Best-Value Medicines:

Teriparatide

Questions and Answers for Healthcare Professionals

1) What is a biological medicine?

A biological medicine is a medicine that contains an active substance made by a biological process or derived from a biological source.[1] Most biological medicines are produced from cell cultures of living organisms, such as mammalian cells, bacterial or yeast cells, which have been engineered to produce a specific therapeutic molecule or group of molecules, usually protein(s).[1] Biological medicines contain larger and more complex active substances than chemically synthesised small molecules and in general, tend to be more targeted in their therapeutic activity.[1] Teriparatide is an example of a biological medicine.

2) What is a biosimilar medicine?

A biosimilar medicine ('biosimilar') is a biological medicine that is highly similar to another biological medicine (called the reference biological medicine) that has already been authorised for use in the European Union.[1] The European Medicines Agency (EMA) list the following specific features of biosimilar medicines:[2]

- They are highly similar to the reference biological medicine
- There are no clinically meaningful differences compared with the reference biological medicine
- The variability between the biosimilar and the reference biological medicine is kept within strict limits
- The same strict standards of quality, safety and efficacy apply to the biosimilar as do to the reference biological medicine.

In relation to teriparatide, Movymia®, Terrosa® and Sondelbay® are examples of biosimilar medicines of the reference biological medicine Forsteo®.

3) Why isn't a biosimilar medicine a generic medicine?

As biological medicines are produced by living organisms, there is an inherent degree of natural variability which is not present with chemical entities. Due to this variability, it may not be possible to produce an exact copy of a reference biological medicine. As a result, generic versions of biological medicines are not feasible.[1]

Due to the natural variability of the biological source and to the manufacturing process unique to each manufacturer, minor differences can occur between the biosimilar and the reference biological medicine. Strict controls are in place during the manufacturing process to ensure that the minor differences do not affect the way the biosimilar works or its safety. These differences, therefore, are not clinically meaningful in terms of efficacy or safety.[2]

Biosimilars are similar but not identical versions of their reference biological medicine. They have an overall degree of comparability to the reference biological medicine.[1]

4) Where can I find further information on biological and biosimilar medicines?

The Health Products Regulatory Authority (HPRA), and the European Commission and the EMA have published guidance documents on biosimilars:

www.hpra.ie/docs/default-source/publications-forms/guidance-documents/guide-to-biosimilars-for-healthcare-professionals-v3.pdf

www.ema.europa.eu/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf

5) 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.

6) What is a hybrid medicinal product?

Hybrid medicinal products are medicines whose authorisation depends partly on the results of tests on the reference medicine and partly on new data from clinical trials involving the hybrid medicinal product.[3]

Hybrid medicinal products arise when a manufacturer develops a generic medicine that is based on a reference medicine, but has a different strength, a different route of administration or a slightly different indication from the reference medicine.[3]

Tetridar® is a hybrid medicinal product of the reference medicinal product Forsteo®. In the case of Tetridar®, the marketing authorisation holder synthetically produced a copy of the reference medicinal product. Tetridar®, therefore, was licensed as a hybrid medicinal product.

7) What are best-value medicines (BVMs)?

The availability of biosimilar medicines and hybrid medicinal products present an opportunity to ensure the cost-effective prescribing and utilisation of biological medicines. Where a biosimilar medicine and/or hybrid medicinal product become available for a biological medicine that is reimbursed through the community drug schemes, the Medicines Management Programme (MMP) may evaluate the biological medicine in question and issue a recommendation as to the best-value medicine (BVM). The criteria that may be considered by the MMP in identifying a BVM, and the evaluation process are outlined in the MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting.

8) Why is it important that a BVM is identified and used?

Biological medicines account for a significant amount of the total annual expenditure on medicines by the state. For example, medicinal products reimbursed on the High Tech Arrangement containing teriparatide accounted for total expenditure* of approximately €4.2 million in 2021.[4]

Prescribing of the BVM in a therapeutic area 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. It will also ensure that available efficiencies are realised and savings for the health service are achieved.

* Total expenditure reflects the ingredient cost of the medicinal product, exclusive of value added tax and fees.

Teriparatide

9) Which medicinal products containing teriparatide are reimbursed on the High Tech Arrangement?

The five medicinal products containing teriparatide that are reimbursed on the High Tech Arrangement are included in the table below.

Medicinal Product	Classification
Forsteo®	Reference biological medicine
Movymia®	Biosimilar medicine
Terrosa®	Biosimilar medicine
Tetridar®	Hybrid medicinal product
Sondelbay®	Biosimilar medicine

10) What are the BVMs for teriparatide?

The MMP recommends **Movymia®**, **Sondelbay®** and **Tetridar®** as the BVMs for teriparatide on the High Tech Arrangement.

Prescribing the BVMs will lead to significant savings for the health service.

11) How are BVMs for teriparatide identified?

BVMs are identified in line with the evaluation process outlined in the MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting. The criteria that are considered by the MMP in identifying the BVMs are outlined in the MMP roadmap.

The evaluation reports in relation to the BVMs for teriparatide are available at www.hse.ie/yourmedicines, in the section entitled *Best-value medicines*.

