

RGH Pharmacy E-Bulletin

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A joint initiative of the Patient Services Section and the Drug and Therapeutics Information Service of the Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia. The RGH Pharmacy E-Bulletin is distributed in electronic format on a weekly basis, and aims to present concise, factual information on issues of current interest in therapeutics, drug safety and cost-effective use of medications.

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Update on treatment for Crohn's disease

Crohn's disease is a chronic immune-mediated inflammatory disease of the gastrointestinal tract. Although any part of the gut can be involved the distal small intestine and colon are primarily affected. Crohn's disease is a significant cause of morbidity in Australia. It affects approximately 30,000 people and is most commonly diagnosed in adolescents and young adults. The clinical course of Crohn's disease is characterised by recurrent acute 'flares' followed by periods of remission. Disease symptoms include abdominal pain, diarrhoea, fatigue, fever, bleeding and malnutrition. It is a progressive disease where 50-80% of patients will eventually require surgery. Severe disease can involve deep gastrointestinal ulceration, obstruction, fistula and abscess formation, in addition to potentially life threatening complications such as perforation and haemorrhage. Severe Crohn's disease interferes with basic daily work and social activities and can significantly impair a patient's quality of life.

Conventional treatment for Crohn's disease involves a number of strategies for management of active disease to induce and maintain partial or complete remission. The Crohn's Disease Activity Index (CDAI) is one method used by clinicians to assess disease activity and treatment efficacy. A CDAI score ≤ 150 is considered to represent remission while scores above 450 represent severe disease. Conventional drug treatment includes the use of aminosalicylates, corticosteroids, 6-mercaptopurine, azathioprine, methotrexate and antibiotics. However effective treatment of severe Crohn's disease is complex and approximately 20% of patients do not respond to conventional therapy.

Infliximab for Crohn's disease

Infliximab (Remicade[®]) is a chimeric monoclonal antibody with proven efficacy in the treatment of severe refractory Crohn's disease. Infliximab infusions at the recommended dose of 5 mg/kg are currently associated with an approximate cost of up to \$A30,000 to \$A40,000 per patient. Accordingly not all patients have had access to this important but expensive therapy. Treatment has largely been limited to patients able to self fund the costs of treatment or to those patients able to acquire treatment through application to public hospitals.

Effective October 1st 2007 Infliximab will be listed on the Australian Pharmaceutical Benefits Scheme (PBS) as a Section 100 benefit, Authority Required (Highly Specialised Drug) for adult patients with severe refractory Crohn's disease. The application for PBS listing was successful as it demonstrated both an acceptable cost-effectiveness profile and a convincing body of clinical evidence illustrating the ability of intravenous infusion(s) of infliximab (5mg/kg) to cause significant and rapid clinical response in severe refractory Crohn's disease, improvement in endoscopic, histological and biochemical indices of response and healing of fistulae.

To be eligible for PBS-subsidised treatment patients must be treated by a gastroenterologist at a public or private hospital. Patients must satisfy an extensive set of criteria and the gastroenterologist will be required to provide supporting objective evidence of disease severity, history and activity. Patients must sign a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria. Patients will be eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain an adequate response.

The listing of infliximab on the PBS will improve access to treatment options available for Crohn's patients who continue to suffer severe active disease despite optimal treatment with conventional therapies (including surgery). Approximately 2,000 additional Australians are expected to commence treatment with infliximab for the treatment of Crohn's disease during the first year of listing. It is estimated that this will add an additional \$10-\$30 million to PBS expenditure in 2007-2008.

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FOR FURTHER INFORMATION – CONTACT THE PHARMACY DEPARTMENT ON 82751763 or email: chris.alderman@rgh.sa.gov.au
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