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**FOR IMMEDIATE RELEASE**

**CORRECTION: POSITIVE PAYOR POLICY COVERING coflex® IN SPECIFIC LIMITED SITUATIONS FOR THE SURGICAL TREATMENT OF LUMBAR SPINAL STENOSIS ISSUED BY AMERIHEALTH CARITAS CORPORATE OFFICE**

- **Coverage policy issued by AmeriHealth Caritas for its managed care health plans in six states and the District of Columbia.**
- AmeriHealth Caritas names coflex® interlaminar stabilization® a covered device under certain specific clinical criteria and subject to state laws, regulations, or contract restrictions.
- **coflex® is a non-fusion, motion-preserving implant for treatment of lumbar spinal stenosis**
- **Lumbar spinal stenosis affects 1.6 million U.S. patients annually**

**New York, NY November 27, 2018** – Paradigm Spine, LLC, a leader in providing solutions for the treatment of lumbar spinal stenosis, today announced that AmeriHealth Caritas has issued a clinical policy, dated September 1, 2018, for the coverage of the coflex® interlaminar stabilization device for the treatment of lumbar spinal stenosis under certain specific clinical criteria and subject to state laws, regulations, or contract restrictions. The policy includes AmeriHealth Caritas’ managed care health plans in Delaware, Florida, Louisiana, Michigan, Pennsylvania, South Carolina, and the District of Columbia.

Lumbar spinal stenosis (“LSS”), affecting 1.6 million patients annually, is a debilitating and degenerative disease in older patients (>50 years) often associated with significant leg and back pain, leg numbness and weakness, causing a significant reduction in an active lifestyle. Traditional surgical treatment options for LSS include a decompression that removes bone and soft tissue and may also require a fusion to stabilize the spine. The coflex® device is a non-fusion, motion-preserving stabilization implant that is FDA PMA approved for the treatment of lumbar spinal stenosis and is used in conjunction with a decompression, or used in lieu of a spinal fusion.

Marc Viscogliosi, Paradigm Spine Chairman & CEO, commented, “With this continued payor coverage momentum, we look forward to further expanding access to our coflex® solution, which is backed by more than 90 peer-reviewed published articles, including landmark long-term follow-up clinical studies, and spine medical society guidelines.”

The AmeriHealth Caritas corporate policy lists several necessary evidence-based criteria and contraindications limiting use of the coflex® device. All of the following are required for coflex® to be considered medically necessary: diagnosis of at least moderate lumbar spinal stenosis between L1 and L5 of one or two contiguous vertebrae, requiring surgical decompression; radiography confirming the above diagnosis as well as the absence of gross angular or translatory instability of the spine at index or adjacent levels; the member must experience relief in flexion from their symptoms of leg, buttock, or groin pain, with or without back pain; and completion of at least six months of unsuccessful non-operative treatment consisting of non-steroidal anti-inflammatory drugs and at least one of several conservative approaches.

AmeriHealth Caritas considers the device not medically appropriate if any one of several conditions is present, including: more than two vertebral levels that require decompression; any of several conditions resulting in gross instability of the lumbar spine; isthmic spondylolisthesis or spondylolysis; back or leg pain of unknown origin; axial back pain only, without leg, buttock or groin pain; cauda equine syndrome; active or chronic conditions such as obesity, infection, rheumatoid arthritis or other autoimmune disease requiring chronic steroid use, tobacco use, or



most malignancies within the past five years; certain allergies; or uncertain commitment to postsurgical rehabilitation.

To learn more about coflex® Interlaminar Stabilization®, please visit [www.coflexsolution.com](http://www.coflexsolution.com).

### **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](http://www.paradigmspine.com) or [www.coflexsolution.com](http://www.coflexsolution.com).