Consultation

PHARMAC
TE PĀTAKA WHAIORANGA

Proposal to widen access to adalimumab and award Principal Supply

26 August 2021

What we're proposing

We want to hear from people on a proposal that would give more New Zealanders funded access to adalimumab.

We are seeking feedback on a proposal to make changes to the funded brand of adalimumab, from Humira to a citrate-free biosimilar adalimumab called Amgevita from 1 February 2022 through a provisional agreement with Amgen (New Zealand) Limited. Adalimumab is a biologic medicine used to treat a range of rheumatology, gastrointestinal, dermatological and other autoimmune conditions.

If the proposal is approved, the following changes would occur:

- A biosimilar adalimumab (Amgevita, supplied by Amgen) would be funded from 1 February 2022.
- All people who start on adalimumab treatment after 1 February 2022 would receive Amgevita.
- People who are receiving treatment with the currently listed brand of adalimumab (Humira) before 1 February 2022 would need to move to Amgevita before 31 August 2022
    - We understand there may be some exceptions to this for people who need to move back to, or remain on, Humira. Humira would remain listed for these circumstances, subject to funding criteria.
- Amgevita would become the Principal brand of adalimumab for all funded uses from 1 September 2022 until 30 June 2026. This means it would be the main funded brand of adalimumab available in New Zealand.
- From 1 February 2022, funded access to Amgevita would be widened to include the following uses (links to Application Tracker included):
    - Ulcerative colitis first line
    - Amending existing funding critieria to enable Crohn's disease dose escalation
    - Undifferentiated spondyloarthritis
    - Inflammatory bowel disease-associated arthritis
    - Rheumatoid arthritis; reduction in the number of swollen joints required for access to treatment, and removal of the requirement for CRP to be greater than 15 mg/L
    - Behçet's disease; access to funded treatment with Amgevita as a first line biologic
    - Ocular inflammation; access to funded treatment with Amgevita as a first line biologic

- This proposal would also result in a number of changes to the funding critieria (Special Authority criteria) for currently funded uses to improve access to treatment. From 1 February 2022, the Special Authority (Amgevita brand only) criteria would be widened to include the following changes:

    - Removal of dosing restrictions for people using Amgevita
    - Special Authority renewal periods would be extended from 6 months to 2 years
    - Special Authority renewals could be applied for by any relevant practitioner and in some uses, renewals would not be required

This proposal results from a competitive process for the Principal Supply of funded adalimumab. It would release significant funds for Pharmac to invest in other medicines for the benefit of New Zealanders.

Feedback on this consultation will help us to understand if any changes should be made to this proposal. Consultation closes at **5 pm on Wednesday, 22 September 2022**. Feedback can be emailed to consult@pharmac.govt.nz, or sent using our response form.

What would the effect be?

From 1 February 2022, two brands of adalimumab would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule, each with access criteria for funding.

Pharmac and the supplier of Amgevita (Amgen) would provide information and resources about biosimilar's and biosimilar adalimumab to support this change. It is anticipated that this change would be prescriber led; however, prescribers, pharmacists and patients would need to work together to manage the transition of individual patients from Humira to Amgevita.

Each brand of adalimumab would have separate Special Authority funding criteria.

Proposed funding of adalimumab

- **From 1 February 2022 until 31 August 2022:**
    - Existing patients and uses
        - Amgevita would be listed for all currently funded uses.
        - Either the Humira brand or the Amgevita brand of adalimumab could be funded.
    - New patients and uses
        - Only the Amgevita brand could be prescribed for new uses and new patients.

- **From 1 September 2022:**
    - Amgevita
        - Prescribed for all funded uses (current and new) with access criteria (eg Special Authority or Hospital Restrictions).
    - Humira
        - Prescribed for people with conditions previously controlled on Humira who, after a move to Amgevita, experience clinical difficulties and, following discussion with their doctor, need to return to funded treatment with Humira.

