

U.S. ASR HIP SETTLEMENT

MDL 2197

Claims Administration Procedure (“CAP”)			
CAP Number	2	Effective Date	5/20/14
Subject	Claims Processor Review and Notice Process for PART A and PART B Bilateral Claims		

1. **Purpose.** This Policy describes the process by which the Claims Processor will review claim submissions and issue notices. The Claims Processor, in conjunction with DePuy and the Settlement Oversight Committee (“SOC”), has established this procedure to facilitate the processing of PART A and PART B Bilateral claims in an efficient and friendly manner, with the goal of providing the claimant with full information about the claim’s status as early as possible, providing an opportunity for the claimant to respond, and allowing the medical evaluation of the claim to proceed while the claimant cures deficiencies, if any, to the forms required for Enrollment. The flowchart attached as Exhibit A to this CAP reflects the process described in this CAP and is hereby incorporated. If there is a conflict between the provisions in this CAP and the flowchart, the CAP controls.
2. **Enrollment.** Section 4.1.3 of the Settlement Agreement (“SA”) specifies the documents required for Enrollment (“Required Submissions”) and establishes April 1, 2014, as the Enrollment Deadline. Required Submissions are the following:
 - (a) **“Forms,”** which include the:
 - (1) Enrollment Form;
 - (2) Release;
 - (3) Dismissal with Prejudice Stipulation (if the EUSC has a pending case);
 - (4) Orange Claim Form;
 - (5) Blue Claim Form; and
 - (6) Red Claim Form, if seeking Bilateral benefits.
 - (b) **“Records,”** which include the:
 - (1) Product Code/Lot Code for the Qualified Device implanted into the Product User from the ASR Index Surgery; and
 - (2) Contemporaneous medical records: Admission, including History and Physical Examination Records, Discharge Summaries and Anesthesia Records and Operative Reports pertaining to any ASR Index and ASR Revision Surgery.
3. **Issuance of Program Notice.** The Claims Processor will issue a Program Notice to claimants to inform them of the status or outcome of their claim(s), following each stage of the Claims Processor’s review or, if the claim is ultimately appealed, after the Special Master’s review. The Program Notice will contain information on the Claims Processor’s or Special Master’s findings, including details on any eligible, denied, or incomplete claim, and

the next steps available to claimants. Depending on the completeness of the claim and the stage in the process in which the claim is, the Program Notice will contain one of the following four determination types for each claim advanced: (a) Deficiency Determination, (b) Preliminary Determination, (c) Final Determination; or (d) Special Master Determination.

4. **Initial Claims Review.** The Claims Processor will conduct an initial review of each claim to determine if all Forms and Records are present. The Claims Processor's next step will depend on whether the claim is *missing* a Form or Record as follows:

- (a) **If Claim is Missing a Form or Record.** The Claims Processor will send the claim to DePuy to consider whether to waive the missing Form or Record, pursuant to DePuy's unilateral right to do so under Section 5.1.5 of the SA. If DePuy does not waive the missing Form or Record, the Claims Processor will issue a Deficiency Determination alerting the claimant to the deficiency. The Deficiency Determination will provide claimants with a 60-day deadline for providing the Required Submission(s). Following receipt of the claimant's response, or after expiration of the 60-day deadline with no response, the Claims Processor will review the claim and issue a Preliminary Determination.

- (b) **If Claim is Not Missing a Form or Record.** The Claims Processor will issue a Preliminary Determination if: (1) all of the Required Submissions are present when the Claims Processor first reviews the claim; or (2) following a Deficiency Determination that the claimant has either responded to or where the deadline has passed with no response. The Preliminary Determination will provide claimants with a 45-day deadline for responding. The content of the Preliminary Determination and the action available to the claimant will vary depending on whether all Required Submissions are complete, as follows:

Table 1	Status of Required Submissions		Award Amount Given in Notice?	Action Available Claimant		Eligible for Payment?
	Forms	Records		Forms	Records	
1.	Complete	Complete	Yes	No action required.	Accept award if the claimant agrees. Contest the award and submit additional Records if the claimant disagrees.	Yes, if claimant does not contest.
2.	Incomplete	Complete	Yes	Cure incomplete Forms.	Same as above.	Not until incomplete Forms are cured and claimant's contest, if any, is resolved.
3.	Missing	Complete	No	Supply missing Forms.	No action required.	Not until missing Forms are supplied and award is accepted.
4.	Incomplete	Incomplete or Missing	No	Cure incomplete Forms.	Supply missing Records.	Not until missing Records are supplied, eligibility and award are determined, award is accepted and incomplete forms are cured.
5.	Complete	Incomplete or Missing	No	No action required.	Supply missing Records.	Not until missing Records are supplied, eligibility and award established, and award is accepted.

