Supplemental Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
December 31, 2010	**Prevention of skeletal-related events in patients with bone metastases from solid tumors**
Denosumab ***(Xgeva—Amgen)*** **Antibody for bone metastases from solid tumors**	Data from three randomized, double-blind trials comparing denosumab 120 mg with zoledronic acid 4 mg (Zometa—Novartis), both given once every 4 weeks, showed that denosumab was superior to zoledronic acid in preventing skeletal-related events in patients with breast or prostate cancer and bone metastasis and was noninferior to zoledronic acid in preventing these events in patients with multiple myeloma or other solid tumors. The FDA-recommended dose is 120 mg administered as a subcutaneous injection every 4 weeks. It is important to distinguish the dosing and indication differences between Prolia and Xgeva, both of which contain denosumab. Prolia is dosed as a 60-mg subcutaneous injection once every 6 months and is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture.

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http://www.aphanet.org/antibody-bone-metastases-solid-tumors