Claims Administration Procedure No. 4

1. Purpose. This Claims Administration Procedure No. 4 ("CAP") describes the eligibility requirements for an Enhancement for an Intra-Operative Femur Fracture *without* Osteotomy, specifically when **cabling or prosthetic fixation *is not placed during* the Qualified Revision Surgery or Re-Revision Surgery to repair the fracture *or* if there is no indication of a fracture *during* the Qualified Revision Surgery or Re-Revision Surgery**. This CAP is based on recent decisions issued by the Special Masters regarding the eligibility of Intra-Operative Femur Fracture *without* Osteotomy claims.

2. Applicability of CAP to Pending Appeals. This CAP will be applicable to all remaining and future appeals of Intra-Operative Femur Fracture *without* Osteotomy claims. This CAP will also be applicable to the Claims Processor's review of any future Intra-Operative Femur Fracture *without* Osteotomy claims. **Counsel for patients and unrepresented individuals are strongly encouraged to review their pending Intra-Operative Femur Fracture *without* Osteotomy appeals to ensure that they are indeed eligible for the claimed Enhancements and withdraw all appeals for Intra-Operative Femur Fracture *without* Osteotomy claims that are ineligible as set forth herein. Failure to withdraw ineligible appeals may result in an assessment as per Section 5.2.6.4 of the Master Settlement Agreement**.

3. Description. Under Past Matrix Level I(b), an Enhancement for Intraoperative Femur Fracture *without* Osteotomy is available if an individual experienced an intra-operative femur fracture during a Qualified Revision Surgery or Re-Revision Surgery that required cabling or prosthetic fixation. "Cabling" or "prosthetic fixation" include cables, wires, clamps, screws, plates, etc. and ***excludes*** bone putty, glue, chips, and/or the revision femoral component itself. Thus, in order to be eligible there must be (1) evidence of a femur fracture and (2) application of cabling or hardware fixation during the Qualified Revision Surgery or Re-Revision Surgery to repair the femur fracture.

Accordingly, patients are ***not eligible*** for a an Intra-Operative Femur Fracture *without* Osteotomy Enhancement if they underwent a procedure during which either (1) a femur fracture occurred but no cabling or hardware fixation was applied ***or*** (2) there is no evidence of either a femur fracture or application of cabling or hardware fixation.

4. Examples of Ineligible Intra-Operative Femur Fracture *Without* Osteotomy Appeals

In order to guide individuals and Counsel in assessing their claims and pending appeals, below are anonymized examples of Intra-Operative Femur Fracture *without* Osteotomy appeals that the Special Masters have determined to be ineligible:

	Description of Ineligible Intra-Operative Femur Fracture *Without* Osteotomy Appeals
1.	**QRS Operative Report:** The proximal aspect of the remaining stem within the femur was then identified. It was well aligned and well positioned for insertion per the index procedure. I then went ahead and extracted it. This was a process that involves a series of osteotomes and burr to disrupt the on grown surface of the proximal aspect. The patient's bone was quite solid, so there was some work involved removing the attached bone, however, after satisfactory amount of removal, we went ahead and applied the extraction handles and removed the device in its entirety. The remaining bone appeared to be stable and intact. [*Note: No evidence of either a femur fracture or application of cabling or hardware fixation.*]
2.	**QRS Operative Report:** Smooth curved osteotomes which were flexible were then directed around the proximal femur, taking care to advance slowly. A small crack developed posteriorly but appeared to be relatively stable. The stem was then able to be extracted. . . . The femoral canal was then prepared with the tapered reamers going up to a #17 size. The 195mm restoration modular stem with a distal diameter of 17 mm was impacted down the femoral canal in appropriate position. Locking onto this, proximal reaming was performed going up to 23 mm. The 23mm trial was placed on the stem and reduction was performed with the standard head. There was good stability. The real 20mm (+10) modular hip system was screwed onto the stem using a torque wrench going up to 120 torr. Anteversion was set at approximately 25 degrees. [*Note: Femur fracture occurred but no cabling or hardware fixation was applied.*]

5. Duration of CAP. This CAP will apply to all processed claims and/or pending appeals after the date as indicated below and shall terminate only upon cancellation or modification by the Claims Administrator.

Dated: November 17, 2016

By: Diane M. Welsh

Hon. Diane M. Welsh (Ret.)
Claims Administrator