Australian Rheumatology Association

Post-market review of authority required PBS listings

Joint Submission from Arthritis Australia and the Australian Rheumatology Association

About Arthritis Australia

Arthritis Australia is the peak arthritis organisation in Australia and is supported by affiliate offices in the ACT, New South Wales, Northern Territory, Queensland, South Australia, Tasmania and Western Australia.

Arthritis Australia provides support and information to people with arthritis as well as their family and friends. It promotes awareness of the challenges facing people with arthritis across the community, and advocates on behalf of consumers to leaders in business, industry and government.

In addition, Arthritis Australia funds research into potential causes and possible cures as well as better ways to live with the disease.

About the Australian Rheumatology Association

The Australian Rheumatology Association (ARA) is the Special Society within the Royal Australasian College of Physicians (RACP) that represents rheumatologists. The ARA supports and educates members and other practitioners in the musculoskeletal field to enable provision of best possible management for patients. It fosters excellence in the diagnosis and management of musculoskeletal and inflammatory conditions through training, professional development, research and advocacy.

This submission is authorised by:

- Dr Julian McNeil, Chair of the ARA Therapeutics Committee on behalf of the ARA
- Ms Ainslie Cahill, CEO of Arthritis Australia.

Introduction

The Australian Rheumatology Association (ARA) and Arthritis Australia are pleased to have the opportunity to provide a submission to the current post-market review of authority required PBS listings.

This submission specifically focusses on issues relating to the authority approvals process for biological disease modifying anti-rheumatic drugs (bDMARDs) used for the treatment of rheumatoid arthritis and other forms of inflammatory arthritis.

About rheumatoid arthritis

Rheumatoid arthritis (RA) is a serious, chronic autoimmune condition affecting nearly half a million Australians. If poorly treated, RA can be highly disabling because it causes progressive and irreversible joint damage and loss of function.

Early diagnosis and appropriate treatment of RA can prevent much of the joint damage, deformity and disability associated with the condition.

RA can occur at any age, but is most commonly diagnosed between the ages of 35 and 55 years, affecting people in the prime of their working lives. An Australian study published in 2008 found that one in five Australians diagnosed with RA was out of the workforce within five years because of their condition.[1]

There is no cure for RA but dramatic advances in treatment over the past decade, especially the availability of bDMARDs, have resulted in major improvements to short-, medium- and long-term outcomes for those affected.

Authority required PBS listings for bDMARDs

All bDMARDs require authority approvals for PBS subsidy. Currently, written applications need to be sent by post to Medicare in Hobart which processes the application and then mails the approved script to the patient or prescriber. Written applications are required to initiate, change and continue medication.

The approvals process, with its reliance on paper based application forms, restrictive timelines and the postal system, imposes a substantial regulatory burden on prescribers. In addition, the potential for delays in approvals and lack of flexibility to accommodate the needs of patients in special circumstances, can have a major adverse impact on patients.

High burden of 'red tape' on prescribers

The current manual, paper based authority system for bDMARDs is slow and cumbersome.

The paperwork is onerous and time consuming for prescribers, some of whom may see as many as 8-12 patients a day for whom an authority script is required. This may take up to an hour a day of their time that could otherwise be devoted to patient care.

As more people go onto bDMARD treatment the administrative burden of authority prescriptions will grow both for prescribers and for Medicare, which needs to process an

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[1] Shanahan EM, Smith M, Robert-Thomson L, Esterman A, Ahern M, 2008. Influence of rheumatoid arthritis o work participation in Australia. IMJ 38, 2008: 166-173

increasing number of applications. This will increase the cost of the authority processing system and/or increase administrative processing delays unless more streamlined processes are instituted. Anecdotal evidence suggests that the script approval process has slowed down in recent years, possibly reflecting the increasing numbers of applications as more people receive these medications.

Excessive administrative burden for patients with stable disease

While patients who are new to bDMARD therapy may require frequent dosage adjustments to bring their disease under control, most people on bDMARD therapy have stable disease and require no change to their medication. In these cases the current authority script approval processes seem excessive.

In 2007, the PBAC and the AMA agreed that Authority Required (Streamlined) processes could be applied to medicines that treat chronic and stable long-term conditions with stable dosage regimens.[2] As people with stable rheumatic disease meet these criteria, streamlined authority approval processes should apply in these cases.

