PHARMAC
TE PĀTAKA WHAIORANGA

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Pharmaceutical Management Agency (Pharmac)

Minutes of the Board Meeting

Held on Monday 3 February 2025 at 1.00pm

Via Microsoft Team

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

Apologies

Dr Margaret Wilsher (MD, FRACP, FRACMA)	Board member
Sarah Fitt	Chief Executive

Pharmac staff in attendance

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

Attendees joined the meeting to present relevant papers: Emma Clarke, Conal Edwards, Alex Compton.

Welcome and Opening of Meeting

The Chair welcomed everyone and acknowledged apologies had been received from Margaret Wilshire. The meeting was opened with a karakia at 1.02pm.

1. Proposal to award Principal Supply Status for bevacizumab and to fund medicines for liver and ovarian cancers

This paper sought a decision from the Board on a proposal to fund treatments for ovarian and liver cancers. The proposal would result in a change of the funded brand of bevacizumab, specifically for people with recurrent respiratory papillomatosis.

The Board:

noted the consultation that has been undertaken on this proposal and that no further consultation is to be undertaken at this time

Bevacizumab

resolved to list Celltrion Healthcare New Zealand Limited's brand and presentations of bevacizumab (Vegzelma) in the 'Monoclonal Antibodies' subtherapeutic group of the Oncology Agents and Immunosuppressants Therapeutic Group in Section B of the Pharmaceutical Schedule from 1 March 2025 as follows:

Chemical	Presentation	Brand	Pack Size	List Price and subsidy (ex-man., ex. GST)
Bevacizumab	Inj 25 mg per ml, 4 ml vial	Vegzelma	1	$69.00
Bevacizumab	Inj 25 mg per ml, 16 ml vial	Vegzelma	1	$276.00
Bevacizumab	Inj 1 mg for ECP	Baxter	1 mg	$0.71

resolved to apply PCT only rule to bevacizumab in Section B of the Pharmaceutical Schedule from 1 March 2025

resolved to apply the Special Authority criteria for bevacizumab in Section B of the Pharmaceutical Schedule from 1 March 2025 as follows:

Special Authority for Subsidy
Initial application – (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1. Patient is currently on treatment with bevacizumab, and met all remaining criteria prior to commencing treatment; or
2. All of the following:
   - 2.1. Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and
   - 2.2. Patient has preserved liver function (Child-Pugh A); and
   - 2.3. Transarterial chemoembolisation (TACE) is unsuitable; and
   - 2.4. Any of the following:
     - 2.4.1. Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
     - 2.4.2. Patient received funded lenvatinib before 1 March 2025; or
     - 2.4.3. Both:
       - 2.4.3.1. Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
       - 2.4.3.2. No disease progression since initiation of lenvatinib; and
   - 2.5. Patient has an ECOG performance status of 0-2; and
   - 2.6. To be given in combination with atezolizumab.

Renewal – (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

Initial application – (advanced or metastatic ovarian cancer) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following

1. Either:
   1.1. The patient has FIGO Stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; or
   1.2. Both:
      1.2.1. The patient has previously untreated advanced (FIGO Stage IIIB or IIIC) epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
      1.2.2. Either:
         1.2.2.1. Debulking surgery is inappropriate; or
         1.2.2.2. The cancer is sub-optimally debulked (maximum diameter of any gross residual disease greater than 1cm); and
2. Bevacizumab to be administered at a maximum dose of 7.5 mg/kg every three weeks; and
3. 18 weeks concurrent treatment with chemotherapy is planned.

Renewal – (advanced or metastatic ovarian cancer) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

Initial application – (Recurrent Respiratory Papillomatosis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:
1. Maximum of 6 doses; and
2. The patient has recurrent respiratory papillomatosis; and
3. The treatment is for intra-lesional administration.

Renewal – (Recurrent Respiratory Papillomatosis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:
1. Maximum of 6 doses; and
2. The treatment is for intra-lesional administration; and
3. There has been a reduction in surgical treatments or disease regrowth as a result of treatment.