Existing patients

Approximately 6,400 people received adalimumab treatment in 2020. From 1 February 2022, these people receiving treatment with Humira would need to move to Amgevita. This change would be carefully managed by treating clinicians, working closely with primary care, the patient, their family, whānau, and caregivers.

Patients receiving funded Humira prior to 1 February 2022 would be automatically issued a new Special Authority number to enable dispensing of Amgevita.

Based on clinical advice received (see below), we anticipate that most existing patients who take adalimumab would be able to change to the Amgevita brand of adalimumab. However, if Amgevita is unable to be tolerated by a current patient, after a trial, their clinician can apply via a Special Authority to return to Humira (where it is safe to consider further treatment with adalimumab).

Pharmac has identified that there may be some people with ocular inflammation (uveitis) or Crohn's disease who are at higher risk of experiencing severe adverse clinical outcomes associated with loss of disease control. Where a clinician considers that changing to Amgevita would put their patient at risk of severe disease destabilisation, the clinician can apply via a Special Authority to continue treatment with Humira without the need to trial Amgevita.

New patients

From 1 February 2022, all people starting treatment with adalimumab for any funded indication would receive Amgevita.

This would include patients who receive adalimumab treatment for newly funded uses and as a result of widened access. Pharmac is proposing to widen funded access to adalimumab (Amgevita) for a range of uses. We estimate that approximately 720 people would benefit in the first year from these changes in access.

More information on these proposed changes is available below.

For prescribers and pharmacists

- **From 1 February 2022:**
  - Either the Amgevita or Humira brand could be prescribed for existing patients and uses
  - Only the Amgevita brand could be prescribed for new patients and uses

- **From 1 September 2022:**
  - Only the Amgevita brand could be prescribed for all funded uses (current and new)
  - The Humira brand would be available subject to Special Authority criteria for people who, for clinical reasons, need to change back to Humira. A new Special Authority application would need to be made for these patients following discussion with their doctor.

To dispense and claim a subsidy, the correct brand would need to be prescribed for each patient. Special Authority approvals would not be interchangeable.

Pharmac would work with Primary Care Professionals to provide resources and support (for example, a Brand Switch Fee and learning material) to assist with the transition of patients from Humira to Amgevita.

Who we think will be interested

- People currently using adalimumab and their family, whānau, and caregivers
- Consumer support groups for people living with conditions that are treated with adalimumab
- Clinicians who treat people with conditions that are treated with adalimumab. This includes rheumatologists, gastroenterologists, ophthalmologists, dermatologists, general practitioners, and nurse specialists
- Hospital and community pharmacists
- DHBs
- Wholesalers and suppliers of adalimumab and biologic medicines

Why we're proposing this

Several biosimilar adalimumab products are now approved by Medsafe for use in New Zealand. A biosimilar is a very similar version of a biological medicine and is comparable in all essential aspects of an approved biologic medicine including safety, efficacy and mode of action. Amgevita is a Medsafe approved biosimilar adalimumab treatment which is used in more than 40 countries around the world.

The availability of biosimilar's provides Pharmac with the opportunity to promote competition and reduce the cost of adalimumab. This allows Pharmac to propose wider access to adalimumab for more New Zealanders.

Read more about biosimilars

Pharmac released a Request for Proposal (RFP) for the supply of adalimumab in the community and DHB hospitals on 9 March 2021. As a result of the RFP, Pharmac has entered into a provisional agreement with Amgen for the supply of its biosimilar adalimumab (Amgevita).

Pharmac remains supportive of, and will continue to consider, funding other biosimilar medicines in the future. We remain committed to implementing changes to introduce biosimilar medicines where they would help us improve the health outcomes of New Zealanders.

Clinical advice

In November 2020, Pharmac sought advice from its Pharmacology and Therapeutics Advisory Committee (PTAC) regarding evidence from Amgen for its biosimilar adalimumab product (Amgevita). The Committee recommended that Pharmac could progress a competitive procurement process that may result in the listing of a biosimilar adalimumab.
The full record of the discussion is available on our website.

