tool was validated whilst being used by a specialist in a comprehensive clinic setting (ie an expert in female sexual dysfunction) and with a clinic duration sufficient for thorough review and consideration.

11.17.2. The Committee noted that there is no specialist body in NZ which recognises a definition of experts in female sexual dysfunction currently, and that this would include GPs who have specialised in menopause care.

11.17.3. The Committee considered that administering the DSDS to inform a diagnosis was unlikely to be quick or easy, and noted it has not been validated in other settings where such a diagnosis might be made in NZ (eg during a standard 15-minute GP clinic appointment or when completed online by an individual and taken to a clinic appointment [either GP or relevant expert]).

Health benefit

Benefit of AndroFeme 1 for HSDD in postmenopausal women

11.18. The Committee noted that Androfeme 1 is now approved by Medsafe specifically for HSDD in post-menopausal women, which is the indication requested in the supplier's application and the evidence base presented by the supplier. The Committee therefore focussed its review and consideration on the evidence for benefits in this specific indication.

11.19. The Committee noted the systematic review by Islam et al. which reported on the efficacy of several testosterone formulations in women including postmenopausal women (Islam et al. Lancet Diabetes Endocrinol. 2019;7:754-766). The Committee noted that this review reported a benefit in sexual outcomes and had been previously considered by PTAC in November 2024 as providing reasonable evidence for a benefit in this indication.

11.20. The Committee noted the updated information from the supplier which contained a data package provided to Medsafe (including studies that provide most of the data for the Islam et al. meta-analysis and the 2019 Global Consensus Position Statement on the Use of Testosterone Therapy for Women). The Committee had no additional comments.

11.21. The Committee considered that the health benefit from funding AndroFeme 1 for postmenopausal women with HSDD would be an improvement in sexual utility score outcomes (ie a health-related quality-of-life benefit). The Committee considered that no other health outcomes were identified in the published evidence available and therefore no other outcomes should be included in Pharmac's assessment for AndroFeme 1 for post-menopausal women with HSDD.

11.21.1. However, the Committee acknowledged that consumer input signalled some users received other benefits for symptoms other than HSDD, but noted that the only Medsafe-approved indication for AndroFeme 1 is the treatment of HSDD for post-menopausal women which aligns with the focus of the supplier's application).

11.21.2. Pharmac consideration of other reported benefits for other indications would require a separate funding application supported by relevant clinical trial evidence and, ideally, Medsafe approval of the corresponding clinical indication.

Safety of testosterone in women

11.22. The Committee considered that the short to medium term adverse effects of testosterone in women, including effects of excessive doses of testosterone in women, are known and have been discussed previously by PTAC in November 2024. However, the Committee considered the long-term safety of testosterone use in women is unknown and there is a lack of published evidence for this.

11.23. The Committee noted that the informal survey of women using topical testosterone that was conducted by Pharmac resulted in no reports of clinically significant adverse events (ie those which could not be tolerated, or could not be resolved by changing or discontinuing treatment, including effects of excessive doses of testosterone in women). Some expected events such as hair growth were considered by the individuals concerned to be substantially impactful.

11.24. The Committee noted that Pharmac staff had sought information from several health system partners (MedSafe, Centre for Adverse Reactions Monitoring [CARM], and the Accident Compensation Corporation [ACC]) regarding reports of harm secondary to Testogel use in women in New Zealand. The Committee noted that these organisations had received no reports of harm in women as a result of using topical testosterone, including virilising effects.

11.25. The Committee considered that it is not proven that there is an unacceptable risk associated with the use of Testogel in women in New Zealand, either in the population of postmenopausal women with HSDD or broadly in all women who might use it. However, the Committee noted the body of available evidence for testosterone use in women; that

'yellow card' safety reports regarding any severity of adverse effects experienced by women using testosterone have increased in the United Kingdom in recent years; and the Testogel Medsafe datasheet advice against use of testosterone gel in women due to possibly virilising effects.

Suitability

11.26. The Committee considered that access barriers would exist for some women who would seek AndroFeme 1 for post-menopausal HSDD, for example due to the need for extended GP appointments or specialist assessment to determine eligibility and suitability for treatment according to Medsafe guidelines. The Committee considered that these diagnostic processes were unlikely to be feasible in standard 15-minute GP consultations, likely resulting in an additional financial cost to patients for extended consultations.

11.27. The Committee noted that feedback from women indicated that there is broader interest and, anecdotally, other reported benefits from testosterone use in women. The Committee considered that the Royal New Zealand (NZ) College of GPs (RNZCGP) and the Medical Council of NZ would have a professional role in supporting clinical stakeholders in their conversations with women to ensure appropriate use in line with its registered indication.

11.28. The Committee acknowledged that there is current off-label use of Testogel in women and consumer feedback suggesting some users may not wish to change to AndroFeme 1, if funded. However, the Committee considered that some prescribers might strongly prefer to prescribe a funded alternative that is indicated for post-menopausal women with HSDD rather than an off-label product.

Cost and savings

11.29. The Committee considered that whilst AndroFeme 1 could be sought by women for indications beyond post-menopausal HSDD, this would not align with Medsafe's approved indication or the funding application. The Committee considered that such broader, off-label use should not be included in the PICO for Pharmac's assessment of this proposal.

11.30. The Committee considered that the most appropriate comparator for Pharmac assessment was no funded treatment, rather than an unapproved product (off-label Testogel). The Committee noted that at the time of its previous consideration, both Testogel and AndroFeme 1 were unapproved for HSDD.

Funding criteria

11.31. The Committee considered that the target population for funding AndroFeme 1 should be defined according to the current Medsafe registered indication ie postmenopausal women with HSDD, and that funded access should be after attempts to address modifiable biopsychosocial factors.

