PHARMAC
TE PĀTAKA WHAIORANGA

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Some information may have been redacted for reasons including confidentiality

Pharmaceutical Management Agency (Pharmac)

Minutes of the Board Meeting

Held on Friday 29 November 2024, at 9.30am

At Pharmac, Wellington

Present:

Board members

Paula Bennett	Chair
Dr Peter Bramley (BSc (Hon), LL.B, PhD)	Deputy Chair
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	Board member
Dr Diana Siew (PhD)	Board member
Dr Margaret Wilsher (MD, FRACP, FRACMA)	Board member

Apologies

Robyn Manuel	Board Observer, CAC Chair

Board Observers

Dr Jane Thomas	Board Observer, PTAC Chair

Guests

Debbie Francis	Board only time via Teams

Pharmac staff in attendance

Sarah Fitt	Chief Executive
Catherine Epps	Director, Medical Devices
Michael Johnson	Director, Strategy, Policy & Performance
Geraldine MacGibbon	Director, Pharmaceuticals
Kathryn McInteer	Director, Corporate Services
Nicola Ngawati	Director, Equity & Engagement
David Hughes	Director, Advice and Assessment/CMO
Jacqui Webber	Board Secretary (Minute taker)

Attendees joined the meeting to present relevant papers: Saar Cohen-Ronen, Jared Solloway, and Adrienne Martin.

1. Welcome and Opening of Meeting

The Chair welcomed everyone and opened the meeting at 11.02am.

2. Chair's Report

2.1 Chair's Verbal Update

The Chair:

- updated the Board on recent activity and noted that the consumer engagement workshops had now been completed and they went really well, with great engagement from everyone. An independent report will come to the February Board
- acknowledged that Debbie Francis attended Board Only time and provided a verbal update on her recent interviews on organisational culture, with a written report coming to the February Board
- received a letter from the Minister today re oestradiol patches and the change in brand. Staff spoke to the process leading up to the final tender and acknowledged that our focus had been on securing a reliable supply and hadn't consulted well with consumers
- acknowledged that it was the last meeting for Jane Thomas, PTAC Chair. The Board noted the considerable contribution from Jane during her time on the Board and wished her the very best
- acknowledged Kathryn McInteer retiring and thanked her on behalf of the Board for her contribution.

2.2 Minutes of Board meetings

The Board:

resolved to adopt the minutes of the meeting held on 1 November 2024, subject to minor amendments.

The Chair commented that we will look to approving minutes by email next year, prior to the next Board meeting, so that we can publish them quicker.

2.3 Interest Register

The Board:

noted the interest register and no conflicts were notified.

3. Chief Executive's Update

3.1 Chief Executive's Report

The Chief Executive noted that:

- we hosted the farewell for Te Rōpū this past week, which went well and was really positive
- Budget 2025 paper went up to the Minister this past week with some options

- the Medical Devices review has started – staff from Martin Jenkins are undertaking interviews with key staff and meeting with the Director Medical Devices, weekly

- there has been a lot of activity around MOH Policy work – medicines regulations, enabling publicly funded cancer medicines to be administered by private hospitals

- the Chief Executive and Chair are attending the Health Committee meetings on Monday 2 December.

The Board:

noted the Chief Executive's report for October 2024.

4. Key Items

4.1 Acceleration of Health NZ Health Sector Agreements and Payments (HSAAP) programme

This paper provided the Board with an update on the Health Sector Agreements and Payments (HSAAP) programme, and work that we have commenced with Health NZ to support the delivery of the programme.

The Board:

noted that Health NZ recently agreed to accelerate the delivery of the HSAAP programme

noted that transition of subsidy payments made to community pharmacies to the new system is planned to be delivered by July 2025

noted Pharmac is working with Health NZ to ensure the successful delivery of the community pharmacy payments work as part of the HSAAP programme

noted an internal governance group has been established to oversee the progress, risks and impacts of HSAAP programme for Pharmac

noted there are potentially significant risks for Pharmac in relation to systems and processes, including the determination of subsidy payments and the creation of Pharmhouse data

noted that we are working with Health NZ to better understand the implications for Pharmac, both in terms of our capacity to support the programme and flow-on consequences to our own ageing IT systems.

It was noted that the Board may need to have an out of cycle Board meeting mid to late January to discuss further.

4.2 Litigation Insurance

This follow-up paper reported back on a question referred by the Board, as to the availability of litigation insurance.