5. Failure to Respond Timely to Preliminary Determination. The Preliminary Determination will contain a 45-day deadline to respond. Failure to respond timely to the Preliminary Determination will result in the following:

Table 2	Status of Required Submissions		Award Amount Given in Notice?	Consequence of Failure to Respond to Preliminary Determination
	Forms	Records		
1.	Complete	Complete	Yes	The claimant will be deemed to have accepted the findings of the Preliminary Determination and cannot appeal such findings to the Special Master. The claim will proceed to payment.
2.	Incomplete	Complete	Yes	The claimant will be deemed to have accepted the award amount in the Preliminary Determination and cannot appeal it to the Special Master. Even though the award is deemed accepted, the claimant will not be paid because of lingering deficiencies in the Forms unless DePuy waives deficiencies on a case-by-case basis. Claimants can provide cures to the Form deficiencies until such time as either the Claims Processor determines deficiencies have been resolved or the Claims Processor, in conjunction with DePuy and the SOC, adopts a subsequent CAP identifying a deadline to resolve such incomplete claims.
3.	Complete or Incomplete	Incomplete	No	The Claims Processor will consult with DePuy and the SOC before issuing a Preliminary Determination, and DePuy will have the opportunity to review the claim and waive the applicable requirement, pursuant to Section 5.1.5 of the Settlement Agreement. If, and only if, the Parties confirm that the denial should occur and DePuy does not waive the requirement, and the claimant did not respond timely to the Preliminary Determination, the claimant will be deemed to have accepted the incomplete finding in the Preliminary Determination and cannot appeal it to the Special Master.

6. Second Review and Final Determination Notice Issuance. The Claims Processor will conduct a second review of any claim where the claimant contested the medical determination/value in the Preliminary Determination. Following that review, the Claims

Processor will issue a Final Determination as to the medical determination/value of the claim. The Final Determination will inform the claimant of the right to appeal and will contain a reminder that the claim cannot be placed in line for payment unless all Forms are complete.

7. ***Appeal of Final Determination Notice and Record on Appeal.*** Claimants can appeal the award amount to the Special Master if they disagree with the Claims Processor’s findings in the Final Determination; however, the record on appeal will be limited to all records submitted to the Claims Processor prior to the Claims Processor’s issuance of the Final Determination.
8. ***Status of Claims Following Final Determination Notice Issuance.*** The Claims Processor will take the following action following the issuance of the Final Determination for eligible claims, depending on whether the claimant notes an appeal and whether all Forms are complete:

Table 3	Claimant’s Appeal Status	Are All Forms Complete?	Claims Processor’s Action
1.	Claimant Appeals Final Determination	Yes	After the Special Master issues a decision, the Claims Processor will issue a Special Master Determination and will place claim in line for payment.
		No	After the Special Master issues a decision, the Claims Processor will issue a Special Master Determination with a reminder that the claim cannot be placed in line for payment until all Forms are complete. DePuy has the option to waive the deficiencies on a case-by-case basis.
2.	Claimant Does Not Appeal Final Determination	Yes	The Claims Processor will place the claim in line for payment.
		No	The Claims Processor cannot place the claim in line for payment until all Forms are complete. DePuy has the option to waive the deficiencies on a case-by-case basis.

If a claim is found not eligible by the Claims Processor and/or the Special Masters, the Claims Processor will consult with DePuy and the SOC before issuing a denial, and DePuy will have the opportunity to review the claim and waive the applicable requirement, pursuant to Section 5.1.5 of the Settlement Agreement. If, and only if, the Parties confirm that the denial should occur and DePuy does not waive the requirement, the Claims Processor will send the claimant a Special Master Determination affirming that denial.

9. ***Authority of Claims Processor or Claims Administrator to Correct Awards.*** Pursuant to Section 16.5 of the Settlement Agreement, if the Claims Processor or Claims Administrator learns or determines that all or any part of an Award or determination of ineligibility or denial of an award was incorrect, the Claims Processor may issue a revised determination.
10. ***Change from Eligible to Ineligible During Contest.*** If during a contest or Appeal, the Claims Processor discovers that a claimant previously found eligible for an award is not eligible, the Claims Processor will issue a new Preliminary Determination that affords the claimant all contest and Appeal rights.
11. ***Duration of the CAP.*** This CAP shall apply to all claims processed after the Effective Date stated above and shall terminate upon the earlier of: (a) cancellation or modification of this CAP by the Claims Processor; or (b) an order of the Court canceling or modifying the terms of this CAP.

**APPROVED:
Claims Administrator**

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By: /s/ James J. McMonagle

Date: 5/22/14

Claims Processor

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By: /s/ Lynn C. Greer

Date: 5/22/14

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Date: 5/28/14

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