UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	MDL NO. 1789 1:06-md-1789 (JFK)
This Document Relates to: ALL ACTIONS	

CASE MANAGEMENT ORDER REGARDING
MASTER SETTLEMENT AGREEMENT
ELIGIBILITY AND ALLOCATION DETERMINATION APPEALS PROCESS

Pursuant to Paragraph 60 of the Master Settlement Agreement ("MSA") dated March 24, 2014, and pursuant to the April 10, 2014, Order of District Judge John F. Keenan, this Court has been appointed as the General Special Master for the oversight of the administration of the terms of the MSA. Pursuant to the terms of the MSA, the Eligibility Committee and Allocation Committee currently are reviewing the more than 1,050 settlement claims submitted through the MSA settlement claims portal. This Court, having met with counsel for Defendant and the Plaintiffs Steering Committee, believes it necessary to enter this Case Management Order outlining the procedures which will pertain to the eligibility and allocation appeals process.

Pursuant to Paragraphs 26 and 34 of the MSA, the Eligibility Committee and Allocation Committee will deliver written notice to counsel for the settlement claimants advising them of their eligibility status and allocation category determination. Pursuant to those same paragraphs, any claimant who desires to appeal an eligibility determination or allocation category determination has 14 days to file an appeal to the General Special Master.

Pursuant to the authority vested in this Court as the General Special Master, this Court sets the following procedures and requirements for any such appeal.

To discharge the duties to review and allocate each settlement claim file, the Eligibility Committee and Allocation Committee have created a system by which all claims are to be evaluated by those Committees consistently and according to objective criteria. Attached hereto as Attachment "1" is the document titled Eligibility and Categorization Interpretation Guidelines for Fosamax MDL No. 1789 Master Settlement Eligibility and Allocation Review Process. To discharge its duties as the General Special Master, this Court will use those guidelines to evaluate any eligibility or allocation categorization appeal.

For any claimant desiring to appeal an eligibility or allocation determination, within fourteen days after the date such Participating Claimant or such Participating Claimant's Counsel is notified of the Eligibility Determination or the Allocation Category determination, (A) the Participating Claimant shall notify the PSC, Merck, and the General Special Master of the intent to appeal, and (B) the Participating Claimant must perfect the appeal by (1) providing the submitted claim file record and (2) a letter brief identifying the issue appealed from and the argument in support of the claimant's appeal. The submitted claim file record shall consist solely of: (a) the Fosamax Claim Coversheet for Counsel which every online claimant received as a receipt upon submission of the claimant's claim and (b) the supporting medical and dental record documentation uploaded through the settlement claims portal. In the event a claimant does not have her submitted claim file record, the claimant's counsel may request a copy of the same from the Eligibility Committee and Allocation Committee at the email addresses provided below. Upon written application of the claimant's counsel, and for good cause shown, this Court may extend the fourteen day time period to perfect the appeal by up to an additional fourteen days.

Absent prior leave of this Court, the letter brief will not exceed five pages in length. The

claimant's counsel must: (1) specifically identify the issue appealed from; (2) identify by bates-stamp number the record(s) which counsel believes requires a different determination than that reached by the Eligibility Committee and/or Allocation Committee. The Eligibility Committee and/or Allocation Committee will then have five days to respond to the issue on appeal via letter brief, no more than five pages in length.

As this is a matter of private settlement pursuant to the MSA, the appeal will not be filed on the CM/ECF system. Rather, the appeal will be served via email as follows:

- michael bacchus@nysd.uscourts.gov (Chambers of General Special Master)
- tobrien@levinlaw.com (Eligibility Committee & Allocation Committee)
  jgreen@ashcraftlaw.com (Eligibility Committee & Allocation Committee)

A courtesy copy of the appeal will be served upon Defendant's counsel via email as follows:

- beausole@HughesHubbard.com
  semarshall@venable.com

For purposes of hearing oral arguments on any appeals filed on behalf of claimants, the Court has reserved the following dates: the morning of November 17, all day November 18, and all day November 19. The specific dates and times allotted for any particular appeal presented will be worked out between the Eligibility & Allocation Committee and the claimant's counsel. Appearance at the oral argument is not required by claimant's counsel, but a member of the Eligibility Committee and Allocation Committee will appear and make presentation on those dates for any and all appeals filed.

