VERSION FOR PUBLIC RELEASE, SOME INFORMATION MAY HAVE BEEN EXCLUDED DUE TO CONFIDENTIALITY

MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING NOVEMBER 2019

The meeting was held at Level 9, 40 Mercer Street, Wellington, starting at 9:15am with the following attendees:

Board members

Steve Maharey	Chair
Jan White	Deputy Chair
Ross Lawrenson	Board Member
Nicole Anderson	Board Member
Claudia Wyss	Board Member
David Lui	Observer, CAC Chair
Stephen Munn	Observer, Acting PTAC Chair
Peter Bramley	Observer, DHB Representative

PHARMAC staff in attendance

Sarah Fitt	Chief Executive
Lisa Williams	Director of Operations
Alison Hill	Director of Engagement & Implementation
Michael Johnson	Director of Strategic Initiatives
Mark Woodard	Director of Corporate Services/CFO
Ken Clark	Acting Medical Director
Lizzy Cohen	Board Secretary

April-Mae Marshall, Janet Mackay, Alyssa Currie, Geraldine MacGibbon, Sarah Beri, Danae Staples-Moon, Adrienne Martin, Jeremy Price, Katie Brownless, Sarah Le Leu, Josh Wiles, Lindsay Ancelet, Catherine Proffitt, Rachel Read, Rachel Watt, Jannel Fisher (PHARMAC staff) attended for relevant items.

1. Directors' Only Discussion

1.3 Board Cultural Competence

noted the paper presented by Nicole Anderson for Board discussion.

1.4 Update on Board Reporting and External Engagement

noted the contents of this paper to support Board discussion; and

noted and agreed to the updated Annual Board Agenda 2020.

2. Apologies

Mark Weatherall, Observer, PTAC Chair.

3. Record of Previous Board and Committee Meetings

3.1 Minutes of October 2019 Board Meeting

resolved to adopt the minutes of the October 2019 meeting as being a true and correct record.

Nicole and Ross Lawrenson **(carried)**

3.2 Minutes of October Health and Safety Committee Meeting

noted the minutes of the October 2019 Health and Safety Committee meeting.

4. Interests Register

noted the interests register; and

noted any decisions by the Chair to manage actual or potential conflicts of interest, as follows:

[None required]

5. Matters Arising

noted the matter's arising.

6. Chair's Report

6.1 Verbal Report

noted the Chair's verbal report.

6.2 Correspondence

noted the correspondence report.

7. Chief Executive's Report

noted the Chief Executive's Report.

noted the update on staff turnover and the next update to be provided to the Board in January 2020.

The Board discussed the recent brand switches and identified the need to partner more with pharmacists and general practitioners for future brand switches

The Board requested staff add a report to the Board annual agenda on the People and Capability Strategy, once finalised. The Board would like more comprehensive reporting on staff culture, impact on staff relating to the external environment and other organisational issues, if any.

8. Key Items

8.1 Final Combined Pharmaceutical Budget Bid 2020/21

noted the contents of this paper.

8.2 Summary Risk Report

noted the contents of this report; and

noted that a paper on a revised risk framework will be presented early in 2020.

8.3 Proposed Appointment to the Pharmacology and Therapeutics Advisory Committee (PTAC)

noted the contents of this report;

resolved to recommend to the Director-General of Health the appointment of proposed members of Pharmacology and Therapeutics Advisory Committee (PTAC) below;

- Rhiannon Braund
- Bruce King
- Lisa Stamp
- Elizabeth Dennett.

noted that staff have a programme of work underway regarding PHARMAC's clinical advisory network and future recruitment of new members. Staff will keep the Board updated as this work progresses.

Jan White and Nicole Anderson (carried)

8.4 PHARMAC's approach to brand changes

noted the contents of this paper.

9. Schedule and Funding

9.1 Medical Devices Transaction and Investment Report

noted the contents of this paper.

9.2 Pharmaceutical Expenditure and Transaction Report

noted that this is a new report that combines the previous Pharmaceutical Transactions and Investments and Expenditure reports; and

noted the contents of this paper.

9.3 AstraZeneca Multiproduct Proposal

resolved to approve the amendments to the Pharmaceutical Schedule relating to olaparib, fulvestrant and gefitinib as set out below;

resolved to approve the 20 September 2019 agreement with AstraZeneca Pty Limited; and

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

Olaparib

resolved to list olaparib in the Oncology Agents and Immunosuppressants Therapeutic Group (Chemotherapeutic agents – Other Cytotoxic Agents subgroup) of Section B and Part II of Section H of the Pharmaceutical Schedule, from 1 February 2020, as follows (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Olaparib	Cap 50 mg	Lynparza	448	$7,402.00
Olaparib	Tab 100 mg	Lynparza	56	$3,701.00
Olaparib	Tab 150 mg	Lynparza	56	$3,701.00

resolved to apply the wastage rule to olaparib (Lynparza) cap 50 mg in Section B of the Pharmaceutical Schedule from 1 February 2019;

resolved to apply the following Special Authority to olaparib in Section B of the Pharmaceutical Schedule from 1 February 2020:

Special Authority for Subsidy – Retail Pharmacy - Specialist
Initial application - only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1. Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
3. Patient has received at least two lines of previous treatment with platinum-based chemotherapy; and
4. Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line of platinum-based chemotherapy; and
5. Patient's disease must have achieved partial or complete response to treatment with the immediately preceding platinum-based regimen; and
6. Patient's disease has not progressed following prior treatment with olaparib; and
7. Treatment will be commenced within 8 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
8. Treatment to be administered as maintenance treatment; and
9. Treatment not to be administered in combination with other chemotherapy.