The Board:

noted the follow up advice regarding litigation insurance

confirmed its **decision** to make no changes to the Legal Risk Fund and review the topic in two years.

Action: Review in two years' time.

5. Schedule and Funding

5.1 Pharmaceutical transactions report

The purpose of this paper was to provide the Board with an advanced overview of current issues relating to pharmaceuticals funded through the medicines budget, current significant supply issues, the contentious, large or significant pharmaceutical transactions and investments that staff are currently progressing and an update on vaccines and COVID-19 treatments.

The Board:

resolved to delegate decision-making to the Chief Executive for a number of proposals that fall within the Board's financial delegations. This is to enable decisions to be made at the earliest available opportunity, to meet proposed timeframes, enable faster access to medicines for patients, and/or to support implementation of the proposals (both from a health sector perspective and for suppliers who need time to build up sufficient stock). These proposals are:

- [redacted]
- a proposal to fund bevacizumab for ovarian cancer and hepatocellular carcinoma, award Principal Supply Status to the preferred supplier's brand, and widen access to atezolizumab for hepatocellular carcinoma.

noted that if, following consultation, any of the above proposals were considered to be contentious, we would take them to the Board for a decision

noted the update on current medicines issues and the large and/or significant medicines transactions that are currently planned or in progress

noted the summary of decisions made under Delegated Authority during September 2024.

5.2 Proposal to fund treatments for lung cancer, breast cancer, and respiratory conditions

This paper sought a decision from the Board on a proposal to fund treatments for lung cancer, breast cancer and respiratory conditions. The proposal would result in listing four new medicines on the Pharmaceutical Schedule and reduce the net price of a currently funded medicine.

The Board:

resolved to approve the listing of osimertinib (Tagrisso) on the Pharmaceutical Schedule from 1 January 2025 as set out below

resolved to approve the listing of trastuzumab deruxtecan (Enhertu) on the Pharmaceutical Schedule from 1 January 2025 as set out below

resolved to approve the listing of palivizumab (Synagis) on the Pharmaceutical Schedule from 1 January 2025 as set out below

resolved to approve the listing of budesonide with glycopyrronium and eformoterol (Breztri Aerosphere) on the Pharmaceutical Schedule from 1 January 2025 as set out below

resolved to approve the 8 November 2024 provisional listing agreement with AstraZeneca Ltd (AstraZeneca) for Tagrisso, Enhertu, Synagis, Breztri Aerosphere and Lynparza

noted the 8 November 2024 provisional agreement includes amendments to the price of olaparib (Lynparza)

resolved to approve the 6 September 2024 provisional listing agreement with AstraZeneca for trastuzumab deruxtecan (Enhertu)

resolved to approve amendments to the eligibility criteria for erlotinib, gefitinib and trastuzumab emtansine as set out below

resolved that the consultation on this proposal was appropriate, and no further consultation is required

noted that this proposal is a multiproduct proposal and individual components could not be progressed in isolation

Osimertinib

resolve to list osimertinib (Tagrisso) in the Oncology Agents and Immunosuppressants Therapeutic group, Protein Tyrosine Kinase Inhibitors therapeutic subgroup in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 January 2025 as follows:

Chemical	Brand	Presentation	Pack size	Proposed price and subsidy
Osimertinib	Tab 40 mg	Tagrisso	30	$9,310.00
Osimertinib	Tab 80 mg	Tagrisso	30	$9,310.00

resolve to apply the following Special Authority to osimertinib in Section B of the Pharmaceutical Schedule from 1 January 2025 as follows:

Special Authority for Subsidy
Initial application – (NSCLC – first line) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1. Patient is currently on treatment with osimertinib and met all remaining criteria prior to commencing treatment; or
2. All of the following:
   - 2.1. Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC); and
   - 2.2. Any of the following:
     - 2.2.1. Patient is treatment naïve; or
     - 2.2.2. Patient has received prior chemotherapy in the adjuvant setting and/or while awaiting *EGFR* results; or
     - 2.2.3. Both:
       - 2.2.3.1. The patient has discontinued gefitinib or erlotinib due to intolerance; and
       - 2.2.3.2. The cancer did not progress while on gefitinib or erlotinib; and
   - 2.3. There is documentation confirming that the cancer expresses activating mutations of *EGFR*; and

2.4. Patient has an ECOG performance status 0-3; and
2.5. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal – (NSCLC – first line) from any relevant practitioner. Approvals valid for 6 months for applications where response to or stable disease with treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

Initial application – (NSCLC – second line) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either::