IT IS SO ORDERED.

Dated: New York, New York
September 4, 2014.

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE
SOUTHERN DISTRICT OF NEW YORK

APPENDIX 1

ELIGIBILITY & CATEGORIZATION INTERPRETATION GUIDELINES FOR FOSAMAX MDL NO. 1789 MASTER SETTLEMENT ELIGIBILITY AND ALLOCATION REVIEW PROCESS

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I. ELIGIBILITY DETERMINATION:

A. OVERVIEW.

Per the Master Settlement, in order to be treated as a "Qualified Program Claimant", the individual claimant must:

1. Have at least 84 days of Fosamax usage documented in pharmacy records and;

2. Have proof of osteonecrosis of the jaw through any 1 of the following 3 methods:

   a. a diagnosis of ONJ or BRONJ documented in a medical record created by either a dentist or an oral surgeon prior to December 10, 2013; or

   b. eight weeks of exposed bone documented in the treatment records created by a dentist or an oral surgeon prior to December 10, 2013; or

   c. a Rule 26 expert report from a board-certified oral and maxillofacial asserting that the Claimant has ONJ or BRONJ.

B. INTERPRETATION GUIDELINES:

1. 84 days of Fosamax use requirement.

ELIGIBILITY & CATEGORIZATION INTERPRETATION GUIDELINES FOR FOSAMAX MDL NO. 1789 MASTER SETTLEMENT ELIGIBILITY AND ALLOCATION REVIEW PROCESS

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a. in pharmacy records, 12 weeks = 84 days. Some pharmacies will call a 12 week fill 83 days, some will call it 84 days, and some will call it 85 days. The intent from the negotiation of this provision was to have at least a 12 weeks fill of Fosamax so the 12 weeks is determinative of this requirement.

b. The 84 days does not have to be continuous. Thus, if the claimant had three 4-week fills of Fosamax but scattered over a couple years, that is sufficient to establish the 84 days use requirement.

c. "Alendronate" fill: any fill before February 2008 identified as "alendronate" constitutes a Fosamax fill. After Fosamax's generic availability after February 2008, "alendronate" indicates a generic fill unless the first five numbers of the NDC code are "00006" which establishes that the "alendronate" was manufactured and/or distributed by Merck. "Alendronate" use does not satisfy the 84 days of "Fosamax" use requirement. The only exception to this is the Veterans Administration or military records, as the VA and military simply record the chemical name, and not the brand name, and thus we will accept all VA or military pharmacy references to "alendronate" as Fosamax.

ELIGIBILITY & CATEGORIZATION INTERPRETATION GUIDELINES FOR FOSAMAX MDL NO. 1789 MASTER SETTLEMENT ELIGIBILITY AND ALLOCATION REVIEW PROCESS

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d. The "pharmacy records" requirement can be satisfied by any of the following:

i. pharmacy print-out;

ii. patient receipts and/or pill bottles or blister-packs from the pharmacy;

iii. health insurance records showing payment to pharmacy specifically for Fosamax, sufficient to establish at least 84 days of prescription fills for Fosamax;

iv. clinical trial evidence for patients who received Fosamax in any Merck clinical trial.

2. Proof of ONJ or BRONJ requirement.

a. The "dentist or oral surgeon" records requirement was intended to eliminate references to "ONJ" by family doctors who have not treated the underlying jaw condition and, thus, is not satisfied by medical doctors who have not performed surgery on the patient. The "dentist or oral surgeon" requirement includes the following:

I. general dentist;

ii. any specialty dentist, including oral pathologist, oral surgeon, endodontist, pedodontist, etc.;

iii. and any medical doctor who actually performed "oral surgery" or hospital-based interventions on the patient's jaw qualifies as an oral surgeon for eligibility determinations: typically, this will be an otolaryngologist (ENT) or head and neck surgeon or an infectious disease specialist.

b. Meeting the requirement via diagnosis of ONJ or BRONJ.

i. The "diagnosis of ONJ or BRONJ" requirement is met by the following:

A. An unequivocal diagnosis of ONJ (or BRONJ);

B. "Probable" or "likely" ONJ;

C. Any reference to a specific stage of BRONJ;

D. A diagnosis of osteoradionecrosis or ORN, as that is ONJ.

E. Deposition testimony of the oral surgeon or dentist in which the doctor says that the patient has either ONJ or BRONJ.

i. The "diagnosis of ONJ or BRONJ" requirement is not met in instances where the following is the closest to a

diagnosis of ONJ or BRONJ:

A. "Possible ONJ ";

B. "Will consider ONJ";

C. "? ONJ";

D. Osteomyelitis;

E. "Oste●";

F "Necrotic bone" or "necrosis" or "devitalized bone".

c. Meeting the requirement by showing at least 8 weeks of exposed bone in oral surgery or dental records.

i. Must have occurred before December 1●, 2013.

ii. The 8 weeks does not have to be constant. Any proof of exposed bone over a chart period of at least 8 weeks will suffice. For instance, if there is an entry of "exposed bone #14 extraction site" on 03/12/09, and several entries in between with no mention of exposed bone, and then another entry on 07/15/09 mentioning "exposed bone #14 extraction site", the requirement is met.

iii. "Exposed bone" includes any record that tends to prove that

there is delayed healing resulting in an open wound, such as the following synonyms:

A. Dehiscence;

B. Exostosis;

C. Lesion;

D. Open socket;.

E Osteitis;

F. Perforation;

G. Sequestra

H. Spicule;

I. Ulceration.

d. Meeting the requirement through a Rule 26 expert report from a board-certified oral and maxillofacial surgeon asserting that the Claimant has ONJ or BRONJ

i. The "board-certified oral and maxillofacial surgeon" is an absolute requirement.

ii. The report must meet the education, experience, training, and sources and data relied upon requirements of Rule 26.

However, a Daubert analysis of the expert report is not required.

iii. Summary conclusions do not satisfy Rule 26 requirement. Thus, if an expert does not articulate the reason why, based upon specific citations to the claimant's records, he or she believes that claimant has ONJ, the report will not satisfy the eligibility requirement.

II. THE CATEGORY ALLOCATION.

A. OVERVIEW.

Per the Master Settlement Agreement, there are four allocation categories:

1. Category 1: for any claimant deemed to be non-eligible, Merck has the right to "push" the claimant into Category 1 allocation.

2. Category 2: ONJ without surgery, intravenous antibiotics, or hyperbaric treatment.

3. Category 3: (a) ONJ with resulting outpatient surgery, intravenous antibiotics, or hyperbaric treatment; or (b) pathologic jaw fracture with no-inpatient jaw resection surgery; or (c) extra-oral or intraoral fistula.

4. Category 4: ONJ with resulting in-patient jaw resection surgery.

ELIGIBILITY & CATEGORIZATION INTERPRETATION GUIDELINES FOR FOSAMAX MDL NO. 1789 MASTER SETTLEMENT ELIGIBILITY AND ALLOCATION REVIEW PROCESS

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B. INTERPRETATION GUIDELINES.

1. Category 1: no claim will be categorized as Category 1 by the Allocation Committee. Category 1 is reserved solely for those cases which do not meet eligibility but Merck still pushes into eligibility status, at which point they are automatically assigned Category 1 status, per the Master Settlement Agreement.

2. Category 2: any claimant deemed to be "eligible" as a Qualified Program Claimant has, for Master Settlement Agreement purposes, ONJ. Any such claimant who does not fall into either Category 3 or 4 will automatically be allocated to Category 2: i.e., ONJ without surgery, intravenous antibiotics, hyperbaric oxygen treatment, pathologic jaw fracture, or extra-oral or oro-antral fistula..

