Minutes of the Pharmaceutical Management Agency (Pharmac)

Board Meeting October 2021

The meeting was held at Pharmac offices, Level 9, 40 Mercer Street, Wellington and by videoconference starting at 10.00am 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
Elizabeth Zhu	Institute of Directors, Future Director
Mark Weatherall	Observer, PTAC Chair
Peter Bramley	Observer, DHB Representative

PHARMAC staff in attendance

Sarah Fitt	Chief Executive
Lizzy Cohen	Board Secretary

The meeting was conducted under level 2 restrictions. Lisa Williams, Director of Operations Peter Alsop, Director of Engagement & Implementation, Michael Johnson Director of Strategic Initiatives, Mark Woodard, Director of Corporate Services/CFO, David Hughes Chief Medical Officer, Jannel Fisher, Josh Wiles, Caroline De Luca, Sarah Beri, Laura Baker, Casim Alabere, Tal Sharrock, Andrew Davies, Brent McPherson, Rebekah Heap and Kathryn McInteer (Pharmac staff) attended for relevant items. Some attendees joined via videoconference to present papers.

1. Directors' Only Discussion

1.1 Glossary of Terms

1.2 Board Actions

The Board noted the Board Actions.

1.3 Board Annual Agenda 2021

The Board noted the Board Annual Agenda 2021.

1.4 Board Annual Agenda 2022

The Board noted the Annual Agenda 2022.

2. Apologies

Lisa Lawrence, Observer, CAC Chair

The Board Chair noted the desire for one of the Deputy CAC Chair members to attend future Board meetings if the CAC Chair is not available.

3. Record of Previous Board and Committee Meetings

3.1 Minutes of September 2021 Board Meeting

resolved to adopt the minutes of the September 2021 meeting as being a true and correct record.

Jan White and Claudia Wyss **(carried)**

3.2 Minutes of September 2021 Audit and Risk Committee meeting

The Board **noted** the minutes from the September 2021 Board Audit and Risk Committee meeting.

3.3 Board Health and Safety Committee Recommendations

A verbal update was provided by the Committee Chair on the October Committee meeting. The Board:

noted that the Committee reviewed the draft 2022 annual agenda and acknowledged that changes may have to be made in the future (with the review of the Health and Safety framework). The 2022 annual agenda will be recommended for Board approval at the next Board meeting.

noted that Working Wise completed an independent audit of Health and Safety (H&S) and presented findings to the Committee. As part of these findings staff will be supporting the Committee to review the role and responsibilities of H&S which will include the role of the Board and the Committee which was highlighted in the due diligence findings in the report. The Committee Chair noted that the Committee and Board may like to consider the functions of the Committee versus the Board in 2022 once some of the findings have been implemented by staff.

noted that staff will be considering how the Board and staff best interreact in relation to H&S check-ins.

noted that the Committee discussed the H&S responsibilities of Pharmac for the Committee and sub-committee members and has questioned if there is benefit in having a consumer representative on the Board H&S Committee. Staff agreed to consider this as part of the roles and responsibilities of H&S and H&S reporting to the Board.

noted that the Committee Chair raised an H&S issue which was deferred to Board discussion regarding COVID-19 vaccination of Pharmac staff from a H&S perspective. It was noted that while vaccination is a strong control measure, it does not eliminate the risk of staff contracting and transmitting COVID-19, even if they are fully vaccinated, but it has been proven to reduce the transmission in conjunction with following public health measures.

It was the Board's view that Pharmac staff should be encouraged to get vaccinated and that they are aware that the Public Service Commission (PSC) has been asked by public sector Chief Executives for clear guidelines and next steps on vaccination of state sector staff. The Chief Executive noted the steps being undertaken to look at possible mitigations on H&S risks to staff. The Board agreed to discuss this again at the next Board meeting in the hope that we will by then have advice from PSC. To

support this staff will prepare further information on the actions Pharmac is undertaking to mitigate any H&S risks.

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 matters arising and actions progressed.

6. Chair's Report

6.1 Verbal Report

A verbal update was provided by the Board Chair. The Board:

noted that Pharmac has been designated as the lead agency for securing COVID-19 treatments

noted that the Board met via videoconference to discuss the Pharmac review interim report, a copy was provided by the Minister of Health.

noted that the Board Chair and Chief Executive's regular meeting with Medicines NZ has moved from 29 October to 12 November.

6.2 Correspondence

noted the correspondence report

7. CE Report

7.1 Chief Executive's Report

noted the Chief Executive's Report

The Board **noted** that Cabinet has agreed to a new progressive procurement policy with a focus on Māori businesses (announced in December 2020). Pharmac staff are focussing on how to increase access for New Zealand businesses, including Māori, Pasifika businesses, as well as social enterprises and will be reporting on our progress towards a target of 5% of total operational contracts being awarded to Māori businesses to MBIE/TPK. The Chief Executive noted that staff do not see the 5% target as a cap, however acknowledged that Pharmac is quite limited in what we can do. The Chief Executive agreed to report back to the Board on Pharmac's current percentage of contracts in relation to our target and also identify if these contracts include H&S.

7.2 Monthly Communications Report

The purpose of this paper was to summarise the communications activity for September. The Board:

noted that our media impact score for July to September was 0.8 and it is the first time we have had a positive score

noted that our quarterly media impact score provides insights on our progress between the annual Colmar Brunton public sector reputation index reports

noted that since the launch of the new website, traffic has been trending up with the biggest increases to the news and consultation pages

noted that while the media impact score is positive, staff still agree that the reputation score target is still ambitious for Pharmac.

8. Key Items

8.1 Covid-19 Treatments Purchasing Arrangements

The purpose of this paper was to outline our approach to securing COVID-19 treatments and our advice to Ministers on the roles of Pharmac and the Ministry of Health for future COVID-19 treatments purchasing arrangements. The Board:

noted that Pharmac has been designated as the lead agency for COVID-19 treatments to secure pharmaceutical treatments for patients with an active COVID-19 infection or at high risk of infection

noted that Pharmac is taking a portfolio approach to secure access to a range of COVID-19 treatments

noted that the funding for COVID-19 treatments will be managed separately from the Combined Pharmaceutical Budget

noted there are currently funds available in 2021/22 from the additional funding the Government provided from the COVID Relief Fund to meet CPB related COVID-19 expenditure and meet the immediate needs for securing COVID-19 treatments

noted that the Government has indicated additional funding will be made available if required, and that there is some work to be done to align existing funding arrangements for future purchasing of COVID-19 treatments with the expectations outlined in this paper

noted that staff consider this approach to secure a range of COVID-19 treatments would support and contribute to more equitable outcomes as the funding of these treatments will be directed to where they are needed most, including populations that are most effected by COVID-19 such as people living with disabilities and multiple health conditions and Māori, Pacific peoples, and older people who are likely to derive greater health benefits than are other population groups

noted that the process and approach Pharmac is undertaking to secure COVID-19 treatments is unique given the urgency and the early stage of development for many treatments. The Board acknowledged that this meant the approach could not be compared with Pharmac's rigorous assessment process for funding medicines from

within the Combined Pharmaceutical Budget, as the same level of information is not available to be presented to the advisory committee to support the assessment and approval of these treatments

noted the comments from the PTAC Chair that there is some risk with this approach due to the uncertainty of the numbers of people needing access to these treatments, with hospitalisation rates currently being low

noted that a Pharmac COVID-19 Treatments Advisory Group has been established to support the evaluation of and advise on commercial arrangements for potential new treatments. This formalises the merger of several temporary advisory groups Pharmac has used for specific COVID-19 related issues over the last 18 months into a permanent group that can support our ongoing work. The Board noted that the membership of the Advisory Group does not currently include a consumer representative and that staff are considering how to include consumer input into this process

noted that Pharmac staff will continue ongoing engagement with the Ministry of Health and Treasury