Summary for assessment

11.32. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for AndroFeme 1 if it were to be funded in New Zealand for postmenopausal women with HSDD. 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	Postmenopausal women with hypoactive sexual desire dysfunction (HSDD) who have received insufficient health benefit from addressing modifiable biopsychosocial factors including oestradiol based HRT (as per the International Society for the Study of Women's Sexual Health (ISSWSH)'s process of care).
Intervention	Testosterone cream 1% (AndroFeme 1) initially dosed at 5mg of testosterone (0.5ml) applied once daily. If no improvement within 3 months and total serum testosterone concentration is within premenopausal range, dose may be increased to 10mg testosterone (1.0ml) daily.
Comparator(s)	No funded treatment
Outcome(s)	44% increase in BISF (brief index for sexual function) scores, (8.8 points increase), which includes increase of sexual desire, frequency of intercourse and sexual initiation by the female partner. El-Hage et al. Climacteric. 2007;10:335-43, There is a health-related quality of life (HRQOL) loss of 0.1 associated with post-menopausal HSDD, AndroFeme 1 may help address this.
Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the patient population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data.	

12. International Normalized Ratio (INR) point-of-care testing equipment for long-term anticoagulation management with warfarin

Application

12.1. The Committee reviewed a clinician application and a consumer application regarding funding International Normalized Ratio (INR) point-of-care meters and test strips (branded as Roche CoaguChek® XS system) for the following groups:

12.1.1. Individuals using warfarin who have rheumatic heart disease and a mechanical heart valve.

12.1.2. Any individual who requires long-term anticoagulation management with warfarin.

12.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

12.3. The Committee **recommended** funding International Normalized Ratio point-of-care testing equipment to enable self-testing for people who require long-term anticoagulation management on warfarin with a **high** priority.

12.4. In making this recommendation, the Committee considered:

12.4.1. The additional health benefits associated with self-testing compared to standard outpatient INR testing models, including the reduced risk of thromboembolic events, reduced rate of hospitalisation, and improved quality of life.

12.4.2. The health benefits associated with self-testing are available to any individual undergoing long-term anticoagulation therapy, irrespective of the indication for warfarin.

12.4.3. The improved suitability of at-home testing would reduce the burden of long-term warfarin therapy and support an improved work-life-health balance.

12.4.4. The current health disparity experienced by Māori and Pacific peoples in the subgroup with mechanical heart valves secondary to rheumatic heart disease.

12.5. The Committee noted they would prefer their recommendation to include both self-testing and self-management (self-testing with self-dose adjustment), but considered self-management would be challenging to implement in the short-term given the currently available dosing support pathways.

12.6. The Committee considered that, should self-management programmes become feasible, Pharmac's assessment should be updated to reflect the costs and benefits associated with this approach.

12.7. The Committee noted the complexity regarding whether the assessment and potential funding responsibility best sits with Health New Zealand or Pharmac for INR point-of-care testing equipment in the community, and that this will be further discussed between the two health agencies.

Discussion

Māori impact

12.8. The Committee discussed the impact of funding INR point-of-care testing equipment on Māori health outcomes and noted that Manawa Ora (Heart Health) is a Hauora Arotahi | Pharmac Māori Health Area of Focus.

Populations with high health needs

12.9. The Committee discussed the health needs of people requiring long-term anticoagulation treatment with warfarin, particularly Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs.

12.10. The Committee reviewed the health needs of people requiring long-term anticoagulation treatment with warfarin within the context of people who have mechanical heart valves secondary to rheumatic heart disease (RHD):

12.10.1. The Committee noted that poverty and overcrowding, together with a higher frequency of streptococcal throat and skin infections and reduced access to medical care for Māori, contribute to the high rates of acute rheumatic fever observed in New Zealand (White et al. HLC. 2010;19:273-81). Members noted that RHD can develop after acute rheumatic fever, and that while RHD has largely disappeared from countries with high-income economies, the condition prevails in underprivileged and indigenous populations (Marijon et al Lancet. 2012;379:953-64).

12.10.2. The Committee noted the findings associated with the establishment of the Aotearoa New Zealand Rheumatic Heart Disease Registry (Tilton et al. BMJ Open. 2022;12:e066232), which detail the substantial health disparity experienced by Māori and Pacific peoples in the RHD setting. The Committee noted from 2010-2019, RHD cases in the registry were 10.7% European, 37.4% Māori and 47.2% Pacific.

12.10.3. The Committee noted a substantial proportion of people with RHD eventually require surgery (predominantly mitral valve), most commonly in young adults aged 20–25 years, though it can occasionally be necessary in children under 10 years old (Anutunes et al. Acute Rheum Fever Rheum Heart Dis. 2020:147-70). The Committee noted that when conservative approaches (eg valve repair) are not feasible, heart valve replacement with a mechanical valve may be performed despite the requirement for long-term anticoagulation on warfarin introducing a lifelong risk of severe complications such as thromboembolic events, stroke, and haemorrhage (Mangnall et al. Heart Asia. 2016;8:8-13).

12.10.4. The Committee noted the findings of Bennett et al. Emerg Infect Dis. 2021;27:36-46, which reported the breakdown of mortality in New Zealand for RHD by ethnicity, with the mean age at RHD-related death being 55 years for Pacific populations, 59 years for Māori and 80 years for Europeans. Among deaths attributed to RHD, the study reported 73.8% were of Māori and Pacific Islander ethnicity.

12.10.5. The Committee noted the following New Zealand based clinical audits:

12.10.5.1. Tangirala et al. NZMJ. 2025;138:53-60, a retrospective review of individuals aged 25 years or younger who received anticoagulation therapy with warfarin following mechanical valve replacement for RHD in Counties Manukau. The study identified 53 people (19% Māori, 81% Pacific peoples), and over a median follow-up of four years, 71% experienced at least one hospitalisation related to their anticoagulation therapy. A third of the 80 total hospitalisations were due to significant complications such as haemorrhage, stroke, other thromboembolic events and prosthetic valve thrombosis.

12.10.5.2. Singh et al. Cardiothorac Surg. 2022:92:1060-5, a retrospective cohort study consisting of 73 young adults (15-24 year olds, 85% were Māori or Pacific Islanders) who underwent mitral valve surgery for RHD at Auckland Hospital. Members noted the observed medium-term (6-year) mortality rate of 15.8% for those with valve replacement. The Committee noted individuals on warfarin were reported to be inside their therapeutic range only 23% of the time during the 6-year follow-up period.

12.10.6. Overall, the Committee considered there to be substantial health disparity for Māori and Pacific peoples with mechanical heart valves secondary to RHD, who require long-term anticoagulation management. The Committee considered that funding point-of-care INR testing equipment would offer people the convenience of testing at home alongside the additional health benefits associated with the self-testing model (see *Health Benefits*).

12.11. The Committee considered the general difficulties associated with routine outpatient INR testing are exacerbated for those experiencing higher socioeconomic deprivation or those who live rurally with reduced access to care.

Background

12.12. The Committee noted Pharmac received both a clinician and a consumer application for the point-of-care INR testing equipment branded as CoaguChek®, which includes a coagulometer, a lancet device, and an on-going supply of testing strips and lancets. The Committee noted the clinician application requested access for people with a mechanical heart valve secondary to rheumatic heart disease and the consumer applicant requested access for the entire population of warfarin users.

12.13. The Committee noted point-of-care INR monitoring devices enable people who require long-term warfarin-based anticoagulation management to engage with either the self-testing or self-management model:

12.13.1. Self-testing involves the person on warfarin, or a trained carer, performing regular INR testing at home, recording the results, and promptly reporting values to their anticoagulation clinic or clinician for interpretation and warfarin dosing instructions.

12.13.2. Self-management involves the person on warfarin, or a trained carer, performing regular INR testing at home, using an approved dosing algorithm to interpret the results, and then making warfarin dose adjustments independently.

12.14. The Committee noted three letters received by Pharmac in support of funding a point-of-care INR monitoring device, including a submission from the New Zealand Heart Foundation.

12.15. The Committee noted that Pharmac had previously consulted with its clinical network regarding these funding applications. Members noted five consultation responses from healthcare professionals.

12.16. The Committee noted that some individuals with implanted mechanical heart valves have received a CoaguChek device and a limited supply of test strips following their procedure.

12.17. The Committee noted that self-testing is already used by a small proportion of people in New Zealand, while self-management is currently not practiced. The Committee considered that, for those who already own a point-of-care INR monitor, the ongoing cost of test strips is a significant barrier to continuing with self-testing.

12.18. The Committee noted the treatment of cardiovascular disease has been identified as a government health priority (See Government health priorities 2024-7).

Health need

12.19. The Committee noted the heath needs associated with funding a point-of-care INR testing equipment arise from the management of long-term anticoagulation therapy with warfarin. Members noted that warfarin has a narrow therapeutic window and management is complicated by interpatient variability, numerous drug-drug and drug-food interactions, comorbidities, and nonmodifiable factors such as age, genetics, and ethnicity (Praz et al. Eur Heart J. 2025;46:4635-736).

12.20. The Committee noted maintaining an individual's INR within the therapeutic range is central to safe and clinically effective anticoagulation therapy, and that time spent outside that range increases the risk of serious adverse events such as haemorrhage, thrombosis, embolism and death (Morgan et al. Thromb Res 2009;124: 37-41, Johansson et al. thromb Haemost. 2024;124:613-624).

12.21. The Committee considered the general approach to warfarin management is to routinely monitor an individual's INR, and adjust the dosage as needed to achieve the target INR.

12.22. The Committee noted there are multiple clinical indications for long-term warfarin treatment, including mechanical heart valves, atrial fibrillation, venous thromboembolism, and people with contraindications to direct oral anticoagulants (DOACs).

12.23. The Committee noted that in the year ending in June 2025, 16,790 people received publicly funded warfarin in New Zealand.

12.24. The Committee noted the findings of Harper et al. NZMJ. 2022:135, which reported warfarin utilisation in New Zealand has progressively declined due to the introduction of DOACs, with use halving between 2011 and 2021 and falling by an additional 40 percent between 2020 and 2025. The Committee considered the number of warfarin users would continue to decline but noted there would likely be a persistent group of people who require warfarin, and not a DOAC (eg individuals with mechanical heart valves). The

Committee considered that not all people taking warfarin would choose to use a point-of-care testing device and would continue to use current testing options.

12.25. The Committee discussed the INR monitoring options currently available in New Zealand, which primarily include general practitioner-led monitoring or the Community Pharmacy Anticoagulation Management Service (CPAMS).

12.26. The Committee noted that CPAMS enrolment remains limited, and that patients must be referred to the service by a clinician.

12.27. The Committee considered that INR monitoring with outpatient services imposes a substantial and ongoing time burden on the individual. Members identified barriers to access include geographic distance from testing sites, limited clinic hours that frequently conflict with work and education schedules, and regional variation in service availability. The Committee noted that the requirement for regular testing necessitates time away from employment, education, and whānau, and that travel time, travel costs, and appointment availability are major obstacles for people requiring long-term warfarin management under current INR monitoring arrangements.

12.28. The Committee noted the findings reported by Harper et al. 2015 NZMJ;128:31-41, who conducted a clinical audit of the CPAMS between 2013-2014. At the time of the audit, 63% of individuals enrolled in the service were diagnosed with atrial fibrillation and 11.7% had a mechanical heart valve. The Committee considered that, because the proportion of individuals with atrial fibrillation receiving warfarin has since declined substantially (Harper et al. 2022), the relative proportion of atrial fibrillation relative to other indications would now be lower than the estimates reported by Harper et al 2015.

12.29. The Committee noted increased time in the therapeutic range is associated with a reduced risk of stroke and mortality for people with atrial fibrillation (Morgan et al. Thromb Res. 2009;124:37-41), and decreased risk of thromboembolism, bleeding & death in people with mechanical heart valves (Johannson et al. Thromb Haemost: 2024;124:613-24).

