

Zoledronic Acid for Paget's Disease Ranks Well on Cost

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FT. LAUDERDALE, FLA. — Zoledronic acid, if approved for the treatment of Paget's disease of bone, could prove a slightly cheaper therapeutic option than other available therapies in the setting of a managed care formulary, Lee S. Stern said at a meeting sponsored by the Paget Foundation for Paget's Disease of Bone and Related Disorders.

That conclusion is based on a budget impact analysis sponsored by Novartis Pharmaceuticals Corp., the maker of zoledronic acid (Zometa). Ms. Stern, a health economist with Analytica International, New York, said a typical 1-million-member managed care organization that adds the drug to its formulary could expect to save about \$2,000 per year.

At press time, Zometa is licensed solely for the treatment of hypercalcemia of malignancy. The Food and Drug Admin-

istration is reviewing an indication for the drug's use in Paget's disease and could act as early as this month. Zoledronic acid is administered as an intravenous infusion.

Based on the speed and extent of disease suppression with zoledronic acid, and the drug's ability to suppress bone turnover for up to 2 years, it is viewed as an advance over available IV and oral bisphosphonates. In a pivotal randomized, double-blind, controlled trial, 96% of patients with Paget's disease had a therapeutic response

to zoledronic acid, compared with a response in 74% receiving 60 days of oral risedronate. Response was achieved in a median of 64 days with zoledronic acid and 89 days with oral risedronate (N. Engl. J. Med. 2005;353:898-908).

"Given the clinical profile of zoledronic acid in terms of these higher response rates, we can expect a lower overall cost to the managed care plan," said Ms. Stern.

The analysis modeled the introduction of zoledronic acid into the formulary of a theoretical managed care organization with 1 million members and an annual growth rate of 0.85% per year. Using data from the literature, market research, and other sources, the model assumed that the prevalence of Paget's disease is 1.04% and that 3.24 individuals per 100,000 would be newly diagnosed each year.

Further, the prevalence of Paget's disease is falling by about 5% per year, and the annual mortality among diagnosed individuals is about 1.8%, Ms. Stern said.

In 2004, an estimated 7.6% of a managed care plan's Paget's disease population would have been treated with bisphosphonates. In 2005, zoledronic acid would take away 2% of that market. If given the Paget's indication, that percentage would increase to 11% in 2006, to 18% in 2007, and to 22% in 2008 and thereafter.

Annual treatment costs were derived from a model that weighed the efficacy (response and relapse rates) for each of the bisphosphonates based on clinical trial results, the type and extent of medical and pharmacy resource use based on expert opinion, and cost estimates from official fee schedules and published sources.

Compared with the other oral and intravenous bisphosphonates, zoledronic acid had the lowest mean annual treatment cost per patient, \$829. Alendronate was second, at \$923, followed by risedronate (\$938), pamidronate (\$1,277), etidronate (\$1,712), and tiludronate (\$2,039). In the case of zoledronic acid, "The high response rate and ease of use offset the actual cost of the drug," Ms. Stern said.

Overall, the projected overall annual cost savings to the managed care organization would be \$2,078, a per patient per year savings of \$2.70, and a per patient per month savings of \$0.22. While this might look small, "Any kind of savings to managed care is always good news and usually means that the drug will have good pull-through once it gets approved," she noted. ■

It turns out that the biggest resistance to insulin therapy may come from your patients.

Weight gain has long been accepted as an unavoidable consequence of most insulin therapies, including basal insulin therapy. But the burden on your patients is more than just cosmetic. A pronounced change in weight may also have a negative impact on your patients' mental and physical well-being.^{1,2} In fact, fear of weight gain is a major factor that can affect patient compliance with their insulin regimens. Many patients intentionally administer a lower dose of insulin than is required for good glycemic control. Others may simply stop taking their insulin altogether—placing them at greater risk of further complications from diabetes.²

As you know, even the most effective insulin preparations are of little value if your patients become noncompliant. That's why we remain steadfast in our commitment to developing therapeutic solutions that will improve glycemic control while helping to keep the weight off your patients' bodies—and off their minds. At Novo Nordisk, we're changing the shape of things to come.

References: 1. Purnell JQ, Hokanson JE, Marcovina SM, Steffes MW, Cleary PA, Brunzell JD. Effect of excessive weight gain with intensive therapy of type 1 diabetes on lipid levels and blood pressure: results from the DCCT. *JAMA*. 1998;280:140-146. 2. Bryden KS, Neil A, Mayou RA, Peveler RC, Fairburn CG, Dunger DB. Eating habits, body weight, and insulin misuse: a longitudinal study of teenagers and young adults with type 1 diabetes. *Diabetes Care*. 1999;22:1956-1960.



Annual Expense per Patient

Alendronate	\$923
Etidronate	\$1,712
Pamidronate	\$1,277
Risedronate	\$938
Tiludronate	\$2,039
Zoledronic acid	\$829

Note: Based on multiyear costs using economic modeling.

Source: Analytica International for Novartis Pharmaceuticals