JULIAN MCNEIL, MB, BS, FRCP(UK), FRACP, PhD
Associate Professor in Medicine
Rheumatologist
Provider Number: [redacted]

DISCIPLINE OF MEDICINE
[redacted]

Adelaide appointments phone: [redacted] Fax: [redacted] After hours (**Emergency Only**) [redacted]

For Mt Gambier Appointments phone: [redacted]

Practice Manager: [redacted] **ph:** [redacted] **email:** [redacted]

11th June 2014

Dear Sir/Madam

I write on behalf of the Therapeutics Committee of the Australian Rheumatology Association.

Background

Biological disease modifying anti-rheumatic drugs (bDMARD's) have been available for the treatment of rheumatic diseases in Australia for the last 10 years. They have made a dramatic impact on the success of treatments for the major inflammatory rheumatic diseases (Rheumatoid arthritis, Psoriatic Arthritis and Ankylosing Spondylitis). The PBAC in consultation with stakeholders, including the ARA, set up a process to make available these agents to those patients who had not responded to conventional DMARD therapy. This process needed to be cognisant that these were expensive agents and the uptake was uncertain. It involved a document having to be signed by the patient, the doctor and witnessed by an independent person to say that if the patient did not fulfil key objective criteria of response the agent would no longer be supplied. This was therefore a paper-based process. It is fair to say that the uptake of bDMARD's has been less than expected in the first years of use implying that the precautions built into the original paper-based process were more than was required. In addition an assessment must be repeated by a specialist rheumatologist every 6 months for those patients who are stable and responding to these agents, for them to receive a continuing supply.

Problems

Ten years on we are left with a paper based system that requires the patient to be seen in the last month of therapy – a face to face assessment to be done including blood tests – the results sent by post to Tasmania and at least the script posted to the patient. The default is the script being posted back to the doctor and then to the patient.

This process involves difficulties at each level

(a) Rural patients are at a significant disadvantage due to specialists visiting country areas infrequently (It is difficult to do a joint count in a telemedicine consultation and telemedicine hasn't made a great impact on this process)

(b) The process is dependent on Australia Post – the slowest form of communication - and today it was announced in the press that Australia Post was asking the Government to reduce required deliveries from daily to several times per week further delaying this process. If there is problem identified in an application requiring a written amendment this mail induced delay is multiplied.

(c) This is an administrative burden at the Special Drugs Authority and our members became aware over the 2013/14 Christmas/New Year period a longer than usual delay in our patients receiving their scripts due to problems within the Special Drugs Authority.

Unlike conventional DMARD therapy a holdup in therapy is poorly tolerated by patients who are dependent on these drugs for control of their disease activity. In general for bDMARDs, the onset of action is quick and so is the offset, thus a delay in therapy may result in a flare of disease activity for the patient.

Recommendation

In general we would like to see an internet based system where the prescriber would log into a website, key in the information confirming that their patient has fulfilled the response criteria and receiving the authority in the one consultation, so that the patient could walk out of the office with an authorised script.

I understand that such a system already exists for agents used to treat infertility.

Advantages

(a) Not only would this system reduce the administrative burden for the patients and rheumatologists involved but we believe it would also reduce the workload for the Special Drugs Authority.

(b) Over the 10 years that bDMARD's have been available through the PBS we have seen the number of agents increase from two to eight. We are on the cusp of seeing biosimilars, (analogous to generic bDMARD's) and a new class of anti-rheumatic agent Tofacitinib, a JAK pathway inhibitor. We believe that these factors will drive down the price of bDMARD's this making the administrative oversight less crucial.

Finally any system which ensures the ready availability of effective treatments to our patients and ensures that control of their disease is not compromised by what we see as an outdated administrative process would be welcome by our association.

Yours sincerely

Julian McNeil
Chair of the Therapeutics Committee
Australian Rheumatology Association