Medicines Management Programme

Best-value medicine:

Teriparatide on the High Tech Arrangement

Review of submission for Tetridar®

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List of Abbreviations

BVB	Best-value biological
BVM	Best-value medicine
CPU	Corporate Pharmaceutical Unit
EU	European Union
Ex	Excluding
G	Gauge
HSE	Health Service Executive
Inc	Including
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) aims to promote safe, effective and cost-effective prescribing of biological medicines, including biosimilar medicines. 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]

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

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

Clinicians should give due consideration to prescribing Movymia®, Sondelbay® 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® or Tetridar®.

Switching

Patients currently on teriparatide should be considered for switching to Movymia®, Sondelbay® or Tetridar® when their next repeat High Tech prescription is being issued.

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]

2.2 Biosimilar medicines

There are three biosimilar medicines containing teriparatide available on the High Tech Arrangement; Movymia®, Sondelbay®, Terrosa®.[2] In each case, the reference biological medicine is Forsteo® .There is now considerable national and international experience with the usage of biosimilar medicines. They have been used safely in clinical practice in the European Union (EU) for over 15 years and have demonstrated similar efficacy, safety and immunogenicity with their reference medicine. Analysis of more than one million patient-treatment years of safety data for biosimilar medicines did not raise any safety concerns.[3,4]

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

2.3 Hybrid medicinal products

There is one hybrid medicinal product containing teriparatide available on the High Tech Arrangement; Tetridar®.[2] Tetridar® was licensed using a decentralised procedure with Germany as the reference member state. Article 10(3) of Directive 2001/83/EC was considered by the reference member state to be the appropriate legal basis for consideration of the licensing application for Tetridar®, i.e. as an application as a hybrid medicinal product of the reference medicine Forsteo®. Following evaluation, Tetridar® was considered a legitimate hybrid form of the reference product, Forsteo®, and was granted a marketing authorisation.[5]

2.4 HSE-Primary Care Reimbursement Service Request

The CPU of the PCRS requested the MMP to review a submission for BVM status from Teva Pharmaceuticals Ireland in relation to their hybrid medicinal product containing teriparatide, Tetridar®.

3. Scope

In line with the original BVM evaluation process (February 2023), the presentation of Tetridar® for which Teva Pharmaceuticals 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 High Tech Drug File maintained by the PCRS. It may not represent the final acquisition cost to the HSE of the medicinal product, which may also include any rebates and commercial-in-confidence arrangements that are in place. The reimbursement price is exclusive of value-added tax (VAT).

All prices and costs are correct as of 31 March 2024.

5. Evaluation process

The review of the submission received from Teva Pharmaceuticals Ireland was carried out in accordance with the evaluation process in the *MMP roadmap for the prescribing of best-value biological (BVB) medicines*.[6]

In line with the *MMP Roadmap for the prescribing of best-value biological medicines (BVB) medicines,* the MMP considered the following criteria when identifying BVMs for teriparatide:[6]

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 INN

6. Evaluation

6.1 Acquisition cost

The current reimbursement price, total cost per pack and annual cost of treatment for Tetridar® under the High Tech Arrangement as of 31 March 2024 are outlined in table 1.

The submission received from Teva Pharmaceuticals Ireland included revised commercial terms for Tetridar®, resulting in a significant reduction in costs to the HSE.[7]

Table 1: Annual cost, reimbursement price and total cost per pack of Tetridar®[2]

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)
Tetridar® 20 mcg/80 microliter PFP	€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 31 March 2024

* Each pack contains a 28-day supply of teriparatide

Recommendation
The acquisition cost to the HSE for Tetridar® 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:[8]

- 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.

Tetridar® is licensed for the full range of therapeutic indications in line with the reference biological medicine.[9]

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

6.3 Formulation considerations

Tetridar® and the BVMs for teriparatide (Movymia® and Sondelbay®) are all formulated as colourless, clear solutions for injection.[9-11] Each of the medicinal products contains the following excipients: [9-11]

- 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.[9-11]

Tetridar® and the MMP BVMs for teriparatide contain less than 1 millimole of sodium (23 milligrams) per dose, i.e. they are essentially 'sodium-free'.[9-11]

Administration site conditions are reported in the section on undesirable effects in the Summary of Product Characteristics (SmPC) of the reference biological medicine 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.[8]

The SmPCs for the BVMs for teriparatide and Tetridar® all carry the same statements as Forsteo® in relation to administration site conditions.[9-11]

6.3.1 Public Assessment Report – Tetridar®

In the clinical safety section of the public assessment report for Tetridar®, injection site erythema was observed in one patient in both the Tetridar® and the Forsteo® treatment groups.[5]

Recommendation

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

6.4 Product range including pack sizes and strengths available

Table 2 outlines the presentation of Tetridar® that is available 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[2,9-11]

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

mcg: micrograms; PFP: Pre-filled pen

Sondelbay® and Tetridar® have the same presentations, i.e. a disposable pre-filled pen (PFP) device. Movymia® is 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®. For further supplies, a cartridge should be provided to the patient for use with the re-usable pen device.[9-11]

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.[9-11]