Initial application – (Ocular Conditions) from any relevant practitioner. Approvals valid without further renewal for applications meeting the following criteria:

Either:
1. Ocular neovascularisation; or
2. Exudative ocular angiopathy.

resolved to amend the chemical 'bevacizumab' to 'bevacizumab (ocular)' in the Monoclonal Antibodies' subtherapeutic group of the Oncology Agents and Immunosuppressants Therapeutic Group in Part II of Section H of the Pharmaceutical Schedule from 1 March 2025

resolved to amend the hospital indication restriction of bevacizumab (ocular) from 1 August 2025 as follows (additions in **bold**, deletions in ~~strikethrough~~):

Restricted
~~Initiation – Recurrent Respiratory Papillomatosis~~
~~*Re-assessment required after 12 months*~~
~~All of the following:~~
~~1. Maximum of 6 doses; and~~
~~2. The patient has recurrent respiratory papillomatosis; and~~
~~3. The treatment is for intra-lesional administration.~~

~~Continuation – Recurrent Respiratory Papillomatosis~~
~~*Re-assessment required after 12 months*~~
~~All of the following:~~
~~1. Maximum of 6 doses; and~~
~~2. The treatment is for intra-lesional administration; and~~
~~3. There has been a reduction in surgical treatments or disease regrowth as a result of treatment.~~

Initiation – ocular conditions
Either:

1. Ocular neovascularisation; or
2. Exudative ocular angiopathy.

resolved to list Celltrion Healthcare New Zealand Limited's brand of bevacizumab (Vegzelma) in the 'Monoclonal Antibodies' subtherapeutic group of the Oncology Agents and Immunosuppressants Therapeutic Group in Part II of Section H of the Pharmaceutical Schedule from 1 March 2025 as follows:

Chemical	Presentation	Brand	Pack Size	List Price (ex-man., ex. GST)
Bevacizumab	Inj 25 mg per ml, 4 ml vial	Vegzelma	1	$69.00
Bevacizumab	Inj 25 mg per ml, 16 ml vial	Vegzelma	1	$276.00

resolved to accept the bid from Celltrion Healthcare New Zealand Limited's for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical bevacizumab (Vegzelma) inj 25 mg per ml, 4 ml vial and inj 25 mg per ml, 16 ml vial with an ABA limit of 10% from 1 August 2025 until 31 August 2028

noted that Principal Supply Status would not apply in Section B as per the agreement for Vegzelma

noted that a confidential rebate would apply to Vegzelma that would reduce the net price

resolved to apply the following hospital indication restrictions to Bevacizumab (Vegzelma) in Part II of Section H of the Pharmaceutical Schedule from 1 March 2025 as follows:

Restricted
Initiation - Unresectable hepatocellular carcinoma
Re-assessment required after 6 months

Either:
1. Patient is currently on treatment with bevacizumab and met all remaining criteria prior to commencing treatment; or
2. All of the following:
   - 2.1. Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and
   - 2.2. Patient has preserved liver function (Child-Pugh A); and
   - 2.3. Transarterial chemoembolisation (TACE) is unsuitable; and
   - 2.4. Any of the following:
     - 2.4.1. Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
     - 2.4.2. Patient received funded lenvatinib before 1 March 2025; or
     - 2.4.3. Both:
       - 2.4.3.1. Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
       - 2.4.3.2. No disease progression since initiation of lenvatinib; and
   - 2.5. Patient has an ECOG performance status of 0-2; and
   - 2.6. To be given in combination with atezolizumab.

Continuation - Unresectable hepatocellular carcinoma
Re-assessment required after 6 months
No evidence of disease progression

Initiation - advanced or metastatic ovarian cancer
Re-assessment required after 4 months

All of the following
1. Either:
   - 1.1. The patient has FIGO Stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; or
   - 1.2. Both:
     - 1.2.1. The patient has previously untreated advanced (FIGO Stage IIIB or IIIC) epithelial ovarian, fallopian tube, or primary peritoneal cancer; and

1.2.2. Either:
1.2.2.1. Debulking surgery is inappropriate; or
1.2.2.2. The cancer is sub-optimally debulked (maximum diameter of any gross residual disease greater than 1cm); and
2. Bevacizumab to be administered at a maximum dose of 7.5 mg/kg every three weeks; and
3. 18 weeks concurrent treatment with chemotherapy is planned.