8.2 Proposal to secure supply of Casirivimab and Imdevimab for Treatment of Covid-19

This proposal was recommended to the Board for decision as the process and approach Pharmac is undertaking to secure COVID-19 treatments is unique given the urgency and the early stage of development for many treatments. The proposal was to enter an advanced purchase agreement (APA) with Roche to secure supply of casirivimab and imdevimab (Ronapreve) for the treatment of patients with COVID-19 in New Zealand. The Board:

resolved to approve the Advanced Purchase Agreement with Roche Products (New Zealand) Limited (Roche) to secure supply of casirivimab and imdevimab for the treatment of New Zealand patients with mild to moderate COVID-19

noted that the Advanced Purchase Agreement would commit Pharmac to the purchase of 5,300 treatment courses of casirivimab and imdevimab and would be conditional upon Medsafe approval

noted that, following approval of this proposal by the Pharmac Board, the Chief Executive would sign the Advanced Purchase Agreement on behalf of Pharmac

noted that the costs associated with this decision would be met from available COVID-19 funds

noted that clinical advice has been sought from Pharmac's recently established COVID-19 Treatments Advisory Group to ensure the treatment is targeted to the patients most likely to benefit

noted if secured, supply of casirivimab and imdevimab could be available to New Zealand patients from November 2021

noted that public consultation on this proposal is not possible prior to making any decision due to the urgency required to secure supply for New Zealand

noted that the target population for treatment with casirivimab and imdevimab, and eligibility criteria are yet to be proposed. This paper seeks approval of an advance purchase agreement only. Any proposal relating to eligibility criteria would be subject to a separate decision paper and would likely involve targeted consultation with the health sector

noted that there are no explicit terms with regards to continuity of supply in these contracts and due to supply constraints the use of contract terms in this setting would be challenging. The Board noted that the APAs for different COVID19-treatments are not the same as each other and that there would likely be some negotiations on indemnities as the fulsome supply agreement is progressed.

Peter Bramley, Observer, DHB Representative left the meeting.

Jan White and Nicole Anderson (carried)

9. Schedule and Funding

9.1 Pharmaceutical Transactions and Expenditure Report

This paper provided an update on the current Combined Pharmaceutical Budget (CPB) expenditure position and our approach to managing the CPB. It also aims to give the Board an advance overview of the contentious, large or significant pharmaceutical transactions and investments that staff are currently progressing. The Board:

noted the CPB forecast is being presented to the Board in November, rather than October to enable the impact of the most recent COVID-19 alert level changes to be incorporated

noted the update from Pharmac staff on the large and/or significant medicines transactions that are currently planned or in progress.

9.2 Proposal to widen access and award principal supply status for adalimumab

This proposal was to list Amgevita, a citrate free biosimilar adalimumab supplied by Amgen, on the Pharmaceutical Schedule from 1 March 2022 for all currently funded uses and for a range of widened access and new uses, and award Principal Supply Status from 1 October 2022 for all funded adalimumab patients (excluding existing Crohn's disease and ocular inflammation patients). The availability of adalimumab biosimilars provided Pharmac with an opportunity to compete this market in a Request for Proposal (RFP) process issued 9 March 2021, with an aim to reduce costs, secure ongoing supply and consider wider access for more New Zealanders. Having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures, the Board:

resolved to approve the 14 October 2021 provisional agreement with Amgen (New Zealand) Limited

noted that the acceptance of this proposal would result in a change to a biosimilar adalimumab for the majority of patients currently receiving funded adalimumab

noted the planned implementation activities should the proposal be approved

noted the risk identified by Pharmac staff that the proposed list date (1 March 2022) occurs at a time where the health sector could be under pressure from the ongoing impact of the COVID-19 pandemic and that this could impact both primary and secondary care, limiting patient access to clinicians due to movement restrictions or limited capacity. The Board noted that Pharmac staff have considered the possible scenarios that could occur as a result of COVID-19 and identified options to mitigate this risk, including the possibility of extending the proposed list date and transition period. The Board noted that Pharmac staff have determined that it is within Pharmac's role, and control, to use the actions identified in the implementation plan, such as the development of appropriate resources for patients and clinicians to facilitate telehealth and to work with the supplier to enable increased uptake of nursing support, to reduce the impact on clinicians and ensure appropriate engagement with patients

noted the subcommittee members who were not able to attend the meetings to discuss the proposal were able to contribute to the advice outside of this process. The Board noted that PTAC reviewed all of the advice from the different subcommittees.

noted the summary of consultation feedback and full consultation responses

resolved that the consultation on this proposal was appropriate, and that no further consultation is required. The Board noted that Pharmac staff amended the implementation plan and support for patients based on the consultation feedback. Staff agreed to add a section in future funding decision Board papers to specifically identify what, if any, changes were made to the proposal and/or implementation approach based on consultation feedback

resolved to approve the changes to the Pharmaceutical Schedule outlined below:

resolved to accept the proposal from Amgen for its brand Amgevita to be the principal supply brand of the Community Pharmaceutical of adalimumab inj 20 mg per 0.4 ml prefilled syringe, inj 40 mg per 0.8 ml, prefilled syringe and inj 40 mg per 0.8 ml, prefilled pen from 1 October 2022 until 31 July 2026 for all indications excluding existing Crohn's disease and ocular inflammation

resolved to accept the proposal from Amgen for its brand Amgevita to be the Principal Supply brand of the Hospital Pharmaceutical of adalimumab inj 20 mg per 0.4 ml prefilled syringe, inj 40 mg per 0.8 ml, prefilled syringe and inj 40 mg per 0.8 ml, prefilled pen with a DV limit of 5% from 1 October 2022 until 31 June 2026 for all indications excluding existing Crohn's disease and ocular inflammation

resolved to list adalimumab (Amgevita) prefilled syringe 20 mg per 0.4 ml, prefilled syringe 40 mg per 0.8 ml and prefilled pen 40 mg per 0.8 ml in the Oncology agents and Immunosuppressants therapeutic group, Immunosuppressants TG2 and Monoclonal Antibodies TG3 in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 March 2022 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Adalimumab (Amgevita)	Inj 20 mg per 0.4 ml prefilled syringe	Amgevita	1	$190.00
Adalimumab (Amgevita)	Inj 40 mg per 0.8 ml prefilled syringe	Amgevita	2	$375.00

Adalimumab (Amgevita)	Inj 40 mg per 0.8 ml prefilled pen	Amgevita	2	$375.00

resolved to amend the chemical name for adalimumab to adalimumab (Humira) in the Oncology agents and Immunosuppressants therapeutic group in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 March 2022

resolved to add a note to adalimumab (Amgevita) as listed in Section B of the Pharmaceutical Schedule from 1 October 2022 until 1 January 2023 as follows
ADALIMUMAB (Amgevita)**– Brand Switch Fee payable**

resolved to apply the following Special Authority criteria to adalimumab (Amgevita) in Section B of the Pharmaceutical Schedule from 1 March 2022:

Behçet's disease – severe

ADALIMUMAB (AMGEVITA)
Initial application — (Behcet's disease - severe) from any relevant practitioner.
Approvals valid without further renewal unless notified for applications meeting the following criteria:
Both:
1. The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life; and
2. Either:
   2.1 The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s); or
   2.2 The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s).