Renewal – only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1. Treatment remains clinically appropriate and patient is benefitting from treatment; and
2. No evidence of progressive disease; and
3. Treatment to be administered as maintenance treatment; and
4. Treatment not to be administered in combination with other chemotherapy.

*Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component

resolved to apply the following restrictions to olaparib in Part II of Section H of the Pharmaceutical Schedule, from 1 February 2020, as follows:

Restriction
Initiation
Medical Oncologist
Re-assessment required after 12 months
All of the following:

1. Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
3. Patient has received at least two lines of previous treatment with platinum-based chemotherapy; and
4. Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line of platinum-based chemotherapy; and
5. Patient's disease must have achieved partial or complete response to treatment with the immediately preceding platinum-based regimen; and
6. Patient's disease has not progressed following prior treatment with olaparib; and
7. Treatment will be commenced within 8 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
8. Treatment to be administered as maintenance treatment; and
9. Treatment not to be administered in combination with other chemotherapy.

Continuation
Medical Oncologist
Re-assessment required after 12 months
All of the following:
1. Treatment remains clinically appropriate and patient is benefitting from treatment; and
2. No evidence of progressive disease; and
3. Treatment to be administered as maintenance treatment; and
4. Treatment not to be administered in combination with other chemotherapy.

*Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component

noted a confidential rebate would apply to Lynparza that would reduce the net price to the Funder; and

noted Lynparza would have protection from delisting and subsidy reduction until 31 January 2023.

Fulvestrant

resolved to list fulvestrant in the Oncology Agents and Immunosuppressants Therapeutic Group (Endocrine Therapy) in Section B and Part II of Section H of the Pharmaceutical Schedule, at a date to be determined, as follows (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Fulvestrant	Inj 50 mg per ml, 5 ml prefilled syringe	Faslodex	2	$1,068.00

resolved to apply the following Special Authority to fulvestrant in Section B of the Pharmaceutical Schedule at a date to be determined:

Special Authority for Subsidy – Retail Pharmacy - Specialist
Initial application - only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer; and
2. Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease; and
3. Patient is amenorrhoeic for 12 months or greater, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and

4. Treatment to be given at a dose of 500 mg monthly following loading doses; and
5. Treatment to be discontinued at disease progression.

Renewal – only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Treatment remains appropriate and patient is benefitting from treatment; and
2. Treatment to be given at a dose of 500 mg monthly; and
3. No evidence of disease progression.

resolved to apply the following restrictions to fulvestrant in Part II of Section H of the Pharmaceutical Schedule, at a date to be determined:

Initiation
Medical Oncologist
Re-assessment required after 6 months
All of the following:
1. Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer; and
2. Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease; and
3. Patient is amenorrhoeic for 12 months or greater, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and
4. Treatment to be given at a dose of 500 mg monthly following loading doses; and
5. Treatment to be discontinued at disease progression.

Continuation
Medical Oncologist
Re-assessment required after 6 months
All of the following:
1. Treatment remains appropriate and patient is benefitting from treatment; and
2. Treatment to be given at a dose of 500 mg monthly; and
3. No evidence of disease progression.

noted a confidential rebate would apply to Faslodex that would reduce the net price to the Funder;

noted Faslodex would have protection from delisting and subsidy reduction until 30 June 2021; and

noted that Faslodex would be listed as soon as reasonably practicable following Medsafe approval.

Gefitinib

resolved to maintain the current price and subsidy for gefitinib (Iressa) tab 250 mg in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 February 2020 as follows (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Gefitinib	tab 250 mg	Iressa	30	$1,700.00

noted a new confidential rebate would apply to Iressa that would reduce the net price to the Funder;

noted there would be no changes to the current Special Authority criteria or hospital restrictions for gefitinib (Iressa); and

noted Iressa would have protection from delisting and subsidy reduction until 31 January 2023.

Jan White and Claudia Wyss (carried)

9.4 Proposal to award sole supply of apomorphine hydrochloride

resolved to accept the tender from Stada Pharmaceuticals Australia Pty Ltd ("Stada") for Movapo to be the sole subsidised brand of the Community Pharmaceutical apomorphine hydrochloride inj 10 mg per ml, 2 ml ampoule from 1 January 2020 until 30 June 2023;

resolved to accept the tender from Stada Pharmaceuticals Australia Pty Ltd ("Stada") for Movapo to be the Hospital Supply Status brand of the Hospital Pharmaceutical apomorphine hydrochloride inj 10 mg per ml, 2 ml ampoule, with a DV limit of 1%, from 1 January 2020 until 30 June 2023;

resolved to amend the price and subsidy of apomorphine hydrochloride (Movapo) inj 10 mg per ml, 2 ml ampoule in the Nervous System, therapeutic group Dopamine Agonists and Related Agents in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 January 2020, as follows:

Chemical	**Presentation**	**Brand**	**Pack Size**	**Current price and subsidy** (ex-man., ex. GST)	**Price and subsidy** (ex-man., ex. GST)
Apomorphine hydrochloride	Inj 10 mg per, 2 ml ampoule	Movapo	5	$ 119.00	$59.50

resolved to accept the tender from Stada Pharmaceuticals Australia Pty Ltd ("Stada") for Movapo to be the sole subsidised brand of the Community Pharmaceutical apomorphine hydrochloride inj 10 mg per ml, 5 ml ampoule from 1 February 2020 until 30 June 2023;

resolved to accept the tender from Stada Pharmaceuticals Australia Pty Ltd ("Stada") for Movapo to be the Hospital Supply Status brand of the Hospital Pharmaceutical apomorphine hydrochloride inj 10 mg per ml, 5 ml ampoule, with a DV limit of 1%, from 1 February 2020 until 30 June 2023;

resolved to list apomorphine hydrochloride (Movapo) inj 10 mg per ml, 5 ml ampoule in the Nervous System, therapeutic group Dopamine Agonists and Related Agents in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 February 2020, as follows:

Chemical	**Presentation**	**Brand**	**Pack Size**	**Price and subsidy** (ex-man., ex. GST)
Apomorphine hydrochloride	Inj 10 mg per ml, 5 ml ampoule	Movapo	5	$121.84

noted that acceptance of this proposal would not result in a brand change for apomorphine hydrochloride;

noted that the acceptance of this proposal would result in the provision of infusion pumps, on loan and at no cost to patients (the cost would be met by Stada as a requirement of the funding agreement with PHARMAC);

noted that acceptance of this proposal would result in the provision of continuous infusion and intermittent injection consumables supplied to patients at no cost to patients (the cost would be met by Stada as a requirement of the funding agreement with PHARMAC);

resolved to approve the 21 October 2019 agreement with Stada New Zealand Limited; and

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

Claudia Wyss and Nicole Anderson (carried)

9.5 Proposal to widen access and award sole supply of rituximab

resolved to approve 19 November 2019 provisional agreement with Novartis New Zealand Limited;

noted that the acceptance of this proposal would result in a brand change for rituximab;

noted the proposed implementation activities should the proposal be approved (Appendix Two);

noted the summary of consultation feedback and full copies of consultation responses (Appendix Three);

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

resolved to approve the changes to the Pharmaceutical Schedule below:

Resolutions for the rituximab funding proposal

resolved to list rituximab (Riximyo) inj 100 mg per ml 10 ml vial, inj 500 mg per 50 ml vail and inj 1 mg for ECP in the Oncology agents and Immunosuppressants therapeutic group in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 March 2020 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Rituximab (Riximyo)	Inj 100 mg per 10 ml vial	Riximyo	2	$275.33
Rituximab (Riximyo)	Inj 500 mg per 50 ml vial	Riximyo	1	$688.20
Rituximab (Riximyo)	Inj 1 mg for ECP	Baxter	1 mg	$1.38

resolved to amend the chemical name for rituximab to rituximab (Mabthera) in the Oncology agents and Immunosuppressants therapeutic group in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 March 2020;

resolved to list rituximab (Riximyo) in Section B of the Pharmaceutical Schedule subject to the following subsidy restrictions from 1 March 2020:

PCT only - Specialist
Special Authority for Subsidy
Initial application — (ABO-incompatible organ transplant) from any relevant practitioner. Approvals valid without further renewal unless notified where patient is to undergo an ABO-incompatible solid organ transplant*.
Note: Indications marked with * are unapproved indications.

Initial application — (ANCA associated vasculitis) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:
All of the following:
1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks; and
3 Any of the following:
- 3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or
- 3.2 Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g; or
- 3.3 Cyclophosphamide and methotrexate are contraindicated; or
- 3.4 Patient is a female of child-bearing potential; or
- 3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

Note: Indications marked with * are unapproved indications.

Renewal — (ANCA associated vasculitis) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:
All of the following:
1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
3 The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks.
Note: Indications marked with * are unapproved indications.

Initial application — (Antibody-mediated organ transplant rejection) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has been diagnosed with antibody-mediated organ transplant rejection*.
Note: Indications marked with * are unapproved indications.

Initial application — (Chronic lymphocytic leukaemia) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
2. Any of the following:
- 2.1. The patient is rituximab treatment naive; or
- 2.2 Either:
  - 2.2.1 The patient is chemotherapy treatment naive; or
  - 2.2.2 Both:
    - 2.2.2.1. The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and

2.2.2.2. The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; or

2.3. The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and

3 The patient has good performance status; and

4. Either:

4.1 The patient does not have chromosome 17p deletion CLL; or

4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and

5. Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and

6. It is planned that the patient receives full dose fludarabine, cyclophosphamide (orally or dose equivalent intravenous administration) bendamustine or venetoclax.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

Renewal — (Chronic lymphocytic leukaemia) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

1 Either:

1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or

1.2 All of the following:

1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and

1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and

1.2.3 The patient does not have chromosome 17p deletion CLL; and

1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and

2 Rituximab to be administered in combination with fludarabine and cyclophosphamide or bendamustine for a maximum of 6 treatment cycles.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

Initial application — (Neuromyelitis Optica Spectrum Disorder (NMOSD)) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m^2 administered weekly for four weeks; and

2 Either:

2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or

2.2 All of the following:

2.2.1 The patient has experienced a breakthrough attack of NMOSD; and

2.2.2 The patient is receiving treatment with mycophenolate; and

2.2.3 The patient is receiving treatment with corticosteroids.

Renewal — (Neuromyelitis Optica Spectrum Disorder) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:
1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m^2 administered weekly for four weeks; and
2 The patient has responded to the most recent course of rituximab; and
3 The patient has not received rituximab in the previous 6 months.

Initial application — (Post-transplant) from any relevant practitioner. Approvals valid for 12 months for applications meeting
the following criteria:
Both:
1 The patient has B-cell post-transplant lymphoproliferative disorder*; and
2 To be used for a maximum of 8 treatment cycles.
Note: Indications marked with * are unapproved indications.

Renewal — (Post-transplant) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:
1 The patient has had a rituximab treatment-free interval of 12 months or more; and
2 The patient has B-cell post-transplant lymphoproliferative disorder*; and
3 To be used for no more than 6 treatment cycles.
Note: Indications marked with * are unapproved indications.

