Record of the Rheumatology Subcommittee of PTAC
Meeting held on 18 August 2021

Present from the Rheumatology Subcommittee:
Marius Rademaker (Chair, PTAC member)
Alan Fraser (PTAC member)
Michael Corkhill
Andrew Harrison
Priscilla Campbell-Stokes
Janet Hayward
Lisa Stamp (PTAC member)
Keith Colvine

Apologies
Elizabeth Dennett
Will Taylor

1. Welcome and overview

1.1. This record is a summary of relevant discussion of the key issues and feedback relating to the proposed changes for access to adalimumab and is not to be considered an exhaustive detailed account of all discussions.

1.2. The purpose of this meeting was to discuss and provide feedback on the proposal to widen access to adalimumab and award Principal Supply Status to the citrate-free biosimilar brand of adalimumab (Amgevita), in advance of public consultation.

2. Discussion

2.1 The Subcommittee reviewed a paper from Pharmac staff on the proposed changes to the funding of adalimumab for patients treated for rheumatology indications.

2.2 The Subcommittee noted the proposed Special Authority criteria for access to the alternative brand of adalimumab (Humira) and considered these to be appropriate, noting no concerns regarding the proposed approach for access to Humira for rheumatology patients.

2.2.1 The Subcommittee noted the minimum trial period of 4 weeks of Amgevita to be appropriate; however, considered that access would be more appropriately defined in circumstances of 'loss of disease control' rather than 'disease progression', noting there is an important distinction between these states where loss of disease control implies a state of stability prior to the change.

2.2.2 The Subcommittees considered that, due to the nature of adalimumab as a biologic treatment, patients are expected to experience loss of treatment response over time; however, this would not be attributed to a change to a biosimilar such as Amgevita if occurring over six months after the change, and rather part of expected loss of treatment response. The Subcommittee considered it would be appropriate to restrict access to the alternative brand of adalimumab for patients who have changed to Amgevita (after previously being controlled on Humira) and considered six months would be a reasonable amount of time to determine if Amgevita was ineffective or intolerable due to a change in brand.

2.2.3 The Subcommittee considered, from anecdotal feedback, that Amgevita has been well received internationally; however, considered it may be difficult to quantify what adverse events would be associated with changing compared to adverse events driven by patient anxiety. The Subcommittee considered whether adverse events should be defined as significant or severe to assist clinicians in the interpretation of intolerance to Amgevita to reduce the risk of people changing back to Humira inappropriately. The Subcommittee noted that patient concern and anxiety would need to be carefully managed by treating clinicians including General Practitioners and indicated that the provision of support for prescribers would be important in assisting with this.

2.3 The Subcommittee considered that the introduction of a citrate-free adalimumab product, and increased access to adalimumab would provide benefit to patients.

2.4 The Subcommittees considered the proposed changes to the Special Authority criteria for access to existing indications of adalimumab:

2.4.1 The Subcommittee considered the extension to the renewal periods up to 24 months (2 years) would reduce the risk of patient level interruptions in access to adalimumab due to application delays and would relieve pressure on prescribers reducing the administrative burden of reassessing stable patients every six months which could improve access.

2.4.2 The Subcommittee considered the proposed change enabling any relevant practitioner to apply for a renewal Special Authority would enable applications to be made by any prescriber following initial diagnosis and initiation of treatment by a relevant specialist. The Subcommittee noted that identification of a response to treatment within the first 6 months of starting a biologic is important and this may present risk that a patient isn't fully assessed by a specialist for response to treatment; however, the Subcommittee considered this risk could be managed by the expected routine follow up review scheduled by a specialist at the time of initiating treatment.

2.4.3 The Subcommittee considered the changes to the Special Authority for rheumatoid arthritis, removing the requirement for CRP measurements was beneficial and considered the same changes should be made to the criteria for psoriatic arthritis. The Subcommittee noted patients with psoriatic arthritis often present with normal CRP and so removal of this criteria would result in fewer courses of prednisone required prior to accessing biologic treatment. Pharmac staff noted that the access changes proposed were based on applications that had been previously assessed and whilst this change could be considered, it may not be possible to assess as part of this proposal; however, evaluation could continue outside of this process.

2.4.4 The Subcommittee noted the 'Notes' on individual Special Authority were proposed for removal including the chest expansional values associated with ankylosing spondyloarthritis and considered these were a useful point of reference. The Subcommittee considered it would be useful to have a link to this information, and BADSAI score details, readily available for clinicians however it wasn't required for these to be included in the Special Authority criteria.

2.4.5 The Subcommittee recommended the requirement to trial intramuscular gold be removed from relevant Special Authority criteria, noting intramuscular gold is no longer available.

2.5 The Subcommittee noted the proposed listing and Principal Supply dates, with a seven-month transition for existing patients to change to Amgevita and considered these to be appropriate.

2.6 The Subcommittee noted that throughout the transition period, prescribing would need to be by brand and considered that it was important to ensure the management of two brands in the market simultaneously was clear to enable easy and practical prescribing of the required brand.

2.7 The Subcommittee considered that there may be some patients who change to Amgevita in consultation with their primary health care team, depending on their level of comfort with the proposed change, with guidance from the specialist. The Subcommittee considered this to be appropriate noting there would be limited capacity for every patient to be seen by their specialist (or specialist nurse) throughout the transition period and recommended that support and education be provided to assist primary care with this, provide confidence in the use of biologics and biosimilars, and specifically provide information and evidence supporting the use and efficacy of Amgevita. The Subcommittees considered that education material should be aimed at all healthcare professionals who are likely to engage with patients managed on adalimumab, particularly pharmacists, to ensure communication with patients regarding the change enables patients to feel confident with the advice provided.

2.7.1 The Subcommittee considered it was important that patients were aware of any change to treatment prior to dispensing and considered whether Pharmac could assist DHBs in running information sessions for patients to address questions or concerns without requiring additional individual appointments or provide material for rheumatologists and nurses to use when identifying and communicating with their patients.

2.7.2 The Subcommittee considered support for both patients and healthcare professionals would be valued in both supporting a change and providing ongoing support for people using adalimumab. The Subcommittee noted that the supplier of Amgevita (Amgen) would provide support including education material and resources for healthcare professionals and patients, access to telephone and/or videoconferencing nurse support and general product support such as sharps bins.

2.8 The Subcommittee noted the importance of communication of any changes and engagement with relevant clinician and patient groups. The Subcommittee noted the New Zealand Rheumatology Association (NZRA) was the relevant rheumatological clinician group to engage with; however, noted not all rheumatologists were members and recommended utilising additional engagement and education tools such as prescriber updates and webinars to engage all relevant clinicians, and distribution of information through hospital pharmacies to distribute to relevant clinicians.

2.9 The Subcommittee recommended messaging regarding the change should include a focus on the benefits associated with the proposal including a citrate free product, wider access and Special Authority changes that improved access and reduced administrative burden to prescribers.

2.10 The Subcommittee noted that public consultation on the proposed change would be released in the coming weeks and all members were able to submit individual feedback in response.