Note: Indications marked with * are unapproved indications.

Hidradenitis suppurativa

ADALIMUMAB (AMGEVITA)
Initial application — (Hidradenitis suppurativa) only from a dermatologist.
Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1. Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and
2. Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or patient has demonstrated intolerance to or has contraindications for systemic antibiotics; and
3. Patient has 3 or more active lesions; and
4. The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application.

ADALIMUMAB (AMGEVITA)
Renewal — (Hidradenitis suppurativa) from any relevant practitioner
Approvals valid for 2 years for applications meeting the following criteria:
All of the following:
1. The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
2. The patient has a DLQI improvement of 4 or more from baseline.

Plaque psoriasis – severe chronic

ADALIMUMAB (AMGEVITA)
Initial application — (Plaque psoriasis - severe chronic) only from a dermatologist.
Approvals valid for 4 months for applications meeting the following criteria:
Either:
1. Both:
   1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects; or
      1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
2. All of the following:
   2.1 Either:
      2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a PASI score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
      2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
   2.2 Patient has tried, but had an inadequate response to, or has experienced intolerable side effects from at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
   2.3 A PASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application.

ADALIMUMAB (AMGEVITA)
Renewal — (Plaque psoriasis - severe chronic) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. Both:
   1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
   1.2 Either:
      1.2.1 The patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
      1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or
2. Both:
   2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
   2.2 Either:
      2.2.1 The patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
      2.2.2 The patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value.

Pyoderma gangrenosum

ADALIMUMAB (AMGEVITA)
Initial application — (pyoderma gangrenosum) only from a dermatologist. Approvals valid without renewal unless notified for applications meeting the following criteria:
Both:
1. Patient has pyoderma gangrenosum*; and
2. Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response.

Note: Indications marked with * are unapproved indications.

Crohn's disease – adults

ADALIMUMAB (AMGEVITA)
Initial application — (Crohn's disease - adults) only from a gastroenterologist.
Approvals valid for 3 months for applications meeting the following criteria:
All of the following:
1. Patient has active Crohn's disease; and
2. Any of the following:
   2.1 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
   2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
   2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
   2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

ADALIMUMAB (AMGEVITA)
Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:
1. CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on adalimumab; or
2. CDAI score is 150 or less, or HBI is 4 or less; or
3. The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed.

Crohn's disease – children

ADALIMUMAB (AMGEVITA)
Initial application — (Crohn's disease - children) only from a gastroenterologist.
Approvals valid for 3 months for applications meeting the following criteria:
All of the following:
1. Paediatric patient has active Crohn's disease; and
2. Either:
   2.1 Patient has a PCDAI score of greater than or equal to 30; or
   2.2 Patient has extensive small intestine disease; and
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

ADALIMUMAB (AMGEVITA)
Renewal — (Crohn's disease - children) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:
1. PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
2. PCDAI score is 15 or less; or
3. The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed.

Crohn's disease – fistulising

ADALIMUMAB (AMGEVITA)
Initial application — (Crohn's disease - fistulising) only from a gastroenterologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has confirmed Crohn's disease; and
2. Any of the following:
   2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
   2.2 Patient has one or more rectovaginal fistula(e); or
   2.3 Patient has complex peri-anal fistula; and

3. A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

ADALIMUMAB (AMGEVITA)
Renewal — (Crohn's disease - fistulising) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. The number of open draining fistulae have decreased from baseline by at least 50%; or
2. There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

Ocular inflammation – chronic

ADALIMUMAB (AMGEVITA)
Initial application — (Ocular inflammation - chronic) from any relevant practitioner.
Approvals valid for 4 months for applications meeting the following criteria:
Either:
1. Patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
2. Both:
   2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
   2.2 Any of the following:
      2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
      2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
      2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

ADALIMUMAB (AMGEVITA)
Renewal — (Ocular inflammation - chronic) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:
1. The patient has had a good clinical response following 12 weeks' initial treatment; or
2. Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
3. Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Ocular inflammation – severe

ADALIMUMAB (AMGEVITA)
Initial application — (Ocular inflammation - severe) from any relevant practitioner.
Approvals valid for 4 months for applications meeting the following criteria:
Either:
1. Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or
2. Both:
   2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
   2.2 Any of the following:
      2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
      2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
      2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

ADALIMUMAB (AMGEVITA)
Renewal — (Ocular inflammation - severe) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:
1. The patient has had a good clinical response following 3 initial doses; or
2. Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
3. Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Ankylosing spondylitis

ADALIMUMAB (AMGEVITA)
Initial application — (ankylosing spondylitis) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:
   1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
   1.2 Either:
      1.2.1 The patient has experienced intolerable side effects; or
      1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
2. All of the following:
   2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
   2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
   2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and
   2.4 Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
   2.5 Either:
      2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
      2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the following average normal values corrected for age and gender; and
3. A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment and is no more than 1 month old at the time of application.

ADALIMUMAB (AMGEVITA)
Renewal — (ankylosing spondylitis) from any relevant practitioner.
Approvals valid for 2 years for applications where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

Arthritis – oligoarticular course juvenile idiopathic

ADALIMUMAB (AMGEVITA)
Initial application — (Arthritis - oligoarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:
   1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects; or
      1.2.2 Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA; or

2. All of the following:
    2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
    2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
    2.3 Either:
        2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
        2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose).

ADALIMUMAB (AMGEVITA)
Renewal — (Arthritis - oligoarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
2. On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Arthritis – polyarticular course juvenile idiopathic

ADALIMUMAB (AMGEVITA)
Initial application — (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:
    1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
    1.2 Either:
        1.2.1 Patient has experienced intolerable side effects; or
        1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
2. All of the following:
    2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
    2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
    2.3 Any of the following:
        2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
        2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
        2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

ADALIMUMAB (AMGEVITA)
Renewal — (Arthritis - polyarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
2. On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Arthritis – psoriatic

ADALIMUMAB (AMGEVITA)
Initial application — (Arthritis - psoriatic) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:

1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
1.2 Either:
1.2.1 Patient has experienced intolerable side effects; or
1.2.2 Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis; or

2. All of the following:
2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and
2.4 Either:
2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
2.4.2 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
2.5 Any of the following:
2.5.1 Patient has CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
2.5.2 Patient has an ESR greater than 25 mm per hour; or
2.5.3 ESR and CRP 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.