Pharmac also sought advice on a competitive procurement process for adalimumab from the Dermatology, Ophthalmology, Gastrointestinal and Rheumatology Subcommittees of PTAC. Records of those discussions are available on our website (Dermatology and Ophthalmology record, Gastrointestinal record and Rheumatology record).

About adalimumab and its uses

Adalimumab is a monoclonal antibody (a biologic medicine) that acts as an inhibitor of inflammatory and immune responses often associated with chronic autoimmune based conditions. About 6,400 people used adalimumab in 2020 for a range of different dermatological, gastrointestinal, ophthalmic, and rheumatological diseases.

Adalimumab (as the brand Humira) has been listed on the Pharmaceutical Schedule since 2009 subject to Special Authority criteria. It is available as a 20 mg and 40 mg prefilled syringe and a 40 mg prefilled pen. People generally self-administer adalimumab via subcutaneous injection, usually every 14 days.

Proposed biosimilar adalimumab

Amgevita is a biosimilar brand of adalimumab and would be supplied as a citrate free formulation. Clinical advice has previously indicated that the absence of citrate may reduce the pain of injecting adalimumab.

Amgevita is Medsafe-approved for use in New Zealand and is approved for the same uses as Humira. This includes (currently funded uses shown only):

- Rheumatoid arthritis
- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Ankylosing spondylitis
- Crohn's disease
- Plaque psoriasis
- Hidradenitis Suppurativa
- Uveitis (ocular inflammation)

The similarity of Amgevita to Humira has been demonstrated with regard to physiochemical characteristics, pharmacology, safety and efficacy outcomes. Amgevita has also been approved for use by the EMA in Europe, by the FDA in the United States and the TGA in Australia and is used extensively internationally for the same uses as Humira (see information on the Amgevita prefilled pen, from Amgen's Australian introduction).

Pharmac sought early advice on the use and feel of the Amgevita device, with initial feedback indicating that Amgevita looks and functions similarly to Humira. The injection volume and needle size of Amgevita is the same as the currently available Humira product.

Details about our proposal

From 1 February 2022, Amgevita would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule as follows:

Chemical	Formulation	Brand	Pack size
Adalimumab (Amgevita)	Inj 20 mg per 0.4 ml prefilled syringe	Amgevita	1
Adalimumab (Amgevita)	Inj 40 mg per 0.8 ml prefilled syringe	Amgevita	2
Adalimumab (Amgevita)	Inj 40 mg per 0.8 ml prefilled pen	Amgevita	2

The price and subsidy would be notified should Pharmac decide to progress the proposal following consideration of consultation feedback. A confidential rebate would apply to all presentations of Amgevita, which would reduce the net price to the funder.

The list price of Amgevita would be lower than the current adalimumab list price. Pharmac is aware of the impact this may have on the supply chain and would engage with relevant stakeholders as needed to assist in the managing the impact of this.

From 1 February 2022, new Special Authority criteria would apply to biosimilar adalimumab (Amgevita), based on current adalimumab criteria with amendments and additions (see full list).

Please follow the below links for information categorised for the different uses of adalimumab:

- Gastrointestinal conditions: Gastroenterology
- Ophthalmology conditions: Ophthalmology
- Dermatology conditions: Dermatology
- Rheumatology conditions: Rheumatology

The same restrictions for the Amgevita brand of adalimumab would apply in Part II of Section H of the Pharmaceutical Schedule.

From 1 September 2022, Amgevita would be awarded Principal Supply Status in the Pharmaceutical Schedule. This means it will be the main funded brand of adalimumab available in New Zealand and would be guaranteed at least 95% of the funded adalimumab patient groups, with a 5% Alternative Brand Allowance. This excludes the existing patient groups of Crohn's disease and Ocular inflammation.

