The Cost-effectiveness of Denosumab (Prolia®) for the Prevention of Osteoporotic Fractures in Postmenopausal Women.

July 2010

Summary

1. An economic evaluation on the use of denosumab (Prolia®) for the prevention of osteoporotic fractures in postmenopausal women was submitted by the manufacturer, Amgen UK Ltd, on the 27th May 2010. The dossier aimed to support the application for reimbursement of denosumab under the Community Drugs Schemes.

2. Denosumab is a human monoclonal IgG_2 antibody which inhibits osteoclast activity. Its therapeutic indications include the treatment of osteoporosis in postmenopausal women at increased risk of fractures and the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.

3. A cost utility analysis was undertaken using a Markov cohort model. The perspective was that of the Health Service Executive (HSE). The comparators included alendrenate, risedronate, raloxifene and strontium. Costs and effects were discounted at 4% and a lifetime time horizon was applied.

4. The incremental cost-effectiveness ratio (ICER) for denosumab versus alendronate (weekly) in patients aged 70 years, with no prior fracture and a BMD T-Score ≤ - 2.5 SD (base case) under the General Medical Services (GMS) scheme was estimated at €12,360 per quality adjusted life year (QALY). For patients aged 70 years with a prior fracture (BMD T-Score ≤ - 2.5 SD) the ICER for denosumab versus alendronate (weekly) was €4,340/QALY. Denosumab dominated risedronate (weekly), strontium and raloxifene.

5. Under the Drugs Payment (DP) scheme the ICER for denosumab versus alendronate (weekly) for patients aged 70 years with no prior fracture and a BMD T-Score ≤ - 2.5 SD was €18,513/QALY, for those patients with a prior fracture the ICER for denosumab versus alendronate (weekly) was €8,130/QALY. Denosumab dominated the other comparators in patients with or without a prior fracture.

6. A comprehensive deterministic sensitivity analysis demonstrated the ICER was sensitive to a number of input parameters including patient age, time horizon and compliance with treatment. Incorporating a €30 administration fee for subcutaneous administration of denosumab resulted in an increase in the ICER from €12,360/QALY to €31,827/QALY (no prior fracture, GMS) and €4,340/QALY to €16,325/QALY (prior fracture, GMS).

7. Probabilistic sensitivity analysis indicated the probability of denosumab being cost-effective at the thresholds of €20,000/QALY and €45,000/QALY to be in the region of 44% and 65% respectively (no prior fracture, GMS). Corresponding figures for patients with a prior fracture under the GMS scheme were approximately 60% and 70% respectively.

8. In estimating budget impact the number of women eligible for osteoporosis treatment in Ireland was predicted to increase from approximately 134,000 in 2010 to over 152,000 in 2015. It was estimated that the percentage of eligible patients receiving denosumab would exceed 16% by 2015. The cost of denosumab therapy could exceed €14.4million per annum by 2015.

9. Based on current available evidence the review group considers denosumab a cost-effective therapy for the prevention of osteoporotic fractures in postmenopausal women in the Irish healthcare setting. We are happy to recommend reimbursement of denosumab under the Community Drugs Schemes.