Best Practice Message

June 2022

Focus on efficacy: Adalimumab biosimilar – Amgevita®

Practice changing moments

- Amgevita® is a funded (subject to Special Authority criteria) biosimilar of Humira® (adalimumab).
- Humira® and Amgevita® are not able to be automatically substituted by the pharmacist and so it is important that prescriptions for adalimumab are prescribed by brand.
- From 1st October 2022 Humira® will only be available for patients who have failed treatment with Amgevita® or have Crohn's disease or ocular inflammation and at risk of disease destabilisation if treatment regimen is changed.
- The switch from prescribing Humira® to Amgevita® in stable patients can occur within Primary care following a consultation with the patient.
- Positive discussions with patients around the transition may help alleviate the nocebo effect and perceived treatment adverse events.

Background

From the 1st of March, Amgevita®, a funded biosimilar of Humira®, has been available. Amgevita is available in the same dose and delivery options as Humira®.

We are currently in a transition period, but from the 1st of October, Humira® will only be available for patients who have tried and failed treatment with Amgevita® or if the patient has either Crohn's Disease or Ocular inflammation and the patient would be at risk of disease destabilisation if the treatment regimen is changed. Humira® and Amgevita® are not able to be automatically substituted and so it is important that prescriptions for adalimumab are prescribed by brand. Patients will need to have the change discussed with them. Consider discussing at their next consultation about the transition from Humira® to Amgevita®.

Biosimilars vs. Generics

Generic medications are a cheaper alternative to the original product (originator). It will contain the same active ingredient but may contain different excipients. The generic is tested to show that it has the same pharmacokinetic properties of the originator.[1] Because of this it is expected to have a similar effect in the patient while costing less to the pharmaceutical budget.

Biologic medications are much more complex to create. Because of this complexity and inherent variability of biologic manufacturing, the typical picture of a generic medication does not fit[1]. The proprietary manufacturing process is confidential making it impossible to recreate an exact copy of the originator, even if the protein chain is identical. For this reason the biosimilars are structurally similar but distinct from the originator. When a biosimilar is being developed it must undergo rigorous evaluation to ensure that preclinical pharmacology, efficacy, immunogenicity and safety match the originator. [2,3] This should provide confidence as to the lack of clinically meaningful differences between the products.[1,3,4]

Discussing the transition

Patients often experience hesitancy with regards to transitioning between funded brands and this is unlikely to differ. Internationally there has been success with patients being transitioned to biosimilars from the originator, however there has also been consideration that the nocebo effect may be

responsible for most of the adverse effects experienced in clinical trials where patients were switched.[5] Patient-clinician dialogue is important to phrase the transition in a positive light. Head to head studies have also been carried out which shows that the biosimilar Amgevita® is non-inferior to Humira® [3,5]. Another consideration that can be made is that Amgevita® is citrate free[6] which may reduce the pain experienced when injecting a dose compared with Humira®.

Funding considerations

Due to the cost savings forecasted from the transition from Humira® to Amgevita®, PHARMAC has been able to widen access to this medication by adding more indications, reduced the criteria for some indications and extended the renewal period for special authorities to two years.

All patients with a special authority for Humira® valid at 1 March 2022 have been issued a special authority number for Amgevita®. Prescribers should complete a special Authority renewal application at the same time as discussing the change to Amgivita® with the patient. The approval will then last for 2 years.

Further reading:

- He ako Hiringa education found here.
- Pharmac press release found here.
- Amgevita website found here.

References:

1. Weise M, Bielsky M-C, De Smet K, Ehmann F, Ekman N, Giezen TJ, et al. Biosimilars: what clinicians should know. Blood. 2012 Dec 20;120(26):5111–7.
2. Markus R, McBride HJ, Ramchandani M, Chow V, Liu J, Mytych D, et al. A Review of the Totality of Evidence Supporting the Development of the First Adalimumab Biosimilar ABP 501. Adv Ther. 2019;36(8):1833–50.
3. Zhao S, Chadwick L, Mysler E, Moots RJ. Review of Biosimilar Trials and Data on Adalimumab in Rheumatoid Arthritis. Curr Rheumatol Rep. 2018;20(10):57.
4. Rezk MF, Pieper B. To See or NOsee: The Debate on the Nocebo Effect and Optimizing the Use of Biosimilars. Adv Ther. 2018;35(6):749–53.
5. Fleischmann R, Jairath V, Mysler E, Nicholls D, Declerck P. Nonmedical Switching From Originators to Biosimilars: Does the Nocebo Effect Explain Treatment Failures and Adverse Events in Rheumatology and Gastroenterology? Rheumatol Ther. 2020 Jan 16;7(1):35–64.
6. Amgen. Amgevita Datasheet [Internet]. Medsafe; [cited 2022 Mar 8]. Available from: https://www.medsafe.govt.nz/profs/datasheet/a/amgevitainj.pdf

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