NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

14 May 2013

Approval of proposal to widen access to adalimumab for juvenile idiopathic arthritis and for fistulising Crohn's disease

PHARMAC is pleased to announce the approval of a proposal to widen access to adalimumab (Humira and HumiraPen) to include juvenile idiopathic arthritis and fistulising Crohn's disease, and to list a 20 mg strength of Humira, from 1 July 2013, through an agreement with AbbVie Limited.

This proposal was the subject of a consultation letter dated 12 April 2013 which can be found on PHARMAC's website at www.pharmac.health.nz/news/item/adalimumab-for-juvenile-idiopathic-arthritis-and-for-fistulising-crohn-s-disease.

Details of the decision

- A new strength of Humira (adalimumab inj 20 mg per 0.4 ml prefilled syringe) will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013 at a price and subsidy of $1,799.92 per 2 syringes (ex-manufacturer, excluding GST).

- Access to adalimumab (Humira and HumiraPen) in Section B of the Pharmaceutical Schedule will be widened from 1 July 2013 via addition of the following criteria to the existing Special Authority:

> **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 Either:
> 1.1.1 The patient has experienced intolerable side effects from etanercept; or
> 1.1.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for JIA; or
> 2 All of the following:
> 2.1 Patient diagnosed with JIA; and
> 2.2 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 had severe active polyarticular course JIA for 6 months duration or longer; and
> 2.4 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
> 2.5 Both:
> 2.5.1 Either:
> 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
> 2.5.1.2 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
> 2.5.2 Physician's global assessment indicating severe disease.

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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 (a copy of which is available at www.pharmac.govt.nz/latest/BaselineFistulaAssessment.pdf) 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 - (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 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.

Renewal – (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months 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.

- Access to adalimumab (Humira and HumiraPen) in Part II of Section H of the Pharmaceutical Schedule will be widened from 1 July 2013 via addition of criteria essentially similar to those outlined above.

- Confidential rebates will apply to all sales and subsidies for all listed presentations of Humira and HumiraPen from 1 July 2013, reducing their net price to DHBs and the Funder.

- The Special Authority and hospital restrictions for etanercept for JIA will be amended from 1 July 2013 as follows (additions in **bold**):

> **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:**
> **2.3 The patient has had an initial Special Authority approval for adalimumab for juvenile idiopathic arthritis (JIA); and**
> **2.4 Either:**
> **2.4.1 The patient has experienced intolerable side effects from adalimumab; or**
> **2.4.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for JIA; or**
> 2 All of the following:
> 2.1 Patient diagnosed with JIA; and
> 2.2 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 had severe active polyarticular course JIA for 6 months duration or longer; and
> 2.4 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
> 2.5 Both:
> 2.5.1 Either:
> 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
> 2.5.1.2 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
> 2.5.2 Physician's global assessment indicating severe disease.

- The restrictions applying to the initiation of etanercept (Enbrel) for JIA in Part II of Section H of the Pharmaceutical Schedule will be amended from 1 July 2013 essentially as outlined above.

- The restrictions applying to the initiation of infliximab (Remicade) for fistulising Crohn's disease in Part II of Section H of the Pharmaceutical Schedule will be amended from 1 July 2013 as follows (deletions in strikethrough):

> **Initiation – fistulising Crohn's disease –** gastroenterologist
> 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 Either:~~
> ~~3.1 An adequate trial of conventional treatment has not been successful (defined as at least 4 months therapy with an adequate dose of thiopurine); or~~

~~3.2 A trial of immunomodulators is not appropriate due to rapid and severe onset of fistulae; and~~

~~3~~4 Patient must be reassessed for continuation after 4 months of therapy.

Feedback received

We appreciate all the feedback we received and acknowledge the time people took to respond. All consultation responses received were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal (all in relation to the proposal for adalimumab for fistulising Crohn's disease):

Theme	Comment
A 4-month trial of thiopurines should not be required prior to commencement of adalimumab as these treatments do not work well for fistulising Crohn's disease and patients may deteriorate rapidly.	This proposed requirement has been removed from the Special Authority criteria, and has also been removed from the Special Authority criteria for infliximab for fistulising Crohn's disease in DHB hospitals.
There should be potential to increase the dose or shorten the dose interval.	We intend to review the evidence and cost effectiveness (including seeking further PTAC advice) of weekly adalimumab for both severe Crohn's disease and fistulising disease.
Swapping to another biologic should be permitted, as in the Australian rules. These should be interchangeable.	The criteria would not prevent switching from one biologic to another providing the Special Authority criteria for each are met.
Criteria for adalimumab for Crohn's disease should be consistent with infliximab in hospitals with respect to paediatric use.	Adalimumab is not currently indicated for use in paediatric patients with Crohn's disease. Infliximab is available for the paediatric population.
Two responders requested changes to the response definitions.	We consider that the renewal criteria are appropriate and consistent with the clinical advice we have received. However, we will monitor implementation of this decision and could review the criteria at a later date if need be (including taking further clinical advice if necessary).
One responder asked if it is the intention to use the Fistula Assessment Form used by Medicare Australia.	Yes, we anticipate that this tool would be used. We will make a version of this form available on our website (the web address is included in the Special Authority criteria and hospital restrictions).

We also received feedback relating to the cost to pharmacies associated with distribution of adalimumab (including wholesaler markups), which we have passed on to DHBs as distribution costs are dealt with in the Community Pharmacy Services Agreement which is managed by DHBs.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.