CONSULTATION

PHARMAC
Pharmaceutical Management Agency

12 April 2013

Proposal to widen access to adalimumab for juvenile idiopathic arthritis and for fistulising Crohn's disease

PHARMAC is seeking feedback on 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 a provisional agreement with AbbVie Limited.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5:00 pm on Monday 29 April 2013** to:

Geraldine MacGibbon	Email: geraldine.macgibbon@pharmac.govt.nz
Senior Therapeutic Group Manager	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do. 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.

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.

Details of the proposal

- A new strength of Humira (adalimumab inj 20 mg per 0.4 ml prefilled syringe) would 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 would 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:

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

1.1 The patient has had an initial Special Authority approval for etanercept for juvenile idiopathic arthritis (JIA); and
1.2 Either:
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

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.

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 An adequate trial of conventional treatment has not been successful (conventional treatment is defined as at least 4 months treatment with an adequate dose of thiopurine); and
4 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application; and
5 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 would be widened from 1 July 2013 via addition of criteria essentially similar to those proposed above.

- Confidential rebates would 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 would 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:
  1.1 The patient has had an initial Special Authority approval for adalimumab for juvenile idiopathic arthritis (JIA); 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 juvenile idiopathic arthritis; 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.

Background

Adalimumab is a recombinant human immunoglobulin monoclonal antibody that inhibits tumour necrosis factor (TNF) alpha. It is a 'biologic' treatment and is currently funded as a last-line treatment for rheumatoid arthritis, psoriatic arthritis, Crohn's disease, chronic plaque psoriasis and ankylosing spondylitis.

Juvenile idiopathic arthritis (JIA)

JIA is a chronic, autoimmune, inflammatory joint disease. It is the most common rheumatic disease in children and adolescents. Currently, the only community-funded biologic treatment for JIA is etanercept.

The Pharmacology and Therapeutics Advisory Committee (PTAC) reviewed an application to fund adalimumab for JIA at its November 2010 meeting. In summary, the Committee recommended that access to adalimumab be widened to include treatment of JIA, subject to similar Special Authority criteria to those applying to etanercept in this indication but with a note encouraging the use of adalimumab in combination with methotrexate, only if it was cost-neutral to the Pharmaceutical Budget. The criteria in this proposal are broadly in line with this recommendation.

Fistulising Crohn's disease (fCD)

Crohn's disease is an idiopathic, chronic, transmural inflammatory process of the bowel that often leads to fibrosis and obstructive symptoms. Fistulae occur in around 17%-43% of patients with Crohn's disease, at some stage. Eventually, many patients with Crohn's disease require surgery, which often results from the development of a perianal fistula subsequent to an abscess. Although some patients with fCD meet the current Special Authority criteria for adalimumab for Crohn's disease, others do not and there is no other community-funded biologic treatment for fCD.

PTAC reviewed an application to fund adalimumab for fCD at its November 2011 meeting. In summary, the Committee recommended that the Special Authority criteria for adalimumab for the treatment of Crohn's disease be amended to include fistulising disease with a medium priority. The criteria in this proposal are essentially similar to those recommended by PTAC.

Minutes of the PTAC meetings can be found on PHARMAC's website at www.pharmac.health.nz/about/committees/ptac/ptac-minutes