Changes to the listing of Humira

From 1 February 2022, the Pharmaceutical Schedule listing for the Humira brand of adalimumab would be amended as follows (additions in bold):

Chemical	Formulation	Brand	Pack size
Adalimumab **(Humira)**	Inj 20 mg per 0.4 ml prefilled syringe	Humira	2
Adalimumab **(Humira)**	Inj 40 mg per 0.8 ml prefilled syringe	Humira	2
Adalimumab **(Humira)**	Inj 40 mg per 0.8 ml prefilled pen	HumiraPen	2

From 1 February 2022, the current Special Authority criteria for Humira would be amended so only existing patients could continue to access funded treatment with the Humira brand of adalimumab. All new patients would be started on Amgevita.

From 1 September 2022, new Special Authority criteria for Humira would be in place to enable access for patients who, for clinical reasons, have been unable to change to Amgevita (see list of changes, replacement criteria shown only).

Please follow the below links for information categorised for the different uses of adalimumab:

- Gastrointestinal conditions: Gastroenterology
- Ophthalmology conditions: Ophthalmology
- Dermatology conditions: Dermatology
- Rheumatology conditions: Rheumatology

Widening access

Changing to a biosimilar adalimumab means that more New Zealanders would be able to access adalimumab.

We are proposing to widen access to Amgevita for a range of uses. These proposed changes in access reflect requests for funding that have been made to Pharmac and include previous applications we have considered through our exceptions process (waivers and NPPA).

The proposed price reduction of adalimumab (Amgevita) means we are able to prioritise these applications for funding now. More information on each application, including relevant clinical advice records, can be found through below links to the Application Tracker:

- Ulcerative colitis first line
- Crohns disease dose escalation
- Undifferentiated spondyloarthritis
- Inflammatory bowel-disease associated arthritis
- Behçet's disease first line biologic
- Ocular inflammation – first line biologic
- Rheumatoid arthritis – Special Authority change; joint counts
- Rheumatoid arthritis – Special authority change; CRP levels

We estimate that approximately 720 people would benefit in the first year of funding as a result of these changes in access.

We are also proposing changes to the adalimumab (Amgevita) Special Authority criteria for currently funded uses to improve access to adalimumab treatment:

- Removal of dosing restrictions for people using Amgevita
- Special Authority renewal periods would be extended from 6 months to 2 years
- Special Authority renewals could be applied for by any relevant practitioner and in some uses, would not be required

Please follow the below links for information categorised for the different uses of adalimumab:

- Gastrointestinal conditions: Gastroenterology
- Ophthalmology conditions: Ophthalmology
- Dermatology conditions: Dermatology
- Rheumatology conditions: Rheumatology

For further information on the proposed Special Authority for these uses, please see the full list of changes.

Patient and Healthcare professional support

Pharmac would work alongside the supplier (Amgen) to provide information for healthcare professionals and patients to support the proposed change.

This would include educational material and resources for both patients and healthcare professionals, alert cards, demonstration devices and access to nurse support by telephone and/or videoconferencing.

To provide feedback

Feedback on this consultation will help us to understand will help us to understand if any changes should be made to this proposal.

Consultation closes at **5 pm on Wednesday, 22 September 2022**.

Use our response form or send us an email consult@pharmac.govt.nz by **Wednesday, 22 September 2021**.

All feedback received before the closing date will be considered by Pharmac's Board prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA). Please be aware that we may need to share your feedback, including your identity, in response to an OIA request. This applies to anyone providing feedback, whether they are providing feedback themselves or for an organisation, in a personal or professional capacity.

We can only keep feedback confidential as allowed under the OIA and other related laws. If you want any part of your feedback treated as confidential, you need to tell us. Please let us know if you want to keep part of your feedback confidential and why. Is it commercially sensitive, confidential or proprietary, or personal information? Clearly state this and tell us which parts of your feedback you want to keep confidential for these reasons. We will consider your request under our OIA requirements.