1. Patient is currently on treatment with osimertinib and met all remaining criteria prior to commencing treatment; or
2. All of the following:
   2.1. Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC); and
   2.2. Patient has an ECOG performance status 0-3; and
   2.3. The patient must have received previous treatment with erlotinib or gefitinib; and
   2.4. There is documentation confirming that the cancer expresses T790M mutation of *EGFR* following progression on or after erlotinib or gefitinib; and
   2.5. The treatment must be given as monotherapy; and
   2.6. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal – (NSCLC – second line) from any relevant practitioner. Approvals valid for 6 months for applications where response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

resolve to apply the following Hospital Restrictions to osimertinib in Part II of Section H of the Pharmaceutical Schedule from 1 January 2025 as follows:

NSCLC – first line

Restricted
Initiation – NSCLC – first line
Re-assessment required after 4 months
All of the following:

1. Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC); and
2. Any of the following:
   2.1. Patient is treatment naïve; or
   2.2. Patient has received prior treatment in the adjuvant setting and/or while awaiting *EGFR* results; or
   2.3. Both:
      2.3.1. The patient has discontinued gefitinib or erlotinib due to intolerance; and
      2.3.2. The cancer did not progress while on gefitinib or erlotinib; and
3. There is documentation confirming that the disease expresses activating mutations of *EGFR*; and
4. Patient has an ECOG performance status 0-3; and
5. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Continuation – NSCLC – first line
Re-assessment required after 6 months
Response to or stable disease with treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and

NSCLC – second line

Restricted
Initiation – NSCLC – second line
Re-assessment required after 4 months
All of the following:

1. Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC); and
2. Patient has an ECOG performance status 0-2; and
3. The patient must have received previous treatment with erlotinib or gefitinib; and
4. There is documentation confirming that the disease expresses T790M mutation of *EGFR* following progression on or after erlotinib or gefitinib; and
5. The treatment must be given as monotherapy; and
6. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Continuation – NSCLC – second line
Reassessment required after 6 months
Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and

note that a confidential rebate would apply to Tagrisso that would reduce the net price

note that Tagrisso would have subsidy and delisting protection until 31 December 2027

Erlotinib and gefitinib

resolve to amend the Special Authority criteria for gefitinib in Section B of the Pharmaceutical Schedule from 1 January 2025 as follows (additions in bold, deletions in ~~strikethrough~~):

Special Authority for Subsidy
Initial application ~~only~~ from ~~a relevant specialist or~~ ~~medical practitioner~~ **any relevant practitioner** ~~on the recommendation of a relevant specialist~~. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

1. Patient has locally advanced, or metastatic, unresectable, non-squamous non-small cell lung cancer (NSCLC); and
2. ~~Either~~ **Any of the following**:
   - 2.1. Patient is treatment naïve; or
   - **2.2. Patient has received prior treatment in the adjuvant setting and/or while awaiting *EGFR* results; or**
   - 2.3. Both:
     - 2.3.1. The patient has discontinued **osimertinib or** erlotinib due to intolerance; and
     - 2.3.2. The cancer did not progress while on **osimertinib or** erlotinib; and
3. There is documentation confirming that the disease expresses activating mutations of ~~EGFR tyrosine kinase~~ ***EGFR***~~;~~ ~~and~~
4. ~~Gefitinib is to be given for a maximum of 3 months~~

Renewal ~~only~~ from ~~a relevant specialist or~~ any relevant practitioner ~~on the recommendation of a relevant specialist~~. Approvals valid for 6 months for applications where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed

~~**Renewal (pandemic circumstances)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:~~

~~1. The patient is clinically benefitting from treatment and continued treatment remains appropriate~~
~~2. Gefitinib to be discontinued at progression~~
~~3. The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on health sector~~

resolve to amend the Hospital Restriction criteria for gefitinib in Part II of Section H of the Pharmaceutical Schedule from 1 January 2025 as follows (additions in bold, deletions in ~~strikethrough~~):

Initiation
Re-assessment required after 4 months

All of the following:

1. Patient has locally advanced, or metastatic, unresectable, non-squamous non-small cell lung cancer (NSCLC); and
2. ~~Either~~ **Any of the following**:
   - 2.1. Patient is treatment naïve; or
   - **2.2. Patient has received prior treatment in the adjuvant setting and/or while awaiting *EGFR* results; or**
   - 2.3. Both:
     - 2.3.1. The patient has discontinued **osimertinib or** erlotinib due to intolerance; and
     - 2.3.2. The cancer did not progress while on **osimertinib or** erlotinib; and