A substantial reduction in the administrative burden on prescribers could be achieved by allowing streamlined authority processes in these cases.

Timely supply of medication is vulnerable to postal and administrative delays

The current process for authority scripts for bDMARDs is fraught with the potential for delays, potentially compromising the timely supply of medication for patients.

Delays in filling scripts for bDMARDs are of major concern because cessation of therapy may trigger a disease flare where a person's condition suddenly worsens. In addition to causing severe pain and fatigue, the inflammation associated with disease flares can cause irreversible structural damage to the joints. If a patient does experience a disease flare while waiting for their bDMARD script, other drugs with serious side-effects, such as prednisolone, need to be prescribed to try to bring the disease back under control until the original medication can be resumed. Consequently many people become anxious and distressed if there is any delay in receiving their script, especially if they think that the delay means that their script may not be approved.

While the turnaround time for approval and receipt of a script is usually around a week, delays of up to one month are not uncommon and over the Christmas period may be up to six weeks. Whilst Medicare staff are dedicated and helpful, delays are sometimes inevitable. In January 2014 for example a processing backlog resulted in Australia-wide delays in issuing authority scripts.

In addition to administrative processing delays, there is the potential for application forms and scripts to be lost in the mail. Any minor errors or omissions in completing the application form can also create delays as Medicare staff need to send a letter to the prescriber seeking rectification before the script can be issued.

Chasing up delays and issues with authority scripts also increases the administrative burden on prescribers as the patient cannot liaise directly with Medicare to resolve any issues.

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[2] http://www.pbs.gov.au/reviews/streamlined-authorities/streamlined-authorities-12-month-review-2009.pdf

The use of an electronic application and lodgement system would provide a more efficient and less time-consuming process for authority required scripts, as well as reducing the potential for postal delays. This would help to free up prescriber time to devote to patient care.

Inflexible timing constraints add to the administrative burden on prescribers and are inconvenient for patients

Various timing constraints apply for issuing authority required bDMARD scripts. Applications need to be lodged within one month of patient assessment and ESR/CRP blood tests and scripts are only issued when a patient has already filled all previous scripts. As a result patients are only issued with a new script when they have just one month of medication supply remaining, so they are vulnerable in the event of any postal delays.

In addition, the one-month window for script renewals means that appointments with the rheumatologist need to coincide with the expiry of existing scripts. This is often difficult to achieve in an environment where waiting times for an appointment with a rheumatologist may extend to months. People in rural areas, where rheumatology clinics are infrequent or non-existent, are particularly affected.

Patients who need or wish to travel for extended periods are also affected, as current processes mean they may not have adequate supplies of their medication to do so.

The need to align appointments with scripts adds to the administrative burden on prescribers.

There is no flexibility to accommodate patients in special circumstances.

The current authority script approvals system has no flexibility to accommodate the needs of complex patients or those in special circumstances.

For example under the existing eligibility criteria someone who has ceased taking bDMARDs for more than two years needs to go through the preliminary stages of trialling conventional DMARD therapy again for six months before they are able to resume bDMARDS. This creates issues for young women having a child who may need to suspend therapy for more than two years to accommodate the pre-conception, pregnancy and breastfeeding period. These women are unable to immediately resume their previous bDMARD therapy but have to again requalify by taking conventional DMARDs for six months, even though it is known that these therapies were ineffective for them.

Providing a review or appeal mechanism, such as allowing Medicare staff to refer such cases to a panel of rheumatology experts, may provide the system with some much needed flexibility where clinically appropriate.

Recommendations

To reduce the administrative burden of the authority process and to streamline access to bDMARDs for patients, the ARA and Arthritis Australia make the following recommendations:

1) An online process for authority required script approvals should be put in place as soon as possible. An online process would substantially increase the efficiency and speed of the approvals process and remove the potential for postal delays.

2) A streamlined authority process should be available for patients with stable disease who do not require any changes to their medication.

3) Less restrictive timing constraints on issuing authority required scripts should be adopted to ensure adequate supply of medication to patients, such as those residing in rural and remote areas who have difficulty in accessing a rheumatologist.

4) A review or appeal mechanism should be put in place to provide some flexibility in approving bDMARD scripts for complex patients or those in special circumstances to ensure optimal clinical outcomes.

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