12.30. The Committee considered the health needs of the various populations who require anticoagulation with warfarin (mechanical heart valves, atrial fibrillation, those contraindicated to DOACs etc) in terms of anticoagulation management and noted that any individual on warfarin would be at risk of warfarin-related complications. The Committee noted the relative health needs associated with specific clinical indications (eg. atrial fibrillation vs mechanical heart valves) would have material differences due to factors such as their therapeutic INR range and average patient age. The Committee considered that while there may be material differences in health need between populations, each population is experiencing an unmet health need given the currently available options for INR monitoring. The Committee reiterated that time, travel costs, and service availability are all major barriers to routine outpatient INR monitoring for people who require long-term warfarin management.

Health benefit

12.31. The Committee noted that the analytical reliability of the self-testing devices is comparable to those obtained in a laboratory setting (Roche Diagnostics White Paper: Multicenter performance evaluation of the CoaguChek® INRange system).

12.32. The Committee noted the findings of Heneghan et al. Cochrane Database Syst Rev. 2016;7;1465-858 as key evidence, a Cochrane systematic review which evaluated the effects of self-testing or self-management of oral anticoagulant therapy on multiple outcomes including thrombotic events, major haemorrhages, and all-cause mortality, compared to standard monitoring models (outpatient). The Committee noted the review identified 28 randomised trials of people on long-term anticoagulation therapy irrespective of the indication for treatment.

12.32.1. The Committee noted the risk of thromboembolic events was reduced compared to standard care for study participants who self-tested (Relative risk (RR): 0.69, 95%CI: 0.49-0.97) or self-managed (RR: 0.47, 95%CI: 0.31-0.70) their anticoagulation therapy. The Committee also noted the duration of follow-up in the included studies for this outcome in the pooled analysis (n=18) ranged from 3-57 months, and that the authors graded the overall quality of evidence for both individual INR-testing strategies and the pooled findings as moderate.

12.32.2. The Committee noted the risk of all-cause mortality was reduced compared to standard care with self-management only (RR: 0.55; 95%CI: 0.36-84) but not for those who self-tested (RR: 0.94; 95%CI: 0.78-1.15) or for the pooled (self-testing and self-management) estimate (RR: 0.85; 95%CI: 0.71-1.01). The Committee also noted that the authors graded the quality of evidence across the 11 studies contributing to the pooled analysis as moderate, with follow-up periods ranging from 6-57 months.

12.32.3. The Committee noted there was no change in risk of major haemorrhage events compared to standard care associated with either self-testing (RR: 0.90; 95%CI: 0.74-1.09), self-management (RR: 1.08; 95%CI: 0.79-1.47) or the pooled estimate (RR: 0.95; 95% CI:0.80-1.12). The Committee also noted that these findings were informed by 20 studies, that the underlying evidence informing the pooled analysis was assessed as moderate or low quality, and that follow-up durations ranged from 4-57 months.

12.32.4. The Committee noted no significant differences were reported regarding the risk of minor haemorrhage compared to standard care either. The Committee noted the quality of evidence for these estimates was ranked low for the pooled analysis due to the risk of bias and substantial heterogeneity.

12.32.5. The Committee reviewed the quality of the evidence and concurred with the authors' grading, which was predominantly moderate, but low for minor haemorrhagic events and considered the findings to be generalisable to the New Zealand context.

12.33. The Committee noted the findings of Heneghan et al. Lancet 2012;379:322-34, a systematic review and meta-analysis of individual patient data which investigated the value of self-monitoring (including both self-testing and self-management) oral anticoagulation compared to standard care (primary care or anticoagulation clinic) irrespective of indication. Members noted that self-monitoring was associated with a significant reduction in overall thromboembolic events (HR: 0.51; 95%CI 0.31-0.85) but not for major haemorrhagic events or mortality. The Committee noted the significant reduction in thrombotic events observed in the younger than 55 years subgroup (HR: 0.33; 95%CI 0.17-0.66), as well as the mechanical heart valve subgroup (HR: 0.52; 95%CI: 0.35-0.77).

12.34. The Committee noted the findings of Sharma et al. BMJ Open. 2015;5:e007758, a systematic review with economic modelling on the clinical and cost-effectiveness of self-monitoring (including both self-testing and self-management) compared to standard care. Members noted the non-significant effect of self-monitoring on major bleeding and considered that self-management appeared to be associated with better outcomes than self-testing.

12.35. The Committee was made aware the findings of Harper et al. Intern Ned J. 2011;41:332-7, a NZ-based, prospective comparative study of 41 people on long-term warfarin where participants used laboratory testing for at least 12 months prior to changing to self-testing combined with online computer-decision support. The Committee noted that self-testing with online computer-decision support was reported to be at least as good as laboratory management with respect to the proportion of time an individual was inside their therapeutic INR range. While recognising the small study size, the Committee considered

the results to suggest that self-testing and/or self-management are feasible options for implementation in New Zealand.

12.36. The Committee noted the findings of Beek et al. J Gen Intern Med. 2024;39:1127-34, a retrospective claims-based study comparing self-testing with standard care (testing at a laboratory of physician's office) among people using warfarin. Members noted that people who received standard care had significantly higher rates of adverse events, including thromboembolism, major bleed, and stroke. Members noted that people on standard care had a significantly higher rate of emergency department visits than people who self-tested. The Committee discussed the limited generalisability of these findings and considered the bias with respect to the self-selecting nature of the self-testing group to be a concern.

12.37. The Committee noted having reviewed the following studies:

12.37.1. Cumberworth et al. Interact Cardiovasc Thorac Surg. 2012;16:198-201, a best-evidence review which summarised the findings of 5 meta-analyses. Members noted that the authors concluded self-testing/self-management appears to be safer than conventional management, given its association with consistently lower rates of thromboembolism and a possible reduction in bleeding and mortality.

12.37.2. Pozzi et al. Vasc. Health Risk Manag. 2016;12:387-92, a meta-analysis of twenty studies which compared self-testing and self-management with standard care.

12.37.3. Azarnoush et al. Thromb Res. 2014;133:149-53, a 4 year follow-up study for participants of a study on INR self-measurement (NCT00925197). Members noted only a fraction of the participants persisted for 4 years, and the main reason for discontinuation was cost and difficulty obtaining strips. The Committee noted that compared to standard care, those who self-measured had significantly less bleeding complications and a significantly improved quality of life.

