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Clarie Kerrane, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

15th May 2024

PQ: 19246/24

To ask the Minister for Health if a medicine (details supplied) can be made available under the medical card scheme for a patient where the current medicine, available under medical card scheme, has given them a bad reaction.-Claire Kerrane

Details Supplied:
Fosteo injection for persons with osteoporosis

Dear Deputy Kerrane,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 19246/24), which you submitted to the Minister for Health for response.

The HSE-Medicines Management Programme (MMP) has completed a review of the medicinal products containing teriparatide that are available on the High Tech Arrangement. The MMP recommends the biosimilar medicines Movymia®, Sondelbay® and Tetridar ® as the best-value medicines (BVMs) for teriparatide under the High Tech Arrangements. An evaluation report entitled Best-Value Medicines: Teriparatide on the High Tech Arrangement is available at www.hse.ie/mmp in the section entitled Best-value medicines.

The BVMs are provided to the HSE at a significantly lower cost than the originator medicine (Forsteo®). 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.

Reimbursement of teriparatide on the High Tech Arrangement is only supported for the identified BVMs (i.e. Movymia®, Sondelbay® and Tetridar®) in adult patients commencing such therapy. Where a patient

has been established on the reference biological medicine (Forsteo®) prior to the 1st March 2023, they can continue to access this under the High Tech Arrangement.

The HSE-MMP notes the Health Products Regulatory Authority (HPRA) Guide to Biosimilars for Healthcare Professionals. 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 other biosimilars of that reference medicine.

In addition, the HSE-MMP notes the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) joint statement (19th September 2022), which confirms that biosimilar medicines are interchangeable with their reference medicine and with an equivalent biosimilar medicine. This follows a review of the efficacy and safety data that is available for all biosimilar medicines that have been approved in the European Union.

If a prescriber wishes to access the reference biological medicine Forsteo® which is not a BVM, a submission is required to the MMP at mmp@hse.ie outlining the extenuating circumstances for consideration. Submissions can only be accepted from the hospital prescriber.

Yours sincerely,

Suzanne Doyle
Primary Care Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie