June 8, 2016

Alan J. Rosenberg, MD
VP, Medical and Clinical Pharmacy Policy
Office of Medical Policy & Technology Assessment
Anthem, Inc.
120 Monument Circle
Indianapolis, IN 46204

RE: Anthem Policy on Cervical Total Disc Arthroplasty (SURG.00055)

Dear Dr. Rosenberg:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing to share our Society's support for coverage of cervical total disc arthoplasty ("cTDA") at one-level and two contiguous levels based on the literature establishing the safety and effectiveness of the procedures.

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 spinal care including motion preservation, stabilization, innovative technologies, MIS procedures, biologics and other fundamental topics to restore and improve motion and function of the spine.

I would like to submit the attached ISASS Cervical Artificial Disc Policy Statement for inclusion in your upcoming annual review of Anthem's Cervical Total Disc Arthroplasty Policy (SURG.00055). ISASS maintains that the safety and effectiveness of cTDA at one-level and two contiguous levels is well established by a growing body of Level 1 evidence evaluating multiple devices, at multiple sites with short- and long-term follow-up.

ISASS developed and supports the following clinical indications for cTDA:

- Skeletally mature
- Clinically symptomatic cervical radiculopathy and/or myelopathy due to neural compression C3-C7 at one-level or two contiguous levels
    - Clinically symptomatic pertains to one of the following:
        - Intractable radiculopathy (arm pain and/or a neurological deficit) with or without associated neck pain
        - Myelopathy (due to abnormality localized to the level of the disc space)
- Failed at least 6 weeks of nonsurgical treatment or shows signs of progressively clinical deterioration

ISASS believes that if these clinical indications are met and the cTDA is performed using an FDA approved device in a manner consistent with the FDA approval, Anthem should consider cTDA at one-level and two contiguous levels medically necessary and a covered benefit under its plans.

Thank you for your consideration of our comments and policy statement as part of your upcoming review of SURG.00055. Please do not hesitate to contact Liz Vogt, Director of Health Policy & Advocacy by email at liz@isass.org or by phone at (630) 375-1432 with questions or requests for additional information. We look forward to establishing a continued partnership with Anthem, so together we can advocate for quality patient care and superior patient outcomes.

Sincerely,

Morgan P. Lorio, MD, FACS
Chair, Coding and Reimbursement Task Force
International Society for the Advancement of Spine Surgery

Enclosure:
ISASS Policy Statement – Cervical Artificial Disc