Medicines Management Programme

Best-value medicine:

Teriparatide on the High Tech Arrangement

Review of submission for Terrosa®

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List of Abbreviations

BVB	Best-value biological
BVM	Best-value medicine
CPU	Corporate Pharmaceutical Unit
EMA	European Medical Agency
EPAR	European Public Assessment Report
EU	European Union
Ex	Excluding
G	Gauge
HMA	Heads of Medicines Agencies
HPRA	Health Products Regulatory Authority
HSE	Health Service Executive
Inc	Including
INN	International nonproprietary name
ISO	International Organisation for Standardisation
Mcg	Micrograms
Ml	Millilitres
MM	Millimetres
MMP	Medicines Management Programme
PCRS	Primary Care Reimbursement Service
PIL	Patient information leaflet
PFP	Pre-filled pen
SmPC	Summary of Product Characteristics
VAT	Value-added tax

1. Executive Summary

The Health Service Executive (HSE)-Medicines Management Programme (MMP) supports the safe, effective and cost-effective prescribing of biological medicines, including biosimilar medicines (or 'biosimilars'). The MMP recognises the potential savings arising from the availability of biosimilars and hybrid medicinal products. These savings, however, can only be realised by increased utilisation of best-value biological (BVB) medicines or best-value medicines (BVM), including biosimilars and hybrid medicinal products.

The MMP published a report on 7 February 2023 in which it identified BVMs for teriparatide; **Movymia®** and **Sondelbay®**.[1] On 31 March 2024, the MMP published a report in which it recommended that BVM status be assigned to **Tetridar®**.[2]

The MMP has reviewed a submission received from Gedeon Richter Ireland at the request of the Corporate Pharmaceutical Unit (CPU) of the HSE-Primary Care Reimbursement Service (PCRS). The MMP considers **Terrosa®** to be comparable to the MMP BVMs for teriparatide. The MMP recommends that BVM status be assigned to **Terrosa®**.

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

Clinicians should give due consideration to prescribing Movymia®, Sondelbay®, Terrosa® or Tetridar® when issuing a prescription for teriparatide on the High Tech Arrangement.

Implementation of this recommendation will lead to significant savings for the health service.

Initiation

When initiating a patient on teriparatide, the clinician should prescribe Movymia®, Sondelbay®, Terrosa® or Tetridar®.

2. Background

2.1 Best-value medicines - Teriparatide

The MMP published a report on 7 February 2023 in which it identified BVMs for teriparatide; **Movymia®** and **Sondelbay®**.[1] On 31 March 2024, the MMP published a report in which it recommended that BVM status be assigned to **Tetridar®**.[2]

2.2 Biosimilar medicines

There are three biosimilar medicines containing teriparatide available on the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement; Movymia®, Sondelbay®, Terrosa®.[3-6] In each case, the reference biological medicine is Forsteo®.

The BVMs for teriparatide that were recommended by the MMP in February 2023 are both biosimilar medicines; Movymia® and Sondelbay®.[1]

2.3 Hybrid Medicinal Products

There is one hybrid medicinal product containing teriparatide available on the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement; Tetridar®.[3] Tetridar® is considered a legitimate hybrid form of the reference product, Forsteo®.[7]

The MMP recommended that BVM status be assigned to Tetridar® in March 2024.[2]

2.4 HSE-Primary Care Reimbursement Service Request

The CPU of the PCRS requested the MMP to review a submission for BVM status from Gedeon Richter Ireland in relation to their biosimilar medicine containing teriparatide, Terrosa®.

3. Scope

In line with the original BVM evaluation process for teriparatide (February 2023), the presentation of Terrosa® for which Gedeon Richter Ireland have provided a submission is considered to be within scope of evaluation for BVM status as it is a medicinal product containing teriparatide that is the subject of a marketing authorisation that allows for supply in Ireland.

