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DIPLOMATES OF THE AMERICAN BOARD OF ORAL & MAXILLOFACIAL SURGERY

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XGEVA AND OSTEONECROSIS OF THE JAW

In the June 2008 edition of the *OMS Quarterly*, Biphosphonate-Related Osteonecrosis of the Jaw (BRONJ) was first reviewed from the position paper of the AA-OMS. There was an update on Bisphosphonate-Related Osteonecrosis of the Jaw discussed in the *OMS Quarterly* June 2010 edition (see www.drbrriansimpson.com, click on newsletters). Now there is a new development in relation to XGEVA.

XGEVA (denosumab) is indicated for the prevention of skeletal-related events in patients with bone metastases from solid tumors. Denosumab is a fully human monoclonal antibody for the treatment of osteoporosis, treatment-induced bone loss, bone metastases, rheumatoid arthritis, multiple myeloma, and giant cell tumor of bone. It is designed to inhibit RANKL (RANK ligand), a protein that acts as the primary signal for bone removal. It is also indicated for treatment of adults

and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. XGEVA is not indicated for the prevention of skeletal-related events in patients with multiple myeloma.

Osteonecrosis of the jaw (ONJ) can occur in patients receiving XGEVA (denosumab), manifesting as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival erosion. Persistent pain or slow healing of the mouth or jaw after dental surgery may also be manifestations of ONJ.

In clinical trials in patients with osseous metastasis, 2.2% of patients receiving XGEVA (denosumab) developed ONJ after a median exposure of 13 doses; of these patients, 79% had a history of tooth extraction, poor oral hygiene, or use of a dental appliance. In a clinical

trial conducted in patients with prostate cancer at high risk for osseous metastasis, a condition for which denosumab is not approved, 5.4% of patients developed ONJ after a median exposure of 20 doses.

It is advisable to perform an oral examination and appropriate preventive dentistry prior to the initiation of XGEVA (denosumab) and periodically during XGEVA therapy. Advise patients regarding oral hygiene practic-

es. Avoid invasive dental procedures during treatment with XGEVA.

Patients who are suspected of having or who develop ONJ while on XGEVA (denosumab) should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.

The most common adverse reactions in patients

continued on reverse

DENTAL FUN FACT

DID YOU KNOW...

Say Cheese! The calcium and phosphorous found in cheese is healthy for your teeth- it reduces the pH level in plaque and re-mineralizes the enamel.

(<http://www.obteam.com/Fun-Facts.aspx>)

NEWS YOU CAN USE

*You and your staff
are invited to*

**SIMPSON ORAL AND
MAXILLOFACIAL SURGERY'S**

4th annual

Wine & Beer Tasting



**Friday, October 18th
4-7pm
113 North Middletown Rd
Nanuet, NY 10954**

RSVP to Tamar
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receiving XGEVA (denosumab) with bone metastasis from solid tumors were fatigue, asthenia, hypophosphatemia, and nausea. The most common serious adverse reaction was dyspnea. The most common adverse reactions resulting in

discontinuation of the medication were osteonecrosis and hypocalcemia.

The most common adverse reactions in patients receiving XGEVA (denosumab) for giant cell tumor of bone were arthral-

gia, headache, nausea, back pain, fatigue, and pain in the extremities. The most common serious adverse reactions were osteonecrosis of the jaw and osteomyelitis. The most common adverse reactions resulting in discontinuation of

XGEVA were osteonecrosis of the jaw and tooth abscess or tooth infection.

For more info, please see, <http://www.xgeva.com>

Dr. Brian Simpson
announces the seventeenth meeting of the
NANUET IMPLANT STUDY GROUP

Speaker: Joseph Pinto, R. Ph, MS
Director of Pharmacy Services, Nyack Hospital

**“Opioid Prescribing in Dentistry and
NYS’s I-Stop Regulation and Requirements”**

Thursday, November 14, 2013
Dinner: 6:30 Presentation: 7:00 — 9:00 pm

Restaurant X 117 North Rte. 303 Congers, NY

2 CE credits awarded by the Ninth District Dental Association
Cost: \$45.00

To register, contact Tamar: 845-623-3497
or email her at tamarsaintil89@gmail.com

“Tenacity is a pretty fair substitute for bravery.”
-Eric Sevareid, American journalist