Initial application — (Severe Refractory Myasthenia Gravis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years for applications meeting the following criteria:
Both:
1 One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
2 Either:
    2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective; or
    2.2 Both:
        2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and
        2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

Renewal — (Severe Refractory Myasthenia Gravis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:
1 One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
2 An initial response lasting at least 12 months was demonstrated; and
3 Either:
    3.1 The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months; or
    3.2 Both:
        3.2.1 The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months; and
        3.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

Initial application — (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:
All of the following:
1 Patient is a child with SDNS* or FRNS*; and
2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and
3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and
4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
5 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.
Note: Indications marked with * are unapproved indications.

Renewal — (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:
All of the following:
1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.
Note: Indications marked with * are unapproved indications.

Initial application — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:
All of the following:
1 Patient is a child with SRNS* where treatment with steroids and ciclosporin for at least 3 months have been ineffective; and
2 Treatment with tacrolimus for at least 3 months has been ineffective; and
3 Genetic causes of nephrotic syndrome have been excluded; and
4 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.
Note: Indications marked with * are unapproved indications.

Renewal — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:
All of the following:
1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.
Note: Indications marked with * are unapproved indications.

Initial application — (aggressive CD20 positive NHL) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Either:
1 All of the following:
    1.1 The patient has treatment naive aggressive CD20 positive NHL; and
    1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and

1.3 To be used for a maximum of 8 treatment cycles; or
2 Both:
2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
2.2 To be used for a maximum of 6 treatment cycles.
Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

Renewal — (aggressive CD20 positive NHL) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1 The patient has had a rituximab treatment-free interval of 12 months or more; and
2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
4 To be used for a maximum of 4 treatment cycles.
Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

Initial application — (haemophilia with inhibitors) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months for applications meeting the following criteria:
Any of the following:
1 Patient has mild congenital haemophilia complicated by inhibitors; or
2 Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy; or
3 Patient has acquired haemophilia.

Renewal — (haemophilia with inhibitors) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1 Patient was previously treated with rituximab for haemophilia with inhibitors; and
2 An initial response lasting at least 12 months was demonstrated; and
3 Patient now requires repeat treatment.

Initial application — (immune thrombocytopenic purpura (ITP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:
Both:
1 Either:
1.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre; or
1.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
2 Any of the following:
2.1 Treatment with steroids and splenectomy have been ineffective; or
2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy).
Note: Indications marked with * are unapproved indications.

Renewal — (immune thrombocytopenic purpura (ITP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned; or

2 All of the following:
- 2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura*; and
- 2.2 An initial response lasting at least 12 months was demonstrated; and
- 2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Initial application — (indolent, low-grade lymphomas or hairy cell leukaemia*) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:
Either:
1 Both:
- 1.1 The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and
- 1.2 To be used for a maximum of 6 treatment cycles; or

2 Both:
- 2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy; and
- 2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

Renewal — (indolent, low-grade lymphomas or hairy cell leukaemia*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Either:
1. All of the following:
   - 1.1 The patient has had a rituximab treatment-free interval of 12 months or more; and
   - 1.2 The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and
   - 1.3 To be used for no more than 6 treatment cycles; or

2. Both:
   - 2.1 Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy, and
   - 2.2 Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m^2 every 8 weeks (maximum of 12 cycles).

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

Initial application — (pure red cell aplasia (PRCA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks where patient has autoimmune pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder.
Note: Indications marked with * are unapproved indications.

Renewal — (pure red cell aplasia (PRCA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks where patient was previously treated with rituximab for pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months.
Note: Indications marked with * are unapproved indications.

Initial application — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:
Both:
1 Patient has cold haemagglutinin disease*; and

2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms.

Note: Indications marked with * are unapproved indications.

Renewal — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Either:

1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned; or

2 All of the following:

2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease*; and

2.2 An initial response lasting at least 12 months was demonstrated; and

2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Initial application — (thrombotic thrombocytopenic purpura (TTP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Either:

1 Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or

2 Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology.

Note: Indications marked with * are unapproved indications.

Renewal — (thrombotic thrombocytopenic purpura (TTP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura*; and

2 An initial response lasting at least 12 months was demonstrated; and

3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Initial application — (treatment refractory systemic lupus erythematosus (SLE)) only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 7 months for applications meeting the following criteria:

All of the following:

1 The patient has severe, immediately life- or organ-threatening SLE*; and

2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and

3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and

4 Maximum of four 1,000 mg infusions of rituximab.

Note: Indications marked with * are unapproved indications.

Renewal — (treatment refractory systemic lupus erythematosus (SLE)) only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Patient's SLE* achieved at least a partial response to the previous round of prior rituximab treatment; and

2 The disease has subsequently relapsed; and

3 Maximum of two 1,000 mg infusions of rituximab.
Note: Indications marked with * are unapproved indications.

Initial application — (warm autoimmune haemolytic anaemia (warm AIHA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:
Both:
1 Patient has warm autoimmune haemolytic anaemia*; and
2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin.
Note: Indications marked with * are unapproved indications.

Renewal — (warm autoimmune haemolytic anaemia (warm AIHA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned; or
2 All of the following:
2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*; and
2.2 An initial response lasting at least 12 months was demonstrated; and
2.3 Patient now requires repeat treatment.
Note: Indications marked with * are unapproved indications.

Initial application – (severe antisynthetase syndrome) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. Patient has confirmed antisynthetase syndrome; and
2. Patient has severe, immediately life or organ threatening disease, including interstitial lung disease; and
3. Either:
   3.1 Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease; or
   3.2 Rapid treatment is required due to life threatening complications; and
4. Maximum of four 1,000mg infusions of rituximab.

