PHARMAC
TE PĀTAKA WHAIORANGA

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Some information may have been redacted for reasons including confidentiality

Minutes of Out of Cycle Board Meeting

Held 9 February 2024 at 2.00pm

Via Microsoft teams

Present:

Board members

Dr Peter Bramley (BSc (Hon), LL.B, PhD)	Acting Chair
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	Board member
Dr Margaret Wilsher (MD, FRACP, FRACMA)	Board member
Dr Anthony Jordan (BHB, MBChB, FRACP)	Board member

Apologies

Dr Diana Siew (PhD)	Board member

Pharmac staff in attendance

Sarah Fitt	Chief Executive
Geraldine MacGibbon	Director, Pharmaceuticals
David Hughes	Director, Advice and Assessment/CMO
Jacqui Webber	Minute taker
Adrienne Martin	Manager, Pharmaceutical Funding
Jared Solloway	Senior Therapeutic Group Manager

Novartis multiproduct proposal to fund treatments for breast cancer and leukaemia

This paper sought a decision from the Board on a significant pharmaceutical transaction, which would result in funding new treatment for breast cancer and leukaemia and amendments to contractual arrangements for already funded treatments, that would release [redacted] funds to reinvest in other medicines.

Recommendations

The Board:

resolved to approve the listing of ribociclib (Kisqali) on the Pharmaceutical Schedule

resolved to approve the listing of midostaurin (Rydapt) on the Pharmaceutical Schedule

resolved to approve the amendments to the Pharmaceutical Schedule relating to sacubitril with valsartan (Entresto)

resolved to approve the 6 December 2023 agreement with Novartis New Zealand Ltd (Novartis)

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

Resolutions for Novartis multiproduct proposal to fund treatments for breast cancer and leukaemia

Ribociclib

resolved to list ribociclib (Kisqali) 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 July 2024 as follows:

Chemical	Presentation	Brand	Pack size	Proposed price and subsidy
Ribociclib	Tab 200 mg	Kisqali	21	$1,883.00
Ribociclib	Tab 200 mg	Kisqali	42	$3,767.00
Ribociclib	Tab 200 mg	Kisqali	63	$5,650.00

resolved to list ribociclib in Section B of the Pharmaceutical Schedule subject to the following Special Authority criteria from 1 July 2024:

Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Patient has unresectable locally advanced or metastatic breast cancer; and
2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
3 Patient has an ECOG performance score of 0-2; and
4 Either:
  4.1 Disease has relapsed or progressed during prior endocrine therapy (second or subsequent line setting); or
  4.2 Both:
  first-line setting
    4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state; and
    4.2.2 Patient has not received prior systemic endocrine treatment for metastatic disease; and
5 Treatment to be used in combination with an endocrine partner; and
6 Patient has not received prior funded treatment with a CDK4/6 inhibitor.

Renewal – 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

resolved to apply wastage claimable to ribociclib in Section B of the Pharmaceutical Schedule from 1 July 2024

resolved to list ribociclib in Part II of Section H of the Pharmaceutical Schedule subject to the following hospital indication restriction from 1 July 2024:

Restricted
Initiation
Reassessment required after 6 months
All of the following:

1 Patient has unresectable locally advanced or metastatic breast cancer; and
2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
3 Patient has an ECOG performance score of 0-2; and
4 Either:
  4.1 Disease has relapsed or progressed during prior endocrine therapy (second or subsequent line setting); or
  4.2 Both:
  first line setting
    4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state; and

4.2.2 Patient has not received prior systemic endocrine treatment for metastatic disease; and
5 Treatment to be used in combination with an endocrine partner; and
6 Patient has not received prior funded treatment with a CDK4/6 inhibitor.

Continuation
Reassessment required after 12 months
Both:
1. Treatment to be used in combination with an endocrine partner; and
2. There is no evidence of progressive disease

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

noted that Kisqali would have subsidy and delisting protection until 1 July 2027

Palbociclib

resolved to remove the Specialist Endorsement requirement for palbociclib (Ibrance) in Section B of the Pharmaceutical Schedule from 1 July 2024

resolved to amend the Special Authority for palbociclib (Ibrance) in Section B of the Pharmaceutical Schedule from 1 July 2024 as follows (additions in **bold**, deletions in ~~strikethrough~~):

Special Authority for Subsidy
Initial application – ~~only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist~~ **from any relevant practitioner**. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1 Patient has unresectable locally advanced or metastatic breast cancer; and
2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
3 Patient has an ECOG performance score of 0-2; and
4 Either:
4.1 Disease has relapsed or progressed during prior endocrine therapy (second or subsequent line setting); or
4.2 Both:
first line setting
4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal **or without menstrual-potential state**; and
4.2.2 Patient has not received prior systemic endocrine treatment for metastatic disease; **and** ~~or~~
~~4.2.2.1. Patient commenced treatment with palbociclib in combination with an endocrine agent prior to 1 April 2020; and~~
~~4.2.2.2. Patient has not received prior systemic endocrine treatment for metastatic disease; and~~
~~4.2.2.3. There is no evidence of disease progression; and~~
5 Treatment to be used in combination with an endocrine partner; and
6 **Patient has not received prior funded treatment with a CDK4/6 inhibitor**.

