NHS
Fylde and Wyre
Clinical Commissioning Group

Denosumab (Prolia®) 60mg solution for injection
for the treatment of Glucocorticoid-induced osteoporosis

Commissioning Statement

Fylde and Wyre Clinical Commissioning Group has agreed to fund the prescribing of Denosumab for treating glucocorticoid-induced osteoporosis.

Patients with any of the following clinical features would be considered for treatment with denosumab:

- Upper gastrointestinal abnormalities, including oesophageal stricture, achalasia, abnormalities which delay oesophageal emptying, dysphagia, oesophageal disease (oesophagitis, ulcers, erosions), gastritis, duodenitis, gastric ulcers, previous upper GI surgery.
- Inability to sit or stand upright for at least 30 minutes.
- Renal impairment (eGFR <35ml/min). (Denosumab's SPC states there is no data for patients with eGFR < 30ml/min. Many clinicians are happy to use if eGFR > 20ml/min, provided serum calcium is closely monitored after each injection).
- Concerns about compliance with treatment – may include patients with cognitive impairment.
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For patients with corticosteroid induced osteoporosis the LMMG has agreed that the choice of denosumab or zoledronic acid should be based on the clinical judgement of the responsible clinician.

This medicine is classified as AMBER1 for this indication

Summary of supporting evidence:

- Relatively large active controlled trial
- In the glucocorticoid-initiating subpopulation, denosumab significantly increased lumbar spine BMD compared to the active-control at one year (active-control 2.3% [1·7–2·9], denosumab 4.4% [95% CI 3·8–5·0] p<0·0001) with a treatment difference of 2.2% (p < 0.001).
- In the glucocorticoid-continuing subpopulation, denosumab significantly increased lumbar spine BMD compared to active-control at one year (active-control 0.8% [0·2–1·5], denosumab 3.8% [3·1–4·5] p<0·0001) with a treatment difference of 2.9% (p < 0.001).
- Consistent effects on lumbar spine BMD were observed regardless of gender; race; geographic region; menopausal status; and baseline age, lumbar spine BMD T-score, and glucocorticoid dose within each subpopulation.

For details around the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/