Oifig an Stiúrthóra Chúnta Náisiúnta
Seirbhís Aisíocaíochta Incháilitheacht agus Cúraim Phríomhúil
Scoir 5, M50, An Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8915729

Office of Assistant National Director
Primary Care Eligibility & Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8915729

31st January 2020

Circular 003/20

Re: MMP Best-Value Biological Medicines – Copy of Letter to Consultants

Dear Pharmacist,

Please find enclosed a copy of a letter and supporting documentation issued to prescribing consultants, by the Medicines Management Programme, in relation to Best-Value Biological (BVB) Medicines; Adalimumab and Etanercept.

From 1st February 2020, for patients who have never been treated with Adalimumab or Etanercept previously under the High Tech Arrangements, reimbursement will only be supported for the BVB medicines (i.e. Imraldi® or Amgevita® for Adalimumab, and Benepali® for Etanercept) in adult patients commencing such therapy.

The HSE will continue to identify BVB medicines for Adalimumab and Etanercept in 2020.

Your cooperation with this important HSE initiative and your continued support of the High Tech Hub is appreciated.

Yours sincerely,

Shaun Flanagan,
Interim Assistant National Director,
Primary Care Eligibility & Reimbursement Services.

Re: Best-Value Biological Medicines; Adalimumab & Etanercept

23 January 2020

Dear Colleagues,

The purpose of this letter is to notify you that a recommendation of the HSE-Medicines Management Programme (MMP) in relation to biological medicines containing adalimumab and etanercept has been accepted by the HSE Executive Management Team. It is HSE policy that adult patients who are being initiated on adalimumab or etanercept (i.e. new patients to such therapy) should be prescribed a best-value biological (BVB) medicine.

I have previously written to you (21 May 2019) in relation to the BVB medicines that the MMP recommend for adalimumab and etanercept. These include:

- Adalimumab: **Imraldi®**. Where the clinician wishes to prescribe a citrate-free formulation of adalimumab, the MMP recommends **Amgevita®**
- Etanercept: **Benepali®**

Since the publication of our recommendations, we have seen an increase in the prescribing of the BVB medicines for adalimumab and etanercept. I would like to take this opportunity to thank those who have embraced our recommendations. 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.

At this point in time, in order to ensure that the potential savings arising from this initiative are fully realised, additional measures are being put in place for adult patients who are initiated on adalimumab or etanercept in line with HSE policy.

Accordingly, from 1 February 2020, reimbursement of adalimumab and etanercept under the High Tech Arrangement will only be supported for the BVB medicines (i.e. Imraldi® or Amgevita® for adalimumab, and Benepali® for etanercept) in adult patients commencing such therapy.

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

Please find enclosed frequently asked questions for healthcare professionals, and information for patients. Further information on the BVB medicine initiative including information for healthcare professionals, and resources to support initiating patients on, or switching them to the BVB medicines are available on the MMP website (www.hse.ie/yourmedicines) in the section entitled *Best-value biological medicines*.

MMP pharmacists are available to engage with consultants and clinical teams to provide support for initiation of, and switching to the BVB medicines. Please contact the MMP (mmp@hse.ie) if you wish to avail of this support.

My thanks for your ongoing support in promoting safe, effective and cost-effective prescribing.

With best wishes,

Michael Barry

Professor Michael Barry,
National Clinical Lead,
Medicines Management Programme.
www.hse.ie/yourmedicines

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

Information about Biological Medicines containing Adalimumab & Etanercept

January 2020

A biological medicine contains an active substance, made from a biological source, such as living cells. Biological medicines containing adalimumab or etanercept treat a variety of inflammatory conditions including:

- rheumatoid arthritis
- inflammatory bowel disease; and
- psoriasis.

What is a biosimilar medicine?

A biosimilar medicine is a newer version of the original biological medicine. A biosimilar medicine is very similar to the original biological medicine. It works in the same way.

Are biosimilar medicines safe?

Biosimilar medicines are tested to show they are just as safe and effective as the original biological medicine.

What are the Best-Value Biological Medicines for adalimumab and etanercept?

The Best-Value Biological (BVB) Medicines identified by the HSE for adalimumab and etanercept are:

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

The HSE will continue to identify BVB medicines for adalimumab and etanercept in 2020.

What's changing?

From **February 2020**, we are changing the way biological medicines containing adalimumab and etanercept are prescribed under the HSE's High Tech Arrangement.

I am a new patient, what do the changes mean for me?

- From **1 February 2020**, if you are starting treatment on adalimumab or etanercept, you will be prescribed one of the BVB medicines.

What's the definition of a new patient?

A new patient, is an adult, who has not been prescribed or received adalimumab or etanercept within the last six months.

I am an existing patient prescribed adalimumab or etanercept, what does the change mean for me?

- If you are an existing patient, you will continue to receive your medicine from your community pharmacy. The changes outlined above do not apply to you.

If you are currently on a non-BVB medicine, your consultant or a member of their team may discuss with you the possibility of switching to a BVB medicine.

Does my consultant know about these changes?

Yes. Consultants in dermatology, gastroenterology and rheumatology are aware of these changes.

Why have the changes been introduced?

BVB medicines tend to cost less than the original biological medicines. Switching patients to BVB medicines will save the HSE money. This means we can give new innovative medicines to even more patients.

What supports are available?

Supports for patients prescribed these medicines include:

- home nurse visit to provide training on administering the injection
- supply of sharps bins and waste collection service
- access to patient support telephone line
- provision of product information

Your consultant or a member of their team will register you for these services.

Where can I get more information on biosimilar medicines?

Further information for patients on biosimilar medicines is available on the following websites:

HSE Medicines Management Programme: https://www.hse.ie/yourmedicines under Best-value biological medicines

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