Renewal – ~~only from a medical oncologist or medical practitioner on the recommendation of a Medical oncologist.~~ **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~~; and~~
~~3 The treatment remains appropriate and the patient is benefitting from treatment.~~

resolved to amend the hospital indication restriction for palbociclib (Ibrance) in Part II of Section H of the Pharmaceutical Schedule from 1 July 2024 as follows (additions in **bold**, deletions in ~~strikethrough~~):

Restricted
Initiation
~~Medical oncologist~~ *Reassessment required after 6 months*
All of the following:
1 Patient has unresectable locally advanced or metastatic breast cancer; and
2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
3 Patient has an ECOG performance score of 0-2; and

4 Either:

~~second or subsequent line setting~~

4.1 Disease has relapsed or progressed during prior endocrine therapy **(second or subsequent line setting)**; or

4.2 Both:

first-line setting

4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal **or without menstrual-potential state**; and

4.2.2 ~~Either:~~ Patient has not received prior systemic endocrine treatment for metastatic disease; **and** ~~or~~

~~4.2.2.1 All of the following:~~

~~4.2.2.1. Patient commenced treatment with palbociclib in combination with an endocrine agent prior to 1 April 2020; and~~

~~4.2.2.2. Patient has not received prior systemic endocrine treatment for metastatic disease; and~~

~~4.2.2.3. There is no evidence of disease progression; and~~

5 Treatment to be used in combination with an endocrine partner**; and**

6 **Patient has not received prior funded treatment with a CDK4/6 inhibitor.**

Continuation

~~Medical oncologist~~

Reassessment required after 12 months

~~All of the following~~ **Both**:

1. Treatment to be used in combination with an endocrine partner; and
2. There is no evidence of progressive disease~~; and~~
3. ~~The treatment remains appropriate and the patient is benefitting from treatment.~~

Midostaurin

resolved to list midostaurin (Rydapt) 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 July 2024 as follows:

Chemical	Presentation	Brand	Pack size	Proposed price and subsidy
Midostaurin	Cap 25 mg	Rydapt	56	$10,981.00

resolved to apply PCT only to midostaurin in Section B of the Pharmaceutical Schedule from 1 July 2024

resolved to list midostaurin in Section B of the Pharmaceutical Schedule subject to the following Special Authority criteria from 1 July 2024:

Special Authority for Subsidy

Initial application — from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

1. Patient has a diagnosis of acute myeloid leukaemia; and
2. Condition must be FMS tyrosine kinase 3 (FLT3) mutation positive; and
3. Patient must not have received a prior line of intensive chemotherapy for acute myeloid leukaemia; and
4. Patient is to receive standard intensive chemotherapy in combination with midostaurin only; and
5. Midostaurin to be funded for a maximum of 4 cycles.

resolved to list midostaurin in Part II of Section H of the Pharmaceutical Schedule subject to the following hospital indication restriction from 1 July 2024:

Restricted

Initiation

All of the following:

1. Patient has a diagnosis of acute myeloid leukaemia; and
2. Condition must be FMS tyrosine kinase 3 (FLT3) mutation positive; and
3. Patient must not have received a prior line of intensive chemotherapy for acute myeloid leukaemia; and

4. Patient is to receive standard intensive chemotherapy in combination with midostaurin only; and
5. Midostaurin to be funded for a maximum of 4 cycles.

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

noted that Rydapt would have subsidy and delisting protection until 1 July 2027.

Sacubitril with valsartan

resolved to amend the Special Authority criteria for sacubitril with valsartan in Section B of the Pharmaceutical Schedule from 1 March 2024 as follows **(**amendments in **bold,** deletions in ~~strikethrough~~**):**

Initial application — from any relevant practitioner. Approvals valid ~~for 12 months~~ **without further renewal unless notified** for applications meeting the following criteria:
All of the following:

1. Patient has heart failure; and
    - 1.1. Patient Is in NYHA/WHO functional class II; or
    - 1.2. Patient is in NYHA/WHO functional class III; or
    - 1.3. Patient is in NYHA/WHO functional class IV; and
2. Patient has documented left ventricular ejection fraction of less than or equal to 35%; or
3. An ECHO is not reasonably practical, and in the opinion of the treating practitioner the patient would benefit from treatment; and
4. Patient is receiving concomitant optimal standard chronic heart failure treatments

~~Renewal application – from any relevant practitioner. Approvals valid for 12 months for applications where the treatment remains appropriate and the patient is benefiting from treatment.~~

resolved to amend the Hospital Medicine Restriction for sacubitril with valsartan in Part II of Section H of the Pharmaceutical Schedule from 1 March 2024 as follows (amendments in **bold**, deletions in ~~strikethrough~~):

Initiation
~~*Reassessment required after 12 months*~~
All of the following:

1. Patient has heart failure; and
    - 1.1. Patient Is in NYHA/WHO functional class II; or
    - 1.2. Patient is in NYHA/WHO functional class III; or
    - 1.3. Patient is in NYHA/WHO functional class IV; and
2. Patient has documented left ventricular ejection fraction of less than or equal to 35%; or
3. An ECHO is not reasonably practical, and in the opinion of the treating practitioner the patient would benefit from treatment; and
4. Patient is receiving concomitant optimal standard chronic heart failure treatments

~~Continuation~~
~~*Reassessment required after 12 months where treatment remains appropriate and patient is benefiting from treatment*~~

noted a new confidential rebate would apply to Entresto that would further reduce the net price to the Funder from 1 March 2024

noted that Entresto would have subsidy and delisting protection until 1 March 2027.

Anthony Jordan/Margaret Wilsher ***Carried***

Approved:

Approved *28 March 2024*

Peter Bramley, Acting Board Chair Date