

## Damon Schultz

**From:** PDQ Communications, Inc. [mem@mmslist.a.messages3.com]  
**Sent:** Tuesday, September 28, 2010 10:50 AM  
**To:** Damon Schultz  
**Subject:** Prolia(TM) (denosumab) Is Now FDA Approved

This message contains graphics. If you do not see the graphics, [click here to view](#).

[Full Prescribing Information](#)   [Medication Guide](#)   [Important Safety Information](#)



The graphic is a promotional advertisement for Prolia (denosumab) injection. It features a central image of a human spine and pelvis, with a magnified view of a vertebra showing a fracture. The background is a gradient of green and blue. In the top right corner, there is a logo for 'NEW prolia (denosumab) injection' with a 'NOW APPROVED' seal. The main text reads 'In Treating Your Postmenopausal Osteoporosis Patients at High Risk for Fracture, Help . . . BE A FORCE AGAINST FRACTURE'. Below this, it says 'Introducing Prolia™' followed by three bullet points: 'Targets and binds to RANK Ligand, inhibiting osteoclast formation, function, and survival†', 'Significantly reduced fracture risk at key sites\*\*1,2', and 'Administered as a subcutaneous injection every 6 months in your office†'. A 'Learn more!' button with the URL 'www.ProliaHCP.com' is also present. Footnotes at the bottom state: '† Key sites: vertebral, hip, and nonvertebral1,2' and '† 3-year, placebo-controlled trial (N = 7808)'.

### Indication

**Prolia™ is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia™ reduces the incidence of vertebral, nonvertebral, and hip fractures.**

### Important Safety Information



**Hypocalcemia:** Prolia™ is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating Prolia™. Hypocalcemia may worsen, especially in patients with severe renal impairment. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, clinical monitoring of calcium and mineral levels is highly recommended. Adequately supplement all patients with calcium and vitamin D.




**Serious Infections:** In a clinical trial (N=7808), serious infections leading to hospitalization were reported more frequently in the Prolia™ group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia™. Endocarditis was also reported more frequently in Prolia™-treated subjects. The incidence of opportunistic infections was balanced and the overall incidence of infections was similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis.

Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia™, prescribers should assess the need for continued Prolia™ therapy.





**Dermatologic Adverse Reactions:** Epidermal and dermal adverse events such as dermatitis, eczema and rashes

occurred at a significantly higher rate in the Prolia™ group compared to the placebo group. Most of these events were not specific to the injection site. Consider discontinuing Prolia™ if severe symptoms develop.


 **Osteonecrosis of the Jaw (ONJ):** ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving Prolia™. An oral exam should 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.

 **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 see [www.proliasafety.com](http://www.proliasafety.com) or call 1-800-772-6436 for more information about this program.

Please see Prolia™ [Full Prescribing Information](#), including the [Medication Guide](#).

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

*Image of trabecular bone insert reproduced with permission from David W. Dempster, PhD.*

Go to [www.ProliaHCP.com](http://www.ProliaHCP.com) for more information.

**AMGEN**

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MC48438

**NEW**  
**prolia**  
(denosumab) injection

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