ADALIMUMAB (AMGEVITA)
Renewal — (Arthritis - psoriatic) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. Following initial treatment, the patient has at least a 50% decrease in swollen joint count from baseline and a clinically significant response in the opinion of the physician; or
2. Patient demonstrates at least a continuing 30% improvement in swollen joint count from baseline and a clinically significant response in the opinion of the treating physician.

<u>Arthritis – rheumatoid</u>

ADALIMUMAB (AMGEVITA)
Initial application — (Arthritis - rheumatoid) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:
1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects; or
1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis; or

2. All of the following:
2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses (unless contraindicated); and
2.5 Either:
2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or

2.5.2 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 methotrexate; and

2.6 Either:

2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or

2.6.2 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.

ADALIMUMAB (AMGEVITA)
Renewal — (Arthritis - rheumatoid) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:

1 Following initial treatment, the patient has 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

2 On subsequent reapplications, 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.

Stills disease – adult onset

ADALIMUMAB (AMGEVITA)
Initial application — (Still's disease - adult-onset (AOSD)) only from a rheumatologist.
Approvals valid without renewal unless notified for applications meeting the following criteria:
Either:

1. Both:
   1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD; and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
      1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or
2. All of the following:
   2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
   2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate; and
   2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Ulcerative colitis

ADALIMUMAB (AMGEVITA)
Initial application – (ulcerative colitis) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. Patient has histologically confirmed active ulcerative colitis; and
2. Either:
   2.1 Patient's SCCAI score is greater than or equal to 4; or
   2.2 Patient's PUCAI score is greater than or equal to 65; and
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from prior therapy with immunomodulators and systemic corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

ADALIMUMAB (AMGEVITA)
Renewal – (ulcerative colitis) from any relevant Practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:

1. The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on adalimumab; or
2. The PUCAI score has reduced by 30 points or more from the PUCAI score since initiation on adalimumab.

Undifferentiated spondyloarthritis:

ADALIMUMAB (AMGEVITA)
Initial application — (undifferentiated spondyloarthritis) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
2. Patient has tried and not responded to at least three months of each of methotrexate, sulfasalazine and leflunomide, at maximum tolerated doses (unless contraindicated); and
3. Any of the following:
   3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
   3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
   3.3 ESR and CRP 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.

Note: Indications marked with * are unapproved indications

ADALIMUMAB (AMGEVITA)
Renewal — (undifferentiated spondyloarthritis) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. Following initial treatment, the patient has 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
2. The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician.

Inflammatory bowel arthritis – axial

ADALIMUMAB (AMGEVITA)
Initial application — (inflammatory bowel arthritis – axial) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2. Patient has axial inflammatory pain for six months or more; and
3. Patient is unable to take NSAIDs; and
4. Patient has bilateral sacroiliitis demonstrated by radiological imaging; and
5. Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
6. A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment.

ADALIMUMAB (AMGEVITA)
Renewal — (inflammatory bowel arthritis – axial) from any relevant practitioner
Approvals valid for 2 years for applications where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

Inflammatory bowel arthritis – peripheral

ADALIMUMAB (AMGEVITA)
Initial application — (inflammatory bowel arthritis – peripheral) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and

2. Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
3. Patient has tried and not responded to at least three months of methotrexate or azathioprine at a maximum tolerated dose; and
4. Patient has tried and not responded to at least three months of sulfasalazine at a maximum tolerated dose; and
5. Any of the following:
   5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
   5.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
   5.3 ESR and CRP 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.

ADALIMUMAB (AMGEVITA)
Renewal — (inflammatory bowel arthritis – peripheral) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. Following initial treatment, patient has 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
2. Patient demonstrates at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician.

resolved to amend the following subsidy restrictions for etanercept in Section B of the Pharmaceutical Schedule from 1 March 2022 (additions in bold, deletions in strikethrough):

ETANERCEPT
Initial application — (~~rheumatoid a~~Arthritis - rheumatoid) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:
   1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
   1.2 Either:
      1.2.1 The patient has experienced intolerable side effects ~~from adalimumab~~; or
      1.2.2 The patient has received insufficient benefit ~~from adalimumab~~ to meet the renewal criteria ~~for adalimumab~~ for rheumatoid arthritis; or
2. All of the following:
   2.1 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
   2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
   2.3 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 **(unless contraindicated)**; and
   2.4 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 **unless contraindicated**); and
   2.5 ~~Any of the following~~ **Either**:
      2.5.1 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
      ~~Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or~~
      2.5.2 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
   2.6 Either:
      2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least ~~20~~ **15** swollen~~, tender~~ joints; or

2.6.2 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~~

~~2.7 Either:~~

~~2.7.1 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~~

~~2.7.2 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.~~

ETANERCEPT
Renewal — (~~rheumatoid a~~Arthritis - rheumatoid) from any relevant practitioner ~~only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.~~
Approvals valid for **2 years** ~~6 months~~ for applications meeting the following criteria:
All of the following:

~~1 Either:~~

~~1.1 Applicant is a rheumatologist; or~~

~~1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and~~

1. Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2. Either:
   2.1 Following ~~3 to 4 months~~' initial treatment, the patient has 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
   2.2 On subsequent reapplications, 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
3. Etanercept to be administered at doses no greater than 50 mg every 7 days.

resolved to apply the following restrictions to adalimumab (Amgevita) in Part II of Section H of the Pharmaceutical Schedule from 1 March 2022:

<u>Behcet's disease – severe</u>

RESTRICTED
Initiation — Behcet's disease – severe
Any relevant practitioner
Both:

1. The patient has severe Behçet's disease* that is significantly impacting the patient's quality of life; and
2. Either:
   3.1 The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s); or
   3.2 The patient has severe, gastrointestinal, rheumatological and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s).

Note: Indications marked with * are unapproved indications.

<u>Hidradenitis suppurativa</u>

RESTRICTED
Initiation — Hidradenitis suppurativa
Dermatologist
Re-assessment required after 4 months
All of the following:

1. Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and
2. Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or patient has demonstrated intolerance to or has contraindications for systemic antibiotics; and
3. Patient has 3 or more active lesions; and
4. The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application.

Continuation — Hidradenitis suppurativa

Any relevant practitioner
Re-assessment required after 2 years
Both:
1. The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
2. The patient has a DLQI improvement of 4 or more from baseline.

Plaque psoriasis – severe chronic

RESTRICTED
Initiation — Plaque psoriasis - severe chronic
Dermatologist
Re-assessment required after 4 months
Either:
1. Both:
   1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects; or
      1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
2. All of the following:
   2.1 Either:
      2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
      2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
   2.2 Patient has tried, but had an inadequate response to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
   2.3 A PASI assessment or (DLQI) assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application.

Continuation — Plaque psoriasis - severe chronic
Any relevant practitioner
Re-assessment required after 2 years
Either:
1. Both:
   1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
   1.2 Either:
      1.2.1 The patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
      1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or
2. Both:
   2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
   2.2 Either:
      2.2.1 The patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
      2.2.2 The patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value.

