NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

9 September 2015

Decision relating to the funding of TNF inhibitors (Humira and Enbrel) and gabapentin (Neurontin)

The PHARMAC Board has approved the proposal relating to the funding of the TNF-inhibitor medicines adalimumab (Humira) and etanercept (Enbrel), both used to treat people with various autoimmune and immune-mediated conditions, and gabapentin (Neurontin).

This was the subject of a consultation letter dated 14 July 2015, available on PHARMAC's website at: http://www.pharmac.health.nz/news/consultation-2015-07-14-tnf-inhibitors/.
In summary, the effect of the decision is that:

- From 1 October 2015 the prices and subsidies of all presentations of etanercept (Enbrel) listed in the Pharmaceutical Schedule will be reduced.

- From 1 November 2015, the Neurontin brand of gabapentin capsules (100 mg, 300 mg and 400 mg) will be fully funded under the same Special Authority/Hospital restriction criteria that currently apply to other brands of gabapentin (Arrow-Gabapentin and Nupentin).

- From 1 November 2015, the 600 mg Neurontin tablets will no longer be funded and current patients being treated with this strength will need to switch to an alternative funded strength of gabapentin, such as 2 x 300 mg capsules.

- From 1 January 2016, etanercept will be the first-line funded TNF inhibitor medicine for new rheumatology and dermatology patients. Funding for adalimumab will be limited to patients who are intolerant of, or whose disease has not responded to, etanercept.

- There would be no change to the funding of adalimumab for any:
    - current patients using it (for any indication), or
    - new patients who have Crohn's disease or fistulising Crohn's disease, or
    - patients with juvenile idiopathic arthritis (JIA) with pre-existing uveitis.

  All of these patients will continue to have funded access to adalimumab as a first-line TNF inhibitor treatment option.

In addition, we would like to highlight that, as in all cases where Special Authority or hospital restrictions apply to pharmaceuticals, PHARMAC is willing to consider requests for Special Authority/hospital restriction waivers or Named Patient Pharmaceutical Assessment (NPPA) funding applications for unusual clinical situations that may not be covered by the criteria. See http://www.pharmac.health.nz/tools-resources/forms/exceptional-circumstances/ for more information on how to seek a waiver or make a NPPA application.

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Amendments made following consideration of consultation feedback

Some changes to the proposed community Special Authority and hospital restriction criteria for adalimumab were made.

These changes mean that:

- From 1 January 2016, new rheumatology and dermatology patients with co-morbid uveitis which has worsened while taking etanercept will be able to switch to funded adalimumab.
- From 1 January 2016, new patients with juvenile idiopathic arthritis (JIA) with pre-existing co-morbid uveitis prior to commencing TNF inhibitor therapy will be able to receive either funded etanercept or adalimumab as their first-line TNF inhibitor option

Details of the decision

Gabapentin (Neurontin)

From 1 November 2015:

- the prices and subsidies of gabapentin (Neurontin) will be reduced in Section B of the Pharmaceutical Schedule as follows (all prices are ex-manufacturer and exclude GST):

Chemical	Presentation	*Brand*	Pack size	Current Price/Subsidy	New Price/Subsidy 1 November 2015
Gabapentin	Cap 100 mg	*Neurontin*	100	$13.26	$7.16
Gabapentin	Cap 300 mg	*Neurontin*	100	$39.76	$11.00
Gabapentin	Cap 400 mg	*Neurontin*	100	$53.01	$13.75

- the Neurontin brand of gabapentin capsules (100 mg, 300 mg and 400 mg) will be subject to the same Special Authority and hospital restrictions that currently apply to the Arrow-Gabapentin and Nupentin brands of gabapentin.
- Neurontin 100 mg, 300 mg and 400 mg capsules will have protection from subsidy reduction, delisting, and Special Authority/HML restriction changes until 30 June 2016.
- Neurontin 600 mg tablets will be delisted from Section B and Part II of Section H of the Pharmaceutical Schedule.

Etanercept (Enbrel)

From 1 October 2015:

- the prices and subsidies of etanercept (Enbrel) listed in Section B and Part II of Section H of the Pharmaceutical Schedule will be reduced as follows (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current Price/Subsidy	New Price/Subsidy 1 October 2015
Etanercept	Inj 25 mg	Enbrel	4	$949.96	$799.96
Etanercept	Inj 50 mg auto-injector	Enbrel	4	$1,899.92	$1,599.96
Etanercept	Inj 50 mg prefilled syringe	Enbrel	4	$1,899.92	$1,599.96

- confidential rebates will apply to Enbrel, reducing its net price to the funder and DHB hospitals.