12) What is the difference in cost between the reference biological medicine (Forsteo®) and the BVMs (Movymia®, Sondelbay® and Tetridar®)?

The reimbursement prices of the medicinal products containing teriparatide, including biosimilar medicines and hybrid medicinal products, are available on the website of the HSE-Primary Care Reimbursement Service; www.pcrs.ie. The reimbursement price listed may not represent the final acquisition cost of the medicinal product to the HSE, as it not does not include any rebates and commercial-in-confidence arrangements that are in place.

Non-BVM medicines containing teriparatide are substantially more expensive than the identified BVMs for teriparatide, Movymia®, Sondelbay® and Tetridar®. Prescribing of the BVMs for teriparatide will result in significant savings in comparison to the other medicinal products containing teriparatide. This is due to commercial-in-confidence arrangements that are in place with the HSE arising from the evaluation process for the BVMs for teriparatide.

13) When should the BVMs for teriparatide (Movymia®, Sondelbay® and Tetridar®) be prescribed?

If a patient is being **initiated** on teriparatide, one of the identified BVMs should be prescribed:

- **Movymia®**
- **Sondelbay®**
- **Tetridar®**

When **issuing a repeat prescription** for a patient containing teriparatide, patients on a non-BVM for teriparatide should be **considered for switching** to one of the BVMs:

- **Movymia®**
- **Sondelbay®**
- **Tetridar®**

14) What supports are available for consultants and clinical teams?

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

Resources to support prescribing of the BVMs are available on the MMP website (www.hse.ie/yourmedicines) in the section entitled *Best-value medicines > Teriparatide*. These include:

- Best-value medicine: Teriparatide. Questions and Answers for Healthcare Professionals
- Reimbursement of Medicinal Products containing Teriparatide: Questions and Answers for Healthcare Professionals
- MMP Product Information Sheets for Movymia®, Sondelbay® and Tetridar®
- Templates for switching letters for Movymia®, Sondelbay® and Tetridar®
- Information for Patients about Medicines containing Teriparatide
- Patient Information Leaflets on switching from Forsteo® to Movymia®, Sondelbay® or Tetridar®

- BVM Teriparatide Patient and Clinic Support Services

Support is also available for clinics and patients from the marketing authorisation holders of Movymia® (Clonmel Healthcare Ireland), Sondelbay® (Accord Healthcare Ireland) and Tetridar® (Teva Pharmaceuticals Ireland). This includes information on the medicines, training in the usage of the administration devices for each of the products, sharps management service, and the provision of home support to patients by a nurse. The relevant contact details are provided below.

Accord Healthcare Ireland Limited (Sondelbay®)

In order to avail of the patient support services for patients who have been prescribed Sondelbay®, please use the Hibernian Healthcare at Home online portal www.schedule.hahirl.com. If you have not registered on the Hibernian portal previously, please contact Hibernian Healthcare at Home at 01 460 4820 or by email at info@hibernianhealth.com , and access and support will be provided.

In order to obtain training pens and patient support materials for use in clinics, please contact:

- Email: info@hibernianhealth.com
- Phone: 01 460 4792

Clonmel Healthcare Limited (Movymia®)

In order to avail of the patient support services for patients who have been prescribed **Movymia®**, please complete and return the Movymia Patient Support Programme Referral Form to homecare.pcb@tcp.ie. Copies of the Movymia Patient Support Programme Referral Form can be requested by phoning 01 429 1820.

In order to obtain training pens and patient support materials for use in clinics, please contact:

- Email: info@clonmel-health.ie
- Phone: 052 617 7777

Teva Pharmaceuticals Ireland (Tetridar®)

In order to avail of the patient support services for patients who have been prescribed Tetridar®, please contact Point of Care Health Services at (01) 499 2674 or email admin@pointofcare.ie.

Online referral & tracking: www.healthpoint.ie/teva

In order to obtain patient support materials for use in clinics, please contact: Collin Botha

- Email: collin.botha@teva.ie
- Phone: (087) 6685876

Further information on the supports that are available can be found in the following document in the Best-value medicines section of the MMP website www.hse.ie/yourmedicines:

- BVM Teriparatide Patient and Clinic Support Services

References:

1. Health Products Regulatory Authority. Guide to Biosimilars for Healthcare Professionals. August 2020. Accessed at www.hpra.ie on 29/04/2024.
2. European Medicines Agency and the European Commission. Biosimilars in the EU. Information guide for healthcare professionals. October 2019. Last updated 13 November 2023. Accessed at https://www.ema.europa.eu/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf on 29/04/2024.
3. Generic and Hybrid Medicines. European Medicines Agency. Accessed at https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/generic-hybrid-medicines on 29/04/2024.
4. HSE-Primary Care Reimbursement Service (PCRS). Reporting and Open Data Area. Pharmacy Reports. Top 100 Products by Cost. HTS 2021. Accessed at https://www.sspcrs.ie/analytics/saw.dll?PortalPages on 29/04/2024.
5. HSE-Medicines Management Programme. MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting. March 2022. Accessed at https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/best-value-medicines/best-value-biological-medicines/mmp-roadmap-for-the-prescribing-of-best-value-biological-bvb-medicines-in-the-irish-healthcare-setting.pdf on 29/04/2024.