Epidural Steroid Injections for Pain Management

Medicare Advantage Medical Policy No.: MNG-020

The Health Plan reserves the right to amend this policy and procedure at any time. Exceptions to this policy and procedure will be made on a case-by-case basis at the total discretion of the Health Plan.

Original Effective Date: May 28, 2024

Instructions for use

This policy serves to provide guidance in determining coverage based on medical necessity. It also gives a list of resources used to create these guidelines. Medical necessity determinations will be made in accordance with generally accepted standards of medical practice, taking into account credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the views of the physicians practicing in relevant clinical areas, and other relevant factors, as they relate to the member's clinical circumstances.

Medicare Advantage Members

Coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria will be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of the coverage criteria and is to be used by all plans and lines of business unless Federal or State law, contract language, including member or provider contracts, take precedence over the policy.

Basic Requirements for Clinical Appropriateness:

1. Before diagnostic or therapeutic intervention, a clinician must confirm the diagnosis or establish the likelihood based on a history and physical exam and, when appropriate, a review of laboratory studies, previous diagnostic testing and response to any prior interventions, specifically relevant to the clinical situation.
2. An alternative treatment or other appropriate intervention should not offer any greater benefit based on standards of medical practice and/or current literature.
3. The potential benefit to the patient should outweigh the risk of the diagnostic or therapeutic intervention.
4. A reasonable likelihood of the intervention changing management and/or leading to an improved outcome for the patient must exist, based on the clinical evaluation, current literature and standards of medical practice.

If these requirements are not apparent in the request for authorization, including the clinical documentation provided, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous ordering of multiple diagnostic or therapeutic interventions and/or repeated diagnostic or therapeutic interventions in the same anatomic area may be denied, unless individual circumstances support the medical necessity of performing interventions simultaneously or repeatedly. This should be apparent in the clinical documentation or in peer-to-peer conversations.

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When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider epidural steroid injections as a treatment for pain management to be eligible for coverage.**

<u>Covered Indications for Epidural Steroid Injections for Pain Management</u>

1. Epidural steroid injection (ESI) will be considered medically reasonable and necessary when the following 3 requirements are met:
    a. History, physical examination, and concordant radiological image-based diagnostic testing and supporting one of the following.
        i. Lumbar, cervical or thoracic radiculopathy, radicular pain and/or neurogenic claudication due to disc herniation, osteophyte or osteophyte complexes, severe degenerative disc disease, producing foraminal or central spinal stenosis, OR
        ii. Post-laminectomy syndrome, AND
    b. Radiculopathy, radicular pain and/or neurogenic claudication is severe enough to greatly impact quality of life or function. An objective pain scale or functional assessment must be performed at baseline (prior to interventions). The same scale* must be repeated at each follow-up assessment of response, AND
    c. Pain duration of at least 4 weeks, and the inability to tolerate noninvasive conservative care or medical documentation of failure to respond to 4 weeks of noninvasive conservative care.
2. The ESIs must be performed under CT or fluoroscopy image guidance with contrast, unless the patient has a documented contrast allergy or pregnancy where ultrasound guidance without contrast may be considered.

3. Transforaminal epidural steroid injections (TFESIs) involving a maximum of 2 levels in 1 spinal region are considered medically reasonable and necessary. It is important to recognize that most conditions would not ordinarily require ESI at 2 levels in 1 spinal region.1
4. Caudal epidural steroid injections (CESIs) and interlaminar epidural steroid injections (ILESIs) involving a maximum of 1 level are considered medically reasonable and necessary.
5. It is medically reasonable and necessary to perform TFESIs bilaterally only when clinically indicated.
6. Repeat ESI when the first injection directly and significantly provided improvement of the condition being treated may be considered medically reasonable and necessary when the medical record documents at least 50% of sustained improvement in pain relief and/or improvement in function measured from baseline using SAME scale* for at least 3 months. If a patient fails to respond well to the initial ESI, a repeat ESI after 14 days can be performed, using a different approach, level and/or medication if appropriate, with the rationale and medical necessity for the second ESI documented in the medical record.
7. The ESIs should be performed in conjunction with conservative treatments.

*Note: The scales used to measure pain and/or disability must be documented in the medical record.

Limitations

1. Injections performed without image guidance or by ultrasound are not considered reasonable and necessary except in cases of documented contraindication to contrast media (e.g., allergy, pregnancy).
2. ESIs performed with biologicals or other substances not FDA designated for this use is considered investigational and not medically reasonable and necessary.
3. It is not considered medically reasonable and necessary to perform multiple blocks (ESI, sympathetic blocks, facet blocks, trigger point injections etc.) during the same session as ESIs, with the exception of a facet synovial cyst and ESI performed in the same session.
4. Use of Moderate or Deep Sedation, General Anesthesia, and Monitored Anesthesia Care (MAC) is usually unnecessary or rarely indicated for these procedures and therefore not considered medically reasonable and necessary. Even in patients with a needle phobia and anxiety, typically oral anxiolytics suffice. In exceptional and unique cases, documentation must clearly establish the need for such sedation in the specific patient.
5. ESIs to treat non-specific low back pain (LBP), axial spine pain, complex regional pain syndrome, widespread diffuse pain, pain from neuropathy from other causes, cervicogenic headaches are considered investigational and therefore are not considered medically reasonable and necessary.
6. ESIs are limited to a maximum of 4 sessions per spinal region in a rolling 12-month period.1
7. It is not considered medically reasonable and necessary for more than 1 spinal region to be injected in the same session.
8. It is not considered medically reasonable and necessary to perform TFESIs at more than 2 nerve root levels during the same session.

9. It is not considered medically reasonable and necessary to perform CESIs or ILESIs at more than 1 level during the same session.
10. It is not medically reasonable and necessary to perform CESIs or ILESIs bilaterally.
11. It is not medically reasonable and necessary to prescribe a predetermined series of ESIs.
12. It generally would not be considered medically reasonable and necessary for treatment with ESI to extend beyond 12 months. Frequent continuation of epidural steroid injections over 12 months may trigger a focused medical review. Use beyond 12 months requires the following:
    a. Pain is severe enough to cause a significant degree of functional disability or vocational disability.
    b. ESI provides at least 50% sustained improvement of pain and/or 50% objective improvement in function (using same scale as baseline).
    c. Rationale for the continuation of ESIs including but not limited to patient is high-risk surgical candidates, the patient does not desire surgery, recurrence of pain in the same location relieved with ESIs for at least 3 months.
    d. The primary care provider must be notified regarding continuation of procedures and prolonged repeat steroid use.
13. ESIs should not be performed when contraindicated including of the spinal cord, conus medullaris or cauda equina, suspicion or major risk factors for cancer.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan may consider epidural steroid injections for pain management when the coverage criteria are not met and for all other indications to be investigational*.

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Policy History

Original Effective Date: 05/28/2024

05/28/2024: Utilization Management Committee Review

Coding

The five-character codes included in this medical policy are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	62320, 62321, 62322, 62323, 64479, 64480, 64483, 64484
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

    1. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

    2. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Healthcare services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other healthcare provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the Health Plan Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.