4. Definitions

For the purposes of this document, the reimbursement price refers to the reimbursed price of the medicinal product as listed in the HSE Reimbursement List maintained by the PCRS. It may not represent the final acquisition cost to the HSE of the medicine, which may also include any rebates and commercial-in-confidence arrangements that are in place. Both the reimbursement price and the acquisition cost are exclusive of value-added tax (VAT). Costs are correct as of 15 September 2025.

5. Evaluation process

The review of the submission received from Gedeon Richter Ireland was carried out in accordance with the evaluation process in the *MMP roadmap for the prescribing of best-value biological (BVB) medicines.*[8]

In line with the *MMP roadmap for the prescribing of best-value biological (BVB) medicines*, the MMP considered the following criteria when reviewing the BVM submission received from Gedeon Richter Ireland:[8]

1. Acquisition cost
2. Therapeutic indications
3. Formulation considerations
4. Product range including pack sizes and strengths available
5. Product stability including storage requirements
6. Administration devices
7. Patient factors
8. Expenditure in the therapeutic area and potential for cost efficiencies
9. Clinical guidelines
10. Security of supply to the Irish Market
11. Utilisation and clinical experience with the biological medicine
12. Any other relevant factors with respect to the particular international non-proprietary name (INN).

6. Evaluation

6.1 Acquisition cost

The current reimbursement price, total cost per pack and annual cost of treatment for Terrosa® on the High Tech Arrangement as of 15 September 2025 are outlined in Table 1.

The submission received from Gedeon Richter Ireland included revised commercial terms for Terrosa®, resulting in a significant reduction in costs to the HSE.[9]

Table 1 Annual cost, reimbursement price and total cost per pack of Terrosa®[3]

Medicinal Product	Reimbursement Price per pack*	Total cost per pack* (ex VAT)	Total cost per pack* (inc VAT)	Annual Cost (ex VAT)	Annual Cost (inc VAT)
Terrosa® starter pack (20 mcg/80 microliter cartridge + pen)	€214.49	€214.49	€263.82	€2,797.92	€3,441.44
Terrosa® 20 mcg/80 microliter cartridge	€214.49	€214.49	€263.82	€2,797.92	€3,441.44

ex: excluding; inc: including; mcg: micrograms; PFP: Pre-filled pen; VAT: value-added tax
Prices correct as of 15 September 2025
**Each pack contains a 28-day supply of teriparatide*

Recommendation

The acquisition cost to the HSE for Terrosa® is in line with the acquisition cost of the BVMs for teriparatide currently recommended by the MMP.

6.2 Therapeutic indications

The reference biological medicine, Forsteo®, is licensed for the treatment of:[10]

- osteoporosis in postmenopausal women and in men at increased risk of fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures has been demonstrated.
- osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk of fracture.

Terrosa® is licensed for the full range of therapeutic indications in line with the reference biological medicine.[6]

Recommendation

Overall, in relation to the criterion of therapeutic indications, the MMP is of the view that Terrosa® is equivalent to the reference medicine, Forsteo®. Terrosa® is licensed for all of the therapeutic indications that the MMP BVMs for teriparatide are licensed for.

6.3 Formulation considerations

Terrosa® and the BVMs for teriparatide (Movymia®, Sondelbay® and Tetridar®) are all formulated as colourless, clear solutions for injection[4-6,11] Each of the medicinal products contains the following excipients:[4-6,11]

- glacial acetic acid
- sodium acetate
- mannitol
- metacresol
- hydrochloric acid
- sodium hydroxide
- water for injections.