- Enbrel will remain listed in Section B and Part II of Section H of the Pharmaceutical Schedule subject to its current Special Authority and hospital restrictions. These are detailed in the Pharmaceutical Schedule and can be found on the PHARMAC website at http://www.pharmac.health.nz/tools-resources/pharmaceutical-schedule/

- Enbrel will have protection from subsidy reduction, delisting, and Special Authority/ hospital restriction changes until 30 June 2019.

Adalimumab (Humira/Humira Pen)

- From 1 January 2016 the Special Authority criteria applying to all presentations of adalimumab (Humira/HumiraPen) listed in Section B of the Pharmaceutical Schedule will be deleted and replaced with the following (the hospital restrictions in Part II of Section H of the Pharmaceutical Schedule will be deleted and replaced with similar restrictions to the following):

Initial application - (rheumatoid arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
2 Any of the following:
  2.1 The patient has experienced intolerable side effects from etanercept; or
  2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for rheumatoid arthritis; or
  2.3 The patient has co-morbid uveitis which has worsened while taking etanercept.

Renewal - (rheumatoid arthritis) 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 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
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

3 Either:
  3.1 Following 3 to 4 months' initial TNF-inhibitor 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
  3.2 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
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.

Initial application - (Crohn's disease) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:
1 Patient has severe active Crohn's disease; and
2 Any of the following:
  2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
  2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
  2.4 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
  2.5 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 systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
4 Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal - (Crohn's disease) only 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 Either:
  1.1 Applicant is a gastroenterologist; or
  1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Either:
  2.1 Either:
  2.2 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
  2.3 CDAI score is 150 or less; or
  2.4 Both:
    2.4.1 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
    2.4.2 Applicant to indicate the reason that CDAI score cannot be assessed; and
3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application - (severe chronic plaque psoriasis) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
Both:
1 The patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
2 Any of the following:
  2.1 The patient has experienced intolerable side effects from etanercept; or
  2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
  2.3 The patient has co-morbid uveitis which has worsened while taking etanercept.

Renewal - (severe chronic plaque psoriasis) 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 Applicant is a dermatologist; or
  1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Either:

2.1 Both:
- 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of TNF-inhibitor treatment; and
- 2.1.2 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

2.2 Both:
- 2.2.1 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
- 2.2.2 Either:
  - 2.2.2.1 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
  - 2.2.2.2 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

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

Note: A treatment course is defined as a minimum of 12 weeks adalimumab treatment.

Initial application - (ankylosing spondylitis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. The patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
2. Any of the following:
   - 2.1 The patient has experienced intolerable side effects from etanercept; or
   - 2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for ankylosing spondylitis; or
   - 2.3 The patient has co-morbid uveitis which has worsened while taking etanercept.

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:
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
2. Following 12 weeks of adalimumab treatment, BASDAI (see Note) has improved by 4 or more points from TNF-inhibitor treatment baseline on a 10 point scale, or by 50%, whichever is less; and
3. Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Notes: The BASDAI prior to TNF inhibitor treatment must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of starting TNF inhibitor treatment.Average normal chest expansion corrected for age and gender:
18-24 years - Male: 7.0 cm; Female: 5.5 cm
25-34 years - Male: 7.5 cm; Female: 5.5 cm
35-44 years - Male: 6.5 cm; Female: 4.5 cm
45-54 years - Male: 6.0 cm; Female: 5.0 cm
55-64 years - Male: 5.5 cm; Female: 4.0 cm
65-74 years - Male: 4.0 cm; Female: 4.0 cm
75+ years - Male: 3.0 cm; Female: 2.5 cm

Initial application - (psoriatic arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. The patient has had an initial Special Authority approval for etanercept for psoriatic arthritis; and
2. Any of the following:
   - 2.1 The patient has experienced intolerable side effects from etanercept; or
   - 2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria

for etanercept for psoriatic arthritis; or
2.3 The patient has co-morbid uveitis which has worsened while taking etanercept.