12.38. Overall, the Committee noted the body of evidence demonstrated health benefits of self-testing and self-management irrespective of indication and considered that all people requiring long-term warfarin therapy are likely to experience comparable benefits.

12.39. The Committee considered self-testing to be associated with a reduced risk of thromboembolic events and potentially an improved QoL. The Committee considered the benefit compared to standard care to be greater for those who self-manage their anticoagulation therapy, noting the associated reduction in mortality as a potential benefit. The Committee discussed the generalisability of the body of evidence it reviewed and considered it to be relevant to the New Zealand context.

12.40. The Committee noted having reviewed the following guidelines:

12.40.1. The 2025 ESC/EACTs Guidelines for the management of valvular heart disease (Praz et al. 2025), which state "INR self-monitoring and self-management are recommended over standard monitoring in selected, trained patients to improve efficacy."

12.40.2. The 2012 American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (Holbrook et al. CHEST 2012;141:e152s-184s), which state "For patients treated with [vitamin K antagonists] who are motivated and can demonstrate competency in self-management strategies, including the self-testing equipment, we suggest patient self-management (PSM) rather than usual outpatient."

Suitability

12.41. The Committee considered that current INR testing options in New Zealand impose a substantial and ongoing burden on patients, their careers, and their whānau. The Committee considered that home INR testing could substantially reduce the time, travel, and resource burdens associated with outpatient INR monitoring.

12.42. The Committee discussed the requirements associated with self-testing and noted that this option will not be suitable for all individuals. Self-testing requires sufficient manual dexterity and visual acuity in the individual or their carer to perform the test reliably. The Committee noted the authors of Heneghan et al. 2016 suggested self-monitoring (including both self-testing and self-management) would not be feasible for up to half of people requiring anticoagulation.

12.43. The Committee noted the findings of Blanch et al. J Comp Eff Res. 2021;4, an observational and retrospective review regarding the impact of implementation of self-testing and self-management for people with mechanical heart valves. The Committee noted the author's discussion regarding the proportion of people who would complete and persist in self-management and self-testing programmes. The Committee agreed with the authors that self-testing and self-management would be an appropriate approach for a proportion of people.

12.44. The Committee noted it is recommended that for people starting warfarin, INR should be checked every 2–3 days until two consecutive results are in the therapeutic range; then weekly until two consecutive weeks are therapeutic; then every two weeks until two consecutive therapeutic results are achieved; and thereafter every month if the INR remains stable. The Committee noted that there is a proportion of people who may not achieve long periods of stability and would need to test frequently. The Committee considered this on-going requirement for regular testing places a high burden on the individual, including travel cost and time requirements that may not be tenable for many people.

Cost and savings

12.45. The Committee considered it might be appropriate for Pharmac to assess the mechanical heart valve population separately, in line with the clinician application, but reiterated their recommendation to fund point-of-care INR testing equipment for the entire population who require long term anticoagulation therapy.

12.46. The Committee considered that funding a point-of-care INR monitor would result in people testing their INR more frequently. The Committee noted Harper et al. 2011 reported the average interval between tests decreased when individual switched from laboratory management (19.6 days) to self-testing (10 days). The Committee discussed the frequency of testing for the purpose of economic modelling and considered that although it was likely an overestimate, Pharmac could consider modelling an average frequency of 1 test per week to capture periods of more frequent testing, reassurance tests, and testing accidents.

12.47. The Committee considered that INR control is affected by multiple clinical and behavioural factors, and that some individuals will routinely require more frequent monitoring (e.g., weekly). This reinforced the rationale for adopting a higher, rather than an optimistic, average testing frequency in economic modelling.

12.48. The Committee noted implementing self-testing programmes would require patient education sessions and additional support to ensure people could receive dosing advice in a timely manner.

12.49. The Committee considered that enabling self-testing would reduce the utilisation of current testing programmes (including CPAMS, Medical Laboratories, and Primary Care facilitated testing). The Committee considered that input from CPAMs and general practitioners would still be needed in the self-testing model to inform dosing adjustments,

and therefore consideration should be given to how self-testing could be efficiently integrated with current anticoagulation services, if funded. The Committee considered it would be reasonable to estimate that each instance where an individual contacts a healthcare professional for dosing advice occupies approximately 15 minutes of a healthcare professional's time.

12.50. The Committee considered self-testing would reduce the occurrence of thromboembolic events and associated hospitalisations for people on warfarin in New Zealand. Members noted a subset of those avoided events would include prosthetic valve thrombosis, which can require complex interventions including reoperation.

12.51. The Committee considered there to be uncertainty regarding the potential uptake of a point-of-care INR testing device.

12.51.1. The Committee reiterated that in Heneghan et al. 2016, the authors suggested self-monitoring (including both self-testing and self-management) would not be feasible for up to half of people requiring anticoagulation.

12.51.2. The Committee was made aware of Ulrich et al. BMC Family Practice. 2014;15:170, which reported screening results from a cluster randomized controlled trial regarding anticoagulant treatment in German family practice. Members noted that 8.5% of their screened participants were self-managing their anticoagulation therapy. The Committee considered 8.5% to likely be an underestimate of the potential uptake in New Zealand, noting differences in rurality and the availability of INR testing services to likely be different.

12.51.3. The Committee noted that uptake might vary across population groups, with high uptake anticipated among those living in rural areas, younger individuals and potentially also among older patients who receive close, ongoing support from carers. Uptake would also depend on the support, training, and service availability provided alongside self-testing programmes, which is likely to vary between regions.

12.51.4. The Committee noted that not all patients would be willing to undertake self-testing. However, members considered that clinicians are likely to encourage self-testing in suitable patients, and that many patients may be willing to adopt self-testing, including with support from carers or other forms of assistance such as health coaches. Overall, the Committee was uncertain regarding the estimated uptake in New Zealand, but considered it will be materially greater than the utilisation reported in international studies, such as Ulrich et al. 2014 (8.5%) and Beek et al. 2024 (4%).

