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May 3, 2019

Tiffany Swygert, Director,

Centers for Medicare and Medicaid (CMS) Division of Outpatient Care

Tiffany.Swygert@cms.hhs.gov

Dear Ms. Swygert,

The International Society for the Advancement of Spine Surgery (ISASS) is a global, scientific, and educational society of spinal surgeons and scientists organized to provide an independent venue to discuss and address the issues involved with the basic and clinical science of surgical spine care. Our Society supports the scientific development of new technologies that will have a positive impact on our patient's lives. We are writing in regards to the application for a CMS C-code for the Barricaid System.

We have reviewed the Barricaid System for the repair of large annular defects post discectomy and have determined that, consistent with our criteria, the Barricaid System is a new technology. The defect measurement, implant sizing assessment, trial, implantation, and radiographic follow up of this bone-anchored annular closure device is not currently represented within the surgeon workflow of a lumbar discectomy. A lumbar discectomy may sometimes inherently include a suture repair of a small annular defect; however, the work involved with a bone-anchored annular closure implant for a large repair is unique. The references listed in the attached Reference List further support the clinical efficacy of the Barricaid system and the typical use of radiographic follow-up.

ISASS' mission is to ensure that new technologies are developed, appropriately studied, and ultimately are accessible to patients. We encourage the Centers for Medicare & Medicaid Services to support our recommendation to designate this procedure as new technology service, establish a C-code for hospital outpatient and ASC reporting, and assign the C-code to a new technology APC for payment.

Sincerely,

A handwritten signature in black ink that reads 'Morgan P. Lorio MD'.

Morgan Lorio, MD
Chair, ISASS Coding and Reimbursement Task Force

Attachment: Reference List