

ISASS Recommendations and Coverage Criteria for Restorative Neurostimulation for Multifidus Dysfunction, Lumbar Region: Coverage Indications, Limitations, and/or Medical Necessity—An ISASS 2025 Guideline Update

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ABSTRACT

Patients suffering from chronic mechanical low back pain secondary to multifidus dysfunction represent a unique and increasingly recognized subset of the overall chronic mechanical low back pain population. Neuromuscular inhibition and fatty infiltration of the dysfunctional multifidus muscle contribute to persistent pain, spinal instability, and disability that fail to resolve with conventional therapy. As of October 2024, the introduction of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code M62.85 provides formal classification of this disease entity and allows providers to diagnose this condition with a higher level of specificity. Permanently implanted restorative neurostimulation systems, of which the ReActiv8 device (Mainstay Medical) is currently the only US Food and Drug Administration (FDA)–approved technology (FDA Product Code QLK), directly target chronic low back pain associated with lumbar multifidus dysfunction to treat the underlying condition. This 2025 International Society for the Advancement of Spine Surgery guideline update (1) summarizes the high-quality clinical data supporting long-term efficacy and safety of restorative neurostimulation, including longitudinal outcomes from a 5-year pivotal study, randomized controlled trials, and other clinical studies, (2) updates all coding guidance to reflect current ICD-10 and FDA device status, and (3) reports on payer trends, including the recent positive Anthem Blue Cross Blue Shield coverage decision. The International Society for the Advancement of Spine Surgery reaffirms its support for coverage of implantable restorative neurostimulation by payers in appropriately selected patients, consistent with the demonstrated evidence.

Testing & Regulatory Affairs

Keywords: chronic low back pain, neurostimulation, insurance coverage, multifidus dysfunction

INTRODUCTION

Since the 2023 International Society for the Advancement of Spine Surgery (ISASS) Statement,¹ new International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) coding; long-term level I evidence; positive payer decisions; and expanded recognition of multifidus dysfunction’s prognostic and economic impact make an updated guideline essential to align coverage criteria with current science and practice.

statement on surgical and device-based management of lumbar spine dysfunction, focusing on restorative neurostimulation for chronic low back pain associated with multifidus dysfunction.¹ This update incorporates the emergence of ICD-10-CM M62.85² and new data, including long-term clinical outcomes and multiple real-world evidence studies, along with recent payer and coding developments, to offer comprehensive medical necessity and coverage guidance for US payers and providers for implantable restorative neurostimulation.

Objective

The goal of this guideline recommendation is to provide an update to the ISASS 2023 guideline

Device Neutrality

ISASS maintains a device-neutral position in all guideline statements. At the time of publication, the

ReActiv8 system³ (Mainstay Medical; PMA P190021, Product Code QLK) is the only US Food and Drug Administration (FDA)-approved restorative neurostimulation technology for lumbar multifidus dysfunction. Future devices that obtain equivalent regulatory approval and demonstrate comparable safety and efficacy should be evaluated using the same evidence-based criteria.

Background

Chronic mechanical low back pain (CLBP) or nociceptive low back pain linked to multifidus muscle dysfunction is a treatment-resistant condition with a high personal and economic burden. Restorative neurostimulation targets the motor fibers of the medial branch of the dorsal ramus to elicit isolated lumbar multifidus contractions, aiming to restore neuromuscular control and spinal stability. This mechanism differs from ablative or sensory neuromodulation approaches.

CLINICAL RELEVANCE

Lumbar multifidus muscle dysfunction is a structural and physiological driver of CLBP whose diagnosis and management have historically been underrecognized. The multifidus, as the principal stabilizer of the lumbar spine, is susceptible to neuromuscular inhibition due to injury, pain, and degenerative conditions, resulting in disuse, muscle atrophy, segmental instability, and recalcitrant symptoms that can fail conservative management and become chronic. Magnetic resonance imaging and ultrasound often reveal muscle fatty infiltration and degeneration in affected patients. Conservative therapies, including physical rehabilitation, injections, and medications, typically do not restore neuromuscular control or muscle quality when the inhibition reaches a chronic state. As a result, many patients progress to long-term opioid use and seek repeated palliative interventions, such as injections and ablations, which fail to address the underlying cause, leading to severe disability and excessive health care resource utilization. This distinction with palliative procedures is critical: whereas many existing therapies provide temporary symptom relief, restorative neurostimulation represents a proactive, disease-modifying approach that restores neuromuscular function. This places it in alignment with curative or corrective strategies rather than maintenance or masking approaches.

The restorative neurostimulation therapy delivers targeted bilateral motor stimulation to the lumbar multifidus via the medial branch of the dorsal ramus at L2.

Restorative neurostimulation facilitates motor rehabilitation as the mechanism leading to pain relief and improved function, rather than merely masking symptoms for sustained pain relief, function improvement, and increased quality of life as demonstrated in 2 randomized controlled trials (RCTs),^{4,5} multiple real-world evidence clinical studies,⁶⁻⁸ and mechanism of action studies.^{9,10}

TECHNICAL DESCRIPTION

Restorative neurostimulation (ReActiv8; Mainstay Medical) consists of a fully implantable device indicated for the treatment of adult patients with severe CLBP attributed to multifidus dysfunction. The system consists of an implanted pulse generator and 2 percutaneous leads, each placed adjacent to the L2 medial branch of the dorsal ramus at the L3 vertebral level.¹ The indicated therapy includes two 30-minute stimulation sessions in which the patient controls the timing of the stimulation. The device delivers bilateral electrical pulses that induce functional contraction of the multifidus muscle. This enhances neuromuscular drive, progressively reversing inhibition and degeneration. The implantable device and leads are designed for chronic, multiyear stimulation and are controlled to minimize the risk of off-target stimulation or adverse events.

SUMMARY OF CLINICAL EVIDENCE

Numerous clinical studies and reviews, including 2 RCTs and multiple real-world evidence studies, are summarized in the Table. The restorative neurostimulation therapy demonstrated safety, effectiveness, durability in 5-year follow-up, and reproducibility in 2 controlled trials and 4 real-world evidence studies. Six studies that reported at minimum 1-year results, 2 studies reported 5-year results, and several additional publications that studied the same patients longitudinally at various time intervals. All 6 studies achieved meaningful functional improvement and pain decrease, achieving minimal clinically important change for patients treated with restorative neurostimulation.

The 2 RCTs and scoping reviews are summarized below. The correlation of fatty infiltration in predicting surgical outcomes after spinal surgery used to treat other spinal pathologies is also reviewed, accentuating the clinical importance of restorative neurostimulation for addressing multifidus dysfunction. Additional studies, including a systematic review, are summarized in the Table.

Table. Summaries of published studies' clinical findings related to restorative neurostimulation.

Source, Year	Design	Sample Size	Level of Evidence ^{11,12}	Publication Goal	Results
Schwab et al, 2025 ⁵	RCT	203	I	Establish restorative neurostimulation effectiveness compared to OMM in the treatment of CLBP.	<ul style="list-style-type: none"> Clinically relevant mean improvement in ODI between restorative neurostimulation arm and OMM arm was statistically significant at the primary 1-y endpoint ($P < 0.001$) Analysis accounting for missing data in all secondary endpoints reported MCID in NRS and quality of life (EQ-5D) that were significantly favorable for restorative neurostimulation 70% with $\geq 30\%$ and 53% with $\geq 50\%$ improvement in CLBP NRS in the treatment arm 73% with $\geq 30\%$ and 52% with $\geq 50\%$ improvement in ODI 48% with $\geq 30\%$ improvement in EQ-5D-5L 52% reported pain remission (≤ 3 of NRS) in the treatment arm; 6% in the OMM arm 89% with "very much improved" or "much improved" in global impression in the treatment arm; 15% in the OMM arm 72% of the treatment arm reached composite endpoint of ≥ 15-point ODI improvement and/or $\geq 50\%$ NRS and no worsening in either measure; 11% in OMM arm
Huang et al, 2025 ⁸	Clinical care pathway	107	II	A clinical care pathway for restorative neurostimulation therapy and report patient compliance, clinical outcomes, and patient satisfaction with the CPW.	<ul style="list-style-type: none"> 172 patients attended the education session, and 107 proceeded to restorative neurostimulation for multifidus muscle therapy and were incorporated into the CPW Patient compliance with the pathway was 88% (95% CI: 79%–94%) at 12 mo Attendance at the dedicated CPW clinic by the various subspecialty clinicians ranged between 74% and 100% Patient function improved with serial reductions in ODI from 38.9 (95% CI: 35.9–41.9) at baseline to 24.7 (95% CI: 21.1–28.3) at 12 mo Pain measured by NRS improved with scores reducing from 6.3 (95% CI: 6.0–6.7) at baseline to 3.3 (95% CI: 2.7–3.9) at 12 mo 77% of treated patients (76 of the 99 patients [95% CI: 67–85%]) had a MCID reduction in either ODI or pain NRS Patient satisfaction with the CPW was very high (mean 26.9; median 27, maximum 28) At 5 y, 34/42 patients (81%) completed follow-up with significant and durable improvements observed in pain (mean NRS reduced from 7.0 to 3.2) Disability (mean ODI reduced from 46.6 to 26.1) Quality of life (EQ-5D index increased from 0.426–0.703). A total of 82% of patients achieved a MCID in either pain and/or disability, and 62% were pain remitters.
Thomson et al, 2025 ⁷	Prospective, postmarket clinical follow-up	42	II	5-y real-world evidence	<ul style="list-style-type: none"> Follow-up range: 1.5–48 mo Weighted pooled effect was pain intensity reduction of 2.9 units (95% CI: 2.1–3.7) Predictive interval of pain intensity reduction of >2 units was 0.84 (0.68–0.98) Medial branch stimulation for the treatment of CLBP showed high probability of a clinically significant change in pain intensity Longer duration of stimulation was associated with decreased low back pain intensities
Copley et al, 2024 ¹³	Systematic review and meta-analysis	419	I	Comprehensive literature search from 2010 to 2022 in adults with CLBP, treated with multifidus or medial nerve stimulation through implanted or percutaneous device	<ul style="list-style-type: none"> Implantable neurostimulation device with 5-y data 72% with $\geq 50\%$ improvement in LBP VAS 61% with ≥ 20-point improvement in ODI 78% with $\geq 50\%$ improvement in VAS and/or ODI 88% were "definitely satisfied" with the treatment 69% of patients on opioids at baseline have eliminated (46%) or reduced (23%) opioid consumption
Gilligan et al, 2024 ¹⁴	Open-label follow-up of randomized, active sham-controlled trial	204	I	5-y effectiveness and durability	<ul style="list-style-type: none"> Four equal-sized cohorts analyzed based on age range ($n = 65$) Statistically significant improvements in disability (ODI) and quality of life (EQ-5D-5L) were seen at all assessment time points compared to baseline Consistent improvements in pain (VAS/NRS) at all time points compared to baseline Patients derived significant and clinically meaningful benefits in disability, health-related quality of life, and pain, irrespective of age
Ardeshiri et al, 2024 ¹⁵	Pooled analysis of RCT (ReActiv8-B) and Real World (ReActiv8-C, and -PMCF) studies.	261	III	2-y effectiveness and durability across 3 different studies looking at all age groups	<ul style="list-style-type: none"> Literature review focused on restorative neurostimulation and the scientific background of the underlying problem being treated Clearly differentiates the restorative therapy over others, including SCS, RFA, and 60-d temporary PNS devices Restorative neurostimulation is the only FDA-approved PNS device to treat CLBP associated with multifidus dysfunction and loss of neuromuscular control resulting in functional lumbar instability While various treatments exist for CLBP, restorative neurostimulation distinguishes itself from traditional neurostimulation in a way that treats a different etiology, targets a different anatomical site, and has a distinctive mechanism of action
Tieppo Francio et al, 2023 ¹⁶	Scoping review	NA	V	Provide comprehensive review of the literature on multifidus dysfunction and restorative neurostimulation	

Table. Continued.

Source, Year	Design	Sample Size	Level of Evidence ^{11,12}	Publication Goal	Results
Thomson et al, 2023 ¹⁷	Prospective, postmarket clinical follow-up	42	II	3-y real-world evidence	<ul style="list-style-type: none"> ● 33/42 (79%) implanted with the device were available at the 3-y appointment ● Patients in this cohort presented with severe CLBP (NRS = 7.0 ± 0.2), severe disability (ODI 46.6 ± 12.0), and severely impacted health care quality of life at baseline (EQ-5D 0.426 ± 0.061) ● Changes in pain, disability, and quality of life at 3-y follow-up demonstrated a statistically significant improvement between baseline and 1, 2, and 3 y ● After 3 y of therapy, average NRS scores decreased to 2.7 ± 0.3 and mean ODI score to 26.0 ± 3.1 while EQ-5D-5L index improved to 0.707 ± 0.036
Shaffrey and Gilligan, 2023 ¹⁸	Retrospective review of prospectively collected data from level I study.	146	III	Analyze the effect of restorative neurostimulation with patients from the ReActiv8-B study on known drivers of direct and indirect long-term health care costs.	<ul style="list-style-type: none"> ● In addition to clinically meaningful improvements in pain and function with long-term durability, the majority of patients transitioned from a high- to low-impact CLBP state ● 71% of patients had high-impact pain at baseline that reduced to 10% at 2 y ● 85% of patients reported low-impact pain at 2 y ● This functional and pain improvement is typically associated with significantly lower direct and indirect health care utilization levels ● The recovery trajectory is consistent with a restorative mechanism of action and suggests that over the long term, these health states will be maintained
Sayed et al, 2022 ¹⁹	Guideline	NA	III	The ASPN Back Guideline was developed to provide clinicians with a review of interventional treatments for low back disorders.	<ul style="list-style-type: none"> ● Level I evidence study of the permanently implanted restorative neurostimulation system was an international, multicenter, prospective, randomized, active, sham-controlled, and blinded trial supporting the significance of the treatment effect ● ReActiv8-B trial “demonstrated clinical effectiveness as measured by substantial and durable improvements in pain, disability, and quality of life in a cohort of patients with a favorable benefit–risk profile” ● Rates of adverse events are consistent with known SAE rates for SCS therapy. There was no finding of lead migration ● The ASPN Back Group recommends offering the permanently implanted PNS system given that there is high certainty that the net benefit is substantial
Chakravarthy et al, 2022 ²⁰	Clinical guide	NA	V	Clinical guide for therapy adoption	<ul style="list-style-type: none"> ● Re-establishing control of the multifidus muscle may not be feasible with physical therapy and exercise alone ● Direct electrical stimulation of multifidus may be a suitable alternative for motor dysfunction ● A combination of history, imaging, and multiple provocative maneuvers has allowed for increased accuracy in diagnosis, leading to excellent outcomes
Ardeshiri et al, 2022 ⁶	Prospective, real-world evidence registry, single center report	44	II	1-y real-world evidence	<ul style="list-style-type: none"> ● 40 patients completed all required testing at the follow-up visit showing statistically significant improvements in pain (NRS), disability (ODI), and quality of life (EQ-5D-5L) ● Restorative neurostimulation therapy is durable, and the benefits accumulate over time consistent with the restorative mechanism of action ● No lead migrations ● Results consistent with the published data from the earlier ReActiv8-A and ReActiv8-B studies
Gilligan et al, 2022 ²¹	Open-label follow-up of randomized, active sham-controlled trial	204	I	3-y effectiveness and durability	<ul style="list-style-type: none"> ● 77% of participants had ≥50% VAS reduction ● 67% reported CLBP resolution (VAS ≤ 2.5 cm) ● 63% had a reduction in ODI of ≥20 points ● Trajectory and durability of 3-y clinical benefits are consistent with restoration of neuromuscular control and muscle rehabilitation
Mitchell et al, 2021 ²²	Prospective, multicenter, single-arm, nonrandomized trial	53	II	4-y effectiveness and durability	<ul style="list-style-type: none"> ● 73% of completers showed improvement ≥2 points on NRS ● 76% of completers showed improvement ≥10 points on ODI ● 97% of completers were very satisfied with treatment ● Treatment satisfaction and results remain durable through 4 y
Gilligan et al, 2023 ²³	Open-label follow-up of randomized, active sham-controlled trial	204	I	2-y effectiveness	<ul style="list-style-type: none"> ● 72% of participants had ≥50% pain relief ● 67% reported CLBP resolved (VAS ≤ 2.5 cm) ● 62% ODI reduced by ≥20 points ● Statistically significant, and clinically substantial benefits in patients with severe, disabling CLBP and multifidus muscle dysfunction
Gilligan et al, 2021 ⁴	RCT, multicenter, active sham-control	204	I	Safety and efficacy	<ul style="list-style-type: none"> ● Overall data from the blinded phase of this trial are consistent with a clinically meaningful benefit at 120 d ● After unblinding, improvements increased over time to 1 y in the combined cohort ● Incidence of serious procedure- or device-related adverse events compared favorably with rates published for other neuromodulation therapies for chronic pain

Table. Continued.

Source, Year	Design	Sample Size	Level of Evidence ^{11,12}	Publication Goal	Results
Thomson et al, 2021 ²⁴	Postmarket prospective clinical follow-up	42	II	2-y real-world evidence	<ul style="list-style-type: none"> • 57% of patients experienced a substantial improvement of $\geq 50\%$ reduction in NRS • 51% of patients experienced substantial improvement of ≥ 15-point reduction in ODI • Excellent safety profile compared to similarly implanted devices
Deckers et al, 2017 ²⁵	Prospective, multicenter, single-arm, non-randomized trial	53	II	Feasibility	<ul style="list-style-type: none"> • Responder rate 58% for patients with 14-y average duration of CLBP and average NRS of 7 • 57% of subjects at 1 y with \geq MCID improvement in single-day NRS • 60% of subjects with \geq MCID improvement in ODI while those with \geq MCID improvement in EQ-5D was 81% at 1 y

Abbreviations: ASPN, American Society of Pain and Neuroscience; CLBP, chronic mechanical low back pain; CPW, clinical care pathway; LBP, low back pain; MCID, minimal clinically important difference; NA, not applicable; NRS, Numeric Pain Rating Scale; ODI, Oswestry Disability Index; OMM, optimal medical management; PMCF, postmarket clinical follow-up; PNS, peripheral nerve stimulation; RCT, randomized controlled trial; RFA, Radiofrequency Ablation; SAE, serious adverse event; SCS, spinal cord stimulation; VAS, visual analog scale.

Long-Term Efficacy (5-Year Pivotal Data)

The pivotal study was a prospective, multicenter, randomized, sham-controlled study enrolling patients with refractory CLBP and documented multifidus dysfunction who had failed conservative management.⁴ At a 5-year follow-up, 72% of patients sustained $\geq 50\%$ reduction in back pain visual analog scale from baseline, 61% achieved ≥ 20 -point Oswestry Disability Index improvement, and opioid use was reduced or eliminated in a large majority. Improvements were durable and consistent throughout 5 years, a landmark in neurostimulation device-based CLBP interventions.¹⁴

RESTORE Trial

The RESTORE trial was published in early 2025⁵ as a multicenter RCT comparing restorative neurostimulation therapy treatment to Optimized Medical Management for treatment of CLBP. At the 12-month follow-up, patients randomized to the treatment group experienced a mean reduction of -19.7 points in Oswestry Disability Index, a -3.6 reduction in NRS back pain, and a +0.16 improvement in EQ-5D-5L quality of life. All primary and secondary endpoints were met vs Optimized Medical Management, and the safety profile was very favorable.⁵

Systematic Review

A recent systematic review synthesized data from RCTs, prospective cohorts, and registries, concluding that implantable restorative neurostimulation delivers consistent and clinically meaningful reductions in disability and pain with very low rates of device-related adverse events and broad clinical applicability for patients meeting inclusion criteria.¹³

Patient Compliance and Satisfaction

Equally important, restorative neurostimulation demonstrates high patient adherence, with real-world registry data confirming low explant rates and strong satisfaction scores. This distinguishes it from other implantable pain therapies, where compliance and tolerance may diminish long term.⁷

Economic Impact

Economic analyses, though limited, indicate that restorative neurostimulation may reduce overall spine care costs by lowering reoperation rates, minimizing chronic opioid dependence, and decreasing utilization of repeat injections and other palliative procedures. For payers, this positions restorative neurostimulation not only as clinically necessary but as a cost-offsetting intervention in appropriately selected patients.^{18,26}

Correlation of Pre-existing Multifidus Fatty Infiltration and Patient-Reported Outcomes After Spine Surgery

The literature is replete with the negative effects of pre-existing multifidus fatty infiltration on patient-reported long-term outcomes. For patients undergoing laminectomy for stenosis, fusion, or lumbar total disc arthroplasty, the outcomes of these procedures are negatively impacted in the presence of fatty infiltration in the multifidus in comparison to patients who do not have this condition.²⁷⁻³⁰ Therefore, spine surgeons should be informed of this condition and consider restorative neurostimulation for the treatment of multifidus dysfunction in properly selected patients in the absence of clear surgical indications.¹

INDICATIONS/LIMITATIONS OF COVERAGE

Coverage Indications

Implantable restorative neurostimulation therapy is medically necessary in adult patients with all of the following:

- Documented multifidus dysfunction, lumbar region (ICD-10 M62.85) confirmed by imaging (magnetic resonance imaging and/or ultrasound) findings, and clinical presentation.
- CLBP with failed ≥ 6 months of comprehensive, guideline-driven conservative management.
- No clear indications for spine surgery (eg, progressive neurologic deficit, spinal instability, and severe stenosis).
- Older than 18 years.

Limitations of Coverage

Exclusions apply if any of the following apply:

- Severe spinal instability or deformity requiring surgical reconstruction.
- Contraindications to lead or pulse generator implantation.
- Active infection or coagulopathy.

CODING

ICD-10-CM Diagnosis Coding

- M62.85: Dysfunction of multifidus muscles and lumbar region.

FDA Device Coding

- Product Code QLK: Stimulation of nerves that innervate muscles to treat or aid in the management of chronic, intractable lower back pain.³

Current Procedural Terminology Coding

Current procedural interventions can be reported using the following codes:

- 64590: Insertion of replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connections between the electrode array and the pulse generator or receiver.

- 64555 \times 2: Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve).

Payer Policy Trends

Since the adoption of ICD-10-CM code M62.85, payers have shifted in their approach to multifidus dysfunction. The coding specificity has enabled precise patient identification, and accumulating long-term data has reinforced payer confidence. Regional and national carriers have issued positive coverage determinations or initiated policy revisions, reflecting growing recognition of restorative neurostimulation as medically necessary. Anthem Blue Cross Blue Shield's 2025 decision marking restorative neurostimulation as medically necessary for defined patient populations signals a broader shift across payers. Other commercial payers and certain Medicare Administrative Contractors are also covering.

Limitations of Evidence

1. Current evidence is strongest in non-surgical patients with mechanical/nociceptive pain and confirmed multifidus dysfunction; further study is warranted in postsurgical and neuropathic populations.
2. While long-term clinical outcomes are well documented, economic analyses remain limited and should be expanded to strengthen cost-effectiveness assessments.

CONCLUSION

Patients with CLBP due to multifidus muscle dysfunction represent a high-need population with limited effective treatment options. Restorative neurostimulation—delivered by an implantable system designed to re-activate the lumbar multifidus muscle—is now supported by multiple level I RCTs, long-term follow-up extending to 5 years, and real-world evidence studies demonstrating consistent, durable improvements in pain, disability, opioid use, and quality of life. With the addition of ICD-10-CM coding (M62.85) to define this condition and with expanding payer recognition, restorative neurostimulation has matured into a validated, durable, and economically relevant therapy. ISASS affirms that coverage criteria should align with this body of evidence and urges payers to adopt positive policies enabling appropriate patient access. As with all guidelines, ISASS will continue to review emerging

data, including physiological markers and economic analyses, to ensure guidance remains evidence based, patient focused, and fiscally responsible.

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