PEER REVIEW / UTILIZATION REVIEW DETERMINATION

Basivertebral Nerve Ablation (BVNA) — CPT 64628 / 64629

CASE SUMMARY

Reviewing entity: [IRO]

Plan: [Plan]

Patient: CLAIMANT

Diagnosis as submitted: M54.51 — Vertebrogenic low back pain

Requested service: Intracept Procedure (intraosseous basivertebral nerve ablation), L3, L4, and L5, utilizing the Stryker OptaBlate BVN Intraosseous Nerve Ablation System (FDA 510(k) K250213, cleared May 2025).

CPT codes under review: 64628 (BVNA, first two vertebral bodies, lumbar/sacral, with imaging guidance) and 64629 (BVNA, each additional vertebral body).

DOCUMENTS REVIEWED

- Provider request and clinical narrative.
- Lumbar MRI.
- [Plan] Coverage Policy: Intraosseous Radiofrequency Ablation of the Basivertebral Nerve (Origination Date January 2024; Next Review November 2026).
- CMS Local Coverage Determination L39644 (Intraosseous Basivertebral Nerve Ablation).
- FDA 510(k) summaries for Intracept (K190504, May 2019) and Stryker OptaBlate (K250213, May 2025).
- ASPN 2022 Best Practice Guidelines; ISASS 2020 policy statement; NASS / IPSIS coverage criteria; Hayes Health Technology Assessment Rating C (November 2025).

DOCUMENTED CLINICAL HISTORY

Chronic low back pain radiating to the posterior aspect of the right leg with associated numbness and tingling. Difficulty with prolonged walking and standing. Prior interventional injections provided temporary relief. Tylenol and meloxicam were used between injections.

DOCUMENTED IMAGING FINDINGS

- Early spinal stenosis at L4-L5 including narrowing, with anterior, posterior, and lateral osteophytes, and endplate reactive changes diffusely.
- Anterior, posterior, and lateral osteophytes and endplate reactive changes in the superior endplate of L3.
- 1.5 mm disc bulging at L2-L3 and at L5-S1.
- Moderate facet arthrosis throughout the lumbar spinal region.

The radiology impression characterizes the endplate findings as "reactive changes" and does not specify Modic Type 1 or Type 2 typing on T1- and T2-weighted sequences. The treating provider's narrative

quotes the FDA Indications-for-Use language describing what Modic Type 1 and Type 2 changes are, but does not identify the specific Modic typing (Type 1 or Type 2) at any individual endplate at L3, L4, or L5.

DETERMINATION

The proposed Intracept / basivertebral nerve ablation procedure (CPT 64628 and 64629) at L3, L4, and L5, performed with the Stryker OptaBlate BVN System, is NOT MEDICALLY NECESSARY under the [Plan] Coverage Policy for Intraosseous Radiofrequency Ablation of the Basivertebral Nerve and under generally accepted standards of medical practice.

Question 1: Is the proposed procedure, billed under CPT codes 64628 and 64629, considered the standard of care in treating this patient's condition?

Answer: Not as documented for this patient.

BVNA is FDA-cleared (Intracept K190504, May 2019; Stryker OptaBlate K250213, May 2025) and is a recognized, standard-of-care option — but only for patients with chronic vertebrogenic low back pain. It is not a treatment for radicular pain, lumbar radiculopathy, neurogenic claudication, symptomatic lumbar spinal stenosis, or pain attributable to facet arthropathy or other alternative dominant structural pain generators.

The guideline requires ALL of the following:

- Skeletally mature adult.
- Chronic axial (non-radicular) low back pain ≥ 6 months' duration, with low back pain as the dominant symptom.
- Documented failure of ≥ 6 months of structured non-surgical management.
- MRI demonstrating Type 1 and/or Type 2 Modic changes at the vertebral endplate(s) of the level(s) proposed for treatment, between L3 and S1.
- Absence of an alternative dominant pain generator (lumbar spinal stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis, or facet arthropathy with clinically suspected facet-mediated pain).
- Absence of radicular pain, radiculopathy, or neurogenic claudication as a primary symptom.

