Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

22nd February 2023

Circular 011/23

**RE: Medicines Management Programme (MMP) Best-Value Medicines - Teriparatide**

Dear Pharmacist,

Please find enclosed a copy of a letter and supporting FAQs issued to prescribing consultants by the HSE Medicines Management Programme (MMP) in relation to Best-Value Medicines (BVMs): Teriparatide under the High Tech Arrangement.

From 1st March 2023, for patients who have never been treated with Teriparatide under the High Tech Arrangements, reimbursement will only be supported for the BVMs i.e. Movymia® and Sondelbay® in adult patients commencing such therapy.

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

Yours faithfully,

Shaun Flanagan
Assistant National Director
Primary Care Reimbursement Service

**Re: Best-Value Medicines - Teriparatide**

20 February 2023

Dear Colleagues,

I am writing to inform you that the HSE-Medicines Management Programme (MMP) has completed a review of the medicinal products containing teriparatide that are available on the High Tech Arrangement, and is now recommending a number of best-value medicines (BVMs) for teriparatide.

Expenditure on medicinal products containing teriparatide under the High Tech Arrangement was approximately €4.2 million in 2021. Biosimilar medicines and a hybrid medicinal product containing teriparatide are now available; the MMP recognises the potential savings arising from these. These savings, however, can only be realised by increased utilisation of the BVMs recommended by the MMP.

The MMP recommends **Movymia®** and **Sondelbay®** as the BVMs for teriparatide on the High Tech Arrangement. An evaluation report entitled **Best-Value Medicines: Teriparatide on the High Tech Arrangement** is available at www.hse.ie/yourmedicines in the section entitled *Best-value medicines.*

Prescribing of the recommended BVMs for teriparatide reduces the financial burdens on the HSE arising out of the funding of reimbursed medicines, and 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 recommendation are fully realised, additional measures are being put in place for adult patients who are being initiated on teriparatide.

**Accordingly, from 1 March 2023, reimbursement of teriparatide on the High Tech Arrangement will only be supported for the identified BVMs (i.e. Movymia® and Sondelbay®) in adult patients commencing such therapy.** When issuing a repeat prescription for a patient who is established on a medicinal product containing teriparatide, the patient should be considered for switching to **Movymia®** or **Sondelbay®**.

Please find enclosed Questions and Answers document for Healthcare Professionals, and information for patients. Further information on this initiative, including information for healthcare professionals and resources to support initiating patients on, or switching them to the recommended BVMs are available on the MMP website (www.hse.ie/yourmedicines) in the section entitled *Best-value medicines*.

The MMP are available to engage with consultants and clinical teams to provide support for initiation of, and switching to the BVMs for teriparatide. This includes the provision of information sessions, in conjunction with the High Tech Co-ordination Unit, on the BVMs and the High Tech Hub. Please contact the MMP (mmp@hse.ie) if you wish to avail of this support.

I would ask that you support this important initiative, which helps to secure ongoing access for patients to new and innovative medicines.

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,**
**HSE-Medicines Management Programme**

# Reimbursement of Medicinal Products containing Teriparatide: Questions and Answers for Healthcare Professionals February 2023

## Introduction

In February 2023, following a review of medicinal products containing teriparatide, the HSE-Medicines Management Programme (MMP) identified best-value medicines (BVMs) for teriparatide on the High Tech Arrangement; **Movymia®** and **Sondelbay®**.

The MMP recommends that when initiating a patient on a medicinal product containing teriparatide, the clinician should prescribe **Movymia®** or **Sondelbay®**. The MMP also recommends that prescribers should give consideration to switching a patient to **Movymia®** or **Sondelbay®** when a repeat prescription is being issued for a medicinal product containing teriparatide.

An evaluation report, which includes information on the process followed to identify the BVMs, is available on the website of the MMP under *Best-value medicines*:
www.hse.ie/yourmedicines

## What changes are being introduced for teriparatide from 1 March 2023?

From 1 March 2023, it is HSE policy that all adult patients who are commencing treatment with teriparatide should be prescribed one of the MMP BVMs, **Movymia®** or **Sondelbay®**.