Renewal – (severe antisynthetase syndrome) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function; and
2. The patient has not received rituximab in the previous 6 months; and
3. Maximum of two cycles of 2 x 1,000mg infusions of rituximab given two weeks apart.

Initial application – (graft versus host disease) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria.
All of the following:
1. Patient has refractory graft versus host disease following transplant; and
2. Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease; and

3. The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.

Initial application – (severe chronic inflammatory demyelinating polyneuropathy) only from a neurologist or any medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria.
All of the following
1. Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD); and
2. Either
    2.1 Both
        2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and
        2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
    2.2 Rapid treatment is required due to life threatening complications; and
3. One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Renewal – (severe chronic inflammatory demyelinating polyneuropathy) only from a neurologist or any medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria.
All of the following:
1. Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function compared to baseline; and
2. The patient has not received rituximab in the previous 6 months; and
3. One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Initial application – (anti-NMDA receptor autoimmune encephalitis) only from a neurologist or any medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria.
All of the following
1. Patient has severe anti-NMDA receptor autoimmune encephalitis; and
2. Either
    2.1 Both
        2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease;
        2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
    2.2 Rapid treatment is required due to life threatening complications; and
3. One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Renewal – (anti-NMDA receptor autoimmune encephalitis) only from a neurologist or any medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria.
All of the following:
1. Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function; and
2. The patient has not received rituximab in the previous 6 months; and
3. The patient has experienced a relapse and now requires further treatment; and

4. One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

resolved to list rituximab (Riximyo) in Part II of Section H of the Pharmaceutical Schedule subject to the following Indication Restrictions from 1 March 2020:

Restricted
Initiation – haemophilia with inhibitors
Haematologist
Any of the following:
1 Patient has mild congenital haemophilia complicated by inhibitors; or
2 Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy; or
3 Patient has acquired haemophilia.

Continuation – haemophilia with inhibitors
Haematologist
All of the following:
1 Patient was previously treated with rituximab for haemophilia with inhibitors; and
2 An initial response lasting at least 12 months was demonstrated; and
3 Patient now requires repeat treatment.

Initiation – post-transplant
Both:
1 The patient has B-cell post-transplant lymphoproliferative disorder*; and
2 To be used for a maximum of 8 treatment cycles.
Note: Indications marked with * are unapproved indications.
Continuation – post-transplant
All of the following:
1 The patient has had a rituximab treatment-free interval of 12 months or more; and
2 The patient has B-cell post-transplant lymphoproliferative disorder*; and
3 To be used for no more than 6 treatment cycles.
Note: Indications marked with * are unapproved indications.

Initiation – indolent, low-grade lymphomas or hairy cell leukaemia*
Re-assessment required after 9 months
Either:
1 Both:
- 1.1 The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and
- 1.2 To be used for a maximum of 6 treatment cycles; or

2 Both:
- 2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy; and
- 2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

Continuation – indolent, low-grade lymphomas or hairy cell leukaemia*
Re-assessment required after 12 months
Either:
1. All of the following:
   - 1.1 The patient has had a rituximab treatment-free interval of 12 months or more; and
   - 1.2 The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and
   - 1.3 To be used for no more than 6 treatment cycles; or

2. Both:
    2.1 Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy, and
    2.2 Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m^2 every 8 weeks (maximum of 12 cycles).

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

Initiation – aggressive CD20 positive NHL
Either:
1 All of the following:
    1.1 The patient has treatment naive aggressive CD20 positive NHL; and
    1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
    1.3 To be used for a maximum of 8 treatment cycles; or
2 Both:
    2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
    2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.

Continuation – aggressive CD20 positive NHL
All of the following:
1 The patient has had a rituximab treatment-free interval of 12 months or more; and
2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
4 To be used for a maximum of 4 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.

Initiation – Chronic lymphocytic leukaemia
Re-assessment required after 12 months
All of the following:
1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
2 Any of the following:
    2.1 The patient is rituximab treatment naive; or
    2.2 Either:
        2.2.1 The patient is chemotherapy treatment naive; or
        2.2.2 Both:
            2.2.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
            2.2.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; or
    2.3 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and
3 The patient has good performance status; and
4 Either:
    4.1 The patient does not have chromosome 17p deletion CLL; or
    4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and

6 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

Continuation – Chronic lymphocytic leukaemia
Re-assessment required after 12 months
Both:
1 Either:
- 1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or
- 1.2 All of the following:
  - 1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
  - 1.2.2 The patient has had an interval of 36 months or more since the commencement of initial rituximab treatment; and
  - 1.2.3 The patient does not have chromosome 17p deletion CLL; and
  - 1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and

2 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

Initiation – severe cold haemagglutinin disease (CHAD)
Haematologist
Re-assessment required after 4 weeks
Both:
1 Patient has cold haemagglutinin disease*; and
2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms.

Note: Indications marked with * are unapproved indications.

Continuation – severe cold haemagglutinin disease (CHAD)
Haematologist
Re-assessment required after 4 weeks
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned; or
2 All of the following:
- 2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease*; and
- 2.2 An initial response lasting at least 12 months was demonstrated; and
- 2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Initiation – warm autoimmune haemolytic anaemia (warm AIHA)
Haematologist
Re-assessment required after 4 weeks
Both:

1 Patient has warm autoimmune haemolytic anaemia*; and
2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin.
Note: Indications marked with * are unapproved indications.

