



## Claims Administration Procedure No. 2

- 1. Purpose.** This Claims Administration Procedure No. 2 (“CAP”) describes the eligibility requirements for an Enhancement for either a **Surgical Repair/Reattachment of a Damaged Abductor Muscle Complex during a Qualified Revision Surgery or Re-Revision Surgery (EBP Award Schedule, I(b)(ii)(4)) and/or a Reattachment/Repair of a Damaged Abductor Muscle Complex during an Additional Surgery (EBP Award Schedule, II(a)(ii)(3))** (the “abductor-related Enhancements”, such claims the “abductor-related claims”). This CAP is based on recent decisions issued by the Special Masters regarding the eligibility of abductor-related claims.
- 2. Applicability of CAP to Pending Appeals.** This CAP will be applicable to all remaining and future appeals of abductor-related claims. This CAP will also be applicable to the Claims Processor’s review of any future abductor-related claims. **Counsel for patients and unrepresented individuals are encouraged to review their pending abductor-related appeals to ensure that they are indeed eligible for the claimed Enhancements and withdraw all appeals for abductor-related claims that are ineligible as set forth herein. Failure to withdraw ineligible abductor-related appeals may result in an assessment as per Section 5.2.6.4 of the Master Settlement Agreement.**
- 3. Description.** An abductor-related Enhancement is available if an actual **repair** to a **damaged** abductor occurred during a Qualified Revision Surgery or Re-Revision Surgery. The Enhancement is also available if the actual repair of a **damaged** abductor occurred during an Additional Surgery, separate and apart from a Qualified Revision Surgery or Re-Revision Surgery. In order to be eligible, the patient **must** present with (1) objective evidence of **damage** to the abductor muscle complex related to the reasons for the Voluntary Recall (2) that is sufficient to require **actual surgical repair** of the damaged abductor muscles. The “abductor muscles” include the gluteus medius, gluteus minimus, and tensor fascia latae **only**. These Enhancements are intended to compensate patients for repair **beyond** debridement of tissue (including necrotic and/or scar tissue) and **beyond** ordinary closure of the abductors.

Accordingly, patients whose abductors were debrided, or even those whose abductors are noted to be damaged, during the Qualified Revision Surgery, Re-Revision Surgery, or Additional Surgery are **not eligible** for abductor-related Enhancement(s) if his/her surgeon only performed an ordinary closure of the hip capsule at the conclusion of the surgery. It is important to note in this regard that, in order to access the hip joint in certain procedures, surgeons must open the abductor muscle complex and later “repair it” at the conclusion of the surgery. As a result, mere

mention of a “repair” in the operative report without more evidence that is consistent with the abductor-related Enhancement(s) does not qualify a patient for the Enhancement(s).

#### 4. Use of Non-Contemporaneous Documents

In addition to the eligibility requirements set forth in Section 3 above, the Special Masters have confirmed and reinforced that *the Master Settlement Agreement does not permit the use of non-contemporaneous documents, including affidavits, to support abductor-related claims.* For example, absent support in the actual, contemporaneous medical records, a letter, opinion, affidavit, or addendum from a surgeon stating that a compensable abductor repair occurred during a Qualified Revision Surgery, Re-Revision Surgery, or Additional Surgery is insufficient to establish eligibility for the claimed abductor repair.

#### 5. Examples of Ineligible Abductor Repair Appeals

In order to guide individuals and Counsel in assessing their claims and pending appeals, below are anonymized examples of abductor repair appeals that the Special Masters have determined to be ineligible:

Description of Ineligible Abductor Repair Appeals	
1.	<b>QRS Operative Report:</b> The incision was carried down through the skin and subcutaneous tissue down to the fascia. The fascia was opened sharply. The incision was carried slightly more distal than used previously. The patient was noted to have an adverse tissue reaction. Once the fascia was opened, there was thickened bursal tissue that extended from the posterior capsule. . . . Next, this tissue was excised off the posterior capsule. The posterior capsule was then carefully elevated with electrocautery. There was significant [ALTR] about the prosthesis and this was removed. . . . The [ALTR] thickened tissue was excised about the acetabulum. . . . Next, the posterior pseudocapsule was tagged with #2 Ethibond sutures and repaired through drill holes in the greater trochanter. A ConstaVac drain was placed deep in the wound and the fascia was closed with 0 Vicryl interrupted sutures. The skin was closed in layers. The staples to the skin.
2.	<b>QRS Operative Report:</b> There was markedly thickened capsule consistent with [ALTR]. This was debulked and debrided. Next, the posterior pseudocapsule was completely taken down. There was slight dehiscence at the more inferior aspect. The capsular tissue was tagged with #2 Ethibond sutures. . . . A ConstaVac drain was placed deep in the wound. A posterior pseudocapsule repair was then closed through drill holes in the greater trochanter creating excellent repair. Next, the fascia was closed with 0 Vicryl interrupted sutures. The hip was again copiously irrigated and suctioned. The skin was closed in layers.
3.	<b>QRS Operative Report:</b> Next, the greater trochanteric region was noted to have a thickened bursa, consistent with and [ALTR]. This was excised. There was a thickened posterior capsule consistent with an [ALTR]. This was debrided. . . . The posterior pseudocapsule was then repaired with #2 Ethibond sutures through drill holes in the greater trochanter. There was an excellent posterior repair. Next, a ConstaVac drain was placed

### Description of Ineligible Abductor Repair Appeals

deep in the wound. The hip was copiously irrigated and suctioned once again. The fascia was closed with 0 Vicryl interrupted sutures. The skin was closed in layers using 0 Vicryl and 2-0 Vicryl sutures.

