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November 19, 2015

Contractor Medical Directors – JK & J6
National Government Services, Inc.
P.O. Box 7108
Indianapolis, IN 46207-7108

RE: Comments to draft LCD DL36406 – Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint

Dear Drs. Clark & Cunningham:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing to submit comments to draft LCD DL36406 – Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint.

ISASS is a global, scientific and educational society organized to provide an independent venue to discuss and address the issues involved with all aspects of basic and clinical science of motion preservation, stabilization, innovative technologies, MIS procedures, biologics and other fundamental topics to restore and improve motion and function of the spine.

On behalf of our members, I am writing in support of NGS' draft LCD for minimally invasive sacroiliac joint fusion (MIS SIJ fusion). ISASS supports decision-making at the physician-patient level based on medical necessity and achieving the best outcomes to address the patient's medical condition and, therefore, supports patient access to and coverage of MIS SIJ fusion.

In 2008, the U.S. Food and Drug Administration approved the first MIS device for SIJ fusion and MIS SIJ fusion surgery obtained a Category I CPT® code effective January 1, 2015. The body of literature on MIS SIJ fusion has grown substantially and continues to show positive outcomes for patients who receive the surgery. ISASS commends NGS for conducting a thorough review of the data and literature and looking to

professional society guidelines, including those developed by ISASS, when drafting this coverage policy for MIS SIJ fusion.

Based on the literature, ISASS supports coverage of this procedure based on the following criteria, which is reflected in our guidelines for coverage:

- Significant SI joint pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) or significant limitations in activities of daily living because of pain from the SI joint(s);
- SI joint pain confirmed with typical pain reproduction on at least 3 positive physical provocative examination maneuvers that stress the SI joint;
- Confirmation of the SI joint as a pain generator with $\geq 75\%$ acute decrease in pain immediately following fluoroscopically guided diagnostic intra-articular SI joint block using local anesthetic. This improvement is specifically accomplished in the immediate post-injection period when the anesthetic agent is active (i.e., 4 hours dependent on the agent, dose level, and concentration);
- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and/or opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SI joint steroid injection or rhizotomy. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability; and
- Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been clearly considered, investigated and ruled out.

Limitations to coverage include:

- Less than 6 months of back pain;
- Failure to pursue conservative treatment of the SIJ (unless contra-indicated);
- Pain not confirmed with a diagnostic SIJ block; and
- Existence of other pathology that could explain the patient's pain.

The NGS coverage criteria, as stated in the draft policy, supports our Society's guidelines and will ensure appropriate patient selection to support positive patient outcomes. ISASS supports coverage for MIS SIJ fusion and commends NGS for developing a comprehensive positive coverage policy based on the outcomes cited in the literature and professional society guidelines.

Thank you for your time and consideration of our comments. For your reference, I have attached a copy of the ISASS coverage guidelines for MIS SIJ fusion. Please feel free to contact Liz Vogt,

ISASS Director of Health Policy and Advocacy at liz@isass.org with any questions or requests for additional information.

Sincerely,

A handwritten signature in black ink that reads "Morgan P. Lorio MD". The signature is written in a cursive style.

Morgan P. Lorio, MD, FACS
Chair, ISASS Coding and Reimbursement Task Force

Enclosure:

ISASS Proposed Recommendations/Coverage Criteria for Minimally Invasive Sacroiliac Joint Fusion 2015