Continuation – warm autoimmune haemolytic anaemia (warm AIHA)
Haematologist
Re-assessment required after 4 weeks
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned; or
2 All of the following:
    2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*; and
    2.2 An initial response lasting at least 12 months was demonstrated; and
    2.3 Patient now requires repeat treatment.
Note: Indications marked with * are unapproved indications.

Initiation – immune thrombocytopenic purpura (ITP)
Haematologist
Re-assessment required after 4 weeks
Both:
1 Either:
    1.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre; or
    1.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
2 Any of the following:
    2.1 Treatment with steroids and splenectomy have been ineffective; or
    2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
    2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy).
Note: Indications marked with * are unapproved indications.

Continuation – immune thrombocytopenic purpura (ITP)
Haematologist
Re-assessment required after 4 weeks
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned; or
2 All of the following:
    2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura*; and
    2.2 An initial response lasting at least 12 months was demonstrated; and
    2.3 Patient now requires repeat treatment.
Note: Indications marked with * are unapproved indications.

Initiation – thrombotic thrombocytopenic purpura (TTP)
Haematologist
Re-assessment required after 4 weeks
Either:
1 Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or

2 Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology.
Note: Indications marked with * are unapproved indications.

Continuation – thrombotic thrombocytopenic purpura (TTP)
Haematologist
Re-assessment required after 4 weeks
All of the following:
1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura*; and
2 An initial response lasting at least 12 months was demonstrated; and
3 Patient now requires repeat treatment.
Note: Indications marked with * are unapproved indications.

Initiation – pure red cell aplasia (PRCA)
Haematologist
Re-assessment required after 6 weeks
Patient has autoimmune pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder.
Note: Indications marked with * are unapproved indications.

Continuation – pure red cell aplasia (PRCA)
Haematologist
Re-assessment required after 6 weeks
Patient was previously treated with rituximab for pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months.
Note: Indications marked with * are unapproved indications.

Initiation – ANCA associated vasculitis
Re-assessment required after 4 weeks
All of the following:
1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks; and
3 Any of the following:
    3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or
    3.2 Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g; or
    3.3 Cyclophosphamide and methotrexate are contraindicated; or
    3.4 Patient is a female of child-bearing potential; or
    3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.
Note: Indications marked with * are unapproved indications.

Continuation – ANCA associated vasculitis
Re-assessment required after 4 weeks
All of the following:
1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
3 The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks.
Note: Indications marked with * are unapproved indications.

Initiation – treatment refractory systemic lupus erythematosus (SLE)
Rheumatologist or nephrologist

All of the following:
1 The patient has severe, immediately life- or organ-threatening SLE*; and
2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and
3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and
4 Maximum of four 1,000 mg infusions of rituximab.
Note: Indications marked with * are unapproved indications.

Continuation – treatment refractory systemic lupus erythematosus (SLE)
Rheumatologist or nephrologist
All of the following:
1 Patient's SLE* achieved at least a partial response to the previous round of prior rituximab treatment; and
2 The disease has subsequently relapsed; and
3 Maximum of two 1,000 mg infusions of rituximab.
Note: Indications marked with * are unapproved indications.

Initiation – Antibody-mediated organ transplant rejection
Patient has been diagnosed with antibody-mediated organ transplant rejection*.
Note: Indications marked with * are unapproved indications.

Initiation – ABO-incompatible organ transplant
Patient is to undergo an ABO-incompatible solid organ transplant*.
Note: Indications marked with * are unapproved indications.

Initiation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Nephrologist
Re-assessment required after 4 weeks
All of the following:
1 Patient is a child with SDNS* or FRNS*; and
2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and
3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and
4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
5 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.
Note: Indications marked with a * are unapproved indications.

Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Nephrologist
Re-assessment required after 4 weeks
All of the following:
1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for > 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.
Note: Indications marked with a * are unapproved indications.

Initiation – Steroid resistant nephrotic syndrome (SRNS)
Nephrologist
Re-assessment required after 4 weeks
All of the following:

1 Patient is a child with SRNS* where treatment with steroids and ciclosporin for at least 3 months have been ineffective; and
2 Treatment with tacrolimus for at least 3 months has been ineffective; and
3 Genetic causes of nephrotic syndrome have been excluded; and
4 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.
Note: Indications marked with a * are unapproved indications.

Continuation – Steroid resistant nephrotic syndrome (SRNS)
Nephrologist
Re-assessment required after 4 weeks
All of the following:
1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.
Note: Indications marked with a * are unapproved indications.

Initiation – Neuromyelitis Optica Spectrum Disorder (NMOSD)
Re-assessment required after 6 months
Both:
1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m^2 administered weekly for four weeks; and
2 Either:
    2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or
    2.2 All of the following:
        2.2.1 The patient has experienced a breakthrough attack of NMOSD; and
        2.2.2 The patient is receiving treatment with mycophenolate; and
        2.2.3 The patient is receiving treatment with corticosteroids.

Continuation – Neuromyelitis Optica Spectrum Disorder (NMOSD)
Re-assessment required after 2 years
All of the following:
1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m^2 administered weekly for four weeks; and
2 The patient has responded to the most recent course of rituximab; and
3 The patient has not received rituximab in the previous 6 months.

Initiation – Severe Refractory Myasthenia Gravis
Neurologist
Re-assessment required after 2 years
Both:
1 One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
2 Either:
    2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective; or
    2.2 Both:
        2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and
        2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

Continuation – Severe Refractory Myasthenia Gravis
Neurologist
Re-assessment required after 2 years
All of the following:
1 One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
2 An initial response lasting at least 12 months was demonstrated; and
3 Either:
- 3.1 The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months; or
- 3.2 Both:
  - 3.2.1 The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months; and
  - 3.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

Initiation – severe antisynthetase syndrome.
Re-assessment required after 12 months
All of the following:
1. Patient has confirmed antisynthetase syndrome; and
2. Patient has severe, immediately life or organ threatening disease, including interstitial lung disease; and
3. Either:
   - 3.1 Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease; or
   - 3.2 Rapid treatment is required due to life threatening complications; and
4. Maximum of four 1,000 mg infusions of rituximab.