4. **QRS Operative Report:** Attention was directed toward incision which was made through the old incision. Dissection was then carried down through skin and subcutaneous tissue, down to fascia. Fascia was opened sharply. . . The posterior pseudocapsule was taken down, tagged with #2 Ethibond sutures. There was significant synovitis. This was excised. . . Two drill holes that were made previously in the trochanter were found and #2 Ethibond sutures were passed through these drill holes that were in the pseudocapsule and this was repaired carefully. ConstaVac drain was placed deep in the wound. The hip was copiously irrigated and suctioned. The fascia was closed with 0 Vicryl interrupted suture. Skin was closed in layers, and staples used for skin.
5. **QRS Operative Report:** The patient was noted to have an [ALTR]; the tissue was excised over the posterior capsule, it was thickened. This was debulked. . . The vastus lateralis which had been elevated to put the plate on the femur [to repair a compensable femur fracture] was then secured with #2 Ethibond suture. Two drill holes were placed in the greater trochanter. Keith needles were inserted. #2 Ethibond sutures were placed in the capsular flap posteriorly and then repaired for a very strong posterior repair. . . The fascia was closed with 0 Vicryl interrupted sutures. The skin was closed in layers.
6. **QRS Operative Report:** The adverse tissue reaction area was literally peeled off the abductors and trochanteric region. . . At this point, the capsular flap that involved the posterior pseudocapsule was then created. This had to be carefully elevated off the tissue posteriorly which was all scarred in from the adverse tissue reaction. . . Three #2 Ethibond sutures were passed through the capsular flap. Drill holes were placed through the greater trochanter and the capsular flap was repaired with the leg abducted on a Mayo standard. . . The fascia was closed with 0 Vicryl interrupted sutures. The skin was closed in layers. Staples were used for the skin.
7. **QRS Operative Report:** We repeated the incision line with the superior border of the piriformis and reflected back the entire posterior structures as previously described, this time including the intense scar tissue. . . I did intracapsular debridement of the necrotic tissue. This also includes some necrotic bone about . . . the calcar and trochanter was small and a small portion of the posterior superior abductors. The anterior and anterior superior abductors remain intact. . . Drill holes were placed in the posterior trochanter and #5 Tycron suture was utilized to repair the posterior capsule, short rotators and piriformis in a figure-of-eight interrupted fashion. This was followed by a #1 simple sutures subcu, followed by 2 inverted and running 4-0 Monocryl longitudinally. Steri-Strips were applied, as well as a sterile dressing.
8. **QRS Operative Report:** Attention was now directed towards the abductors. A Hohmann retractor was placed underneath the abductors. The posterior capsule, the short rotators and the piriformis were then removed from the posterior trochanter of the femur. . . Multiple drill holes were placed in the posterior trochanter and #5 Tycron suture was utilized to repair the posterior capsule, short rotators, and piriformis. This was done in a figure-of-eight interrupted fashion. This was followed by repairing the IT band to the gluteus maximus fascia with #1 Vicryl suture in a figure-of-eight interrupted fashion, followed by #1 simple sutures subcu, followed by 2-0 inverted and running 4-0 Monocryl

### Description of Ineligible Abductor Repair Appeals

longitudinally.