Pyoderma gangrenosum

RESTRICTED
Initiation — pyoderma gangrenosum
Dermatologist

Both:
1. Patient has pyoderma gangrenosum*; and
2. Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response.

Note: Indications marked with * are unapproved indications.

Crohn's disease – adults

RESTRICTED
Initiation — Crohn's disease - adults
Gastroenterologist
Re-assessment required after 3 months
All of the following:
1. Patient has active Crohn's disease; and
2. Any of the following:
   2.1 Patient has a CDAI score of greater than or equal to 300 or HBI score of greater than or equal to 10; or
   2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
   2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
   2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

Continuation — Crohn's disease – adults
Any relevant practitioner.
Re-assessment required after 2 years
Any of the following:
1. CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced 3 points, from when the patient was initiated on adalimumab; or
2. CDAI score is 150 or less, or HBI is 4 or less; or
3. The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed.

Crohn's disease – children

RESTRICTED
Initiation — Crohn's disease - children
Gastroenterologist
Re-assessment required after 3 months
All of the following:
1. Paediatric patient has active Crohn's disease; and
2. Either:
   2.1 Patient has a (PCDAI) score of greater than or equal to 30; or
   2.2 Patient has extensive small intestine disease; and
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

Continuation — Crohn's disease - children
Any relevant practitioner
Re-assessment required after 2 years
Any of the following:
1. PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
2. PCDAI score is 15 or less; or
3. The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed.

Crohn's disease – fistulising

RESTRICTED
Initiation — Crohn's disease - fistulising
Gastroenterologist
Re-assessment required after 6 months
All of the following:
1. Patient has confirmed Crohn's disease; and
2. Any of the following:
   2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
   2.2 Patient has one or more rectovaginal fistula(e); and or
   2.3 Patient has complex peri-anal fistula; and
3. A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

Continuation — Crohn's disease - fistulising
Any relevant practitioner
Re-assessment required after 2 years
Either:
1 The number of open draining fistulae have decreased from baseline by at least 50%; or
2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

Ocular inflammation – chronic

RESTRICTED
Initiation — Ocular inflammation - chronic
Any relevant practitioner
Re-assessment required after 4 months
Either:
1. Patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
2. Both:
   2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
   2.2 Any of the following:
      2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
      2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
      2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

Continuation — Ocular inflammation - chronic
Any relevant practitioner
Re-assessment required after 2 years
Any of the following:
1. The patient has had a good clinical response following 12 weeks' initial treatment; or
2. Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
3. Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Ocular inflammation – severe

RESTRICTED
Initiation — Ocular inflammation - severe
Any relevant practitioner
Re-assessment required after 4 months
Either:

1. Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or
2. Both:
   2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
   2.2 Any of the following:
      2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
      2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
      2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

Continuation — Ocular inflammation - severe
Any relevant practitioner
Re-assessment required after 2 years
Any of the following:
1. The patient has had a good clinical response following 3 initial doses; or
2. Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
3. Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

<u>Ankylosing spondylitis</u>

RESTRICTED
Initiation — ankylosing spondylitis
Rheumatologist
Re-assessment required after 6 months
Either:
1. Both:
   1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
   1.2 Either:
      1.2.1 The patient has experienced intolerable side effects; or
      1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
2. All of the following:
   2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
   2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
   2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and
   2.4 Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
   2.5 Either:
      2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
      2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the following average normal values corrected for age and gender; and
3. A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment and is no more than 1 month old at the time of application.

Continuation — ankylosing spondylitis
Any relevant practitioners
Re-assessment required after 2 years

For applications where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

Arthritis – oligoarticular course juvenile idiopathic

RESTRICTED
Initiation — Arthritis - oligoarticular course juvenile idiopathic
Named specialist or rheumatologist
Re-assessment required after 6 months
Either:
1. Both:
   1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects; or
      1.2.2 Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA; or
2. All of the following:
   2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
   2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
   2.3 Any of the following:
      2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
      2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose).

Continuation — Arthritis - oligoarticular course juvenile idiopathic
Any relevant practitioner
Re-assessment required after 2 years
Either:
1. Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
2. On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Arthritis – polyarticular course juvenile idiopathic

RESTRICTED
Initiation — Arthritis - polyarticular course juvenile idiopathic
Named specialist or rheumatologist
Re-assessment required after 6 months
Either:
1. Both:
   1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects; or
      1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
2. All of the following:
   2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
   2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
   2.3 Any of the following:
      2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
      2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
      2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Continuation — Arthritis - polyarticular course juvenile idiopathic
Any relevant practitioner
Re-assessment required after 2 years
Either:
1. Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
2. On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Arthritis – psoriatic

RESTRICTED
Initiation — Arthritis - psoriatic
Rheumatologist
Re-assessment required after 6 months
Either:
1. Both:
   1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects; or
      1.2.2 Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis; or
2. All of the following:
   2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
   2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
   2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and
   2.4 Either:
      2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
      2.4.2 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
   2.5 Any of the following:
      2.5.1 Patient has CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
      2.5.2 Patient has an elevated ESR greater than 25 mm per hour; or
      2.5.3 ESR and CRP 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.

Continuation — Arthritis - psoriatic
Any relevant practitioner
Re-assessment required after 2 years
Either:
1. Following initial treatment, the patient has at least a 50% decrease in swollen joint count from baseline and a clinically significant response in the opinion of the physician; or
2. Patient demonstrates at least a continuing 30% improvement in swollen joint count from baseline and a clinically significant response in the opinion of the treating physician.

Arthritis – rheumatoid

RESTRICTED
Initiation — Arthritis - rheumatoid
Rheumatologist
Re-assessment required after 6 months
Either:
1. Both:
   1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
   1.2 Either:
      1.2.1 The patient has experienced intolerable side effects; or
      1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis; or

2. All of the following:
   2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
   2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
   2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
   2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses (unless contraindicated); and
   2.5 Either:
      2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
      2.5.2 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 methotrexate; and
   2.6 Either:
      2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
      2.6.2 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.

Continuation — Arthritis - rheumatoid
Any relevant practitioner
Re-assessment required after 2 years
Either:
1. Following initial treatment, the patient has 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
2. On subsequent reapplications, 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.

Stills disease – adult onset

RESTRICTED
Initiation — Still's disease - adult-onset (AOSD)
Rheumatologist
Either:
1. Both:
   1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for (AOSD); and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
      1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or
2. All of the following:
   2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
   2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate; and
   2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Ulcerative colitis

RESTRICTED
Initiation — ulcerative colitis
Gastroenterologist
Re-assessment required after 3 months
All of the following:
1. Patient has histologically confirmed active ulcerative colitis; and
2. Either:

2.1 Patient's SCCAI score is greater than or equal to 4; or
2.2 Patient's PUCAI score is greater than or equal to 65; and
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

Continuation – ulcerative colitis
Any relevant practitioner
Re-assessment required after 2 years
Either:
1. The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on adalimumab; or
2. The PUCAI score has reduced by 30 points or more from the PUCAI score since initiation on adalimumab.