The submitted record does not establish that this patient meets these criteria. The history describes pain radiating to the right posterior leg with numbness and tingling — which is consistent with lumbar radiculopathy. The MRI documents early spinal stenosis at L4-L5 (a level proposed for ablation), 1.5 mm disc bulging at L5-S1, and moderate facet arthrosis throughout the lumbar spine. The MRI characterizes endplate findings as "reactive changes" without specifying Modic Type 1 or Type 2 on T1/T2 sequences.

The treating provider's narrative correctly cites the criteria but does not identify the specific Modic typing on this patient's MRI. The patient is therefore not a candidate for BVNA.

Question 2: Using the Plan's definition (attached), is the proposed procedure (CPT 64628 and 64629) considered medically necessary in treating this patient's condition?

Overall determination: NOT MET — the request does not satisfy the Plan's definition of medical necessity, and it does not satisfy the [Plan]-specific Coverage Policy for Intraosseous Radiofrequency Ablation of the Basivertebral Nerve.

Question 3: If the patient is classified as having chronic low back pain and has not responded to non-surgical treatment for more than six months, would the BVNA procedure be considered medically necessary for managing this condition?

Answer: No — not on the basis of those two criteria alone.

Six months of chronic low back pain plus six months of failed conservative care correspond to [Plan] criteria A and B, but they are only two of the four required inclusion criteria. The evidence base supporting BVNA — and every payer policy that derives from it, including the [Plan] policy applicable here — additionally requires:

- **[Plan] criterion C:** Absence of non-vertebrogenic pathology that could explain the patient's pain. The claimant's MRI documents early L4-L5 spinal stenosis, moderate lumbar facet arthrosis, and L5-S1 disc bulging — none of which has been excluded as the dominant pain generator.
- **[Plan] criterion D:** Modic Type 1 or Type 2 changes on MRI at L3-S1. The claimant's MRI documents "endplate reactive changes" without explicit Modic Type 1 or Type 2 typing.
- **[Plan] exclusion F:** Absence of primary radicular pain. The claimant's documented right posterior leg pain with numbness and tingling, combined with the MRI structural correlates, engages this exclusion.
- **[Plan] exclusion H:** Absence of primary symptomatic lumbar spinal stenosis. Engaged here.
- **[Plan] exclusion J.4:** Absence of facet arthrosis correlated with facet-mediated pain. Engaged here.

Duration of pain and duration of failed conservative care, even if fully documented, would not by themselves convert this request into a medically necessary service under the operative [Plan] Coverage Policy.

Question 4: What are the treatment indications and limitations for the proposed procedure?

Treatment indications under the operative [Plan] Coverage Policy

BVNA is medically necessary under [Plan] policy only when ALL of the following are met:

- **A.** Chronic lumbar back pain ≥ 6 months' duration causing functional deficit measured on a validated pain or disability scale at baseline.
- **B.** Documented failure to respond to ≥ 6 months of non-surgical management — which may include activity avoidance, chiropractic manipulation, physical therapy, cognitive support, epidural and/or facet injection therapy, and pharmacotherapy.
- **C.** Absence of non-vertebrogenic pathology by clinical assessment or radiology studies that could explain the source of the patient's pain.
- **D.** Evidence of Type 1 or Type 2 Modic changes on MRI in 1 or more vertebrae from L3-S1.

Limitations under the operative [Plan] Coverage Policy

- Thermal destruction of the intraosseous BVN must only be performed once per vertebral body from L3-S1 per lifetime.
- Up to 4 vertebral bodies may be treated during 1 procedure.

Contraindications / non-coverage under the [Plan] Coverage Policy

- **A.** Skeletal immaturity (≤ 18 years).
- **B.** Severe cardiac or pulmonary compromise.
- **C.** Active systemic infection or local infection at the intended treatment level.
- **D.** Bleeding diathesis.
- **E.** Pregnancy.
- **F.** Primary radicular pain into the lower extremities.
- **G.** Previous lumbar spine surgery at the intended treatment level.
- **H.** Primary symptomatic lumbar or lumbosacral spinal stenosis.
- **I.** Diagnosed osteoporosis spine fragility fracture history, trauma/compression fracture at the intended treatment level, or spinal cancer.
- **J.** Radiographic evidence of (1) lumbar disc extrusion or protrusion > 5 mm at L3-S1; (2) spondylolisthesis > 2 mm at any level; (3) spondylolysis at L3-S1; or (4) facet arthrosis/effusion correlated with facet-mediated pain at L3-S1, when correlated with predominant physical complaints.
- Advanced generalized systemic disease limiting QOL improvements (without statement of treatment objective).
- Active, untreated substance abuse disorder.