Continuation - severe antisynthetase syndrome.
Re-assessment required after 12 months
All of the following:
1. Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function; and
2. The patient has not received rituximab in the previous 6 months; and
3. Maximum of two cycles of 2 x 1,000 mg infusions of rituximab given two weeks apart.

Initiation – graft versus host disease
All of the following:
1. Patient has refractory graft versus host disease following transplant; and
2. Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease; and
3. The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.

Initiation – severe chronic inflammatory demyelinating polyneuropathy)
Neurologist
Re-assessment required after 6 months
All of the following
1. Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD); and
2. Either
   - 2.1 Both

2.1.1. Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and

2.1 2. At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or

2.2 Rapid treatment is required due to life threatening complications; and

3. One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Continuation - severe chronic inflammatory demyelinating polyneuropathy
Neurologist or medical practitioner on the recommendation of a neurologist.
Re-assessment required after 6 months
All of the following:

1. Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function compared to baseline; and
2. The patient has not received rituximab in the previous 6 months; and
3. One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Initiation – anti-NMDA receptor autoimmune encephalitis
Neurologist
Re-assessment required after 6 months
All of the following

1. Patient has severe anti-NMDA receptor autoimmune encephalitis; and
2. Either
   2.1 Both
      2.1.1. Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and
      2.1.2. At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
   2.2 Rapid treatment is required due to life threatening complications; and
3. One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Continuation – anti-NMDA receptor autoimmune encephalitis
Neurologist
Re-assessment required after 6 months
All of the following:

1. Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function; and
2. The patient has not received rituximab in the previous 6 months; and
3. The patient has experienced a relapse and now requires further treatment; and
4. One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

resolved to remove all initial Special Authority criteria that apply to rituximab (Mabthera) for all indications excluding rheumatoid arthritis in Section B of the Pharmaceutical Schedule from 1 March 2020;

resolved to replace all initiation Hospital Indication Restriction criteria that apply to rituximab (Mabthera) for all indications excluding rheumatoid arthritis in Part II of Section H of the Pharmaceutical Schedule from 1 March 2020 as follows:

Initiation

No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.

resolved to amend the Special Authority criteria that applies to rituximab (Mabthera) in Section B of the Pharmaceutical Schedule from 1 December 2020 by removing the current Special Authority criteria and replacing it with the following:

Special Authority for Subsidy
Initial application — (rheumatoid arthritis - TNF inhibitors contraindicated) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
2 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
5 Any of the following:
    5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
    5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
    5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
6 Either:
    6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
    6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
7 Either:
    7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
    7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and
8 Either:
    8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
    8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Initial application — (rheumatoid arthritis - prior TNF inhibitor use) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1 Both:
    1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and
    1.2 Either:

1.2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
1.2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis; and

2 Either:
2.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
2.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

3 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Renewal — (rheumatoid arthritis - re-treatment in 'partial responders' to rituximab) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1 Any of the following:
1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
1.2 At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
1.3 At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
3 Either:
3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Renewal — (rheumatoid arthritis - re-treatment in 'responders' to rituximab) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1 Either:
1.1 At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
1.2 At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
3 Either:
3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

resolved to amend the hospital Indication Restrictions that applies to rituximab (Mabthera) in Part II of Section H of the Pharmaceutical Schedule from 1 December 2020 by removing the current restrictions and replacing it with the following:

Restricted
Initiation – rheumatoid arthritis - prior TNF inhibitor use
Rheumatologist
Limited to 4 months treatment
All of the following:
1 Both:
- 1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 1.2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis; and

2 Either:
- 2.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
- 2.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

3 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Initiation – rheumatoid arthritis - TNF inhibitors contraindicated
Rheumatologist
Limited to 4 months treatment
All of the following:
1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
2 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
5 Any of the following:
- 5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of cyclosporin; or
- 5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
- 5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and

6 Either:
- 6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
- 6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

7 Either:
- 7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
- 7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and

8 Either:
- 8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
- 8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Continuation – rheumatoid arthritis - re-treatment in 'partial responders' to rituximab

Rheumatologist
Re-assessment required after 4 months
All of the following:
1 Any of the following:
1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
1.2 At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
1.3 At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
3 Either:
3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Continuation – rheumatoid arthritis - re-treatment in 'responders' to rituximab
Rheumatologist
Re-assessment required after 4 months
All of the following:
1 Either:
1.1 At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
1.2 At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
3 Either:
3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

resolved to generate new Special Authority approvals for rituximab (Riximyo) for all patients with current Special Authority approvals for rituximab (Mabthera) for all indications excluding rheumatoid arthritis as soon as practicable from 1 March 2020;

resolved to expire all Special Authority approvals for rituximab (Mabthera) for all indications excluding rheumatoid arthritis from 1 December 2020;

noted that all renewal Special Authority criteria and Hospital restrictions that apply to rituximab (Mabthera) for all indications are to remain available during the transition period to 30 November 2020;

noted PHARMAC staff will need to provide Ministry of Health staff with lists of which Special Authority approvals need a Riximyo approval generated and which Special Authority approvals need expiring;

resolved to accept the proposal from Novartis for its brand Riximyo to be the sole subsidised brand of the rituximab inj 100 mg per 10 ml vial and inj 500 mg per 50 ml vial in Section B of the Pharmaceutical Schedule from 1 December 2020 until 30 September 2023 for all indications excluding rheumatoid arthritis;

noted that Hospital Sole Supply status will not apply and there is no DV limit. An alternative brand allowance will apply for the duration of Sole Supply.