Undifferentiated spondyloarthritis:

RESTRICTED
Initiation — undifferentiated spondyloarthritis
Rheumatologist
Re-assessment required after 6 months
All of the following:
1. Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
2. Patient has tried and not responded to at least three months of each of methotrexate, sulphasalazine and leflunomide, at maximum tolerated doses (unless contraindicated); and
3. Any of the following:
   3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
   3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
   3.3 ESR and CRP 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.

Note: Indications marked with * are unapproved indications

Continuation — undifferentiated spondyloarthritis
Any relevant practitioner
Re-assessment required after 2 years
Either:
1. Following initial treatment, the patient has 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
2. The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician.

Inflammatory bowel arthritis – axial

RESTRICTED
Initiation — inflammatory bowel arthritis – axial
Rheumatologist
Re-assessment required after 6 months
All of the following
1. Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2. Patient has axial inflammatory pain for six months or more; and
3. Patient is unable to take NSAIDs; and
4. Patient has bilateral sacroiliitis demonstrated by radiological imaging; and

5. Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
6. A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment.

Continuation — inflammatory bowel arthritis – axial
Any relevant practitioner
Re-assessment required after 2 years
For applications where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

Inflammatory bowel arthritis – peripheral

RESTRICTED
Initiation — inflammatory bowel arthritis – peripheral
Rheumatologist
Re-assessment required after 6 months
All of the following:
1. Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2. Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
3. Patient has tried and not responded to at least three months of methotrexate or azathioprine at a maximum tolerated dose; and
4. Patient has tried and not responded to at least three months of sulphasalazine at a maximum tolerated dose; and
5. Any of the following:
   5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
   5.2 Patient has an ESR greater than 25 mm per hour; or
   5.3 ESR and CRP 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.

Continuation — inflammatory bowel arthritis – peripheral
Any relevant practitioner
Re-assessment required after 2 years
Either:
1. Following initial treatment, patient has 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
2. Patient demonstrates at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician.

resolved to amend the following subsidy restrictions for etanercept in Part II of Section H of the Pharmaceutical Schedule from 1 March 2022: (additions in bold, deletions in ~~strikethrough~~):

RESTRICTED
Initiation — ~~rheumatoid a~~Arthritis - rheumatoid
Rheumatologist
Re-assessment required after 6 months
Either:
1. Both:
   1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
   1.2 Either:
      1.2.1 The patient has experienced intolerable side effects ~~from adalimumab~~; or
      1.2.2 The patient has received insufficient benefit ~~from~~ to meet the renewal criteria for ~~adalimumab for~~ rheumatoid arthritis; or
2 All of the following:

2.1 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
2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2.3 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 **(unless contraindicated)**; and
2.4 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 **(unless contraindicated)**;; and
2.5 ~~Any of the following~~ **Either**:
2.5.1 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
~~2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or~~
2.5.3 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
2.6 Either:
2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least ~~20~~ **15** swollen~~, tender~~ joints; or
2.6.2 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~~
~~2.7 Either:~~
~~2.7.1 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~~
~~2.7.2 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.~~

Continuation — ~~rheumatoid a~~Arthritis - rheumatoid
Any relevant practitioner ~~Rheumatologist~~
*Re-assessment required after **2 years** ~~6 months~~*
All of the following:
1. Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
2.1 Following ~~3 to 4 months~~' initial treatment, the patient has 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
2.2 On subsequent reapplications, 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
3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

resolved to generate Special Authority approval numbers for adalimumab (Amgevita) for all patients with active Special Authority approvals for adalimumab (Humira) prior to 1 March 2022, as soon as practicable to enable ongoing renewals for existing patients

resolved to remove the initial Special Authority criteria that apply to adalimumab (Humira) in Section B of the Pharmaceutical Schedule from 1 March 2022

resolved to remove the initial indication restrictions that apply to adalimumab (Humira) in Part II of Section H of the Pharmaceutical Schedule from 1 March 2022

resolved to cancel all Special Authority approvals for adalimumab (Humira) for all current criteria (both initial and renewal) from 1 October 2022

resolved to amend the chemical name for adalimumab to adalimumab (Humira – alternative brand) in the Oncology agents and Immunosuppressants therapeutic group in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 October 2022

resolved to remove all current Special Authority criteria and apply the below Special Authority criteria to adalimumab (Humira – alternative brand) in Section B of the Pharmaceutical Schedule from 1 October 2022 as follows:

Behçet's disease - severe

ADALIMUMAB (HUMIRA)
Initial application – (Behcet's disease – severe) from any relevant practitioner.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal – (Behcet's disease – severe) from any relevant practitioner.
Approvals valid for 6 months for applications meeting the following criteria:
1. The patient has had a good clinical response to treatment with measurably improved quality of life; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Hidradenitis suppurativa

ADALIMUMAB (HUMIRA)
Initial application – (Hidradenitis suppurativa) only from a dermatologist or Practitioner on the recommendation of a dermatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.

ADALIMUMAB (HUMIRA)
Renewal – (Hidradenitis suppurativa) only from a dermatologist or Practitioner on the recommendation of a dermatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
2 The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline; and
3 Adalimumab is to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered.

Plaque psoriasis – severe chronic

ADALIMUMAB (HUMIRA)
Initial application - (Psoriasis - severe chronic plaque) only from a dermatologist or Practitioner on the recommendation of a dermatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal - (Psoriasis - severe chronic plaque) only from a dermatologist or Practitioner on the recommendation of a dermatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. Either:
   1.1 Both:
      1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
      1.1.2 Either:
         1.1.2.1 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
         1.1.2.2 Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
   1.2 Both:
      1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
      1.2.2 Either:
         1.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
         1.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Pyoderma gangrenosum

ADALIMUMAB (HUMIRA)
Initial application – (Pyoderma gangrenosum) only from a dermatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. A maximum of 8 doses.

ADALIMUMAB (HUMIRA)
Renewal - Pyoderma gangrenosum only from a dermatologist
Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. The patient has demonstrated clinical improvement and continues to require treatment; and
2. A maximum of 8 doses.

Crohn's disease – adult

ADALIMUMAB (HUMIRA)
Initial application – (Crohn's disease - adult) from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following
1. Any of the following:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal – (Crohn's disease - adult) from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.
Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. Any of the following:
   1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
   1.2 CDAI score is 150 or less; or
   1.3 The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days

Crohn's disease – children

ADALIMUMAB (HUMIRA)
Initial application – (Crohn's disease - children) from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following
1. Any of the following:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal – (Crohn's disease - children) from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.
Approvals valid for 6 months for applications meeting the following criteria:
Both:

1. Any of the following:
    1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
    1.2 PCDAI score is 15 or less; or
    1.3 The patient has demonstrated an adequate response to treatment, but PCDAI score cannot be assessed; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days

Crohn's disease – fistulising

ADALIMUMAB (HUMIRA)
Initial application - (Crohn's disease - fistulising) from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following
1. Any of the following:
    1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
    1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
    1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal – (Crohn's disease - fistulising) from a gastroenterologist or any relevant Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. Either:
    1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
    1.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain; and
2. Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Ocular inflammation – chronic