Renewal - (psoriatic arthritis) 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 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
2 Either:
2.1 Following 3 to 4 months' initial TNF-inhibitor 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 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
3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application - (juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
Either
1. Both:
1.1 The patient has had an initial Special Authority approval for etanercept for juvenile idiopathic arthritis (JIA); and
1.2 Any of the following:
1.2.1 The patient has experienced intolerable side effects from etanercept; or
1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for juvenile idiopathic arthritis; or
1.2.3 The patient has co-morbid uveitis which has worsened while taking etanercept; 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 diagnosed with Juvenile Idiopathic Arthritis (JIA); and
2.3 Patient has had severe active polyarticular course JIA for 6 months duration or longer; and
2.4 Patient has pre-existing co-morbid uveitis prior to commencing TNF inhibitor therapy; and
2.5 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10- 20 mg/m2 weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
2.6 Both:
2.6.1 Either:
2.6.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
2.6.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
2.6.2 Physician’s global assessment indicating severe disease.

Renewal - (juvenile idiopathic arthritis) 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 Applicant is a named specialist or rheumatologist; or
1.2 Applicant is a Practitioner and confirms that a named specialist or rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
3 Either:
3.1 Following 3 to 4 months’ initial TNF-inhibitor treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment

from baseline; or

3.2 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.

Initial application - (fistulising Crohn's disease) 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 Either:
  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
3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application; and
4 The patient will be assessed for response to treatment after 4 months' adalimumab treatment (see Note).

Note
A maximum of 4 months' adalimumab will be subsidised on an initial Special Authority approval for fistulising Crohn's disease.

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

1 Either:
  1.1 Applicant is a gastroenterologist; or
  1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Either:
  2.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
  2.2 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.

Initial application - (pyoderma gangrenosum) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1 The patient has had an initial Special Authority approval for etanercept for pyoderma gangrenosum*; and
2 Any of the following:
  2.1 The patient has experienced intolerable side effects from etanercept; or
  2.2 The patient has received insufficient benefit from at least 3 months treatment with etanercept for pyoderma gangrenosum*; or
  2.3 The patient has co-morbid uveitis which has worsened while taking etanercept; and
3 A maximum of 4 doses.

Note
Indications marked with * are Unapproved Indications (refer to (Interpretations and Definitions).

Renewal - (pyoderma gangrenosum) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1 Patient has shown clinical improvement; and
2 Patient continues to require treatment; and
3 A maximum of 4 doses.

Initial application - (adult-onset Still's disease) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 Either:
  1.1 The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD*); or
  1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules; and
2 Any of the following:

2.1 The patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
2.2 The patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab such that they do not meet the renewal criteria for AOSD; or
2.3 The patient has co-morbid uveitis which has worsened while taking etanercept.

Note
Indications marked with * are Unapproved Indications (refer to (Interpretations and Definitions).

Renewal - (adult-onset Still's disease) 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 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
2 The patient has a sustained improvement in inflammatory markers and functional status.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 11 August 2015 were considered in their entirety in making a decision on the proposed changes.

All responses received on the issue of delisting the Neurontin 600 mg tablets were supportive and no issues were raised around any aspects of the proposal relating to gabapentin.

There were mixed responses to the proposal to amend access criteria for adalimumab, and the table below and on the following pages outline issues that were raised in relation to specific aspects of the proposal.

Theme	Comment
Patients with juvenile idiopathic arthritis (JIA) and uveitis should continue to have funded access to adalimumab as a first-line TNF inhibitor option	We understand that, compared with other patient groups, those with JIA have a greater risk of having uveitis and have a higher risk of more severe disease and sight-threatening complications that may not be reversible. Although evidence shows that treatment with TNF inhibitors can reduce uveitis, it also shows that etanercept may be less effective than adalimumab for this. Given the higher risk of irreversible sight-threatening complications from uveitis in this small group of patients, we considered it reasonable to maintain the current choice of either adalimumab or etanercept as a first line TNF inhibitor for these patients.
Patients with rheumatology and/or dermatology conditions with secondary uveitis should continue to have funded access to adalimumab as a first-line TNF inhibitor option	We consider that most patients with secondary uveitis would be effectively treated with topical and/or short course steroids and could remain on first-line etanercept. However, we have clarified in the adalimumab criteria that worsening of uveitis is considered treatment intolerance and that patients can switch to adalimumab if their uveitis worsens whilst on etanercept. We have amended the proposed funding criteria for adalimumab accordingly.

