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The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain

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Objective

- The ASPN Back Guideline was developed to provide clinicians with evidence-based recommendations to address the appropriate utilization of interventional treatments for LBP.
- Clinicians should utilize the ASPN Back Guideline to evaluate the quality of the literature, safety, and efficacy of interventional treatments for lower back disorders.

Indications for "PNS for Low Back Pain–Multifidus Activation via Medial Branch Nerve Stimulation"

More advanced treatments such as PNS should be considered once more conservative options have failed and there is no indication for invasive surgery. Candidates for PNS therapy experience CLBP secondary to multifidus muscle dysfunction, which is often consistent with muscle atrophy.

Atrophy can be confirmed via MRI and dysfunction confirmed via physical exam. The prone instability test and multifidus lift test are physical exam maneuvers used to assess weakness of the multifidi from atrophy. Currently, the literature and experience revolve around both short-term and permanently-implanted techniques.

ReActiv8® Key Takeaways

- "The highest-level trial of the permanently implanted PNS system was an international, multi-center, prospective, randomized, active, shamcontrolled, blinded trial, which generated **high, level I-A evidence supporting the significance of the treatment effect**."
- The 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."
- "The rates of adverse events are consistent with known SAE rates for spinal cord stimulation therapy; however, 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**."

ASPN Back Consensus Group Recommendations for Multifidus Activation via Medial Branch Nerve Stimulation

Recommendation	Grade	Level	Level of certainty
The incidence of serious procedure or device related complications is favorable to other neuromodulation techniques.	B	I-B	Moderate
Improvements in baseline are clinically significant at both 1, 2 and 3 years after implant in a cohort of patients with severe, disabling chronic LBP.	B	I-B	Moderate
Improvements in pain and disability increase the longer duration of treatment.	B	I-B	Moderate

Abbreviations: LBP, low back pain; PNS, peripheral nerve stimulation.

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Evidence Summary for Multifidus Activation via Medial Branch Nerve Stimulation

Source, Year	Design	Sample Size	Level of Evidence	Outcome Measures	Results
Deckers et al, 2018	Prospective, multi-center, single-arm, non-randomized trial	53	I-B	NRS (back), ODI, EQ-5D	The percentage of subjects at 90 days, 6 months and 1 year with greater than or equal to MCID in single day NRS was 63%, 61% and 57% respectively. The percentage of subjects with greater than or equal to MCID in EQ-5D was 88%, 82% and 81% respectively. There were no unanticipated adverse events related to the device, procedure or therapy.
Gilligan et al, 2021	Randomized, multi-center, active-sham-clinical trial	204	I-A	Comparison of responder subjects with greater than equal to 30% relief on VAS (LBP) without analgesic increase at 120 days; ODI, EQ-5D, PPR, PGIC and LBP resolution	The primary endpoint comparing the responder proportions was inconclusive in superiority; however, prespecified secondary outcomes and analyses were consistent with a modest but clinically significant meaningful treatment benefit at 120 days.
Gilligan et al, 2021	Open-label follow-up of randomized, active-sham-controlled trial	204	I-A	VAS, opiod intake at 6, 12, and 24 months	At two years, 76% subjects experience ≥50% CLBP relief and 65% reported CLBP resolution; 61% had a reduction in ODI of ≥20% points, and 56% had these substantial improvements in both VAS and ODI.
Thomson et al, 2021	Post-market prospective clinical follow-up	42	I-B	NRS, ODI, EQ-5D-5L	Among the 37 patients completing 2-year follow-up, NRS pain scores improved from 7.0 ± to 3.5 ± 0.3, ODI scores improved from 46.2 ± 2.2 to 29.2 ± 3.1, and health-related quality of life improved from 0.426 ± 0.035 to 0.675 ± 0.030. Additionally, 57% of patients experienced a greater than 50% reduction in pain, and 51% of patients benefited by a greater than 15-point reduction in ODI, both substantial improvements.

Abbreviations: NRS, numeric rating scale; ODI, Oswestry Disability Index; EQ-5D, EuroQOL Health Questionnaire; MCID, minimum clinically important difference; PGIC, patient global impression of change; VAS, visual analog scale; PPR, percentage pain relief; LBP, low back pain.

Definitions

Grade	Definition	Suggestions for practice
A	The ASPN Back Group recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The ASPN Back Group recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The ASPN Back Group recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The ASPN Back Group recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The ASPN Back Group concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is of poor quality, or conflicting and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Level of Certainty	Description
High	**Evidence Level: I-A** - At least one controlled and randomized clinical trial, property designed
Moderate	**Evidence Level: I-B** - Well-designed, controlled, non-randomized clinical trials **Evidence Level: I-C** - Retrospective cohort or large case studies (>20 subjects)
Low	**Evidence Level: II** - Expert opinion based of risk-to-benefit or based upon case reports

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