3. There is documentation confirming that the disease expresses activating mutations of ~~EGFR tyrosine kinase~~ ***EGFR***; ~~and~~
4. ~~Gefitinib is to be given for a maximum of 3 months~~

Continuation

Re-assessment required after 6 months

~~1.~~ Radiological assessment (preferably including CT scan) indicates NSCLC has not progressed; and
~~2. Gefitinib is to be given for a maximum of 3 months~~

~~**Continuation (pandemic circumstances)**~~

~~Reassessment required after 6 months~~

~~1. The patient is clinically benefitting from treatment and continued treatment remains appropriate~~
~~2. Gefitinib to be discontinued at progression~~
~~3. The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on health sector~~

resolve to amend the Special Authority criteria for erlotinib in Section B of the Pharmaceutical Schedule from 1 January 2025 as follows (additions in bold, deletions in ~~strikethrough~~):

Special Authority for Subsidy

Initial application ~~only~~ from ~~a relevant specialist or~~ ~~medical practitioner~~ **any relevant practitioner** ~~on the recommendation of a relevant specialist~~. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

1 Patient has locally advanced, or metastatic, unresectable, non-squamous non-small cell lung cancer (NSCLC); and

2 There is documentation confirming that the disease expresses activating mutations of ~~EGFR tyrosine kinase~~ ***EGFR***; and

3 ~~Either~~ **Any of the following**:

3.1 Patient is treatment naïve; or

3.2 Patient has received prior treatment in the adjuvant setting and/or while awaiting *EGFR* results; or

3.3 Both:

3.3.1 The patient has discontinued **osimertinib or** gefitinib due to intolerance; and

3.3.2 The cancer did not progress while on **osimertinib or** gefitinib~~; and~~

~~4 Erlotinib is to be given for a maximum of 3 months~~

Renewal ~~only~~ from ~~a relevant specialist or~~ any relevant practitioner ~~on the recommendation of a relevant specialist~~. Approvals valid for 6 months for applications where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed

~~**Renewal (pandemic circumstances)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:~~

~~1. The patient is clinically benefitting from treatment and continued treatment remains appropriate~~
~~2. Erlotinib to be discontinued at progression~~
~~3. The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on health sector~~

resolve to amend the Hospital Restriction criteria for erlotinib in Part II of Section H of the Pharmaceutical Schedule from 1 January 2025 as follows (additions in bold, deletions in ~~strikethrough~~):

Initiation

Re-assessment required after 4 months

All of the following:

1. Patient has locally advanced, or metastatic, unresectable, non-squamous non-small cell lung cancer (NSCLC); and
2. There is documentation confirming that the disease expresses activating mutations of ~~EGFR tyrosine kinase~~ ***EGFR***; and
3. ~~Either~~ **Any of the following**:
   3.1. Patient is treatment naïve; or
   3.2. Patient has received prior treatment in the adjuvant setting and/or while awaiting *EGFR* results; or

3.3. Both:
3.3.1. The patient has discontinued **osimertinib or** gefitinib due to intolerance; and
3.3.2. The cancer did not progress while on **osimertinib or** gefitinib; and
~~4. Erlotinib is to be given for a maximum of 3 months~~

Continuation
Re-assessment required after 6 months
~~1.~~ Radiological assessment (preferably including CT scan) indicates NSCLC has not progressed; ~~and~~
~~2. Erlotinib is to be given for a maximum of 3 months~~

~~**Continuation (pandemic circumstances)**~~
~~Reassessment required after 6 months~~

~~1. The patient is clinically benefitting from treatment and continued treatment remains appropriate~~
~~2. Erlotinib to be discontinued at progression~~
~~3. The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on health sector~~

Trastuzumab deruxtecan

resolve to list trastuzumab deruxtecan (Enhertu) in the Oncology Agents and Immunosuppressants Therapeutic group, Monoclonal Antibodies therapeutic subgroup in Section B of the Pharmaceutical Schedule from 1 January 2025 as follows:

Chemical	Brand	Presentation	Pack size	Proposed price and subsidy
Trastuzumab deruxtecan	Inj 100 mg per ml, 1 ml vial	Enhertu	1	$2,550.00
Trastuzumab deruxtecan	Inj 1 mg for ECP	Baxter	1 mg	$27.05

resolve to apply the following Special Authority to trastuzumab deruxtecan (Enhertu) in Section B of the Pharmaceutical Schedule from 1 January 2025 as follows:

Special Authority for Subsidy
Initial application only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Patient is currently on treatment with trastuzumab deruxtecan and met all remaining criteria prior to commencing treatment; or
2. All of the following:
   2.1. Patient has metastatic breast cancer expressing HER-2 IHC3+ or ISH+ (including FISH or other current technology); and
   2.2. Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
   2.3. Either:
      2.3.1. The patient has received prior therapy for metastatic disease; or
      2.3.2. The patient developed disease recurrence during, or within six months of completing adjuvant therapy; and
   2.4. Patient has a good performance status (ECOG 0-1); and
   2.5. Patient has not received prior funded trastuzumab deruxtecan treatment; and
   2.6. Treatment to be discontinued at disease progression.

Renewal only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for people meeting the following criteria:
Both:
1. The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab deruxtecan; and
2. Treatment to be discontinued at disease progression.

Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

resolve to apply PCT only rule to trastuzumab deruxtecan in Section B of the Pharmaceutical Schedule from 1 January 2025;

resolve to list trastuzumab deruxtecan (Enhertu) in the Oncology Agents and Immunosuppressants Therapeutic group, Monoclonal Antibodies therapeutic subgroup in Part II of Section H of the Pharmaceutical Schedule from 1 January 2025 as follows:

Chemical	Brand	Presentation	Pack size	Proposed price
Trastuzumab deruxtecan	Inj 100 mg per ml, 1 ml vial	Enhertu	1	$2,550.00

resolve to apply the following Hospital restriction to trastuzumab deruxtecan (Enhertu) in Part II of Section H of the Pharmaceutical Schedule from 1 January 2025 as follows:

Initiation
Re-assessment required after 6 months
All of the following:
1. Patient has metastatic breast cancer expressing HER-2 IHC3+ or ISH+ (including FISH or other current technology); and
2. Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
3. Either:
   3.1. The patient has received prior therapy for metastatic disease; or
   3.2. The patient developed disease recurrence during, or within six months of completing adjuvant therapy; and
4. Patient has a good performance status (ECOG 0-1); and
5. Patient has not received prior funded trastuzumab deruxtecan treatment; and
6. Treatment to be discontinued at disease progression.

Continuation
Re-assessment required after 6 months
Both:
1. The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab deruxtecan; and
2. Treatment to be discontinued at disease progression.

Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

note that a confidential rebate would apply to Enhertu that would reduce the net price

note that Enhertu would have subsidy and delisting protection until 31 December 2027

Trastuzumab emtansine

resolve to amend the Special Authority criteria for trastuzumab emtansine in Section B of the Pharmaceutical Schedule subject from 1 January 2025 as follows (affected criteria shown only, additions in bold, deletions in ~~strikethrough~~):

Special Authority for Subsidy
Initial application – (metastatic breast cancer) only from a relevant specialist or ~~a medical practitioner~~ **any relevant practitioner** on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has metastatic breast cancer expressing HER-2 IHC3+ or ISH+ (including FISH or other current technology); and

2. Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
3. Either:
   3.1. The patient has received prior therapy for metastatic disease*; or
   3.2. The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and
4. Patient has a good performance status (ECOG 0-1); and
5. Either
   5.1. Patient does not have symptomatic brain metastases; or
   5.2. Patient has brain metastases and has received prior local CNS therapy; and
~~6. Patient has not received prior funded trastuzumab emtansine; and~~
6. **Either:**
   6.1. Patient has not received prior funded trastuzumab emtansine or trastuzumab deruxtecan treatment; or
   6.2. Both:
      6.2.1. Patient has discontinued trastuzumab deruxtecan due to intolerance; and
      6.2.2. The cancer did not progress while on trastuzumab deruxtecan; and
7. Treatment to be discontinued at disease progression.

resolve to amend the Hospital Restriction for trastuzumab emtansine in Part II of Section H of the Pharmaceutical Schedule subject from 1 January 2025 as follows (affected criteria shown only, additions in bold, deletions in ~~strikethrough~~):

Initiation – metastatic breast cancer
Re-assessment required after 6 months

All of the following:
1. Patient has metastatic breast cancer expressing HER-2 IHC3+ or ISH+ (including FISH or other current technology); and
2. Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
3. Either:
   3.1. The patient has received prior therapy for metastatic disease*; or
   3.2. The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and
4. Patient has a good performance status (ECOG 0-1); and
5. Either
   5.1. Patient does not have symptomatic brain metastases; or
   5.2. Patient has brain metastases and has received prior local CNS therapy; and
~~6. Patient has not received prior funded trastuzumab emtansine; and~~
7. **Either:**
   7.1. Patient has not received prior funded trastuzumab emtansine or trastuzumab deruxtecan treatment; or
   7.2. Both:
      7.2.1. Patient has discontinued trastuzumab deruxtecan due to intolerance; and
      7.2.2. The cancer did not progress while on trastuzumab deruxtecan; and
8. Treatment to be discontinued at disease progression.