9. **QRS Operative Report:** The capsulotomy was made in line with the superior border piriformis. This was taken through the scar tissue of the piriformis and capsule down to the intracapsular region. The entire posterior sleeve was then taken off going from a proximal to distal fashion. There was the typical yellow fluid with the necrotic debris. This was suctioned at this point in time. Also the intracapsular necrotic debris which was necrotic and debrided. . . . #5 Tycron sutures were utilized to repair the posterior capsule, short rotators and piriformis to the bone of the trochanter. This was followed by #1 simple sutures in a figure-of-eight interrupted fashion over the IT band and gluteus maximus fascia followed by #1 simple sutures subcu, followed by 2-0 inverted and running 4-0 Monocryl longitudinally.
10. **QRS Operative Report:** A Hohmann retractor was placed under the abductors. The posterior scar tissue, capsule, and rotators were then removed en bloc from the posterior trochanter of the femur. The #5 old Tycron sutures were removed as well. . . . Once the capsulotomy was completed, a threaded Steinmann pin was placed in the iliac crest. . . . We then dislocated the hip, removed the femoral neck, and did a thorough debridement of the necrotic tissue which included the capsule, a portion of the short rotators, a portion of the soft tissue attachments to the lateral trochanter, and approximately an eighth of the abductors. . . . We then repaired the posterior capsule, rotators, scar tissue, and piriformis through drill holes in the trochanter with #5 Tycron sutures. This was followed by closure of the IT band and gluteus maximus fascia with #1 Vicryl sutures in a figure-of-eight interrupted fashion followed by #1 simple sutures subcu, followed by 2-0 inverted and running 4-0 Monocryl longitudinally.
11. **QRS Operative Report:** I carried the dissection down through the subcutaneous tissue to the level of the fascia, which I opened in line with the incision. There were a lot of adhesions deep to this and I divided these with electrocautery and then placed a deep Charnley retractor with care being taken that no pressure or contact was placed on the sciatic nerve posteriorly. I then elevated the short external rotators and capsule from the proximal femur with electrocautery and tagged these with #5 Ethibond. We encountered clear synovial fluid that was rather abundant. I sent a sample of synovial tissue as well as greater trochanteric bursa for pathology. . . . I then copiously irrigated the wound again and closed it in layered fashion with #5 Ethibond through the short external rotators and greater trochanter. I placed a couple of sutures in the vastus lateralis proximally. We then closed the fascia with #1 Vicryl and #2 Quill followed by 2-0 Vicryl in subcutaneous tissue and staples in the skin. . . This was a very complex revision [THA] secondary to several factors. Firstly, the patient's BMI was 38 making this very, very, very difficult procedure secondary to her soft tissue envelope which made it difficult to expose the joint, extract implants, implant implants, and assess disability. She had such a large pannus making it very difficult to assess the stability of the hip as I had noted above.
12. **QRS Operative Report:** I utilized the prior incision, carrying the dissection down through subcutaneous tissue which was quite deep to the level of the fascia. The fascia was opened in line with the incision and a deep Charnley retractor was placed with care being taken that no contact or pressure was placed on the sciatic nerve posteriorly. I then elevated the short external rotators and hip capsule from the proximal femur with electrocautery and tagged these with #5 Ethibond. There was a pseudotumor-like tissue

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imbedding and investing the synovium. I excised as much as possible. . . The wound was copiously irrigated and closed in layered fashion with #5 Ethibond through the short external rotators, hip capsule and greater trochanter, followed by #1 Vicryl and #2 Quill in the fascia, followed by 2-0 Vicryl in the subcutaneous tissue and staples in the skin. . . This was a more complex revision [THA] than is typical. The patient's BMI is over 39 and her soft tissue envelope was quite deep. Her prior surgery and resultant fibers and scar tissue as well as pseudotumor required additional time for exposure as well as debridement of the pseudotumor.

13. **QRS Operative Report:** We went through the previous scar, went through skin and subcutaneous through the gluteus maximus, identified the IT band and then opened the corner of the IT band. . . [W]e then closed the IT band with a combination of #2 Tycron and #1 Vicryl. . . We did have one area that I thought was primarily a piriformis, which we had opened up, we pulled up, put that back on the trochanter and then closed the gluteus maximus with #1 Vicryl . . . Closed subcutaneous with 2-0 Vicryl, and closed the skin with staples.

14. **QRS Operative Report:** I made an incision in the fascia lata and it was retracted. I identified the leading edge of the abductors and dissected beneath the abductors and retracted tissue. . . . The abductor tendon insert was intact. . . . The fascia lata was repaired with #1 Vicryl interrupted figure-of-eight sutures, subcu was closed with 2-0 Vicryl, and skin closed with skin staples. Sterile bandage was applied.

15. **QRS Operative Report:** Incised the gluteal fascia and tensor fascia in line with the fibers. . . . Excised the bursal tissue. . . . Separated out thickened pseudocapsule. We dissected that off and it began to excise posteriorly. . . . We then began posteriorly excising all the pseudocapsule . . . once we excised most of the posterior pseudocapsule with cautery, we dislocated the hip. There was a significant amount of scar with some granulation tissue just lateral to the hip. This was next to the stem. We excised that tissue. . . . We then began removing the pseudocapsule anteriorly that we could reach. We removed as much as we could from the periphery of the acetabulum. . . . Removed all the issue from around the iliopsoas. . . . We closed the rim of the pseudocapsule which was benign in appearance to the posterior femur with #1 Vicryl. I then injected the area along with and gluteal fascia with a mixture of Toradol, ropivacaine and morphine. The gluteal fascia and tensor fascia closed with #1 Vicryl. Subcutaneous layer closed with 0 and 2-0 Vicryl and the skin with staples.

16. **QRS Operative Report:** We released the pseudocapsule . . . We then took the pseudocapsule and split it and put #1 Vicryl in it. Then a small amount of fibrinous material and foreign body reaction material was sent for tissue. We then excised some of the pseudocapsule and also sent that for tissue. . . . Closed the pseudocapsule with #1 Vicryl. Injected the pseudocapsule with #1 Vicryl. Injected the pseudocapsule fascia with a mixture of Toradol, ropivacaine, and morphine. Closed the gluteal fascia and tensor fascia with #1 Vicryl. Subcutaneous layer closed with 2-0 Vicryl and skin with staples.

6. **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: October 26, 2016

By: Diane M. Welsh

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