Procedure-specific coding

- CPT 64628 covers thermal destruction of the intraosseous basivertebral nerve at the first two vertebral bodies, lumbar/sacral, including imaging guidance.
- CPT 64629 is an add-on code for each additional vertebral body. For three vertebral bodies (L3, L4, L5), correct coding is 64628 × 1 plus 64629 × 1.
- Each vertebral body proposed for ablation must independently meet criteria — i.e., must demonstrate Modic Type 1 or Type 2 endplate changes at that level.

Question 5: Why is this patient / why is this patient not a good candidate for the procedure?

Answer: The claimant is NOT, as documented, a good candidate for BVNA at this time.

Reasons the patient is not a candidate (as documented)

- Primary radicular symptom pattern with structural MRI correlate ([Plan] exclusion F).
- Lumbar spinal stenosis (MRI) at the proposed treatment level ([Plan] exclusion H).
- Moderate facet arthrosis throughout the lumbar spine on MRI ([Plan] exclusion J.4).
- No documented Modic Type 1 or Type 2 typing on MRI ([Plan] criterion D NOT MET).
- Insufficient documentation of structured conservative care ([Plan] criterion B NOT MET). References to "injections," Tylenol, and meloxicam — without specification of injection type, level,

technique, dates, response, or duration of physical therapy — do not satisfy [Plan]'s structured ≥ 6-month conservative care requirement.
- No documented baseline functional assessment ([Plan] criterion A NOT MET).

Conditions under which the claimant could become a candidate

The claimant could become a candidate for BVNA if, on resubmission, the record demonstrates ALL of the following:

- A current MRI report explicitly identifying Modic Type 1 and/or Modic Type 2 changes at each vertebral endplate proposed for ablation between L3 and S1.
- Reconciliation of the radicular symptoms — the leg symptoms arise from a separately identified cause.
- Evaluation and documented exclusion (or appropriate prior treatment) of the early L4-L5 spinal stenosis as a contributing pain generator.
- Diagnostic medial branch blocks at L3-L5 to exclude facet-mediated pain.
- Documentation of ≥ 6 months of structured conservative care: dates and content of physical therapy, pharmacologic regimen and duration, and the type, level, date, and individual response to any spinal injections.
- Baseline pain and disability scale measurements consistent with [Plan] criterion A.

CONCLUSION

The proposed basivertebral nerve ablation at L3, L4, and L5 (CPT 64628 and 64629), to be performed with the Stryker OptaBlate BVN System, is not medically necessary under the [Plan] Coverage Policy for Intraosseous Radiofrequency Ablation of the Basivertebral Nerve and under generally accepted standards of medical practice in the United States. The request fails on multiple independent grounds: all four [Plan] inclusion criteria (A, B, C, D) are not met; three [Plan] exclusions (F — primary radicular pain; H — primary symptomatic lumbar spinal stenosis; J.4 — facet arthrosis correlated with facet-mediated pain) are independently engaged; and three of the Plan's general medical-necessity elements are not met. The treating provider's narrative quotes the applicable criteria correctly but does not document the specific clinical findings (Modic typing; absence of radicular pain; absence of stenosis at the treatment level; absence of facet-mediated pain) required to meet them. The determination is rendered without prejudice to a future request supported by the additional documentation outlined above.

KEY REFERENCES

- [Plan] Coverage Policy: Intraosseous Radiofrequency Ablation of the Basivertebral Nerve. Origination Date January 2024; Next Review November 2026.

Reviewer: Chinweike Izeogu, MD

Specialty: Interventional Pain Management / Minimally Invasive Spine

Board Certification: ABA — Pain Medicine

Date of Review: [Date of Review]