ADALIMUMAB (HUMIRA)
Initial application - (Ocular inflammation – chronic) from any relevant practitioner.
Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. Any of the following:
    1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
    1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
    1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal application (Ocular inflammation – chronic) from any relevant practitioner.
Approvals valid for 12 months for applications meeting the following criteria:
Both:
1. Any of the following

1.1 The patient has had a good clinical response following 12 weeks initial treatment; or
1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and

2. Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Ocular inflammation – severe

ADALIMUMAB (HUMIRA)
Initial application (Ocular inflammation – severe) from any relevant practitioner.
Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1. Any of the following:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal application – (Ocular inflammation – severe) from any relevant Practitioner.
Approvals valid for 12 months for applications meeting the following criteria:

1. Any of the following
   1.1 The patient has had a good clinical response following 3 initial doses; or
   1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
   1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and
2. Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Ankylosing spondylitis

ADALIMUMAB (HUMIRA)
Initial application – (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita); and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal – (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:
Both:

1. Treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
2. Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Arthritis – oligoarticular course juvenile idiopathic

ADALIMUMAB (HUMIRA)
Initial application (Arthritis – oligoarticular course juvenile idiopathic) only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

ADALIMUMAB (HUMIRA)
Renewal application (Arthritis – oligoarticular course juvenile idiopathic) only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months where the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Arthritis – polyarticular course juvenile idiopathic

ADALIMUMAB (HUMIRA)
Initial application (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

ADALIMUMAB (HUMIRA)
Renewal application (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months where the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Arthritis – psoriatic

ADALIMUMAB (HUMIRA)
Initial application – (Arthritis - psoriatic) only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal application - (Arthritis – psoriatic) only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Arthritis – rheumatoid

ADALIMUMAB (HUMIRA)
Initial application – (Arthritis – rheumatoid) only from a rheumatologist, or Practitioner on the recommendation of a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Either:
   4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
   4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

ADALIMUMAB (HUMIRA)
Renewal application – (Arthritis – rheumatoid) only from a rheumatologist, or Practitioner on the recommendation of a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
2. Either:
   2.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
   2.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Stills disease – adult onset

ADALIMUMAB (HUMIRA)
Initial application – (Still's disease – adult-onset (AOSD)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Both:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and

3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

ADALIMUMAB (HUMIRA)
Renewal application - Still's disease – Adult onset only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has demonstrated a sustained improvement in inflammatory markers and functional status.

resolved to removal all current Hospital Restriction criteria for adalimumab (Humira) (initiation and continuation) from 1 October 2022;

resolved to apply the below Hospital Restriction criteria to adalimumab (Humira – alternative brand) in Part II of Section H of the Pharmaceutical Schedule from 1 October 2022 as follows:

Behcet's disease - severe

ADALIMUMAB (HUMIRA)
Initiation - Behcet's disease - severe
Any relevant Practitioner
Re-assessment required after 6 months
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Continuation - Behcet's disease - severe
Any relevant practitioner
Re-assessment required after 6 months
Both:
1. The patient has had a good clinical response to treatment with measurably improved quality of life; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Hidradenitis suppurativa

ADALIMUMAB (HUMIRA)
Initiation - Hidradenitis suppurativa
Dermatologist or Practitioner on the recommendation of a dermatologist
Re-assessment required after 6 months
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.

ADALIMUMAB (HUMIRA)
Continuation - Hidradenitis suppurativa
Dermatologist or Practitioner on the recommendation of a dermatologist
Re-assessment required after 6 months
All of the following:
1. The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
2. The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline; and
3. Adalimumab is to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered.

Plaque psoriasis – severe chronic

ADALIMUMAB (HUMIRA)
Initiation - Psoriasis - severe chronic plaque
Dermatologist or Practitioner on the recommendation of a dermatologist
Re-assessment required after 6 months
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Continuation - Psoriasis - severe chronic plaque
Dermatologist or Practitioner on the recommendation of a dermatologist
Re-assessment required after 6 months
Both:
1. Either:
   1.1 Both:
      1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
      1.1.2 Either:
         1.1.2.1 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
         1.1.2.2 Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
   1.2 Both:
      1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
      1.2.2 Either:
         1.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
         1.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Pyoderma gangrenosum

ADALIMUMAB (HUMIRA)
Initiation - Pyoderma gangrenosum
Dermatologist

Re-assessment required after 6 months
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. A maximum of 8 doses.

ADALIMUMAB (HUMIRA)
Continuation - Pyoderma gangrenosum
Dermatologist
Re-assessment required after 6 months
Both:
1. The patient has demonstrated clinical improvement and continues to require treatment; and
2. A maximum of 8 doses

<u>Crohn's disease – adult</u>

ADALIMUMAB (HUMIRA)
Initiation - Crohn's disease - adult
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
All of the following:
1. Any of the following:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Continuation - Crohn's disease - adult
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
Both:
1. Any of the following:
   1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
   1.2 CDAI score is 150 or less; or
   1.3 The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days

<u>Crohn's disease – children</u>

ADALIMUMAB (HUMIRA)
Initiation – Crohn's disease - children
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
All of the following
1. Any of the following:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Continuation – Crohn's disease - children
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
Both:
1. Any of the following:
1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
1.2 PCDAI score is 15 or less; or
1.3 The patient has demonstrated an adequate response to treatment, but PCDAI score cannot be assessed; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days

Crohn's disease – fistulising

ADALIMUMAB (HUMIRA)
Initiation - Crohn's disease - adult
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
All of the following
1. Any of the following:
1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Continuation – Crohn's disease - fistulising
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
Both:
1. Either:
1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
1.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain; and
2. Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Ocular inflammation – chronic

ADALIMUMAB (HUMIRA)
Initiation - Ocular inflammation – chronic
Any relevant practitioner
Re-assessment required after 12 months
All of the following:
1. Any of the following:
1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Continuation - Ocular inflammation – chronic
Any relevant practitioner
Re-assessment required after 12 months
1. Any of the following
   1.1 The patient has had a good clinical response following 12 weeks initial treatment; or
   1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
   1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and
2. Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Ocular inflammation – severe

ADALIMUMAB (HUMIRA)
Initiation - Ocular inflammation – severe
Any relevant practitioner
Re-assessment required after 12 months
All of the following:
1. Any of the following:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Continuation – Ocular inflammation – severe
Any relevant practitioner
Re-assessment required after 12 months
Both:
1. All of the following:
   1.1 The patient has had a good clinical response following 3 initial doses; or
   1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
   1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and
2. Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Ankylosing spondylitis

ADALIMUMAB (HUMIRA)
Initiation - Ankylosing spondylitis

Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita); and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Continuation - Ankylosing spondylitis
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
Both:
1. Treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
2. Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Arthritis – oligoarticular course juvenile idiopathic

ADALIMUMAB (HUMIRA)
Initiation - Arthritis – oligoarticular course juvenile idiopathic
Rheumatologist or named specialist
Re-assessment required after 6 months
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

ADALIMUMAB (HUMIRA)
Continuation - Arthritis – oligoarticular course juvenile idiopathic
Rheumatologist or named specialist
Re-assessment required after 6 months
For patients that demonstrate at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Arthritis – polyarticular course juvenile idiopathic