3. Category 3: the following guidelines apply to interpreting those ONJ cases requiring medical or dental intervention, or Stage 3 ONJ cases, but not including jaw resection surgery with overnight hospitalization:

a. ONJ with surgical intervention:

i. Surgical intervention which warrants Category 3 allocation includes the following:

A. Debridement surgery;

B. Jaw biopsy;

C. Any documented surgical procedure where the dentist or oral surgeon physically cuts into or scrapes the patient's jawbone.

ii. Surgical intervention which does not warrant Category 3 allocation includes the following:

A. Tooth extraction;

B. Implant placement;

C. Removal of bone spicules or sequestra without surgery (such as simply picking up a spicule or sequestrum with a hemostat or with fingers but without cutting into the patient's jaw);

iii. Billing records can be used to establish or clarify the procedure performed.

b. If a claimant has intravenous antibiotics administered as a result of jaw infection or jaw issues, that claimant warrants Category 3 allocation:

i. In addition to medical records, hospital billing records can be used to establish intravenous antibiotic administration;

ii. It must be shown that the claimant received the intravenous antibiotics, rather than the intravenous antibiotics were ordered or recommended by a medical provider without proof of actual administration;

iii. Oral antibiotics do not warrant Category 3 allocation;

c. If a claimant undergoes hyperbaric oxygen treatment as a result of jaw issues, that claimant warrants Category 3 allocation:

i. In addition to medical records, hospital billing records can be used to establish hyperbaric oxygen treatment;

ii. It must be shown that the claimant received the hyperbaric oxygen treatment, rather than the hyperbaric oxygen treatment were ordered or recommended by a medical provider without proof of actual administration.

d. If a claimant has a pathologic jaw fracture, that claimant warrants Category 3 allocation:

i. In addition to dentist or oral surgeon, can be diagnosed by a radiologist on an x-ray or CT scan report.

e. If a claimant has an extra-oral or oro-antral fistula, that claimant warrants Category 3 allocation:

i. Must communicate from inside the mouth to outside the mouth (extra-oral), or from inside the mouth to inside the sinus (oro-antral).

ii. Intraoral fistulae do not qualify for Category 3 allocation.

iii. Surgery on any type of fistula, including intra-oral, will qualify as a surgical procedure sufficient to warrant Category 3 allocation.

4. Category 4: ONJ with resulting in-patient jaw resection surgery will result in Category 4 allocation, to which the following interpretation guidelines apply.

a. The medical records must establish that the surgery was a resection surgery:

i. If the oral surgeon calls it a resection surgery, it qualifies as a resection surgery, provided that the overnight hospital stay is also shown by the medical records;

ii. If the oral surgeon calls it an open-reduction internal-fixation ("ORIF") surgery, it qualifies as a resection surgery, provided that the overnight hospital stay is also shown by the medical records;

iii. Any surgery on the mandible which results in placement of a reconstruction bar is a resection surgery, provided that the overnight hospital stay is also shown by the medical records;

iv. Any surgery on the maxilla which results in placement of an obturator is a resection surgery, If the oral surgeon calls it a resection surgery, it qualifies as a resection surgery, provided that the overnight hospital stay is also shown by the medical records.

b. The medical records must also establish that the resection surgery resulted in an overnight hospital stay due to the surgery.

i. The overnight stay can be established by either hospital, doctor, or billing records establishing a discharge date for the surgery subsequent to the date of operation for the surgery. Thus, for instance, if a patient has a surgery on 01/10/08, and provides a discharge date on 01/11/08, or provides a billing record showing intravenous fluid administration on 01/11/08, either will be sufficient to show an overnight hospital stay.

ELIGIBILITY & CATEGORIZATION INTERPRETATION GUIDELINES FOR FOSAMAX MDL NO. 1789 MASTER SETTLEMENT ELIGIBILITY AND ALLOCATION REVIEW PROCESS

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ii. Any record from the same hospitalization showing that treatment was rendered on a date subsequent to the surgery date is sufficient. Thus, for instance, if a patient has a surgery on 01/10/08, and provides a nursing progress note showing a dressing change on 01/11/08, that will be sufficient to show an overnight hospital stay.