12.52. The Committee noted that, in addition to the costs of the device and test strips, the self-testing model is likely to introduce changes in overall costs relative to current practice. Members considered these may arise from training requirements, altered monitoring frequency (higher frequency expected with self-testing), reduced in-person clinic visits, and improved INR control leading to fewer anticoagulation-related adverse events and a decrease in related healthcare utilisation. The Committee additionally noted that self-testing could lead to increased after-hours emergency department visits if patients receive concerning results without access to immediate anticoagulation support, however the extent of this increase in utilisation is highly uncertain.

12.53. The Committee noted the findings of Sharma et al. BMJ Open. 2015;5:e007758, which reported self-monitoring (including self-management and self-testing) had an 80% chance of being cost-effective at a willingness to pay ratio of £20,000 per QALY gained. The Committee noted the cost-effectiveness of the various point-of-care INR testing devices included in the analysis were different, and considered monitoring with CoaguChek appeared to be highly cost-effective. The Committee considered the summary statistics

from the economic modelling would be more favourable if they had been reported on CoaguChek alone.

International Recommendations

12.54. The Committee noted that Canadian Agency for Drugs and Technologies (CADTH) conducted a review of the clinical evidence and performed a health economic analysis to compare point-of-care INR testing with standard INR laboratory testing (CADTH Optimal Use Report, No 3.1C). Members noted CADTH's assessment informed a statement by the Health Technology Expert Review Panel (HTERP), an advisory body to the Canadian Drug Agency (Canada), which recommended that:

12.54.1. Patient self-management with a point-of-care INR testing device should be offered for people who are willing and able to self-manage their oral anticoagulation therapy. *Self-management* includes self-adjusting the dose using a protocol.

12.54.2. For patients who are unwilling/unable to self-adjust their anticoagulation doses (self-management), patient self-testing is recommended only when there are significant barriers to accessing laboratory testing and patients are willing and able to self-test. *Self-testing* includes testing and then a clinician adjusting the dose based on results.

12.55. The Committee noted that National Institute of Care Excellence (NICE; England/Wales) recommended CoaguChek for self-testing coagulation status in adults and children on long term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease (NICE Guidance PDF, Reference number: HTG353).

Summary for assessment

12.56. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for if point-of-care INR testing equipment were to be funded in New Zealand for long-term anticoagulation therapy management with warfarin. 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	Individuals who require long-term anticoagulation and for whom DOAC therapy is unsuitable, where warfarin is considered clinically appropriate and the individual has the capacity or support to undertake self-testing.
Intervention	Self-testing with CoaguChek XS INR Meter and the associated XS PT PST Test Strips (or a comparable point-of-care INR testing equipment)
Comparator(s) (NZ context)	Currently available options for monitoring an individual's international normalised ratio including: • GP-led monitoring (utilising community lab testing or point-of-care devices in clinics) • CPAMS (Community Pharmacy Anticoagulation Management Service)
Outcome(s)	Improved anticoagulation therapy management, including • Reduced rate of thromboembolic events • Improved time-in-therapeutic INR range • Reduced rate of anticoagulation therapy related adverse events • Reduced hospitalisations and emergency department presentations • Reduced requirement for clinician contact • Improved quality of life
Table definitions: **P**opulation: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup) **I**ntervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation). **C**omparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation). **O**utcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.	

13. Multiple proposals to consider for cost neutral list with right-sized advice

Background

13.1. The Committee reviewed a number of funding proposals, with the view of determining if a cost neutral recommendation to the currently funded comparator was appropriate, and if not, providing an understanding of what additional benefit the proposal provided (in accordance with the Factors for Consideration).

13.2. The Committee noted that Pharmac staff proposed this approach as a method of exploring opportunities to right size clinical advice and provide an efficient approach to getting the required clinical advice.

13.3. The Committee noted that if funded, all proposals would be subject to the same Special Authority criteria (if applicable) as the currently funded product and would be listed in addition to the currently funded product(s) rather than instead of.

13.4. The Committee considered that to make a cost neutral recommendation for a proposal they would use the following principles:

- Non-inferiority of efficacy with respect to the comparator
- Similarity of the severity of adverse effect profiles with respect to the comparator
- Cost-neutrality to be calculated on the basis of the entire treatment pathway, accounting for any differences in monitoring tests, dose equivalence and support technology required

13.5. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendations

13.6. The Committee recommended that **salbutamol dry powder inhaler** for the treatment of chronic obstructive pulmonary disease and asthma be funded if **cost neutral** to the funded salbutamol metered dose inhalers subject to the same access criteria.

13.7. The Committee recommended that **whey protein concentrate** for the use as a protein supplement for protein losing enteropathy, high protein needs, or use as a component in a modular formula be funded if **cost neutral** to the funded whey protein concentrate, on a per gram of protein basis, subject to the same Special Authority criteria.

13.8. The Committee recommended that **Fortisip Plant Based** for the use as an oral nutrition support be funded if **cost neutral** to the funded 200 ml Oral feed 1.5kcal/ml liquid supplement subject to the same Special Authority criteria.

13.9. The Committee recommended that **Fortisip Plant Based** for the use as an oral nutrition support be funded if **cost neutral** to the funded amino acid formulation for individuals who are unable to use supplements containing dairy. The Committee considered that specialist advice would be needed to define this group.

13.10. The Committee recommended that **tadalafil** for the treatment of Pulmonary arterial hypertension (PAH) be funded if **cost neutral** to sildenafil subject to the same Special Authority criteria.

13.11. The Committee recommended that **tadalafil** for the treatment of Raynaud's Phenomenon (RP) be funded **cost neutral** to sildenafil subject to the same Special Authority criteria.

13.12. The Committee recommended that **tadalafil** for use in weaning patients from inhaled nitric oxide be funded **cost neutral** to sildenafil subject to the same access criteria.

13.13. The Committee recommended that **tadalafil** for perioperative use in cardiac surgery patients be funded **cost neutral** to sildenafil subject to the same access criteria.

