ORAL AND MAXILLOFACIAL SURGERY FOR PATIENTS WHO HAVE RECEIVED BISPHOSPHONATE DRUGS

Having been treated previously with bisphosphonate (bone support medication) drugs, you should know that there can be a significant risk of future complications associated with dental treatment. Bisphosphonate drugs appear to adversely affect the blood supply to bone, thereby reducing or eliminating its healing capacity. This risk is increased after surgery, especially from dental extraction, implant placement, and/or other “invasive” procedures that might cause even mild trauma to bone. Osteonecrosis (bone death) may result. This is a smoldering, long-term, destructive process in the jawbone that is often very difficult or impossible to eliminate.

Bisphosphonate class of drugs includes injectable medicines Zometa (zoledronic acid) and Aredia (pamidronate disodium). The injectable form is stronger than the oral form. It is used for the management of advanced cancer that has metastasized to the bone (i.e., lung, breast, and prostate cancer, multiple myeloma, and others). It is the injectable form that appears to pose the greatest risk for osteonecrosis of the bones, including the jaws.

The oral form of bisphosphonate drugs includes Fosamax (alendronate) and Actonel (risedronate sodium). These are pills that are taken for osteoporosis by millions of women in the United States. Evidence, as we know so far, shows that the oral form is much less potent than the injectable form and appears to be less likely to cause osteonecrosis of the jaw, yet there have been several reported cases in the literature.

The medical community is in the beginning stages of finding out about this potential problem. Not all of the information we need is available at this time.

Your medication history is very important. We must know the medications and drugs that you are currently receiving or taking or have taken at any time in the past. An accurate medical history, including the names of physicians, is important.

Patient’s Initials

The details of the procedure, including the anticipated benefits and material risks, have been explained to me in terms I understand.

Alternative methods and therapies, their benefits, material risks, and disadvantages have been explained to me.

I understand and accept that the most likely material risks and complications of oral and maxillofacial surgery for patients who have received bisphosphonate drugs have been discussed with me and may include but are not limited to:

- **Significant risk of future complications associated with dental treatment.**
- **Antibiotic therapy may be used to help control possible postoperative infection. For some patients, such therapy may cause allergic responses or have undesirable side effects, such as gastric (stomach) discomfort, diarrhea, colitis (irritated bowel), etc.**
- **Despite all precautions, there may be delayed healing, osteonecrosis, loss of bony and soft tissue, and pathologic fracture of the jaw, among other significant complications.**
- **If osteonecrosis should occur, treatment may be prolonged and difficult, involving ongoing intensive therapy, including hospitalization, hyperbaric oxygen therapy, long-term antibiotics, and debridement (surgery) to remove non-vital bone. Reconstructive surgery may be required, including bone grafting, metal plate and screws, and/or skin flaps and grafts.**
This form is for reference purposes only. It is a general guideline and not a statement of standard of care and should be edited and amended to reflect policy requirements of your practice site(s), CMS, and The Joint Commission requirements, if applicable, and legal requirements of your individual state(s).

- Even if there are no immediate complications from the proposed dental treatment, the area may still experience spontaneous breakdown and infection due to precarious condition of the bony blood supply. Even minimal trauma from a toothbrush, chewing hard food, or denture sores may trigger a complication.

I understand and accept that complications, including the remote risk of death or serious disability, exist with any surgical procedure.

I understand that long-term postoperative monitoring may be required and cooperation in keeping scheduled appointments is important. Regular and frequent dental checkups with your dentist are important to monitor and attempt to prevent breakdown in your oral health.

I am aware that smoking during the pre- and postoperative periods could increase chances of complications (if applicable).

I understand the importance of my health history and affirm that I have given any and all information that may affect my care. I understand that failure to give true health information may adversely affect my care and lead to unwanted complications.

I have informed the surgeon of all my known allergies.

I have informed the surgeon of all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies and supplements, aspirin, and any other recreational drug or alcohol use.

I have been advised whether I should avoid taking any or all of these medications on the days surrounding the procedure.

I am aware and accept that no guarantees about the results of the procedure have been made.

I have been advised of the probable consequences of declining recommended or alternative therapies.

I have been informed of what to expect postoperatively, including, but not limited to, estimated recovery time, anticipated activity level, and the possibility of additional procedures.

The surgeon has answered all of my questions regarding this procedure.

Information for Female Patients:

I have informed my surgeon about my possible use of birth control pills. I have been advised that certain antibiotics and other medications may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy. I agree to consult with my personal physician to initiate mechanical forms of birth control during the period of my treatment and to continue those methods until advised by my personal physician that I can return to the use of oral birth control pills.

I certify that I have read and understand this treatment agreement and that all blanks were filled in prior to my signature.

I authorize and direct __________________, DDS/DMD/MD, with associates or assistants of his or her choice, to perform the procedure of __________________ on __________________ at ______________ on (procedure name) (patient name) (facility name) the (right, left, level, body part).

I further authorize the surgeon(s) and assistants to do any other procedure that in their judgment may be necessary or advisable should unforeseen circumstances arise during the procedure.

Patient or Legal Representative Signature/Date/Time __________________ Relationship to Patient __________________

Print Patient or Legal Representative Name __________________ Witness Signature/Date/Time __________________

I certify that I have explained the nature, purpose, anticipated benefits, material risks, complications, and alternatives to the proposed procedure/treatment and the risks and consequences of not proceeding, to the patient or the patient’s legal representative. I have answered all questions fully, and I believe that the patient/legal representative (circle one) fully understands what I have explained.

Surgeon Signature/Date/Time __________________

copy given to patient _____________ original placed in chart _____________

____________________ initial
____________________ initial