

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	2 nd June 2015 (reviewed 23 rd February 2021 & no change required)
Appraisal & Details	<p>Teriparatide (Forsteo®, Eli Lilly) for the treatment of (bisphosphonate-induced) atypical fractures.</p> <p>The NHS Northern Treatment Advisory Group was requested by a member organisation to conduct an appraisal of, and issue a recommendation on the unlicensed use of teriparatide for the treatment of (bisphosphonate induced) atypical fractures.</p>
Recommendation	<p>The NHS Northern Treatment Advisory Group does not recommend the use of teriparatide for the treatment of (bisphosphonate induced) atypical fractures (unlicensed indication).</p> <p>The group was concerned about the paucity of the data, lack of evidence of robust clinical efficacy of treatment and considered that it did not represent a cost-effective treatment option. However individual patients in exceptional circumstances may be suitable for treatment. Such cases must be referred via local individual funding request mechanisms.</p>
Clinical evidence summary	<p>There is little published evidence for the efficacy of teriparatide in atypical fractures. The majority of evidence is in the form of case reports; no robust randomised controlled trials have been performed. Concurrent pharmacological or surgical treatments, reported outcomes, time to teriparatide initiation, and treatment duration varied between reports.</p> <p>Overall, the results of published case reports and other small studies appear positive but are difficult to interpret. The optimal regimen and precise place in therapy of teriparatide compared to surgery remain uncertain.</p>
Safety	<p>Adverse effects are likely to be similar to those seen for its licensed indication. Most commonly reported adverse effects are nausea, limb pain, headache and dizziness. There are concerns that long term use of teriparatide may be associated with an increased risk of osteosarcoma. Treatment should therefore be limited to a maximum of 24 months.</p>
Patient Perspective	<p>There are no clear guidelines for the treatment of atypical fractures caused by bisphosphonates with limited options available for treatment. Some patients may prefer medical therapy as opposed to surgery however risks and benefits of all options should be discussed with patients.</p>
Cost analysis summary	<p>Teriparatide is a high-cost PbR-excluded drug.</p> <p>The cost of teriparatide varies with brand, from around £230 to £270 (excl. VAT) per pre-filled device containing 28 doses. The annual cost is therefore £3000-£3,500, and the cost for the maximum licensed course of two years is £6,000-£7,000.</p> <p>No other pharmacological options are available, and treatment costs would be additional to the current cost of management.</p> <p>No reliable estimates of the likely frequency of use in the NHS were identified</p>
Financial impact PbR: Excluded.	<p>This financial impact of this recommendation is expected to be nil.</p>