

November 6, 2014

Ms. Jackie Dunn
Novitas Solutions, Inc.
Medical Policy Department
Union Trust Building, Suite 600
501 Grant St
Pittsburgh, PA 15219
Via electronic mail: jackie.dunn@novitas-solutions.com

**RE: Draft LCD -- Lower Extremity Major Joint Replacement (Hip and Knee), DL35594
(Jurisdictions H & L)**

Dear Ms. Dunn:

The American Association of Hip and Knee Surgeons (AAHKS) appreciates this opportunity to provide comments on Novitas' draft local coverage determination (LCD) regarding Lower Extremity Major Joint Replacement (Hip and Knee) ("Draft LCD"). Along with AAHKS the undersigned organizations affected by the LCD share our views.

AAHKS is a national association of orthopaedic surgeons formed to advance and improve hip and knee patient care through leadership in education, advocacy and research. Our vision is to be the essential organization of hip and knee specialists, functioning to serve the needs of patients, care providers and policy makers regarding hip and knee health.

Given our commitment to improving the care of our patients, including promoting Medicare beneficiary access to high-quality orthopaedic procedures, we are very pleased that Novitas has proposed for public comment a Draft LCD for Lower Extremity Major Joint Replacement. We believe that it is critical for surgeons to have clear parameters for coverage and documentation to ensure consistency and enhance certainty for surgeons and patients. A published LCD developed in consultation with the surgical community's input also will minimize disruptions associated with the trend of Medicare auditors applying their own unclear, unsubstantiated and unpublished medical necessity criteria as a basis to deny claims for major joint replacement procedures.

We are pleased that the Draft LCD is largely in alignment with the AAHKS/American Academy of Orthopaedic Surgeons Model Coverage Determination on Total Joint Arthroplasty, which you cite in the "Sources of Information and Basis for Decision" section. We appreciate in particular that the Draft LCD explicitly recognizes the paramount role of the physician in determining the best course of patient care, noting that the "clinical judgment of the treating physician is always a consideration" if clearly documented.

We offer below a limited number of suggested revisions/refinements to the Draft LCD that we believe would enhance the workability of the policy.

Indications

Novitas proposes that Medicare will consider total knee arthroplasty (TKA) or total hip replacement (THA) surgery medically reasonable and necessary when certain criteria are met. One criterion is "Pain **and** functional disability" due to arthritis or trauma. We propose that this language be revised to say "Pain **or** functional disability due to arthritis or trauma to the knee joint." A Medicare beneficiary should not be required to endure both pain and functional disability before surgery is considered, if the patient meets other appropriate criteria.

Limitations

Under the Draft LCD, total knee replacement (TKR) and total hip replacement (THR)¹ will not be considered reasonable and necessary when neuropathic arthritis is present. We recommend that Novitas remove this as a limitation, since there may be instances in which a TKR or THR is appropriate for these patients. For example, a patient with neuropathic arthritis of the opposite extremity or the joint above or below the joint in question may be an appropriate candidate for this surgery. While this diagnosis, if present, must be considered in assessing a patient's suitability for total joint arthroplasty, it should not be absolute contraindications for surgery because there are clinical situations for which surgery would be appropriate.

Indications for Revisions

The Draft LCD provides that a redo / revision of a previous knee replacement may be necessary if certain conditions are present, including "Loosening, fracture, **and** mechanical failure of one or more components." We recommend that this language be revised to "Loosening, fracture, **or** mechanical failure of one or more components." Any of one of these three conditions – a loosened implant/component, a fractured implant/component, or a mechanical failure in a component – should be sufficient grounds to justify a revision of a previous knee replacement if the physician determines it is medically necessary. This change also would ensure that the knee revision language aligns with the corresponding language related to revision of a previous *hip* replacement, which currently reads that revision may be necessary because of "Loosening, fracture **or** mechanical failure of the implant."

Also with regard to the indications for TKA revision, we suggest adding the following two conditions:

1. Bearing surface wear leading to symptomatic synovitis
2. Knee stiffness/arthrofibrosis.

While the Draft LCD recognizes that revision might be necessary for "Other disease or destructive conditions that render the knee impaired to the extent to preclude employment or functional activities," which could encompass these conditions, explicit affirmation as a covered indication will enhance clarity for medical review purposes.

With regard to THA revision, we recommend adding the following two specific conditions:

1. Total hip arthroplasty bearing surface wear leading to symptomatic synovitis
2. Local bone or soft tissue reaction

Inclusion of "other disease or destructive conditions that render the hip impaired to the extent to preclude employment or functional activities" as an indication for revisions also would be appropriate, as Novitas has provided for TKA revisions.

Documentation

In the documentation section, Novitas proposes that for a TKA or THA procedure for a patient with advanced joint disease, the medical records shall document (among other things):

¹ We note that Novitas uses the terms total knee arthroplasty/total hip arthroplasty and total knee replacement/total hip replacement. For consistency, we recommend that the LCD use the term arthroplasty throughout.

Unsuccessful conservative treatment (non-surgical medical management). The documentation should demonstrate a history of a reasonable attempt (**at least 3 months or more**) at conservative therapy as appropriate for the patient in their current episode of care. For example, documented trial of NSAIDs or contraindication to such therapy and/or documented supervised physical therapy.

We commend Novitas for recognizing in this section that conservative care may be contraindicated, and for instructing physicians that certain conservative measures are not necessary for a given patient, it should be directly noted in the pre-procedure documentation. We recommend revising this provision to remove the reference to “at least 3 months or more” of conservative care, however, since it could have the unintended consequence of patients continuing with these treatments (drugs, physical therapy, etc.) even when it is clear they are not resulting in clinical improvement. In such cases, observing the 3-month standard would needlessly delay necessary surgical intervention and potentially risk additional damage. If the reference to 3 months is not entirely removed, we would recommend inserting “typically 3 months or more” to underscore that physicians have flexibility in determining the appropriate length of such conservative treatments.

In the documentation section, Novitas also states that when the procedure is indicated for advanced joint disease, the medical record must document:

Pain **and** functional disability at the hip or knee. For example, documented pain that interferes with ADLs (functional disability), or pain that is increased with initiation of activities or pain that increases with weight bearing.

As noted above in the Indications discussion, we do not support requiring demonstration that the patient has both pain and functional disability – **either** adverse impact of advanced joint disease should be sufficient to justify the need for TKA or THA when other appropriate conditions are met.

Diagnosis Codes for THA

We recommend that Novitas include the following three diagnosis codes in the listing of ICD-9 codes that support medical necessity for THA:

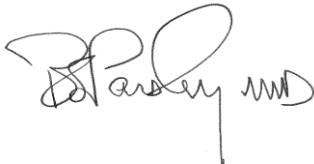
696.0 PSORIATIC ARTHRITIS
714.1 FELTY'S SYNDROME
714.4 CHRONIC POST TRAUMATIC ARTHROPATHY

These all represent potential indications for medically-necessary THA procedures.

* * *

In closing, we commend Novitas for presenting this draft LCD, which we believe would serve to improve clarity and consistency with regard to coverage and documentation requirements associated with the Medicare major joint replacement benefit. We look forward to working with Novitas to finalize this important coverage policy. We would be pleased to discuss these comments with you in greater detail or answer any questions you may have. We would be pleased to discuss this issue with you in greater depth; you can reach us at aahksstaff@aahks.org.

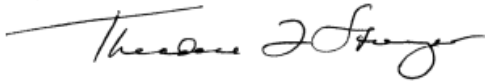
Sincerely,



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American Association of Hip and Knee Surgeons
Texas Alternate Representative to the Novitas MedCAC



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