Palivizumab

resolve to list palivizumab (Synagis) in the Oncology Agents and Immunosuppressants – Immunosuppressants – Monoclonal Antibodies subgroup in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 January 2025, as follows:

Chemical	Brand	Presentation	Pack size	Proposed price and subsidy
Palivizumab	Inj 100 mg per ml, 1 ml vial	Synagis	1	$1,700.00

resolve to apply the following Special Authority to palivizumab in Section B of the Pharmaceutical Schedule from 1 January 2025 as follows:

Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1. Palivizumab to be administered during the RSV season; and
2. Either:
    - 2.1. Infant was born in the last 12 months and was born less than 32 weeks' and zero days gestation; or
    - 2.2. Child was born in the last 24 months; and
        - 2.2.1. Any of the following:
            - 2.2.1.1. Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community; or
            - 2.2.1.2. Both:
                - 2.2.1.2.1. Child has haemodynamically significant heart disease; and
                - 2.2.1.2.2. Any of the following:
                    - 2.2.1.2.2.1. Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B); or
                    - 2.2.1.2.2.2. Child has unoperated or surgically palliated complex congenital heart disease; or
                    - 2.2.1.2.2.3. Child has severe pulmonary hypertension (see Note C); or
                    - 2.2.1.2.2.4. Child has moderate or severe left ventricular (LV) failure (see Note D); or
            - 2.2.1.3. Child has severe combined immune deficiency (not transplanted) or inborn error of immunity increasing susceptibility to life-threatening respiratory viral infections (including IFNAR deficiencies), confirmed by an immunologist

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

All of the following:

1. Palivizumab to be administered during the RSV season
2. Child was born in the last 24 months; and
    - 2.1. Either:
        - 2.1.1. Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community; or
        - 2.1.2. Any of the following:
            - 2.1.2.1. Child has haemodynamically significant heart disease; and
            - 2.1.2.2. Any of the following:
                - 2.1.2.2.1. Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B); or
                - 2.1.2.2.2. Child has unoperated or surgically palliated complex congenital heart disease; or
                - 2.1.2.2.3. Child has severe pulmonary hypertension (see Note C); or
                - 2.1.2.2.4. Child has moderate or severe left ventricular (LV) failure (see Note D); or
        - 2.1.3. Child has severe combined immune deficiency (not transplanted) or inborn error of immunity increasing susceptibility to life-threatening respiratory viral infections (including IFNAR deficiencies), confirmed by an immunologist

Notes:

A. Ventilatory/respiratory support includes those on home oxygen, CPAP/VPAP and those with tracheostomies in situ managed at home
B. Child requires/will require heart failure medication, and/or child has significant pulmonary hypertension, and/or infant will require surgical palliation/definitive repair within the next 3 months
C. Mean pulmonary artery pressure more than 25 mmHg
D. LV Ejection Fraction less than 40%

resolve to apply PCT-only rule to palivizumab in Section B of the Pharmaceutical Schedule from 1 January 2025;

resolve to apply the following Hospital Restriction to palivizumab in Part II of Section H of the Pharmaceutical Schedule from 1 January 2025 as follows:

Restricted
Initiation
Re-assessment required after 6 months
Both:

1. Palivizumab to be administered during the RSV season; and
2. Either:
   - 2.1. Infant was born in the last 12 months and was born less than 32 weeks' and zero days gestation; or
   - 2.2. Child was born in the last 24 months; and
     - 2.2.1. Any of the following:
       - 2.2.1.1. Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community; or
       - 2.2.1.2. Both:
         - 2.2.1.2.1. Child has haemodynamically significant heart disease; and
         - 2.2.1.2.2. Any of the following:
           - 2.2.1.2.2.1. Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B); or
           - 2.2.1.2.2.2. Child has unoperated or surgically palliated complex congenital heart disease; or
           - 2.2.1.2.2.3. Child has severe pulmonary hypertension (see Note C); or
           - 2.2.1.2.2.4. Child has moderate or severe left ventricular (LV) failure (see Note D); or
       - 2.2.1.3. Child has severe combined immune deficiency (not transplanted) or inborn error of immunity increasing susceptibility to life-threatening respiratory viral infections (including IFNAR deficiencies), confirmed by an immunologist