Continuation - advanced or metastatic ovarian cancer
Re-assessment required after 4 months
No evidence of disease progression

Initiation – Recurrent Respiratory Papillomatosis
Re-assessment required after 12 months

All of the following:
1. Maximum of 6 doses; and
2. The patient has recurrent respiratory papillomatosis; and
3. The treatment is for intra-lesional administration.

Continuation – Recurrent Respiratory Papillomatosis
Re-assessment required after 12 months

All of the following:
1. Maximum of 6 doses; and
2. The treatment is for intra-lesional administration; and
3. There has been a reduction in surgical treatments or disease regrowth as a result of treatment.

Initiation – ocular conditions
Either:
1. Ocular neovascularisation; or
2. Exudative ocular angiopathy.

noted use of "any brand" of bevacizumab (ocular) in Health New Zealand hospitals would be managed under the ABA

noted an Exceptional Circumstance form for people with recurrent respiratory papillomatosis would be available

resolved to approve the 18 September 2024 agreement with Celltrion for Vegzelma

Atezolizumab

resolved to amend the Special Authority criteria for atezolizumab in Section B of the Pharmaceutical Schedule from 1 March 2025 as follows (new criteria shown only):

Special Authority for Subsidy
Initial application – (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1. Patient is currently on treatment with atezolizumab and met all remaining criteria prior to commencing treatment; or
2. All of the following:
   2.1. Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and
   2.2. Patient has preserved liver function (Child-Pugh A); and
   2.3. Transarterial chemoembolisation (TACE) is unsuitable; and
   2.4. Any of the following:
      2.4.1. Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
      2.4.2. Patient received funded lenvatinib before 1 March 2025; or
      2.4.3. Both:
         2.4.3.1. Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
         2.4.3.2. No disease progression since initiation of lenvatinib; and
   2.5. Patient has an ECOG performance status of 0-2; and
   2.6. To be given in combination with bevacizumab.

Renewal – (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

resolved to amend the hospital indication restrictions for atezolizumab in Part II of Section H of the Pharmaceutical Schedule from 1 March 2025 as follows (new criteria shown only):

Restricted
Initiation - Unresectable hepatocellular carcinoma
Re-assessment required after 6 months

Either:

1. Patient is currently on treatment with atezolizumab and met all remaining criteria prior to commencing treatment; or
2. All of the following:
   - 2.1. Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and
   - 2.2. Patient has preserved liver function (Child-Pugh A); and
   - 2.3. Transarterial chemoembolisation (TACE) is unsuitable; and
   - 2.4. Any of the following:
     - 2.4.1. Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
     - 2.4.2. Patient received funded lenvatinib before 1 March 2025; or
     - 2.4.3. Both:
       - 2.4.3.1. Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
       - 2.4.3.2. No disease progression since initiation of lenvatinib; and
   - 2.5. Patient has an ECOG performance status of 0-2; and
   - 2.6. To be given in combination with bevacizumab.

Continuation - Unresectable hepatocellular carcinoma
Re-assessment required after 6 months
No evidence of disease progression

resolved to approve amendments to the eligibility criteria for lenvatinib as set out in this paper

Lenvatinib

resolved to amend the Special Authority criteria for lenvatinib in Section B of the Pharmaceutical Schedule from 1 March 2025 as follows (additions in **bold**, deletions in ~~strikethrough~~, affected criteria shown only):

Special Authority for Subsidy
Initial application – (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:
1. Patient has unresectable hepatocellular carcinoma; and
2. Patient has preserved liver function (Childs-Pugh A); and
3. Transarterial chemoembolisation (TACE) is unsuitable; and
4. Patient has an ECOG performance status of 0-2; and
5. **Either:**
   - **5.1.** Patient has not received prior systemic therapy for their disease in the palliative setting**; or**
   - 5.2. **Both:**
     - **5.2.1. Patient has experienced treatment-limiting toxicity from treatment with atezolizumab with bevacizumab; and**
     - **5.2.2. No disease progression since initiation of atezolizumab with bevacizumab.**

Renewal – (unresectable hepatocellular carcinoma) only from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

resolved to amend the hospital indication restrictions for lenvatinib in Part II of Section H of the Pharmaceutical Schedule from 1 March 2025 as follows (additions in **bold**, deletions in ~~strikethrough~~, affected criteria shown only):