## Why have these changes been introduced?

The BVMs for teriparatide are provided to the HSE at a much lower cost than the original version of teriparatide. This provides an opportunity to reduce the cost to the HSE of providing this medicine to patients. Prescribing of the BVMs will lead 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 teriparatide?

From **1 March 2023**, all adult patients who are commencing treatment with teriparatide should be prescribed **Movymia®** or **Sondelbay®**.

## What is the definition of a new patient?

A new patient, is an adult, who has never been prescribed teriparatide before, or has not received this medicine within the last six months.

## What do these changes mean for existing patients prescribed teriparatide prior to 1 March 2023?

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

However, when existing patients present for a repeat prescription for a medicinal product containing teriparatide, **the prescriber could consider switching the patient to Movymia® or Sondelbay®**.

## 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 best-value medicines for teriparatide?

Information on the BVMs is available on the website of the MMP under *Best-value medicines*: www.hse.ie/yourmedicines

This includes support materials for clinical teams who are initiating patients on or switching them to the BVMs:

- Best-value medicine: Teriparatide. Questions and Answers for Healthcare Professionals
- Information for Patients about Medicines containing Teriparatide
- MMP product information sheets for Movymia® and Sondelbay®
- Information on patient support services for Movymia® and Sondelbay®
- Template switching letters for clinics
- Patient Information Leaflets on switching from Forsteo® to Movymia® or Sondelbay®

## Who should I contact if I have any questions?

MMP pharmacists are available to engage with consultants and clinical teams to provide support for initiation of, and switching to the BVMs. This includes the provision of information sessions, in conjunction with the High Tech Co-ordination Unit, on the BVMs and the High Tech Hub.

Please contact the MMP (mmp@hse.ie) if you wish to avail of this support.

## Movymia® and Sondelbay® are both biosimilar medicines; 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:** www.hpra.ie/homepage/medicines/special-topics/biosimilar-medicines

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

## The European Medicines Agency issued a joint statement with the Heads of Medicines Agencies on interchangeability of biosimilar medicines in September 2022. What did this say?

This statement confirmed that biosimilar medicines approved in the EU are interchangeable with their reference medicine or with an equivalent biosimilar medicine.

Interchangeability in this context means that a prescriber can replace the reference medicine with a biosimilar medicine without a patient experiencing any changes in the clinical effect.

The EMA highlighted that the experience obtained from clinical practice has shown that in terms of efficacy, safety and immunogenicity, biosimilar medicines are comparable to their reference medicine and therefore can be prescribed interchangeably.

## Can Movymia® and Sondelbay® be prescribed on the High Tech Hub?

Yes, High Tech Prescriptions for Movymia® and Sondelbay® can be generated on the High Tech Hub.

Since August 2020, the High Tech Hub has been approved as a national electronic prescription transfer system.

Queries in relation to registration for the High Tech Hub should be directed to the HSE-Primary Care Reimbursement Service High Tech Co-ordination Unit at PCRS.HiTech@hse.ie.

**Information for Patients about Medicines containing Teriparatide**

**February 2023**

Teriparatide is a biological medicine used in the treatment of osteoporosis, which is a condition that weakens bones, making them fragile and more likely to break. There are now a number of products available that contain teriparatide.

## What are the best-value medicines for teriparatide?

The best-value medicines identified by the HSE for teriparatide are **Movymia® and Sondelbay®.**

## Movymia® and Sondelbay® are biosimilar medicines; 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's changing?

From **March 2023**, we are changing the way medicines containing teriparatide are prescribed under the HSE's High Tech Arrangement.

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

- From **1 March 2023**, if you are starting treatment on teriparatide, you will be prescribed one of the best-value medicines, **Movymia®** or **Sondelbay®**.

### What's the definition of a new patient?

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

## I am an existing patient prescribed teriparatide, 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 Forsteo®, your consultant or a member of their team may discuss with you the possibility of switching to **Movymia®** or **Sondelbay®**.

## Does my consultant know about these changes?

Yes. Consultants who care for patients with osteoporosis are aware of these changes.

## Why have the changes been introduced?

The best-value medicines cost less than the original biological medicine. Switching patients to the best-value 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 this medicine include:

- nurse home visit to provide training on administering the injection
- supply of sharps bins and waste collection service
- 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:** www.hse.ie/yourmedicines under Best-value medicines

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

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