Insurers to Pay 80%-85% of Premiums for Care

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FROM A PRESS CONFERENCE HELD BY THE HEALTH AND HUMAN SERVICES DEPARTMENT

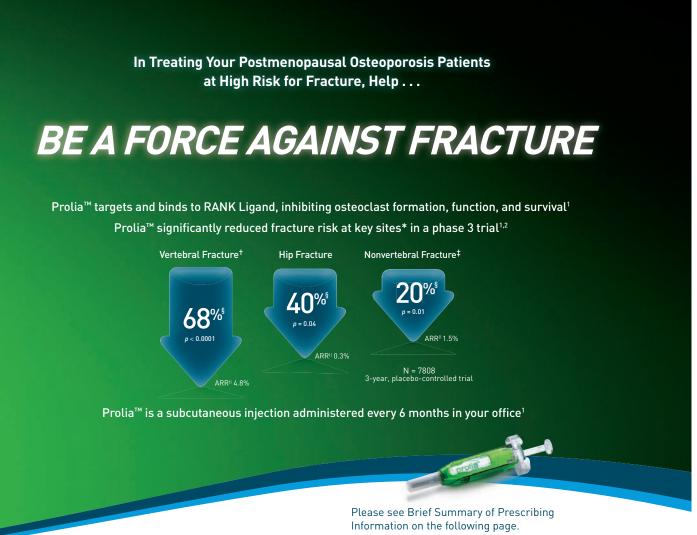
eginning next year, health insurance companies will be required to prove that they spend at least 80% of premium dollars collected on direct medical care and quality improvement efforts under new federal regulations.

The interim final rule took effect Jan. 1 and was required by the Affordable Care Act. The so-called medical loss ratio rule was developed by the National Association of Insurance Commissioners, which submitted its recommendations to the Health and Human Services department in late October.

According to the rule, HHS reviews insurers' medical loss data at the end of 2010. Companies that spend less than 80%-85% of their premium dollar on direct medical care will be required to issue rebates to consumers, said HHS Secretary Kathleen Sebelius at a press briefing. The rebate checks will begin arriving in 2012.

In some markets, insurers spend as little as 60% of the premium dollar on direct care, said Ms. Sebelius, who added that under the rule, those companies might have "to return nearly \$3,500 to every family they insure." Her calculation was based on an average annual premium of \$13,250 paid by a family of four.

Timothy Jost, a professor of law at Washington and Lee University, Lexington. Va., who advised the NAIC task force, said he estimated that insurers currently spend 12% of the premium dollar on pharmaceuticals and 31% for physician services, and 31% on administrative costs.



be performed by the prescriber prior to initiation of Prolia™. A dental examination with appropriate preventive dentistry should be considered prior to treatment in patients with risk factors for ONJ. Good oral hygiene practices should be maintained during treatment with Prolia™.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia™ should be considered based on individual benefit-risk assessment.

- Suppression of Bone Turnover: Prolia™ resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing.
- Adverse Reactions: The most common adverse reactions (> 5% and more common than placebo) are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. Pancreatitis has been reported with Prolia™.

The overall incidence of new malignancies was 4.3% in the placebo and 4.8% in the Prolia™ groups. A causal relationship to drug exposure has not been established. Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

- **Variation Prolia™ Postmarketing Active Safety Surveillance Program:** The Prolia™ Postmarketing Active Safety Surveillance Program is available to collect information from prescribers on specific adverse events. Please go to www.proliasafety.com or call 1-800-772-6436 for more information about this program.

- * Key sites: vertebral, hip, and nonvertebral. 12 † Includes 7393 patients with a baseline and at least one post-baseline radiograph. 12 † Composite measurement excluding pathological fractures and those associated with severe trauma, fractures of the vertebrae, skull, face, mandible, metacarpals, fingers, and toes. 12 † RRR = relative risk reduction.

References: 1. Prolia™ (denosumab) prescribing information, Amgen. 2. Cummings SR, San Martin J, McClung MR, et al. Denosumab for prevention of fractures in postmenopal women with osteoporosis. N Engl J Med. 2009;361:756-765.

For more information, visit www.ProliaHCP.com

