Record of the Dermatology and Ophthalmology Subcommittees of PTAC
Combined Meeting held on 17 August 2021

Present from the Dermatology and Ophthalmology Subcommittees:

Dermatology:
Marius Rademaker (PTAC member)
Rhiannon Braund (PTAC member)
Melissa Copland
Paul Jarrett

Ophthalmology:
Stephen Munn (Chair, PTAC member)

Apologies
Jo Sims (provided advice prior to the meeting)
Malcolm McKellar
David Squirrell
Samuel Whittaker
Lisa Stamp
Julie Betts
Martin Denby
Sharad Paul
Diana Purvis

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 Dermatology Subcommittees and the Ophthalmology Subcommittees (hereafter collectively referred to as the Subcommittees) jointly reviewed a paper from Pharmac staff on the proposed changes to the funding of adalimumab for patients treated for dermatology and/or ophthalmology indications.

2.2 The Subcommittees noted the proposed Special Authority criteria for access to the alternative brand of adalimumab (Humira). The Subcommittees considered that patients that experience a loss of disease control on Amgevita would likely be experiencing a loss of response to adalimumab and considered that returning to the Humira brand of adalimumab would be unlikely to resolve this loss of response, noting that available evidence supports comparable efficacy of Humira and Amgevita.

2.3 The Subcommittees considered the minimum trial period of 4 weeks of Amgevita to be too short to demonstrate loss of disease control as, for many conditions, disease deterioration typically occurs over a longer period of time and may take several months to become apparent. The Subcommittees considered that whilst it was not expected that patients would demonstrate disease deterioration within 4 weeks of changing treatments, retaining this as a minimum time period was reasonable.

2.4 The Subcommittees noted that no maximum time frame was proposed for existing patients to return to the alternative brand of adalimumab. 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. The Subcommittee considered this would not be attributed to a change to a biosimilar such as Amgevita if it occurred over six months after the change, and rather part of expected loss of treatment response. The Subcommittees 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.

2.5 The Subcommittees noted that the alternative brand access would enable access to the alternative brand of adalimumab for existing patients only; all new patients would need to start on Amgevita from the list date to access funded treatment with adalimumab. The Subcommittees considered that this was clinically appropriate as available evidence indicates Amgevita to be equivalent in efficacy and safety to Humira. The Subcommittees noted Amgevita has been used internationally for the majority of indications for several years and Amgen are one of the largest producers of biosimilars worldwide and considered this provided some confidence in the use of Amgevita.

2.6 The Subcommittees noted that patients with severe ocular inflammation who have previously been managed on the Humira brand of adalimumab and considered at risk of severe loss of disease control (including a risk of vision loss) would be able to access the alternative brand without a trial of Amgevita, if considered necessary by their treating clinician.

2.7 The Subcommittees noted that the evidence supporting the use of biosimilar TNF's in uveitis was generalised across a number of TNF inhibitors with most evidence evaluating efficacy and switching of infliximab biosimilars. The Subcommittees considered there was increasing real-world information relating to the use of biosimilars in this patient population which supported use and considered that it would be reasonable to extrapolate the available evidence and real-world information to Amgevita. The Subcommittees further noted Amgevita is Medsafe approved for use in uveitis as with the reference product, and considered this, alongside available evidence, indicates that new patients, with uveitis would likely achieve the same level of health benefit from Amgevita as the reference product. Members suggested Pharmac monitor and assess the impact of the change for new patients to inform whether there is a difference between brands of adalimumab and if changes to the Special Authority and Alternative Brand access criteria are required for this indication.

2.8 The Subcommittees considered that increased access to adalimumab would provide significant benefit for patients and would improve the access for the majority of funded indications.

2.8.1 The Subcommittees noted the proposed widening of access to Amgevita for patients with Behçet's disease and ocular inflammation to enable first line biologic use with adalimumab. The Subcommittees considered that the response rate of adalimumab as a first line biologic is high and therefore early access may act as an early steroid sparing agent for some patients.

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

2.9.1 The Subcommittees considered the extension of renewal periods up to 24 months (2 years) would relieve pressure on specialists and reduce the administrative burden of reassessing stable patients every six months.

2.9.2 The Subcommittees considered the change to enable any relevant practitioner to apply for renewal Special Authorities would enable improved access to Special Authorities for patients and improve continuity of access to treatment within the community setting. The Subcommittees considered initial Special Authorities should remain limited to specialists to ensure accurate diagnoses, appropriate pre-treatment work ups / treatment trials, and to establish appropriate treatment plans for patients before initiation on biologic therapy. The Subcommittees considered that without this restriction there was a risk that patients could be inappropriately initiated on biologic therapy and the relative health benefit could therefore not be realised.

2.9.3 The Subcommittees considered removal of dosing restrictions would enable more effective disease control for some patients, and may be utilised in patients with higher BMI's, or patients achieving less than optimal response to fortnightly adalimumab dosing. The Subcommittees noted there may be a fiscal rather than clinical concern with removal of all dosing restrictions and considered it was important to ensure clinicians do not default to weekly dosing for all patients and reserve this for patients who require increased dosing for optimal treatment response. The Subcommittees considered monitoring of prescribing habits to determine if further education and support regarding the optimal use of Amgevita is required if it appears that uptake of weekly dosing is higher than estimated.

2.9.3.1 The Subcommittees considered that patients with Hidradenitis Suppurativa would be likely to utilise the dosing flexibility with higher loading doses at the initiation for a longer initial duration (beyond the current four months). The Subcommittees considered this may increase the rate of likely response and enable either lower doses later in treatment or early cessation of treatment.

2.10 The Subcommittees 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.

2.11 The Subcommittees 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. The Subcommittees recommended that support and education be provided to assist with this, provide confidence in the use of biologics and biosimilars, and specifically provide information and evidence supporting the use of Amgevita. The Subcommittee's noted that throughout the transition period, prescribers would need to prescribe by brand and considered that it was important to ensure to ensure the logistics (and technology) relating to the management of two brands in the market simultaneously were clear to enable easy and practical prescribing of the required brand.

2.12 The Subcommittees considered changing devices would be a significant component of any change for patients but noted member feedback that Amgevita' s device was very similar to Humira and considered the presence of a citrate-free formulation would assist some patients in accepting a change. The Subcommittees considered support for both patients and healthcare professionals would be valued in both supporting a change and providing ongoing support for people using adalimumab and 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.

2.13 The Subcommittees considered communication of any change was important and recommended engaging with relevant clinician and patient groups, as well as primary care groups that engage with General Practitioners, nurses and pharmacists. 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, noting that a patients first interaction regarding the change is critical to ensure patients feel confident with the advice provided. The Subcommittees considered that the benefits with respect to widened access as a result of the proposed change should be emphasised within communications, as well as the relevant evidence supporting the use of Amgevita.

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