Continuation
Re-assessment required after 6 months

All of the following:

1. Palivizumab to be administered during the RSV season
2. Child was born in the last 24 months; and
   - 2.1. Either:
     - 2.1.1. Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community; or
     - 2.1.2. Any of the following:
       - 2.1.2.1. Child has haemodynamically significant heart disease; and
       - 2.1.2.2. Any of the following:
         - 2.1.2.2.1. Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B); or
         - 2.1.2.2.2. Child has unoperated or surgically palliated complex congenital heart disease; or
         - 2.1.2.2.3. Child has severe pulmonary hypertension (see Note C); or
         - 2.1.2.2.4. Child has moderate or severe left ventricular (LV) failure (see Note D); or
     - 2.1.3. Child has severe combined immune deficiency (not transplanted) or inborn error of immunity increasing susceptibility to life-threatening respiratory viral infections (including IFNAR deficiencies), confirmed by an immunologist

Notes:

A. Ventilatory/respiratory support includes those on home oxygen, CPAP/VPAP and those with tracheostomies in situ managed at home
B. Child requires/will require heart failure medication, and/or child has significant pulmonary hypertension, and/or infant will require surgical palliation/definitive repair within the next 3 months
C. Mean pulmonary artery pressure more than 25 mmHg
D. LV Ejection Fraction less than 40%

note that a confidential rebate would apply to Synagis that would reduce the net price

note that Synagis would have subsidy and delisting protection until 31 December 2027

Breztri Aerosphere

resolve to list budesonide with glycopyrronium and eformoterol (Breztri Aerosphere) aerosol inhaler budesonide 160 mcg with glycopyrronium 7.2 mcg and formoterol 5 mcg per dose in the Respiratory System and Allergies – Inhaled Corticosteroid with Long-Acting Muscarinic

Antagonist and Beta Agonist subgroup in Section B of the Pharmaceutical Schedule from 1 January 2025, as follows:

Chemical	Presentation	Brand	Pack size	Proposed price and subsidy
Budesonide with glycopyrronium and eformoterol	Aerosol inhaler budesonide 160 mcg with glycopyrronium 7.2 mcg and formoterol 5 mcg per dose	Breztri Aerosphere	120 dose OP	$79.15

resolve to apply the following Special Authority to budesonide with glycopyrronium and eformoterol in Section B of the Pharmaceutical Schedule from 1 January 2025 as follows:

Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Both:
1. Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
2. Either:
   2.1. Both:
      2.1.1. Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA) or a long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA); and
      Clinical criteria:
      2.1.2. Any of the following:
         2.1.2.1. Patient has a COPD Assessment Test (CAT) score greater than 10; or
         2.1.2.2. Patient has had 2 or more exacerbations in the previous 12 months; or
         2.1.2.3. Patient has had one exacerbation requiring hospitalisation in the previous 12 months; or
         2.1.2.4. Patient has had an eosinophil count greater than or equal to 0.3 × 10^9 cells/L in the previous 12 months; or
   2.2. Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long-acting muscarinic antagonist and long-acting beta-2 agonist – ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler therapy.

resolve to list budesonide with glycopyrronium and eformoterol (Breztri Aerosphere) Aerosol inhaler, metered dose) in the Respiratory System and Allergies – Inhaled Corticosteroid with Long-Acting Muscarinic Antagonist and Beta Agonist subgroup in Part II of Section H of the Pharmaceutical Schedule from 1 January 2025, as follows:

Chemical	Presentation	Brand	Pack size	Proposed price
Budesonide with glycopyrronium and eformoterol	Aerosol inhaler budesonide 160 mcg with glycopyrronium 7.2 mcg and formoterol 5 mcg per dose	Breztri Aerosphere	120 dose	$79.15

resolve to apply the following Hospital restriction to budesonide with glycopyrronium and eformoterol in Part II of Section H of the Pharmaceutical Schedule from 1 January 2025 as follows:

Restricted
Initiation
Both:
1. Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
2. Either:

2.1. Both:

2.1.1. Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA) or a long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA); and

Clinical criteria:

2.1.2. Any of the following:

2.1.2.1. Patient has a COPD Assessment Test (CAT) score greater than 10; or

2.1.2.2. Patient has had 2 or more exacerbations in the previous 12 months; or

2.1.2.3. Patient has had one exacerbation requiring hospitalisation in the previous 12 months; or

2.1.2.4. Patient has had an eosinophil count greater than or equal to 0.3 × 10^9 cells/L in the previous 12 months; or

2.2. Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long-acting muscarinic antagonist and long-acting beta-2 agonist – ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler therapy.

note that a confidential rebate would apply to Breztri Aerosphere that would reduce the net price

note that Breztri Aerosphere would have subsidy and delisting protection until 30 June 2028.