Restricted
Initiation – unresectable hepatocellular carcinoma
Re-assessment required after 6 months

All of the following:
1. Patient has unresectable hepatocellular carcinoma; and
2. Patient has preserved liver function (Childs-Pugh A); and
3. Transarterial chemoembolisation (TACE) is unsuitable; and
4. Patient has an ECOG performance status of 0-2; and
5. **Either:**
    - **5.1.** Patient has not received prior systemic therapy for their disease in the palliative setting**; or**
    - **5.2.** **Both:**
        - **5.2.1.** **Patient has experienced treatment-limiting toxicity from treatment with atezolizumab with bevacizumab; and**
        - **5.2.2.** **No disease progression since initiation of atezolizumab with bevacizumab.**

Continuation – unresectable hepatocellular carcinoma
Re-assessment required after 6 months
There is no evidence of disease progression

noted that consultation on this proposal was appropriate and no further consultation is required.

2. Update on supply and access to liraglutide for type 2 diabetes

This paper was provided to the Board on Pharmac's work to reinstate the previous eligibility criteria for starting on liraglutide (brand name Victoza), a medicine used in the management of type 2 diabetes. This would allow new patients to start on liraglutide, following removal of this option in May 2024, due to supply issues. Liraglutide is currently only funded for use in existing patients.

There is a small window of opportunity to secure more supply, while staff continue to work on other criteria.

The Board:

noted and **agreed** to the proposed approach for reinstatement of previous criteria for liraglutide.

3. Update on the progress of the Health Sector Agreements and Payments (HSAAP) Programme

This paper provided the Board with a brief update on the Health Sector Agreements and Payments (HSAAP) programme and work that Pharmac has underway with Health NZ to support their delivery of the HSAAP programme. The programme is currently in a discovery and design stage as they develop their delivery plans and high-level design documents.

The Board:

noted that staff formed an internal Governance Group to oversee Pharmac's work to support implementation of the HSAAP programme. The members of this group are the Directors of Strategy, Policy and Performance, Corporate, and Pharmaceuticals

noted Pharmac has worked with Health NZ on the development of a joint programme delivery plan

noted Pharmac is working closely with Health NZ to ensure the successful delivery of the initial delivery phase for community pharmacy payments

noted staff have developed an internal Pharmac Project plan and schedule which will be finalised following agreement of the joint programme plan

noted Pharmac is working with Health NZ on a security review to determine the risks of our current IT systems

noted that Pharmac has requested one-off funding from Health NZ to provide additional staff to support work required to deliver the programme

noted that Pharmac's overall project work is on track at this time, however, additional funding for Pharmac may be required to maintain this status as there is likely work on our aging IT systems and processes required to accommodate the HSAAP changes

noted that Pharmac has a Solution Architect conducting a detailed risk analysis to inform options for potential upgrades to our aging schedule systems to accommodate changes that may be required.

4. Update on funded access to alternative brands of oestradiol patches

This paper provided the Board with an update on work responding to stakeholder feedback about oestradiol patches. The paper summarised this work to the Board and sought the Board's agreement with the proposed approach, given the significant interest in this topic and the risks associated.

The paper outlined a number of risks for the Board to consider with the proposed approach as follows: the financial impact to the medicines budget, limited supply of Estradot due to manufacturing issues, expected ongoing supply issues with Estradot and helping the public to understand how Estradot supply issues may affect them.

The Board commented that communication about oestradiol patches should continue to be proactive, with key messages that focus on the impact for people who use oestradiol patches. The Board commented that for future brand changes in any market, communication and implementation should be better refined to ensure distress is minimised. Staff noted that work is underway to improve the consultation process through the annual tender.

The Board:

agreed with the proposed approach to consult on a proposal to fund the Estradot brand of oestradiol patches alongside the principal brand (Estradiol TDP Mylan), and the proposed timings for this approach subject to commercial negotiations

noted the risks associated with this approach, in particular that there may not be enough supply of Estradot for everyone who wants it

noted the estimated budgetary impact of an updated proposal would be a cost of approximately [redacted] to the medicines budget, subject to commercial negotiations.

The meeting closed at 2.10pm with a karakia.

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Date of Next Meeting: 24/25 February 2025

Approved *25 March*

Hon Paula Bennett, Chair Date