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NYSIPP POSITION STATEMENT

Restorative Neurostimulation for the Management of Chronic Low Back Pain due to Multifidus Muscle Dysfunction May 22, 2025

Position Statement

The New York Society of Interventional Pain Physicians (NYSIPP) strongly supports the use of Restorative Neurostimulation (ReActiv8) in appropriate patients with chronic low back pain due to multifidus muscle dysfunction (ICD-10-CM 62.85, dysfunction of multifidus muscles, lumbar region). The body of evidence on the relationship between persistent low back pain and functional spinal instability and loss of neuromuscular control associated with multifidus muscle dysfunction is well established.¹ Restorative neurostimulation activates the motor fibers of the medial branch of the dorsal ramus causing contraction of the multifidus muscle to aid in the management of intractable chronic low back pain. Assessment for appropriate patients includes clinical history of mechanical low back pain, exams (PIT, MLT, MT3) and MRI imaging to diagnose multifidus dysfunction. These patients have previously failed conservative therapies and are not candidates for surgery. Based upon review of the body of peer reviewed published evidence, PMA approval (P190021) by the United States Food and Drug Administration (FDA), real world experience, and long-term patient outcomes, NYSIPP recommends qualified physicians consider the use of restorative neurostimulation in appropriately selected patients. Because of proven safety and durable effectiveness, restorative neurostimulation is within the standard of care for the indicated use.

Based on the quality of peer-reviewed published evidence, FDA approval, a specific diagnosis code (M62.85) for the etiology, recognition under a Medicare Local Coverage Determination supported by a specific Local Coverage Article, coverage by Anthem and other Blue Cross Blue Shield insurance plans, and available guidelines, consensus, and support statement such as ASIPP guidelines for Peripheral Nerve Stimulation, ISASS statement on restorative neurostimulation and Pacific Spine and Pain Society and WISIPP support statements, NYSIPP further recommends policymakers and payers enable timely access to ReActiv8 when prescribed by a qualified physician who has used his or her best medical judgement in caring for those patients with intractable chronic low back pain due to multifidus dysfunction.

Background

Restorative neurostimulation is a permanently implanted peripheral nerve stimulator targeting the L2 medial branch of the dorsal ramus for motor stimulation of the multifidus muscle. The therapeutic mechanism of action is designed to elicit contractions of the muscle to provide the intended stability to the lumbar spine, leading to reduction in pain.



New York Society of Interventional Pain Physicians

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This mechanism is in contrast to traditional forms of peripheral nerve stimulation which relies on sensory stimulation to palliate nerve-related neuropathic pain. With restorative neurostimulation, the patient activates a 30-minute therapeutic session twice daily. The device has been studied in multiple studies with over 600 patients having a cumulative 2000 years of patient follow-up. The robust body of evidence, including two randomized controlled trials^{2,3} consistently demonstrates durable (5-years) clinical improvement in pain, disability, quality of life, and opioid reduction and cessation.

Conclusions and Recommendations

NYSIPP strongly supports the use of restorative neurostimulation by qualified and trained physicians in patients with intractable chronic low back pain due to multifidus muscle dysfunction, provided they meet established appropriateness criteria. The body of published evidence, long term outcomes demonstrating durable treatment effect, and relatively low complication rate support the medical necessity of restorative neurostimulation in patients who have failed conservative treatment and are not candidates for surgery.

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1. Hodges, PW, Danneels, P, Changes in Structure and Function of the Back Muscles in Low Back Pain: Different Time Points, Observations, and Mechanisms. *J Orthop Sports Phys Ther.* 2019; 49(6): 464–476. <https://www.jospt.org/doi/10.2519/jospt.2019.8827>
 2. Gilligan, C. *et al.* Five-year longitudinal follow-up of restorative neurostimulation shows durability of effectiveness in patients with refractory chronic low back pain associated with multifidus muscle dysfunction. *Neuromodulation: Technology at the Neural Interface.* 2024; 27. 930–943. <https://doi.org/10.1016/j.neurom.2024.01.006>
 3. Schwab, F. *et al.* Restorative neurostimulation therapy compared to optimal medical management: A randomized evaluation (RESTORE) for the treatment of chronic mechanical low back pain due to multifidus dysfunction. *Pain Ther.* 2025;14, 401–423.