Recommendation

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

6.5 Product stability including storage requirements

Tetridar® 20 mcg/80 microliter PFP has a shelf life of 24 months. The MMP BVMs for teriparatide (Movymia® 20 mcg/80 microliter cartridge, Sondelbay® 20 mcg/80 microliter PFP) both have a shelf life of two years. All three medicinal products must be stored in a refrigerator between 2°C and 8°C, and should not be frozen.[9-11]

Once opened, Sondelbay® 20 mcg/80 microliter PFP and Tetridar® 20 mcg/80 microliter PFP should be returned to the refrigerator immediately after use. After insertion of Movymia® 20 mcg/80 microliter cartridge into its re-usable pen, 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.[9-11]

After first use, all three 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.[9-11]

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.[11]

For all medicinal products, the pen device (PFP or re-usable) should not be stored with the needle attached.[9-11]

Recommendation

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

6.6 Administration devices

From examination of the patient information leaflets (PIL), SmPCs and submissions received for Tetridar® 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®). Table 3 provides a summary of various properties for the administration devices of these medicinal products.

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

	Movymia®	Sondelbay®	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 device needs 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 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® and Tetridar®.[1,7]

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 Tetridar® and the MMP BVMs for teriparatide (Sondelbay® and Movymia®).

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

Medicinal Product	Type of needles suitable for use with pen
Movymia®[1,10]	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®[1,11]	Pen needles of a gauge of 31 G or 32 G and a length of 4, 5 or 8 mm
Tetridar®[7,9]	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 is a variety of needles available on the Community Drug Schemes, all supplied in packs of 100. The reimbursement price per pack varies from €4.47 to €17.93.[12] 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 device supplied with Movymia® has a service life of two years.[10]

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® 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 Tetridar® provides a similar offering to the MMP BVMs for teriparatide.

6.7 Patient factors

In their submission, Teva Pharmaceuticals Ireland outlined the support services that are available when a patient is prescribed Tetridar®.[7]

The patient support programme that is available to patients who are prescribed Tetridar® 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 Teva Pharmaceutical 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 Teva Pharmaceutical 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 €4.2 million in 2021.[13] Teriparatide was ranked 14th in terms of prescribing frequency on the High Tech Arrangement in 2021, with a prescribing frequency of 13,653.[14] There are approximately 1,600 patients in receipt of teriparatide on the High Tech Arrangement on a monthly basis.[15]

The MMP has recommended BVMs for teriparatide, Movymia® and Sondelbay®. These biosimilar medicines have the lowest acquisition cost to the HSE in terms of the medicinal products containing teriparatide that are available on the High Tech Arrangement.

The submission received from Teva Pharmaceuticals Ireland included revised commercial terms for Tetridar®, 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 Tetridar® is in line with the acquisition costs of the MMP BVMs for teriparatide.

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

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.

6.10 Security of supply to Irish Market

Teva Pharmaceuticals Ireland outlined the processes that they have in place for supply of their medicinal product containing teriparatide to the Irish market.

Teva Pharmaceuticals Ireland outlined the arrangements that they have in place for the supply chain management of Tetridar® to the Irish market, including the distribution model that they employ. They also outlined the actions that they have taken to manage the implications of Brexit.[7]

Recommendation

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

6.11 Utilisation and clinical experience with the medicine

There is significant clinical experience with the use of teriparatide in the Irish setting, with approximately 1,600 patients in receipt of it on the High Tech Arrangement on a monthly basis.[15] Market exclusivity for Forsteo® lapsed in August 2019, and the first biosimilar medicine containing teriparatide was added to the High Tech Arrangement on 1 September 2019. Tetridar® was added to the High Tech Arrangement on 1 August 2020.[16]

The MMP published a report on 7 February 2023 in which it identified BVMs for teriparatide; **Movymia®** and **Sondelbay®**.[1] Since the implementation of the MMP recommendations, the percentage of patients in receipt of a BVM on the High Tech Arrangement has increased from 15% in February 2023 to 66% in February 2024.[15]

Tetridar® is licensed as a hybrid medicinal product, i.e. following evaluation, Tetridar® was considered a legitimate hybrid form of the reference product, Forsteo®, and was granted a marketing authorisation. Tetridar® was shown to be analytically and functionally comparable to Forsteo®. In

addition, bioequivalence of Tetridar® to the reference product was also demonstrated.[5] The MMP are, therefore, of the opinion that the clinical experience obtained with Forsteo® is transferable to Tetridar®.

Recommendation

Overall, in relation to the criterion of utilisation and clinical experience with the medicine, given that Tetridar® has been deemed to be a hybrid medicinal product 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

Teva Pharmaceuticals Ireland did not submit any information under this criterion.[7]

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.

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 Tetridar® to be comparable to the MMP BVMs for teriparatide. The MMP recommends that BVM status be assigned to Tetridar®

7. MMP Recommendations

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

Clinicians should give due consideration to prescribing Movymia®, Sondelbay® 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® or Tetridar®.

Switching

Patients currently on teriparatide should be considered for switching to Movymia®, Sondelbay®, Tetridar® when their next repeat High Tech prescription is being issued.

The MMP recommends that all new patients being initiated on a medicinal product containing teriparatide should be prescribed the MMP BVMs, Movymia®, Sondelbay® or Tetridar®. Patients currently on teriparatide should be considered for switching to Movymia®, Sondelbay® or Tetridar® when their next repeat High Tech prescription is being issued.

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