Recommendation for the prescribing of Teriparatide for osteoporosis

Recommendation

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered national guidance, evidence of clinical effectiveness and safety, the baseline position and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account the PRGC recommends that:

Teriparatide[1] for osteoporosis is **routinely funded** on the local NHS for a **maximum treatment duration of 18 months** in patients who meet the relevant criteria set out in Kent and Medway Osteoporosis Group guidance on teriparatide for severe osteoporosis.

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*
Date: Jan 2016
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Kent and Medway Policy Recommendation and Guidance Committee Policy Recommendation

Policy:	**PR 2016-03: Teriparatide for osteoporosis**
Issue date:	**January 2016**
Review date:	**January 2019**

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered national guidance, evidence of clinical effectiveness and safety, the baseline position and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account the PRGC recommends that:

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This policy recommendation will be reviewed in light of new evidence or guidance from NICE.

Clinical Commissioning Groups in Kent and Medway will always consider appropriate individual funding requests (IFRs) through their IFR process.

[1] Teriparatide is listed as a High Cost Drug Exclusion (Payment by Results Exclusion).

Supporting documents

Health Care Intervention Appraisal and Guidance (HCiAG) team (2016) *Teriparatide (Forsteo®) for osteoporosis: Extended duration of treatment – Briefing note*

Equality Analysis Screening Tool – Teriparatide for osteoporosis: Extended duration of treatment (2016).

Key points and rationale

What is osteoporosis?

Osteoporosis is a progressive systemic skeletal disease characterised by reduced bone mass and micro-architectural deterioration of bone tissue. As a result, bone is increasingly fragile and more susceptible to fracture. Osteoporotic (fragility) fractures result from mechanical forces that would not ordinarily result in fracture; they are associated with low bone mineral density (BMD) and include spine, forearm, hip and shoulder fractures.

What is teriparatide?

Teriparatide is a recombinant fragment of parathyroid hormone which stimulates new formation of bone and increases resistance to fracture. Teriparatide is licensed for the treatment of postmenopausal osteoporosis in women, osteoporosis in men at increased risk of fracture, and corticosteroid-induced osteoporosis.

Teriparatide was originally licensed for a maximum treatment duration of 18 months; this restriction was based on a clear dose and time dependent relationship between teriparatide exposure and the development of osteosarcoma in nonclinical animal studies. The licensed maximum duration of treatment was subsequently increased to 24 months in 2009 on the basis of additional safety data (see below). A course of treatment with teriparatide may not be repeated.

What does national and local guidance say?

According to NICE Technology Appraisal (TA) 161 (October 2008), teriparatide is recommended as an alternative for women in whom alendronate and either risedronate or editronate, or strontium ranelate are contra-indicated or not tolerated, or where treatment with alendronate, risedronate or editronate has been unsatisfactory (indicated by another fragility fracture and a decline in BMD despite treatment for 1 year) and who comply with particular combinations of BMD measurement, age, and number of fractures, as indicated in the full NICE guidance. The guidance states that *'at the time of appraisal, the maximum total duration of treatment was restricted by marketing authorisation to 18 months'*. There is no planned update of TA161. There is no NICE guidance on teriparatide for osteoporosis in men at increased risk of fracture, or corticosteroid-induced osteoporosis.

Current local Kent and Medway Osteoporosis Group guidance (2013) recommends treatment with teriparatide should be limited to a maximum duration of 18 months.

What is the evidence base for extending treatment duration to 24 months?

The increase in the licensed maximum duration of treatment from 18 to 24 months was based on evidence from two clinical studies and post marketing experience; the European Medicines Agency concluded that 6 additional months of treatment would not significantly change the safety profile of teriparatide. However, there is no evidence from randomised controlled trials that increasing the duration of treatment of teriparatide to 24 months confers additional clinical benefit over 18 months treatment in terms of fracture reduction.

What would be the cost impact of extending treatment duration to 24 months across Kent and Medway?

The annual cost to Kent and Medway CCGs of extending the treatment duration to 24

months is estimated to range from £12,566 (based on 5% of current teriparatide recipients receiving 24 months rather than 18 months treatment) to £62,831 (based on 25% of current teriparatide recipients receiving 24 months rather than 18 months treatment).

Why is teriparatide for osteoporosis recommended for a maximum treatment duration of 18 months?

The PRGC decision to recommend teriparatide for osteoporosis for a maximum treatment duration of 18 months is consistent with current local guidance. There is no evidence that increasing the duration of treatment to 24 months confers additional clinical benefit over 18 months treatment in terms of fracture reduction. In addition, increasing the duration of treatment with teriparaptide from 18 to 24 months would represent a cost-pressure to CCGs.

Change sheet

Reason for review: An individual funding request (IFR) has been received for this drug for 24 months of treatment (Kent and Medway Osteoporosis Group guidelines currently limit treatment with teriparatide to a maximum duration of 18 months); this request was triaged out for policy development as a cohort of similar patients could be envisaged.

Change from baseline position: No change. This topic has not previously been reviewed by the Kent and Medway Policy Recommendation and Guidance Committee (PRGC); however the policy recommendation detailed in this document is consistent with current local Kent and Medway Osteoporosis Group Guidance (2013), which recommends that treatment with teriparatide should be limited to a maximum duration of 18 months.

Estimated cost impact of implementation of policy: No change

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