13.14. The Committee recommended that **tadalafil** for use in intensive care as an alternative to nitric oxide funded **cost neutral** to sildenafil subject to the same access criteria.

13.15. The Committee recommended that **sodium chloride oral liquid 2mmol/mL** for sodium replacement, neonates and children funded **cost neutral** to sodium chloride oral liquid 4mmol/mL subject to the same Special Authority criteria.

Discussion

Salbutamol dry powder inhaler for the treatment of chronic obstructive pulmonary disease and asthma

Discussion

13.16. The Committee considered the comparator for salbutamol dry powder inhaler (DPI) is a pressurised metered dose inhaler (MDI).

13.17. The Committee considered there were concerns regarding the use of propellants in the MDI inhalers that are associated with environmental impacts.

13.18. The Committee considered evidence that many other countries are actively encouraging the use of DPI, however noted this has had limited effect on the market share (Vartiainen et.al. BMJ Open Respir Res. 2025;12:e002424). The Committee considered this is partially due to reluctance to prescribe DPI to children under 12 years of age and considered it was a common misnomer that children are unable to use these devices.

13.19. The Committee considered, based on world data, it was likely DPI would have a very slow growth in market share over time.

13.20. The Committee noted the following studies and considered that DPI and MDI have similar health outcomes:

- Ram et al BMJ. 2001;323:901
- Twohig et al. Paediatr Respir Rev. 2025:S1526-0542(25)00036-3.
- Newhouse et al. Eur Respir J. 2003;21:816-20.
- Vangveeravong J Med Assoc Thai. 2008:91 Suppl 3:S115-23.

13.21. Overall, the Committee considered the DPI and MDI provide a similar health benefit and safety profile, with DPI providing an alternative inhaler device for the delivery of salbutamol for the treatment of COPD and asthma.

13.22. The Committee considered that the below table summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for Salbutamol DPI if it were to be funded in New Zealand for people who require salbutamol to relieve the symptoms of conditions such as COPD and asthma. 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 who require salbutamol inhaler
Intervention	Salbutamol dry powder inhaler
Comparator(s) (NZ context)	Salbutamol aerosol inhaler, at equivalent dose
Outcome(s)	Similar benefits and risks to currently funded comparator

Table definitions:

Population: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup)

Intervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation).

Comparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation).

Outcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.

Whey Protein Concentrate (Unflavoured) - Protein supplement for protein losing enteropathy, high protein needs, or use as a component in a modular formula

Discussion

13.23. The Committee considered whey protein concentrate (WPC) is used for a variety of indications, with two products currently funded.

13.24. The Committee noted the WPC being considered had 7-8% less protein per 100g than the currently funded products. The Committee considered that cost neutrality should be based on the cost per gram of protein.

13.25. The Committee considered that whilst there were no published trials including the WPC considered, including tasted and preference testing, it was reasonable to consider the product was non-inferior to the funded WPCs.

13.26. The Committee noted the user feedback that had been provided by the supplier to support its submission.

13.27. The Committee noted the shelf life of the product was 2 years compared with 3 years for one of the funded comparator products.

13.28. The Committee considered overall the WPC would provide a similar health benefit to the currently funded WPCs.

13.29. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for WPC if it were to be funded in New Zealand for use as a protein supplement for protein losing enteropathy, high protein needs, or use as a component in a modular formula. 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 who would be eligible for protein supplements under the current Special Authority criteria
Intervention	Protein supplement (McLeod Nutrition: Whey Protein Concentrate Unflavoured)
Comparator(s) (NZ context)	Currently funded protein supplements; Resource Beneprotein and Protifar
Outcome(s)	Similar health benefit to currently funded comparators

Table definitions:

Population: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup)

Intervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation).

Comparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation).

Outcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.

Fortisip PlantBased - Oral nutrition support (ONS)

Discussion

13.30. The Committee noted that the currently funded oral feed 1.5 kcal/ml 200 ml bottles (Fortisip and Ensure Plus) contained animal-based products.

13.31. The Committee considered there were a range of individuals who require ONS that are intolerant to animal based ONS, or who would prefer a plant-based alternative for a variety of reasons, including but not limited to lactose intolerance, veganism or religious beliefs.

13.32. The Committee considered individuals with some medical conditions including short bowel syndrome and enteropathy are also advised to avoid lactose.

13.33. The Committee noted that some individuals who have an intolerance to the animal based Fortisip product may be prescribed an amino acid formulation.

13.34. The Committee noted Hernandez et al. Front Nutr. 2025;12:1667954 that compared the plant and animal based ONS. The study reported the plant-based product was non-inferior to the animal based ONS in terms of body weight gain and functional strength. The Committee considered both products provided a similar health benefit.

13.35. The Committee considered it was difficult to define an intolerance to dairy, and that the use of a plant-based product would likely be based on individual choice.

13.36. Overall, the Committee considered the animal and plant-based product provided a similar health benefit and safety profile.

13.37. The Committee further recommended that further advice is sought from paediatric dieticians and the Special Foods Advisory Committee to better define which individuals may be intolerant to the animal based ONS.

13.38. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for Fortisip Plant Based if it were to be funded in New Zealand for ONS. 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	**Restricted population** People with malnutrition and severe documented allergy or intolerance to dairy	**Wider group** People who would be eligible for standard feeds under the current Special Authority criteria and prefer a plant-based product
Intervention	Oral feed 1.5 kcal/ml (Fortisip PlantBased) • Fortisip PlantBased Mango Passionfruit • Fortisip Plantbased Mocha	
Comparator(s) (NZ context)	Amino acid oral feed 0.8 kcal/ml • Elemental 028 Extra (Grapefruit) • Elemental 028 Extra (Apple & Orange) • Elemental 028 Extra (Summer Fruits)	Oral feed 1.5 kcal/ml • Fortisip Banana • Fortisip Chocolate • Fortisip Strawberry • Fortisip Vanilla
Outcome(s)	Similar health benefit and safety profile to currently funded comparators	

Table definitions:
Population: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup)
Intervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation).
Comparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation).
Outcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.

Tadalafil - Pulmonary arterial hypertension (PAH)and other indications eligible for sildenafil

Discussion

13.39. The Committee considered the health benefit and safety profile of tadalafil compared to the currently funded phosphodiesterase type 5 inhibitor (PDE5i) sildenafil for the following indications:

- Pulmonary arterial hypertension (PAH)
- Raynaud's Phenomenon (RP) and
- For use in weaning patients from inhaled nitric oxide
- For perioperative use in cardiac surgery patients
- For use in intensive care as an alternative to nitric oxide

13.40. The Committee noted the half-life of tadalafil is 17.5 hours compared to 4.5 hours for sildenafil. The Committee considered this was clinically advantageous in many settings, due to a reduction in the dosing frequency required. The Committee considered, unlike sildenafil, the absorption of tadalafil is not affected by fatty meal consumption.

13.41. The Committee considered the nature of the safety profile of each PDE5i varies, with sildenafil associated with blue vision and flushing, whilst tadalafil is associated with back pain and muscle aches, however they are similar in terms of the severity of adverse events.

PAH

13.42. The Committee noted Saggar et al. Pulm Circ. 2025;15:e70212 that reported the results of a systematic literature review that indicated that sildenafil and tadalafil were comparable when used as a monotherapy for PAH, however tadalafil may provide more benefit in combination with endothelin receptor antagonist combined therapy when measured by a six minute walk test.

13.43. The Committee noted Kjellström et al. ERJ Open Res. 2020;6:00299-2020 that reported amongst individuals treated for PAH or chronic thromboembolic pulmonary hypertension, tadalafil treatment was associated with higher adherence rates than sildenafil treatment. The Committee considered higher adherence to treatment may be associated with better health outcomes.

RP

13.44. The Committee noted Maltez et al. Cochrane Database Syst Rev. 2023;11(:CD014089 that reported the results of a systematic review that evaluated the benefits and harms of PED5i in the treatment of RP. The Committee noted that PDE5i treatment reduced the frequency and duration of attacks.

13.45. The Committee considered that the intended population for treatment were individuals experiencing secondary RP, who may have an underlying disorder including systemic sclerosis. The Committee considered these individuals were at risk of severe changes including the risk of digital ulcers and loss of tissue. The Committee considered this differed from those experiencing primary RP, who were generally younger individuals, experiencing intermittent vasoconstriction who were not generally treated with PDE5i.

Other indications considered

13.46. The Committee considered that sildenafil is used in individuals for weaning from nitrous oxide (NO) to avoid PAH, and perioperatively for individuals undergoing cardiac surgery with elevated right sided pressures. The Committee considered there was limited, poor quality, evidence on tadalafil usage in this population, however considered it was reasonable to assume there was similar efficacy and safety between sildenafil and tadalafil in these settings.

13.47. The Committee considered that tadalafil could be an alternative medicine for sildenafil for use in weaning individuals from NO, and for use in intensive care for NO. The Committee considered there may be some advantages to the longer half-life, and less frequent dosing.

Overall

13.48. The Committee considered there was reasonable quality evidence to suggest equivalent health benefit for sildenafil and tadalafil for the treatment of PAH and secondary RP. The Committee considered it was reasonable to assume a class effect for PDE5i in the treatment of these indications.

13.49. The Committee considered there was limited low quality data for the remaining indications considered, however it was reasonable to assume a class effect for PED5i for the treatment of these indications also.

13.50. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for tadalafil if it were to be funded in New Zealand for the following indications. 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	**Pulmonary arterial hypertension (PAH)** People with pulmonary arterial hypertension eligible for sildenafil tablets under the current Special Authority criteria	**Raynaud's Phenomenon (RP)** People with Raynaud's Phenomenon eligible for sildenafil tablets under the current Special Authority criteria	**PAH, RP, & additional indications** People with PAH, RP, or the following indications eligible for sildenafil tablets under the current Special Authority criteria: • For use in weaning patients from inhaled nitric oxide • For perioperative use in cardiac surgery patients • For use in intensive care as an alternative to nitric oxide
Intervention	Tadalafil (Tab; 10 mg or 20 mg)		
Comparator (NZ context)	Sildenafil (Tab; 25, 50, or 100 mg)		
Outcome(s)	Similar benefits and risks to sildenafil		
Table definitions: **P**opulation: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup) **I**ntervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation). **C**omparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation). **O**utcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.			

Sodium chloride oral liquid 2mmol/mL - Sodium replacement, neonates and children

Dis*cussio*n

13.51. The Committee considered the majority of individuals who require sodium chloride oral liquid are infants and children who have received diuretic therapy and become hyponatraemic.

13.52. The Committee considered that non-replacement of sodium chloride in children can result in growth restriction.

13.53. The Committee were made aware that a large number of Named Patient Pharmaceutical Assessment requests had been received for this treatment.

13.54. The Committee considered that the currently supplied product is compounded from the 4mmol/mL injection, as the 4 mmol/mL strength is not palatable, and can result in emesis.

13.55. The Committee considered the oral solution was currently compounded at community pharmacies. The Committee considered this may result in inequitable access to the 2 mmol/mL concentration.

13.56. The Committee considered this product offered suitability benefits, and similar health benefits to the compounded liquid.

13.57. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for sodium chloride oral liquid if it were to be funded in New Zealand for the following indications. 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	Children and neonates requiring sodium replacement, typically those on diuretics. To be considered for use in community (already funded in hospital use).
Intervention	Commercially prepared sodium chloride oral liquid 2mmol/ml, 25 ml Dosage varies based on condition and sodium levels
Comparator(s) (NZ context)	Sodium chloride oral liquid extemporaneously compounded from inj 23.4% (4 mmol/ml), 20 ml ampoule
Outcome(s)	Similar health benefit and risk to compounded solution

Table definitions:

Population: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup)

Intervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation).

Comparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation).

Outcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.