ADALIMUMAB (HUMIRA)
Initiation - Arthritis - polyarticular course juvenile idiopathic
Rheumatologist or named specialist
Re-assessment required after 6 months
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

ADALIMUMAB (HUMIRA)
Continuation - Arthritis - polyarticular course juvenile idiopathic
Rheumatologist or named specialist
Re-assessment required after 6 months
For patients that demonstrate at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Arthritis – psoriatic

ADALIMUMAB (HUMIRA)
Initiation – Arthritis – psoriatic
Rheumatologist or named specialist
Re-assessment required after 6 months
All of the following:
1. Either
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Continuation - Arthritis - psoriatic
Rheumatologist or named specialist
Re-assessment required after 6 months
Both:
1. The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Arthritis – rheumatoid

ADALIMUMAB (HUMIRA)
Initiation – Arthritis – rheumatoid
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Either:
   4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
   4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

ADALIMUMAB (HUMIRA)
Continuation – Arthritis – rheumatoid
Rheumatologist, or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
All of the following:
1. The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
2. Either:
   1.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or

1.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Stills disease – adult onset

ADALIMUMAB (HUMIRA)
Initiation - Still's disease – adult-onset (AOSD)
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
All of the following:
1 Either:
1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

ADALIMUMAB (HUMIRA)
Continuation - Still's disease – adult-onset (AOSD)
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
The patient has demonstrated a sustained improvement in inflammatory markers and functional status.

noted that all renewal Special Authority criteria and continuation Hospital restrictions that apply to adalimumab (Humira) for all indications are to remain available during the transition period to 30 September 2022

noted Pharmac staff would work with Ministry of Health staff to manage the transition of Special Authority approvals

noted that an alternative brand allowance of 5% will apply for the duration of Principal Supply.

Ross Lawrenson and Claudia Wyss **(carried)**

9.3 Prioritisation Report

This report described prioritisation activity since the last report was presented to the Board at its July 2021 meeting. It also updated the Board on the progress of selected items from the top 10 proposals on the Options for Investment list, proposals with a high PTAC priority on the Options for Investment or Under Assessment lists, and proposals with a high PTAC priority on the Under-Assessment list. The Board:

noted the prioritisation activity undertaken by Pharmac staff since July 2021 and the progress of selected items from Pharmac's prioritisation list

9.4 Medical Devices and Transaction Investment Report

This paper provided the Board with a monthly update on progress with medical devices national contracting activity. The Board:

noted the update on progress with medical devices national contracting activity and work towards the Statement of Performance Expectations target.

9.5 Summary of decisions made under delegated Authority – September 2021

This report contained a summary of all decisions made by Pharmac staff under delegated authority since the last Board meeting. The Board:

noted the summary of decisions made under Delegated Authority during September 2021 by the Chief Executive, Director of Operations, Manager Pharmaceutical Funding, Senior Advisor/Team Leader and Senior Therapeutic Group Managers/Team Leaders.

10. Strategic Planning and Policy

10.1 Pharmac 2021/22 Quarter One Performance Report

This paper provided the Board with Pharmac's 2021/22 Quarter One Performance Report and information about Pharmac's progress towards our strategic priorities including insights, highlights, challenges and good news stories. The Board:

noted Pharmac's 2021/22 Quarter One Performance Report

noted the following key insights from the Quarter One Performance Report in a new summary format

1. Pharmac staff have made good progress towards delivering the initiatives set out in the first quarter of 2021/22, year two of our new strategic direction

2. Overall, five strategic priority areas have been rated Green (Enhance Key Functions, Medical Devices, Data and Analytics, Public Understanding Trust and Confidence and Relationship and Partnerships) with Equitable Access and Use being rated Amber. Of the two supporting priorities Te Whaioranga is rated Amber, and People and Capability is rated Green

3. Resourcing issues, including recruitment challenges and delays, have continued to affect our capacity to deliver as well as wider health sector capacity issues due principally to COVID-19

4. The quarterly performance measures are on track with one minor exception.

10.2 Progress Update on Enhancing Key Functions Strategic Priority Programme

This paper provided the Board with an update on the Enhancing Key Functions Programme and the programme's focus over the next 12 months. The Board:

noted the progress, and achievements to date, for the Enhancing Key Functions strategic programme

noted that Pharmac's Senior Leadership Team agreed to pause some of the initiatives in the programme due to the inability for our sector partners to engage because of the health sector reforms and COVID-19. These are initiatives which staff have identified as good opportunities to co-design and progress in partnership. Pharmac staff advised that they are progressing with initiatives most within Pharmac's control and prioritising work which will best deliver against expectations of government or respond to future trends

noted that staff issued an RFI for the public preferences work to gather more information on the cost to run the survey and complete the work and that so far, they have had some great interest from Māori suppliers

noted that staff are completing a project on a new category planning process for our management of the Schedule with an aim to be more proactive in seeking applications for specific clinical need. This piece of work is contributing to one of the programme's goals to "ensure that our commercial results are optimal for us and for consumers, both now and into the future"

noted that staff have delivered on the project to modify our approach to competitive procurement, introducing Principal Supply Status to tenders and RFPs. This change provides Pharmac with greater flexibility to respond to the needs of people who experience, or are at heightened risk of experiencing, an adverse clinical outcome from a brand change. Staff advised that they are now looking at the life cycle of a product and what commercial tools Pharmac uses at each stage of the life cycle.

discussed the progress staff have made in this work programme and questioned if we are moving fast enough. Staff advised that this work is a change improvement programme which requires the need to collaborate with people to do the change well and that while we have identified the need to progress this work over the last few years, this programme is part of our refreshed strategy which is in year one of its delivery. Staff noted that our collaboration approach takes time and COVID-19 and other environment impacts have also affected progress. Staff noted that the end-to-end project will help to identify how Pharmac can do things differently across all our work, then clear policies, processes and systems will be developed to support and allow people to work differently, including working faster.

noted the need to maintain delivery of this work programme and to continue to allocate funds to ensure the progress and good momentum of this work.

10.3 Schedule Management Systems – status and next steps

This paper updated the Board on our current work to develop a vison, strategy, and business case for the potential redevelopment of the Schedule systems.

11. Regular Reports and Noting Papers

11.1 Risk Report – Quarter One 2021/22

The full risk register was considered by the Audit and Risk Committee in September 2021 and provided to the Board as an information item. The register lists risks that exceed the Board's identified risk tolerance. This exceptions report also updates the Board on the items on the risk register that have materially changed since it was considered at the Audit and Risk Committee. The Board:

noted that the Audit and Risk Committee reviewed the risk register at its 24 September 2021 meeting

noted that the attached quarter one risk register has been updated following discussion at that Audit and Risk Committee as well as through regular updating by staff as described in this paper

noted that the attached quarter one risk register will be included in the quarter one report to the Minister of Health

11.2 Update on the research activities within Pharmac

This paper provided the annual update to the Board on Pharmac's research commitment and activities. The Board:

noted the update regarding research activities at Pharmac.

12. Interest Articles

noted the interest articles.

13. General Business

None.

Date of Next Meeting

The date for the next Board meeting is set for Friday 3 December 2021.

The meeting closed at 3.00pm with a karakia.

Chair: Date: