Reimbursement of Biological Medicines containing Adalimumab & Etanercept: Questions and Answers for Healthcare Professionals January 2020

Introduction

In May 2019, following a review of biological medicines containing adalimumab and etanercept, the HSE-Medicines Management Programme (MMP) identified Best-Value Biological (BVB) medicines for adalimumab and etanercept:

- Adalimumab: **Amgevita®** or **Imraldi®**
- Etanercept: **Benepali®**

Furthermore, the MMP recommends that when initiating a patient on a biological medicine containing a tumour necrosis factor-alpha (TNF-α) inhibitor, the clinician should prescribe a BVB medicine. The MMP also recommends that consideration should be given to switching a patient to one of the BVB medicines when a repeat prescription is being issued for a biological medicine containing adalimumab or etanercept.

The full report, which includes information on the process to identify the BVB medicines, is available on the website of the MMP under *Best-value biological medicines*: https://www.hse.ie/yourmedicines

Since the publication of the MMP recommendations, there has been an increase in the prescribing of the BVB medicines for adalimumab and etanercept. As of 20 January 2020, over 3,800 patients have been prescribed one of the BVB medicines for adalimumab and etanercept.

The HSE may identify additional BVB medicines for adalimumab and etanercept in 2020.

What changes are being introduced for adalimumab and etanercept from 1 February 2020?

From 1 February 2020, it is HSE policy that all adult patients who are commencing treatment with adalimumab or etanercept should be prescribed a BVB medicine.

Why have these changes been introduced?

The BVB medicines are provided to the HSE at a much lower cost than the original versions of these biological medicines. This provides an opportunity to reduce the cost to the HSE of providing biological medicines to patients. Prescribing of the BVB medicines is leading to significant savings for the health service, which can assist in facilitating access to new, innovative medicines for patients.

What do these changes mean for new patients i.e. those commencing treatment with adalimumab or etanercept?

From **1 February 2020**, all adult patients who are commencing treatment with adalimumab or etanercept should be prescribed a BVB medicine.

What is the definition of a new patient?

A new patient, is an adult, who has never been prescribed adalimumab or etanercept before, or has not received these medicines within the last six months.

What do these changes mean for existing patients prescribed adalimumab or etanercept prior to 1 February 2020?

There is currently no change for existing patients. They will continue to receive their medicine under the High Tech Arrangement from their community pharmacy.

When existing patients present for a repeat prescription for a biological medicine containing adalimumab or etanercept, **the patient should be considered for switching to a BVB medicine.**

Do these changes apply to all patients?

These changes **do not apply to paediatric patients** i.e. patients who are less than 18 years of age.

Where can I get information on the BVB Medicines for adalimumab and etanercept?

Information on the BVB medicines is available on the website of the MMP under *Best-value biological medicines*:

https://www.hse.ie/yourmedicines

This includes support materials for clinical teams who are initiating patients on or switching them to a BVB medicine.

Where can I get more information on biosimilar medicines?

Further information for both healthcare professionals and patients on biosimilar medicines is available on the following websites:

Health Products Regulatory Authority: http://www.hpra.ie/homepage/medicines/special-topics/biosimilar-medicines

European Medicines Agency: https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview#information-for-patients-and-healthcare-professionals-section