All of the medicinal products contain 2.4 millilitres (mL) of solution per pack, corresponding to 600 micrograms (mcg) of teriparatide (i.e. 250 mcg/mL). Each medicinal product delivers a dose of 80

microliters of solution, containing 20 mcg of teriparatide. There are 28 doses of teriparatide 20 mcg within one pack of each product.[4-6,11]

Terrosa® and the MMP BVMs for teriparatide contain less than 1 millimole of sodium (23 milligrams) per dose, i.e. they are essentially 'sodium-free'.[4-6,11]

Administration site conditions are reported in the section on undesirable effects in the Summary of Product Characteristics (SmPC) of Forsteo®. Mild and transient injection site events, including pain, swelling, erythema, localised bruising, pruritus and minor bleeding at the injection site were reported as common adverse reactions associated with the use of Forsteo® in clinical trials and post-marketing exposure. Injection site erythema and injection site reaction were reported as uncommon adverse events.[10]

The SmPCs for the BVMs for teriparatide and Terrosa® all carry the same statements as Forsteo® in relation to administration site conditions.[4-6,11]

6.3.1 European Public Assessment Report – Terrosa®

In the clinical safety section of the European Public Assessment Report (EPAR) for Terrosa®, the European Medicines Agency (EMA) report that injection site erythema was seen more often in the Terrosa® group in comparison to the Forsteo® group in the phase I study that was undertaken (nine [17%] versus six [11%] subjects, respectively). The EMA also note that all of the described erythema were very mild, and thus the observed difference was regarded as of no relevance.[12]

Recommendation

In relation to the criterion of formulation considerations, the MMP is of the opinion that Terrosa® is considered comparable to the MMP BVMs for teriparatide for this criterion.

6.4 Product range including pack sizes and strengths available

Table 2 outlines the presentations of Terrosa® that are available on the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement, and those that are available for the MMP BVMs for teriparatide.

Table 2 Product range of medicinal products containing teriparatide[3-6,11]

Medicinal Product	Product range		
	20 mcg/80 microliter PFP	20 mcg/80 microliter cartridge + re-usable pen	20 mcg/80 microliter cartridge
Movymia®		✓	✓
Sondelbay®	✓		
Terrosa®		✓	✓
Tetridar®	✓		

mcg: micrograms; PFP: Pre-filled pen

Sondelbay® and Tetridar® are available in the same presentation, i.e. a disposable pre-filled pen (PFP) device.[5,11] Movymia® and Terrosa® are available as a re-usable pen device with replaceable cartridges, which contain the solution for injection. A starter pack, containing the re-usable pen and a cartridge, should be supplied to the patient when they are initiated on treatment with Movymia® and Terrosa®. For further supplies, a cartridge should be provided to the patient for use with the re-usable pen device.[4,6]

Each cartridge or disposable PFP contains 2.4 mL of solution per pack, corresponding to 600 mcg of teriparatide (i.e. 250 mcg/mL). Both pen devices (disposable and re-usable) deliver a dose of 80 microliters of solution, containing 20 mcg of teriparatide. Each cartridge or disposable PFP contains 28 doses of teriparatide 20 mcg.[4-6,11]

Recommendation

In relation to the criterion of product range, the MMP is of the opinion that Terrosa® provides a similar offering when compared to the MMP BVMs for teriparatide.

6.5 Product stability including storage requirements

Movymia® 20 mcg/80 microliter cartridge, Sondelbay® 20 mcg/80 microliter PFP and Terrosa® 20 mcg/80 microliter cartridge all have a shelf life of two years.[4-6] Tetridar® 20 mcg/80 microliter PFP has a shelf life of 24 months.[11] All four medicinal products must be stored in a refrigerator between 2°C and 8°C, and should not be frozen.[4-6,11]

After insertion of Movymia® 20 mcg/80 microliter cartridge and Terrosa® 20 mcg/80 microliter cartridge into their re-usable pens, the combined pen and cartridge should be returned to the

refrigerator immediately after use. The cartridge should not be removed from the pen after first use.[4,6] Once opened, Sondelbay® 20 mcg/80 microliter PFP and Tetridar® 20 mcg/80 microliter PFP should be returned to the refrigerator immediately after use.[5,11]

After first use, all four medicinal products should be stored for a maximum of 28 days at 2°C and 8°C, after which time they should be disposed of, even if they are not completely empty.[4-6,11]

In addition, Sondelbay® 20 mcg/80 microliter PFP can be stored at temperature conditions up to 25°C for a maximum of three days when refrigeration is not available, after which it should be returned to the refrigerator and used within 28 days of the first injection. The Sondelbay® 20 mcg/80 microliter PFP should be discarded if it has been kept out of the refrigerator at temperature conditions up to 25°C for more than three days.[5] In the case of Tetridar® 20 mcg/80 microliter PFP, the unopened product may be removed from the refrigerator and stored at a temperature up to 25°C for one single period of up to five days, after which it should be returned to the refrigerator (2°C – 8°C). The unopened product should be discarded if stored above 8°C for more than five days.[11]

For all medicinal products, the pen device (PFP or re-usable) should not be stored with the needle attached.[4-6,11]

Recommendation

In relation to the criterion of product stability including storage requirements, the MMP is of the opinion that the Terrosa® is comparable to the BVMs for teriparatide.

6.6 Administration devices

From examination of the patient information leaflets (PIL), SmPCs and submissions received for Terrosa® and the MMP BVMs for teriparatide, there are two different types of administration devices; a disposable PFP device (Sondelbay® and Tetridar®) and a re-usable pen device with replaceable cartridges (Movymia® and Terrosa®). Table 3 provides a summary of various properties for the administration devices of the MMP BVMs for teriparatide and for Terrosa®.

Table 3 Characteristics of administration devices for Terrosa® and the MMP BVMs for teriparatide

	Movymia®	Sondelbay®	Terrosa®	Tetridar®
Disposable PFP		✓		✓
Re-usable pen device	✓		✓	
Pen requires priming	✓		✓	
Dose delivery indicator	✓	✓	✓	✓
Dose counter		✓		

PFP: Pre-filled pen

The disposable PFPs do not need to be primed; the re-usable pen devices need to be primed each time a new cartridge is inserted. A dose counter is only present on the Sondelbay® PFP; none of the other medicinal products have a dose counter on their pen and therefore, it is not possible to accurately determine how many doses of teriparatide have been administered or how many remain.

The re-usable pen devices that are employed with Movymia® (indicator window) and Terrosa® (indicator window) and the disposable PFP employed with Sondelbay® (indicator window) and Tetridar® (yellow shaft not visible) all contain mechanisms to indicate when the full dose of teriparatide has been administered.

There is no latex present in the administration devices for Movymia®, Sondelbay®, Terrosa® and Tetridar®.[4-6,11]

None of the medicinal products are supplied with injection needles attached. All of the medicinal products require the patient to attach and dispose of an injection needle each time a dose is administered. Injection needles are not supplied with any of the medicinal products, and therefore must be provided separately to the patient. Table 4 provides details of the needles that are suitable for use with Terrosa® and the MMP BVMs for teriparatide (Movymia®, Sondelbay® and Tetridar®).

Table 4 Details of needles suitable for use with Terrosa® and the MMP BVMs for teriparatide

Medicinal Product	Type of needles suitable for use with pen
Movymia®[1,4]	Injection needles developed according to the pen needle ISO standard of a gauge between 29 G and 32 G (diameter 0.23 – 0.33 mm) and a length between 4 mm to 12.7 mm
Sondelbay®[1,5]	Pen needles of a gauge of 31 G or 32 G and a length of 4, 5 or 8 mm
Terrosa®[1,6]	Injection needles developed according to the pen needle ISO standard of a gauge between 29 G and 31 G (diameter 0.25 – 0.33 mm) and a length between 5 mm to 12.7 mm
Tetridar®[1,11]	Becton, Dickinson and Company pen needles of a gauge between 29 G and 31 G (diameter 0.25 – 0.33 mm) and a length of 5, 8 or 12.7 mm

G: gauge; ISO: International Organisation for Standardisation; mm: millimetre

There are a variety of needles available on the HSE Reimbursement List, all supplied in packs of 100. The reimbursement price per pack varies from €4.47 to €17.93.[13] A full 24-month course of teriparatide would require eight packs of needles.

None of the medicinal products include a safety feature upon administration of the injection; in all cases, the patient is required to remove the needle from the pen after administration of the dose of teriparatide, and dispose of it.

The re-usable pen devices supplied with Movymia® and Terrosa® both have a service life of two years.[4,6]

The instructions, within each of the PILs and accompanying pen user manuals, for the administration of a dose from the pen devices of Movymia®, Sondelbay®, Terrosa and Tetridar® are clear and easy to follow. In all cases, the instructions are presented in the form of text with accompanying pictograms.

Recommendation

Overall, in relation to the criterion of administration devices, the MMP is of the opinion that Terrosa® provides a similar offering to the MMP BVMs for teriparatide.

6.7 Patient factors

Gedeon Richter Ireland provide a patient support programme to patients who have been prescribed Terrosa®.

The patient support programme that is available to patients who are prescribed Terrosa® is similar in nature to those available to patients who are prescribed the MMP BVMs for teriparatide, based on the information provided to the MMP in the submission received from Gedeon Richter Ireland.

The MMP did not identify any published evidence that compared the patient support programmes/services that are offered by the marketing authorisation holders of medicinal products containing teriparatide with each other.

Recommendation

In relation to the criterion of patient factors, the MMP is of the opinion that the patient support programme offered by Gedeon Richter Ireland is similar in nature to those offered by the marketing authorisation holders of the MMP BVMs for teriparatide.

6.8 Expenditure in the therapeutic area and potential for cost savings

Expenditure[i] on medicinal products containing teriparatide accounted for approximately €4.1 million in 2023.[14] Teriparatide was ranked 13th in terms of prescribing frequency on the High Tech Arrangement in 2023, with a prescribing frequency of 18,901.[15] There are approximately 2,000 patients in receipt of teriparatide on the High Tech Arrangement on a monthly basis.[16]

The submission received from Gedeon Richter Ireland included revised commercial terms for Terrosa®, resulting in a significant reduction in the acquisition cost to the HSE.

Recommendation

In relation to the criterion of expenditure in the therapeutic area and potential for cost savings, the MMP is of the opinion that the acquisition cost to the HSE for Terrosa® is in line with the acquisition costs of the MMP BVMs for teriparatide.

6.9 Clinical guidelines

No new relevant clinical guidelines in relation to the treatment of osteoporosis were identified since the publication of the initial MMP BVM evaluation report for teriparatide in February 2023.

Recommendation

In relation to the criterion of clinical guidelines, no relevant information was identified by the MMP.

[i]Expenditure reflects the ingredient cost of the medicinal product, exclusive of value added tax and fees.

6.10 Security of supply to Irish Market

Gedeon Richter Ireland outlined the processes that they have in place for supply of their biosimilar medicine containing teriparatide to the Irish market. They outlined the arrangements that they have in place for the supply chain management of Terrosa® to the Irish market, including the distribution model that they employ.[9]

They also outlined the arrangements that they have in place to ensure sufficient supply of Terrosa® to the Irish market.[9]

Recommendation

In relation to the criterion of security of supply to the Irish market, the MMP is of the opinion that Gedeon Richter Ireland have provided evidence of their capacity to meet the ongoing needs of Irish patients with respect to the supply of Terrosa®.

6.11 Utilisation and clinical experience with the biological medicine

There is significant clinical experience with the use of teriparatide in the Irish setting, with approximately 2,000 patients in receipt of it on the High Tech Arrangement on a monthly basis.[16] Market exclusivity for Forsteo® lapsed in August 2019, and the first biosimilar medicine containing teriparatide was added to the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement, on 1 September 2019. Terrosa® was added to the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement, on 1 April 2021.[17]

The MMP published a report on 7 February 2023 in which it identified BVMs for teriparatide; **Movymia®** and **Sondelbay®**.[1] On 31 March 2024, the MMP published a report in which it recommended that BVM status be assigned to **Tetridar®**.[2] Since the implementation of the MMP recommendations, the percentage of patients in receipt of a BVM on the High Tech Arrangement has increased from approximately 15% in February 2023 to approximately 99% in July 2025. Approximately 96% of patients in receipt of teriparatide on the High Tech Arrangement in July 2025 received a biosimilar medicine of teriparatide that had been recommended as a BVM.[16]

Manufacturers of biosimilars must perform an extensive head-to-head comparability with the reference medicine and demonstrate to regulators that they have similar quality, safety and efficacy to the reference medicine such that there are no clinically meaningful differences between the two.[18] The EMA and Heads of Medicines Agencies (HMA), in a joint statement, have confirmed that biosimilar medicines approved in the European Union (EU) are interchangeable with their reference medicine or

with an equivalent biosimilar. Interchangeability in this context means that the reference medicine can be replaced by a biosimilar without a patient experiencing any changes in the clinical effect.[19]

There has been a significant increase in the prescribing of biosimilar medicines of teriparatide on the High Tech Arrangement since March 2023. This demonstrates that significant clinical experience is being obtained for biosimilars of teriparatide in a short timeframe.

Recommendation

Overall, in relation to the criterion of utilisation and clinical experience with the biological medicine, given that Terrosa® has been deemed to be a biosimilar version of the reference medicine Forsteo®, the MMP is of the opinion that it provides a similar offering to the MMP BVMs for teriparatide.

6.12 Any other relevant factors with respect to the particular INN

Gedeon Richter Ireland did not submit any information under this criterion.[9]

6.12.1 Position papers

No published position papers on the usage of biosimilar medicines or hybrid medicinal products, either in general or specifically in relation to teriparatide, were identified from the Irish clinical societies for the specialities for which teriparatide is prescribed (i.e. Irish Gerontological Society, Irish Society of Physicians in Geriatric Medicine and Irish Society of Rheumatology) since the publication of the initial MMP BVM evaluation report in February 2023.

6.12.2 Legislation/Guidance from Medicines Regulators

The MMP reviewed the legislation and guidelines from medicines regulators that relate to the prescribing and utilisation of biosimilar medicines. Pharmacist-led substitution of biological medicines is not permitted under the Health (Pricing and Supply of Medical Goods) Act 2013.[20]

The Health Products Regulatory Authority (HPRA) published an updated version of their Guide to Biosimilars for Healthcare Professionals in August 2020. This guide defines interchangeability as “the possibility of exchanging one medicine with another that is expected to have the same effect. This could mean replacing a reference medicine with a biosimilar (or vice versa), or replacing one biosimilar with another”. The guide states that, once approved, biosimilars can be used interchangeably with the reference medicine, or with biosimilars of that reference medicine.[18]

The EMA and the HMA, in a joint statement issued on 19 September 2022, have confirmed that biosimilar medicines approved in the EU are interchangeable with their reference medicine or with an equivalent biosimilar. Interchangeability in this context means that the reference medicine can be replaced by a biosimilar without a patient experiencing any changes in the clinical effect.[19]

Recommendation

In relation to the criterion of any other relevant factors with respect to the particular INN, the MMP is of the opinion that no new relevant material was submitted under this criterion.

Overall Recommendation

The MMP considers Terrosa® to be comparable to the MMP BVMs for teriparatide. The MMP recommends that Terrosa® is designated a BVM for teriparatide.

7. MMP Recommendations – September 2025

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

Clinicians should give due consideration to prescribing Movymia®, Sondelbay®, Terrosa® or Tetridar® when issuing a prescription for teriparatide on the High Tech Arrangement.

Implementation of this recommendation will lead to significant savings for the health service.

Initiation

When initiating a patient on teriparatide, the clinician should prescribe Movymia®, Sondelbay®, Terrosa® or Tetridar®.

The MMP recommends that all new patients being initiated on a medicinal product containing teriparatide should be prescribed a MMP BVM: Movymia®, Sondelbay®, Terrosa® or Tetridar®.

8. References

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