Jan White and Nicole Anderson **(carried)**

9.6 Proposal to award sole supply of fluticasone and fluticasone with salmeterol metered dose inhalers

resolved to accept the proposal from GlaxoSmithKline NZ Limited (GSK) for its brands Flixotide and Seretide to be the sole subsidised brands of fluticasone metered dose inhalers (MDI) and fluticasone with salmeterol MDI in the community from 1 September 2020 until 30 June 2023;

resolved to accept the proposal from GlaxoSmithKline NZ Limited (GSK) for its brands Flixotide and Seretide to be the Hospital Supply Status Brand of fluticasone metered dose inhalers (MDI) and fluticasone with salmeterol MDI, with a DV Limit of 1% from 1 September 2020 until 30 June 2023;

resolved to amend the presentation descriptions for fluticasone MDIs in Section B of the Pharmaceutical Schedule from 1 March 2020 as follows (deletions in strikethrough):

Chemical	Presentation	Brand	Pack Size
Fluticasone	Aerosol Inhaler 50 mcg per dose ~~CFC-free~~	Flixotide	120 doses OP
Fluticasone	Aerosol Inhaler 125 mcg per dose ~~CFC-free~~	Flixotide	120 doses OP
Fluticasone	Aerosol Inhaler 250 mcg per dose ~~CFC-free~~	Flixotide	120 doses OP

resolved to amend the price and subsidy for the Flixotide brand of fluticasone MDIs and the Seretide brand of fluticasone with salmeterol MDIs in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 March 2020 as follows:

Chemical	Presentation	Brand	Pack Size	Current price and subsidy (ex-man., ex. GST)	Price and subsidy (ex-man., ex. GST)
Fluticasone	Aerosol Inhaler 50 mcg per dose	Flixotide	120 doses OP	$7.50	$7.19
Fluticasone	Aerosol Inhaler 125 mcg per dose	Flixotide	120 doses OP	$13.60	$13.60
Fluticasone	Aerosol Inhaler 250 mcg per dose	Flixotide	120 doses OP	$27.20	$24.62
Fluticasone with salmeterol	Aerosol Inhaler 50 mcg with salmeterol 25 mcg	Seretide	120 doses OP	$33.74	$25.79
Fluticasone with salmeterol	Aerosol Inhaler 125 mcg with salmeterol 25 mcg	Seretide	120 doses OP	$44.08	$32.60

resolved to delist the following products from Section B and Part II of Section H of the Pharmaceutical Schedule on 1 September 2020:

Chemical and presentation	Supplier	Brand
fluticasone aerosol inhaler 50 mcg per dose	Rex Medical	Floair
fluticasone aerosol inhaler 125 mcg per dose	Rex Medical	Floair
fluticasone aerosol inhaler 250 mcg per dose	Rex Medical	Floair
fluticasone with salmeteril aerosol inhaler 50 mcg with salmeterol 25 mcg	Rex Medical	RexAir
fluticasone with salmeteril aerosol inhaler 125 mcg with salmeterol 25 mcg	Rex Medical	RexAir

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

noted that the approval of this proposal would result in a brand change for fluticasone and fluticasone with salmeterol MDIs for approximately 12,000 people currently using the Floair brand of fluticasone MDI and the RexAir brand of fluticasone with salmeterol MDI currently supplied by Rex Medical Limited; and

noted the proposed implementation activities should the proposal be approved.

The Board considered the environmental impacts of this decision and the importance of giving consideration to the sustainability of packaging for future funding decisions.

Nicole Anderson and Claudia Wyss **(carried)**

12.55pm Dr Ken Clark, Acting Medical Director left the meeting

10. Strategic Planning and Policy

10.1 Strategies and Expectations Update

noted the contents of this paper.

10.2 Developing PHARMAC's Performance Framework

noted the contents of this report to support Board discussion; and

resolved to agree that from 2020, the annual Board Strategy Workshop is rescheduled to occur in September.

The Board acknowledged the progress staff have taken within the last year on the strategic priorities and the development of a new performance framework.

The Board supported the proposed approach for developing a performance framework as part of the upcoming refresh of the Statement of Intent and noted the importance of focusing on outcomes, improved output measurement to change from measuring inputs and activity.

Ross Lawrenson and Jan White **(carried)**

10.3 Update on the proposal to trial a cancer medicines early access mechanism

noted the updates from staff since this report was circulated to the Board by email in November 2019.

1.23pm Prof. Stephen Munn, Acting PTAC Chair left the meeting.

11. Regular Reports and Noting Papers

11.1 Communications Report

noted the content of the Communications Report covering October 2019.

11.2 Summary of Decisions Made Under Delegated Authority – September and October 2019

noted the monthly summary of decisions made under Delegated Authority by the Chief Executive, Director of Operations, Manager Pharmaceutical Funding, Senior Advisor/Team Leader and Senior Therapeutic Group Managers/Team Leaders.

12. Interest Articles

13. General Business

The Chair thanked the Board, the Board Observers, the Chief Executive and Senior Leadership Team and staff for their work and support this year.

Nicole Anderson thanked the Chair and Chief Executive.

Date of Next Meeting

The date for the next Board meeting is set for Friday 31 January 2020 in Wellington, commencing with the Directors Only from 9.00am, and attendees and relevant staff from 9.30am.

The meeting closed at 1.35pm.

Chair: Date: