**Doctor’s Instructions for ONJ Study**

*(Circle location: Office, Hospital, Nursing Home)*

**A. General Instructions**

1. You will find all Attachments related to this study in the patient’s Green File Envelope provided
2. Obtain Consent Document for Screening Interview (Attachment 2). If not completed, give it to the patient to read and sign. Explain any questions that they may have. This form must be signed before the patient can be enrolled in the study.
3. Refer to the Diagram of ONJ Study (Attachment 1), which also has the complete list of attachments.

All prospective patientsmust complete three questionnaire interviews (Attachments 4a, 4b and 5a). Review these questionnaires with the patient. The patient may not be able to recall all the information in the questionnaires. It may be necessary to review their outside medical/dental records, or make a phone call to the patient’s PCP or oncologist to obtain the needed information.

1. After completing 4a, 4b, and 5a with the patient, assign the Patient’s Number as described in Attachment 6.

Enter the Patient’s Number on each of the Attachments (upper, right corner) in the green file envelope, as well as the outside of the patient’s green file envelope (upper right corner).

1. “Yes” patients are designated with a “Y”.They have well established biopsy proven diagnosis of ONJ. They should be given the following attachments afterthe interview:

Attachment 000 (Patient’s Instruction Sheet)

Attachment 0 (Patient Contact Info)

Attachment 3 (HIPAA form)

Attachment 7 (Consent for Blood draw)

Attachment 10 (Doctor’s Order/Lab Instruction Sheet)

Be sure to sign and date Doctor’s Order and make a copy, prior to giving it to the patient.

1. “Questionable” patients are designated with a “Q”. These patients do not have a definitive ONJ diagnosis yet. In addition to completing the three questionnaires (4a, 4b, 5a), they need to sign the HIPAA form (3) to release additional medical/dental records, and have a follow-up appointment in 4-6 weeks. They should have regular follow up visits, until it is ascertained they have bona fide ONJ or if they are designated as an “N” patient. An “N” status disqualifies them from the ONJ study, but the patient can continue to be followed by OSG or their referring Doctor.
2. “No” patients are designated with an “N”.No additional attachments are needed, and no follow-up appointments are necessary to be in the study.

 Do not give the Doctor’s Order to patients assigned “N” or “Q”.

1. Make a copy of the Doctor’s Order form (10) and place this copy, together with the other forms completed during the interview, into the green file envelope. Pertinent information, such as operative and pathology reports should be placed in the same green envelope, if there is sufficient space. Store items securely with a large rubber band or string, if needed. Store items in the locked offices of Dr. McMahon or Dr. Hajjar.

1. When available, enter the results of the blood testson the Laboratory Result Form/Interview (8) and the Log Sheet provided (9). When all results are available, schedule a follow-up appointment with the patient to discuss the results of blood studies using attachment 8. Forward results to Drs. McMahon and Hajjar by Fax or email.

**B. Tabulating the Patient’s Score of Questionnaires 4a, 4b and 5a:**

TheQuestionnaires on Risk Factor Assessment are as follows:

1. Medical Risk Factors Questionnaire/Interview (4a)

2. Medication Risk Factors Questionnaire/ Interview (4b)

 I. Antiresorptive Medications

 A. Osteoporosis

 B. Bone Metastases

 C. Malignant Hypercalcemia Therapy

 D. Paget’s Disease

 II. Steroid Medications

 A. Systemic

 B. Inhaled

 III. Cancer Medications

 A. General Cancer chemotherapy

 B. Antiangiogenic Chemotherapy

 C. Multiple Myeloma Therapy

 3. Dental Risk Factor Questionnaire/ Interview (5a)

 A*.* Dental Pain

 B. Jaw Pain

1. Each of the questionnaire interview Attachments 4a, 4b, 5a have questions that prompts the Patient to answer “Yes or “No” or “I don’t know “(signified by a “?” mark). The “Yes” responses are “weighted”, so to reflect a greater risk factor for the development of ONJ.
2. After completing each Questionnaire Interview, add the total number of “Yes” responses in each section, then total all the “Yes” responses at the end of each Questionnaire.
3. Compare your patient’s total score to the maximum score possible at the end of each section and the end of each questionnaire. The maximum score possible is located to the right side of the / within the brackets. For example, in the 4b Questionnaire, Section A. Osteoporosis/ Bone Disease on page 2, the Maximum Score Possible is recorded as 24 in the brackets: [ /24].
4. If the Investigator counts a total of 8 out of the 24 points possible in this section that would represent 33%. This % should also be carried over to the Log 9.
5. The patient’s total score for each questionnaire (4a, 4b, 5a) should be placed on the last page of each questionnaire, (to the left of the maximum score that has already been printed on the right side of the / mark). Again, the Investigator should express the fraction as a %.
6. Add the total score for each questionnaire (4a+4b+5a) to obtain the grand total of the patient’s Risk Factor score. Fill in your score in the appropriate score box [ /337], in the middle portion of the log sheet (9) and fill in the %. For example, if the patient has a score of 168/337, the % is 50%. Both the fraction and % should be transferred to Log 9.

**C. Tabulations Used for Transfer to Log Sheet - (Attachment 9)**

1. Patient’s total Score of Medical Risk Factors (4a*)* is to be placed to the left of the maximum score already printed on the log sheet. i.e. [ /116] in the middle portion of the log sheet (9).

1. Patient’s total Score of Medication Risk Factors (4b) is to be placed to the left of the maximum score already printed on the log sheet. i.e. [ /162] in the middle portion of the log sheet (9).
2. Patient’s total Point Score for Dental Risk Factors (5a) is to be placed to the left of the maximum score already printed on the log sheet. i.e. [ /59] in the middle portion of the log sheet (9).
3. On the log sheet, certain items of the Medication Risk Factors have been selected in each category of 4b and are to be itemized separately on the log sheet, as follows:

 **Antiresorptive Med. Score**- list total score, as well as individual scores of:

 Osteoporosis Score:

 Bone metastases Score:

 Malignant Hypercalcemia Score

 Paget’s Disease Score

**Total Steroid Score-**list total score, as well as individual scores of:

 Systemic steroid Score:

 Inhaled steroid Score:

**Antiangiogenic Med. Score**- list total score:

**Multiple Myeloma**:

**Other Meds-** List any other medication that you think may be pertinent.

Finally, in the lower left corner of Log 9, fill in:

1. The Stage of ONJ at the time of Presentation
2. The Initial location of ONJ: circle if Right or left and Maxilla or Mandibular
3. Your Estimated Duration of Stage 0.

**D. The Timeline of Jaw Pain (5b)** is to be used to illustrate and summarize

important risk factor chronology that may help determine the beginning of

 Stage 0.

1. The timeline on the left of the red line represents time prior to the onset of Stage 1. The timeline on the right side of the red line represents time after the onset offstage 1.
2. The vertical red line represents “time 0”, the date bone first became exposed (Stage 1). Fill in this date in the space \_\_\_/\_\_\_/\_\_\_\_ provided, below the red line.
3. The left sided timeline (I.) shows -60 months, which is represented prior to the onset of Stage 1. The right sided timeline (II.) represents the time +60 months after the onset of Stage 1. The time initially is gradated in days, then to weeks, then months.
4. The columns on the left of each timeline have abbreviations of dental procedures, oral surgery procedures, and certain medications the patient could have received. The key to the abbreviations is below the timeline. Plot each of the items that pertain to your patient.
5. Uses of the timeline are as follows:
6. If the patient’s dental/jaw pain started as a recurrent, intermittent pain, plot the course using a dotted line on the timeline row marked **PAIN**. When the pain becomes persistent, and unresponsive to conventional therapy, draw a continuous line in the **PAIN** row, to mark the duration of this pain on the timeline. Use red pen or red pencil to plot pain on timeline.
7. The onset of either pain could represent the onset of Stage 0, depending on the clinical circumstances. Use your clinical judgement on which time best represents the onset of Stage 0. If unsure, feel free to discuss the case with your colleagues.
8. The beginning of Stage 0 will be the onset of persistent dental /jaw pain that becomes unresponsive to conventional therapy.
9. The duration of Stage 0 will be defined as the time interval from beginning of unresponsive pain, to the time the bone first became exposed.
10. Stage 1 will be the date the bone first became exposed.
11. Fill in the date the bone became exposed (Stage 1) on the timeline, in the space provided (\_\_\_/\_\_\_/\_\_\_\_) under the vertical red line.
12. Estimate the duration of Stage 0 by noting the time of bone exposure and extrapolate backwards to the onset of unresponsive pain. Write your estimation of the duration of Stage 0 in the space provided (below the left side of the timeline, above the Major Risk Factor section).
13. The lower half of this attachment lists the major Dental and Medical risk factors associated with to ONJ. Circle all the items that pertain to the patient. The timeline could also be used to note the initiation of a medication and its discontinuation. If a particular risk factor stands out, please note this on log sheet (9) in lower left hand corner.
14. Completion of this form is important. It is in graphic format to allow the clinician to better visualize the timeline of events that may be related to the development of Stage 0 ONJ in your patient.