5.3 Medical Devices Transactions and Investment Report

This paper provided an update to the Board on progress with medical devices national contracting activity. It also included updates on some wider medical device programme activity.

The Board:

noted the update on progress with medical devices national contracting activity

noted the summary of decisions made under Delegated Authority during October by the Director, Medical Devices.

6. Strategic Planning and Policy

6.1 Final Statement of Intent 2024/25 – 2027/28

This paper presented for Board approval, Pharmac's final Statement of Intent 2024/25 - 2027/28 (SOI).

The Board:

approved the final Statement of Intent 2024/25 - 2027/28 (refer to Appendix One)

noted that following Board approval, the Statement of Intent will be provided to the office of the Associate Minister of Health.

6.2 Update on 'Enhanced Assessment and Decision Making' strategic priority

This paper provided the Board with an update on progress and next steps for the 'Enhanced Assessment and Decision Making' strategic priority, since the last update to the Board in July 2024.

The Board commented we need more of a problem definition. Suggest we need to pause and reflect before we appoint a new PTAC Chair. The Board would like to see a clear strategic plan on how everything aligns.

The Board:

noted that enhanced assessment and decision-making is one of our strategic priorities in our 2023/24 – 2026/27 Statement of Intent and this is currently being updated

noted the key areas of focus over the next three years:

1. enhance how we assess and make funding decisions, to make our processes timelier and more transparent, better coordinated with sector partners, and centred around priorities for populations with high health needs and other Pae Ora health sector principles

2. strengthen the voice of the New Zealand public in our considerations

3. ensure people benefit from funding decisions we make

noted the progress being made towards this strategic priority.

Action: Provide the Board with a strategic plan on how everything aligns.

7. Regular Reporting

7.1 Communications Report

This paper summarised communications activity for the previous month and the impact of our work.

The Board:

noted that Pharmac's website is now part of the Zero Data initiative, which allows people to access our website on their phone without using mobile data

noted that the focus of the 2024 Year in Review publication, will be on engagement and the positive impact our work has on the lives of individuals.

7.2 Proposed guests for 2025 Board Meetings

This paper proposed guests to be invited to attend 2025 Board meetings.

The Board suggested adding ACC Acting Medical Lead [redacted].
The suggestion was also made to add someone to talk on new innovations that are coming through (Diana to provide a name).

The Board:

approved the proposed guest list for 2025 Board meetings.

Action: Update list with additional suggestions.

8. Previous Minutes of Committee Meetings

8.1 Minutes of Finance, Audit & Risk Committee Meeting

The Board:

noted and endorsed the minutes of the Audit & Risk Committee meeting held on 1 November 2024, subject to minor edits.

8.2 Summary of October 2024 Consumer Advisory Committee (CAC) Meetings

The Board:

noted the minutes from the October CAC meetings

noted the summary of key issues across the meetings.

8.3 Summary of August 2024 PTAC advice and recommendations

The Board:

noted the summary of the record of the Pharmacology and Therapeutics Advisory Committee (PTAC) meeting held online on 16 August 2024

noted the August 2024 PTAC record was signed off by the Chair on 19 October 2024 and published on the Pharmac website 18 November 2024.

9. Governance Matters

9.1 Board Correspondence

The Board:

noted the correspondence sent / received for the prior month.

9.2 Board and Committee Member Terms and Attendance Record

The Board:

noted the Board and Committee member terms

noted the 2024 Meeting Attendance Register.

9.3 Board Actions

The Board **noted** there were no new Board Actions.

9.4 Matters Arising

The Board **noted** the Matters Arising schedule.

9.5 Board Annual Agenda for 2025

The Board **noted** the Board Annual Agenda for 2025.

9.6 Glossary of Terms and Abbreviations

The Board **noted** the Glossary of Terms and Abbreviations.

10. General Business

There was no general business discussed.

The meeting closed at 1.47pm with a karakia.

Date of Next Meeting: 25 February 2025

Approved *6 December 2024*

Paula Bennett, Chair Date