PARADIGM SPINE ANNOUNCES NASS COVERAGE POLICY RECOMMENDATION FOR COFLEX® INTERLAMINAR STABILIZATION®

Validates safety and effectiveness of coflex and opens further market access for patients

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Paradigm Spine, LLC, a leader in providing motion preservation solutions for the treatment of lumbar spinal stenosis, today announced that the North American Spine Society (NASS) has issued a coverage policy recommendation for Lumbar Interlaminar Device without Fusion and with Decompression. This is particularly significant for coflex because it provides the evidence private health insurance companies require to allow access for patients to benefit from this important, proven technology. The coflex device is the exclusive lumbar motion preservation solution with proven long-term outcomes for durable pain relief and stability for patients with moderate to severe lumbar spinal stenosis.

NASS is the preeminent U.S. spine society in which health insurance companies and health care providers look to for guidance when determining appropriate coverage decisions for state-of-the-art technologies, such as coflex. NASS' multi-disciplinary team of spine specialists systematically review available scientific literature. Searches include meta-analyses, clinical guidelines, and the highest level of clinical data with randomized controlled trials, of which there are two such trials for coflex.

The recently issued NASS coverage policy recommends the use of coflex for the treatment of patients with lumbar spinal stenosis. The recommendations only apply to devices that are used in conjunction with a direct decompressive procedure, which currently and in the foreseeable future is only coflex, and states, "More recently ISP devices have been used in conjunction with direct decompression via laminotomy. Some devices, such as coflex, according to its FDA labeling and available published data, are specifically approved for use in this manner."

"It's gratifying to see the NASS Coverage Committee issue a coverage recommendation for coflex", said Dr. Richard D. Guyer of the Texas Back Institute and past-President of NASS. "I've been a member of NASS for over 20 years and trust in their process and recommendations for new technologies. I know the process is thorough and evidence-based which gives me confidence in offering the latest and proven technologies to my patients. In particular with coflex, I think we as surgeons have the opportunity and responsibility to utilize the abundant clinical evidence and our experience to provide a superior alternative to decompression alone or spinal fusion for our patients with lumbar spinal stenosis."

"The NASS coverage policy recommendation for coflex is a major milestone for validating our technology and allows us to reach more private payors in the U.S. market," said Marc Viscogliosi, Chairman and CEO of Paradigm Spine. "Over the past decade, Paradigm Spine has worked diligently to build the pieces of the puzzle in establishing coflex as the new standard of care for the treatment of moderate to severe lumbar spinal stenosis. Those pieces have been 1) the FDA IDE clinical trial which demonstrated positive, long-term Level I evidence of coflex compared to fusion, 2) establishment of CPT and site-of-service facility coding pathways 3) the recent publication of the landmark Level 1 ESCADA clinical trial which demonstrated superiority of coflex compared to decompression alone, and now 4) the stamp of approval from NASS with their coverage recommendation in support of coflex. As a company, we believe these achievements provide the evidence private payors require to create access to this important technology for patients suffering from lumbar spinal stenosis."

About Lumbar Spinal Stenosis (LSS)

Lumbar spinal stenosis (LSS), affecting 1.6 million patients annually in the United States, is a debilitating and degenerative disease often associated with significant leg and back pain, leg numbness and weakness, and significant reduction in an active lifestyle. Historically, the two traditional surgical treatment options for LSS included decompression alone or decompression with lumbar fusion. Decompression alone has proven effective at relieving pain symptoms caused by lumbar spinal stenosis, however, patients may not experience long term symptomatic relief, resulting in subsequent opioid pain control, epidural injections for pain management, or additional surgeries for conversion to a fusion. Decompression with fusion has proven to provide pain relief and stabilize the diseased segment, but may lead to adjacent level disease requiring subsequent surgeries.

About NASS

The North American Spine Society (NASS) is comprised of more than 8,000 members from several disciplines, including orthopedic surgery, neurosurgery, physiatry, neurology, radiology, anesthesiology, research and physical therapy. Its mission is to foster the highest quality, evidence-based and ethical spine care.

About Paradigm Spine, LLC:
Paradigm Spine, LLC, founded in 2004, is a privately held company and remains focused on the design and development of solutions for the disease management of spinal stenosis. The Company's signature product is the coflex® Interlaminar Stabilization® device, which is currently used in over 60 countries worldwide. coflex is the only lumbar spinal device that has produced Level I evidence in two separate prospective, randomized, controlled studies against two different control groups, changing the standard of care for lumbar spinal stenosis treatment. For additional information visit www.paradigmspine.com or www.coflexsolution.com.

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