

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Cluneal nerve blocks are used as a proposed treatment for individuals with cluneal nerve entrapment syndromes causing pain in the low back and buttocks. The superior and the middle cluneal nerves are cutaneous nerves that are sensory and dominate sensation in the lumbar area and the buttocks. Entrapment of these nerves around the iliac crest can elicit low back pain. The superior cluneal nerve (SCN) provides sensory innervation to the areas of the posterior iliac crest and upper buttocks. It originates from the upper 3 lumbar spinal nerves (L1–L3), passes through the thoracolumbar fascia, and can be entrapped at the osteofibrous orifice where it penetrates the thoracolumbar fascia. The anatomic and functional bases for the development of SCN entrapment neuropathy are a rigid fascial edge and stretching of the gluteus maximus muscle and skin over a large area during flexion of the hip joint. If the nerve is chronically subjected to stretching, the resulting tissue irritation, edema, inflammatory cell infiltration, and scarring can lead to entrapment. Low-back pain caused by SCN entrapment is induced and exacerbated by movements such as rising, sitting, and rolling over, and by prolonged sitting, standing, or walking. Although the etiology of SCN entrapment neuropathy remains unclear, the symptoms are low-back pain (buttock pain) and paresthesia in the area of SCN innervations. Diagnosis of SCN entrapment neuropathy requires a positive result after a SCN block. Cluneal nerve blocks are performed under fluoroscopy where the physician injects one or more anesthetic agents and/or steroids near an affected cluneal nerve or branch to control pain and inflammation or to aid in diagnosis and treatment. The block is intended to interrupt the conduction of pain impulses and minimize the neuropathic pain and paresthesia associated with the SCN entrapment (Hayes 2023; Hayes 2021).

COVERAGE POLICY

Cluneal nerve injections or blocks for the treatment of low back pain is considered **experimental, investigational, or unproven** due to insufficient evidence in peer reviewed medical literature that have not established safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

There is insufficient evidence pertaining to cluneal nerve blocks for the treatment of low back pain in the peer-reviewed medical literature. Only one randomized controlled trial (RCT) (n=20) was located, and the remaining are small prospective uncontrolled studies and case reports. Hayes (2023; 2021) published two reports and stated minimal or

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unclear support in the medical literature, systematic reviews, and national guidelines for cluneal nerve blocks for the treatment of low back pain.

Gautam et al. (2022) completed a prospective observational study to evaluate the therapeutic role of a single lidocaine injection into the SCN for the treatment of lower back pain associated with SCN entrapment. The study included 25 patients aged 18-60 years with unilateral lower back pain over the iliac crest and buttocks regions for more than 6 months that did not respond to conservative treatment. Patients also had to experience pain relief of > 50% on a numeric rating scale for at least 2 hours after a fluoroscopy guided lidocaine injection. Patients were excluded from the study if they had received any form of surgery or developed infectious diseases or malignancy of the spine, had uncontrolled medical diseases, or had uncontrolled psychiatric ailments. Patients received follow-up over a period of 6 months. Of the 25 patients included in the study, 23 completed all 6 months of follow-up. Approximately 80% of study participants continued to have significant pain relief after 6 months of follow-up following a single lidocaine injection into the SCN.

Nielsen et al. (2019) published findings from the only RCT that describes a novel ultrasound guided SCN block technique for application in the management of postoperative pain after hip surgery as well as other clinical uses such as chronic lower back pain. The study was carried out as two separate investigations. First, dissection of 12 cadaver sides was conducted to test a novel SCN block technique. Second, this technique was applied in a randomized trial of 20 healthy volunteers. Initially, the lateral femoral cutaneous, the subcostal and the iliohypogastric nerves were blocked bilaterally. A transversalis fascia plane (TFP) block technique was used to block the iliohypogastric nerve. Subsequently, randomized, blinded SCN blocks were conducted with active block on one side and placebo block contralaterally. The results showed that successful anesthesia after the SCN block was achieved in 18 of 20 active sides (90%). The area of anesthesia after all successful SCN blocks was adjacent and posterior to the area anesthetized by the combined TFP and subcostal nerve blocks. The addition of the SCN block significantly increased the anesthetic coverage of the several types of hip surgery incisions. The authors concluded that the novel ultrasound-guided nerve block technique reliably anesthetizes the SCN. It anesthetizes the skin posterior to the area innervated by the iliohypogastric and subcostal nerves. It improves the anesthetic coverage of incisions used for hip surgery. Among potential indications, this new nerve block may improve postoperative analgesia after hip surgery and may be useful as a diagnostic block for various chronic pain conditions. The authors indicated that clinical trials are mandated. Limitations of this study include small sample size, healthy subjects without back pain were utilized and there was no randomization to any other low back pain treatment for comparison other than placebo.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

CPT	Description
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch [when used for cluneal nerve block]

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

8/09/2023	Policy reviewed, no changes to coverage criteria. Updated Overview, Summary of Medical Evidence, and References sections. Removed Supplemental Information section. Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. IRO Peer Review on June 23, 2023, by a practicing, board-certified physician with a specialty in Pain Management.
8/10/2022	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and Reference sections.
8/11/2021	Policy reviewed. No new peer-reviewed literature located to change coverage position. Treatment remains experimental. References updated.

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6/17/2020 New Policy. IRO Peer Review. 4/2020. Policy reviewed by practicing physician board-certified in Physical Medicine and Rehab, and Pain Management.

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Accessed June 16, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
2. Gautam S, Gupta N, Khuba S, et al. Evaluation of the efficacy of Superior Cluneal Nerve Block in low back pain: A prospective observational study. *J Bodyw Mov Ther.* 2022 Apr;30:221-225. doi: 10.1016/j.jbmt.2022.03.001. Epub 2022 Mar 3. PMID: 35500974.
3. Hayes. Evolving evidence review: Middle cluneal nerve block for treatment of low back pain. Published January 4, 2022. Accessed June 19, 2023. <https://evidence.hayesinc.com/>.
4. Hayes. Evolving evidence review: Superior cluneal nerve block for treatment of low back pain. Published December 30, 2021. Accessed June 16, 2023. <https://evidence.hayesinc.com/>.
5. Nielsen TD, Moriggl B, Barckman J, et al. Randomized trial of ultrasound-guided superior cluneal nerve block. *Reg Anesth Pain Med.* 2019 May 6:rapm-2018-100174. doi: 10.1136/rapm-2018-100174. Epub ahead of print. PMID: 31061111.