29 October 2015

Proposal to retain first-line biologic access for adalimumab in dermatology and rheumatology indications

PHARMAC is seeking feedback on a provisional agreement with AbbVie Limited to reduce the price and subsidy of adalimumab (Humira and HumiraPen) and to retain the same funded access criteria that currently apply to adalimumab.

The result of this proposal is that access to adalimumab for dermatology and rheumatology indications would not change from 1 January 2016 as notified on 9 September 2015 (www.pharmac.health.nz/notification-tnf-inhibitors/), and both etanercept (Enbrel) and adalimumab would remain options to use as a first-line biologic treatment for dermatology and rheumatology indications.

In summary, the proposal is to:

- Reduce the price and subsidy for all presentations of adalimumab (Humira and HumiraPen) currently listed on the Pharmaceutical Schedule from 1 January 2016.
- Retain the current Special Authority criteria and Hospital Restrictions for adalimumab (Humira and HumiraPen) from 1 January 2016.
- Apply new confidential rebates to all presentations of adalimumab (Humira and HumiraPen) from 1 January 2016 which would reduce the net cost of this treatment.
- List a new presentation injection 10 mg per 0.2 ml prefilled syringe of adalimumab (Humira) on the Pharmaceutical Schedule from 1 January 2016 subject to the same Special Authority criteria and Hospital Restrictions as the other funded strengths and presentations of adalimumab.
- Provide adalimumab (Humira and HumiraPen) with protection from subsidy reduction, delisting, and Special Authority/Hospital Restriction amendment until 30 June 2019.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by**, Thursday 12th November 2015** to:

Geraldine MacGibbon
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PHARMAC

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Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

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Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld. PHARMAC will give due consideration to any such request.

Details of the proposal

- From 1 January 2016 the prices and subsidies of adalimumab (Humira and HumiraPen) would be reduced in Section B and Part II of Section H of the Pharmaceutical Schedule as follows (all prices are ex-manufacturer and exclude GST):

Chemical and presentation	Brand	Pack size	Current Price/Subsidy	Proposed Price/Subsidy
Adalimumab inj 20 mg per 0.4 ml prefilled syringe	Humira	2	$1,799.92	$1,599.96
Adalimumab inj 40 mg per 0.8 ml prefilled syringe	Humira	2	$1,799.92	$1,599.96
Adalimumab inj 20 mg per 0.4 ml prefilled pen	HumiraPen	2	$1,799.92	$1,599.96

- A new lower strength of adalimumab, inj 10 mg per 0.2 ml prefilled syringe (Humira), would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 January 2016 at a price and subsidy of $1,599.96 per pack of 2.

- New confidential rebates would apply to all strengths and presentations of Humira and HumiraPen from 1 January 2016, reducing their net price to the funder and DHB hospitals.

- All strengths and presentations of Humira and HumiraPen would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule subject to the same Special Authority criteria and Hospital Restrictions that currently apply to them as at the date of this consultation letter, and there would be no changes to these criteria on 1 January 2016 as previously notified. The current funding criteria are detailed in the Pharmaceutical Schedule and can be found on PHARMAC's website at www.pharmac.health.nz/pharmaceutical-schedule/

- Humira and HumiraPen would have protection from subsidy reduction, delisting, and Special Authority/Hospital Restriction changes until 30 June 2019.

Background

Adalimumab (Humira and HumiraPen, supplied by AbbVie) and etanercept (Enbrel, supplied by Pfizer) are tumour necrosis factor (TNF)-alpha inhibitor medicines, a class of biologic treatments used to treat various autoimmune and immune-mediated conditions including rheumatoid arthritis, psoriatic arthritis and psoriasis. Adalimumab and etanercept are both administered by subcutaneous injection.

Adalimumab and etanercept are both currently fully funded with similar criteria for patients with rheumatoid arthritis, ankylosing spondylitis, severe chronic plaque psoriasis and psoriatic arthritis, for patients with severe disease that has not adequately benefitted from, or where patients cannot tolerate, at least two other non-biologic treatments. Adalimumab and etanercept are also both funded for the unregistered indications of adult-onset Still's disease and pyoderma gangrenosum. Adalimumab, but not etanercept, is also funded for patients with Crohn's disease and fistulising Crohn's disease (etanercept is not registered or funded for these indications).

On 9 September 2015 PHARMAC announced its decision to approve a proposal relating to etanercept, adalimumab and gabapentin. One aspect of this decision was to amend the Special Authority criteria and Hospital Restrictions applying to adalimumab for its funded dermatology and rheumatology indications from 1 January 2016 such that, with a few exceptions, funding for new patients would be limited to those who are intolerant of, or whose disease has not responded to, etanercept. More details about this decision can be found in the notification letter on PHARMAC's website at www.pharmac.health.nz/notification-tnf-inhibitors/.

The current proposal would result in a reversal of this decision, meaning that from 1 January 2016 adalimumab would continue to be funded subject to the same funding criteria that currently apply to it.

This proposal would have no impact on the Special Authority criteria or Hospital Restrictions applying to etanercept.

This proposal would provide savings certainty in the TNF-inhibitor market as well as providing up-front savings on adalimumab expenditure across all funded indications, with no change to current funding of adalimumab for future patients. PHARMAC would be able to use the savings created to deliver greater health outcomes.