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On Drugs and Therapeutics

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Revised 7/14/09: The first word of the title of the In Brief was changed from *Biannual* to *Biennial*.

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IN BRIEF

Biennial IV Zoledronic Acid *(Reclast)* for Prevention of Osteoporosis

The FDA, which had previously approved intravenous (IV) administration of 5 mg of zoledronic acid (*Reclast* – Novartis) once a year for treatment of postmenopausal osteoporosis (Med Lett Drugs Ther 2007; 49:89), has now approved the same dose for use once every 2 years to prevent osteoporosis in postmenopausal women with osteopenia.

Clinical Studies – In an unpublished study summarized in the package insert, 224 women with osteopenia <5 years after menopause were given an IV infusion of zoledronic acid 5 mg or placebo; 2 years later, total hip bone mineral density (BMD) had increased by 2.6% with the drug and decreased by 2.1% with placebo. Among 357 osteopenic women ≥5 years after menopause, hip BMD 2 years after one IV dose of zoledronic acid increased by 2.1% and decreased by 1.0% with placebo. Both of these differences from placebo were statistically significant. Similarly significant increases occurred in vertebral BMD. No data are available on the incidence of hip or vertebral fractures in these women, but zoledronic acid once a year for treatment of osteoporosis has been shown to decrease the incidence of such fractures.

Adverse Effects — An acute-phase reaction including fever, flu-like symptoms, headache, arthralgia and myalgia can occur with IV administration of zoledronic acid; symptoms usually subside within a few days. Renal damage can occur after a single dose, especially with concomitant use of other nephrotoxic drugs, including nonsteroidal anti-inflammatory drugs (NSAIDs). Jaw osteonecrosis has occurred rarely. Whether long-term use of bisphosphonates, which interfere with bone remodeling, could increase the incidence of long-bone fractures remains to be established. None of these events, except for acute-phase reactions, occurred during the clinical trial, according to the manufacturer.

Cost – The cost of one 5-mg injection of *Reclast* is about $1200 for the drug alone.

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