Theme	Comment
Patients with rheumatology and/or dermatology conditions with secondary inflammatory bowel disease (IBD) should continue to have funded access to adalimumab as a first-line TNF inhibitor option	While adalimumab (but not etanercept) may improve patients' secondary IBD symptoms, a specific application from AbbVie to widen funded access to adalimumab for these patients (moderately to severe ulcerative colitis) was recently reviewed by PTAC and the Gastrointestinal Subcommittee of PTAC. Both the Subcommittee and PTAC recommended that the application be declined because of limited evidence for sustained clinical effectiveness, as well as a lack of long-term safety data and high financial risk. Adalimumab is currently funded, and would remain funded, for patients with Crohn's disease and fistulising Crohn's disease and the in-hospital TNF inhibitor infliximab is also funded for patients with severe ulcerative colitis, Crohn's disease and fistulising Crohn's disease.
Etanercept is considered inferior to adalimumab for severe psoriasis	Both etanercept and adalimumab are approved by Medsafe for the treatment of psoriasis. There are no head-to-head comparative clinical trial studies of etanercept and adalimumab in patients with severe psoriasis and we consider that the published meta-analyses reports should be interpreted with caution because the studies included were heterogeneous and used variable dosing schedules, response definitions and time points. We note that if a patient's psoriasis fails to respond to etanercept treatment they will be able to switch to funded adalimumab. We consider that the sequence change will have no measurable clinical impact on treatment outcomes for psoriasis patients.
Concern over lack of choice in treatment options for patients and health professionals	The decision directs the sequence in which the funded TNF inhibitors are to be used for some patients, but has no impact on the number of treatments funded or the number of lines of treatment funded. We note that currently a proportion of patients already choose etanercept as their first line TNF inhibitor treatment option. There is no head-to-head comparative clinical trial evidence that either TNF inhibitor is more effective than the other in rheumatology and dermatology indications. We consider that it is reasonable for etanercept to be the mandated first line TNF inhibitor treatment for new rheumatology and dermatology patients, as it is a lower cost, and more cost effective, treatment than adalimumab. We consider that the sequence change will have no measurable clinical impact on treatment outcomes for patients.

Theme	Comment
Concern that the proposal is based on economic reasons and not on clinical/scientific reasons	PHARMAC is tasked with managing pharmaceutical funding from within a fixed budget. Current annual expenditure on TNF inhibitors is in excess of $80 million. We agree the primary purpose of the proposal was to create substantial savings in the TNF inhibitor market, savings that could be used to fund new medicines for other patient groups. However budget impact and cost effectiveness are just two of our nine decision criteria. In developing the proposal and coming to our decision all our other decision criteria were considered, including the health needs of eligible people and the clinical benefits and risks of pharmaceuticals. There is no head-to-head comparative clinical trial evidence that either TNF inhibitor is more effective than the other. We consider that both adalimumab and etanercept deliver similar outcomes in patients; therefore, it is reasonable that funding criteria require use of the cheaper, more cost effective, medicine first.
More frequent dosing (ie weekly rather than fortnightly injections) with etanercept may decrease adherence to treatment for patients	We do not consider that the lower dosing frequency of adalimumab would be a significant factor for most patients (once fortnightly vs once weekly). This is evidenced by the current preference for etanercept in children with JIA, a group that we would normally expect would be highly sensitive to injection frequency.
The supplier of adalimumab currently provides a range of support and funding programmes that may not exist following a change in funding	While acknowledging that the support currently provided by AbbVie is likely beneficial for patients, pharmacists and prescribers we note they are provided at the discretion of AbbVie and could therefore be stopped at any time. We note that, even with this change, the adalimumab market value will remain substantial. The supplier of etanercept, Pfizer, also currently provides some support options for health care professionals and patients. Overall, we consider that the health benefits that would be created by the savings generated from this decision outweigh any health benefits from the support AbbVie currently provides for adalimumab.
Can the savings be used to fund other biologic medicines for rheumatology and/or dermatology conditions	PHARMAC is willing to consider applications for funding of new medicines for rheumatology and/or dermatology conditions. These would be assessed and considered alongside other funding options for other medicines and diseases using our standard funding process to ensure we deliver the best health outcomes form within the funding provided.

Theme	Comment
The proposal may affect the potential for more significant savings through the funding of biosimilar products	We are aware that biosimilar TNF inhibitors are in development and have carefully considered this during our decision making. While the decision may delay potential savings from a biosimilar competitive process we consider that overall the decision delivers more certain, and likely greater, savings in both the short and long term. The increased market share for etanercept that will be delivered by this decision will enable greater savings to be achieved from an etanercept biosimilar competitive process at a later date. The decision also gives clinicians and patients some experience of managing changes to funding arrangements for TNF inhibitors.

More information

If you have any questions regarding this decision, please email us at enquiry@pharmac.govt.nz.