Musculoskeletal Program Clinical Appropriateness Guidelines

Interventional Pain Management

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Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details. AIM Specialty Health disclaims any responsibility for the completeness or accuracy of the information contained herein.

Key to Revisions	Indicates
Blue	<u>Insertions</u>
Red	Deletions
Highlighting	Substantive content changes



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Description and Application of the Guidelines

AlM's Clinical Appropriateness Guidelines (hereinafter "AlM's Clinical Appropriateness Guidelines" or the "Guidelines") are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by AlM, the Guidelines establish objective and evidence-based, where possible, criteria for medical necessity determinations. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of healthcare
- To promote the most efficient and cost-effective use of services

AIM's guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up to date clinical principles and best practices. Relevant citations are included in the "References" section attached to each Guideline. AIM reviews all of its Guidelines at least annually.

AIM makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the AIM's Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, AIM considers the Guidelines to be important, proprietary information of AIM, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of AIM.

AIM applies objective and evidence-based criteria and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The AIM Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines. If requested by a health plan, AIM will review requests based on health plan medical policy/guidelines in lieu of the AIM's Guidelines.

The Guidelines may also be used by the health plan or by AIM for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

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General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a
 reasonable likelihood that the intervention will change management and/or lead to an improved outcome for
 the patient.

If these elements are not established with respect to a given request, 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

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered.

Status	Date	Action
Revised	03/09/2019	Retitled Pretest Requirements to "Clinical Appropriateness Framework" to summarize the components of a decision to pursue diagnostic testing. To expand applicability beyond diagnostic imaging, retitled Ordering of Multiple Studies to "Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions" and replaced imaging-specific terms with "diagnostic or therapeutic intervention." Repeated Imaging split into two subsections, "repeat diagnostic intervention" and "repeat therapeutic intervention."
Reviewed	07/11/2018	IMPP review
Revised	07/26/2016	IMPP revised
Created	03/30/2005	Original effective date

Epidural Injection Procedures and Diagnostic Selective Nerve Root Blocks

Description

Epidural steroid injection (ESI) involves the administration of corticosteroid via insertion of a needle into the epidural space surrounding the spinal nerve root. Despite the lack of consistent evidence to support its efficacy, the procedure is widely used in patients with chronic back, neck and radicular pain. In 2014, the US Food and Drug Administration issued a drug safety communication about epidural injection of glucocorticoids, citing the risk for rare but serious adverse effects (loss of vision, stroke, paralysis, and death). The best evidence supporting its use comes from trials that looked specifically at patients with radiculopathy due to disc herniation, where short term benefit has been demonstrated.

Injections may be performed as part of a diagnostic workup of radicular pain, or as a therapeutic modality when noninvasive treatment strategies have failed. Injections may be performed via an interlaminar approach, transforaminal approach, or caudal approach (through the sacral hiatus at the sacral canal).

Selective nerve root block is a related procedure that utilizes a small amount of anesthetic, injected via transforaminal approach, to anesthetize a specific spinal nerve. Diagnostic selective nerve root blocks are used to evaluate a patient's anatomical level and/or source of radicular pain and are often used in surgical planning and decision making.

General Requirements

<u>Documentation supporting medical necessity should be submitted at the time of the request and must include</u> the following components:

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including but not limited to the following: requirements for physical therapy AND at least one complementary conservative management strategy.

Physical therapy requirement includes ANY of the following:

- Physical therapy
- Physician or physical therapist-supervised therapeutic home treatment exercise program which includes flexibility and muscle strengthening exercises or physical therapy
- Exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record

Complementary conservative management requirement includes ANY of the following:

- Complementary alternative medicine including, but not limited to, chiropractic care, acupuncture, cognitive behavioral or massage therapy
- Anti-inflammatory medications and analgesics
- Manual therapy or spinal manipulation
- Prescription strength anti-inflammatory medications and analgesics
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants
- Alternative therapies such as acupuncture

• Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate. Exceptions may be considered on a case by case basis.

Reporting of symptom severity – Severity of pain and its associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refer to pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least two (2) ADLs and/or IADLs.

Imaging studies – All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologyist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Procedural Best Practices to Prevent Neurologic Complications

All providers are expected to adhere to the procedural best practices for epidural steroid injections established by the U.S. Food and Drug Administration (FDA) Safe Use Initiative in 2015. The FDA Safe Use Initiative convened an expert multidisciplinary working group and 13 specialty stakeholder societies to review the existing evidence regarding neurologic complications associated with epidural corticosteroid injections. Seventeen procedural clinical considerations aimed at enhancing the safety of these injections, including the appropriate use of particulate steroids, were published. Providers are strongly encouraged to review the consensus opinions of the multidisciplinary working group (see Safeguards to Prevent Neurologic Complications after Epidural Steroid Injections: Consensus Opinions from a Multidisciplinary Working Group and National Organizations, available at:

https://anesthesiology.pubs.asahq.org/article.aspx?articleid=2119175).

Note: Preauthorization is <u>required for notification purposes only (medical necessity review is not required)</u> when CPT 62320 and 62322 are used for post-procedural pain with any of the following ICD-10-CM diagnoses: G89.11 Acute pain due to trauma, G89.12 Acute post-thoracotomy pain, or G89.18 Other acute post procedural pain.

Criteria

Therapeutic Epidural Steroid Injection (ESI) of the cervical or lumbar spine may be indicated when ALL of the following criteria are met:

- Radicular pain (cervical or lumbar) or neurogenic claudication (lumbar) with associated functional impairment
- Evidence of nerve root compression or spinal stenosis (central or foraminal) is seen on an initial advanced imaging study (MRI or CT) performed within the previous 12 months and correlates with the clinical findings*
- The pain has not responded to at least 4 weeks of appropriate conservative management, unless there is evidence of radiculopathy, in which case ESI may be performed following 2 weeks of conservative management

*Note: The initial epidural injection for a given episode of pain in the lumbar spine may be performed without confirmatory advanced imaging if the exam findings are clearly diagnostic of nerve root compression or spinal stenosis.

Repeat Therapeutic ESI may be indicated when ALL of the following criteria are met:

An injection is considered a repeat injection if the last injection was performed within the previous 12 months. If 12 months or more have elapsed, it is considered a new (initial) injection.

- The prior injection produced at least a 50% reduction in pain with functional improvement of at least 3
 weeks' duration**
- Evidence of nerve root compression or spinal stenosis (central or foraminal) is seen on an initial advanced imaging study (MRI or CT) performed within the previous 12 months and correlates with the clinical findings
- The patient has a recurrence of pain with significant functional disability
- The patient continues to receive conservative treatment between injections

**Note: If the initial therapeutic injection did not result in pain relief, repeat injection may be indicated, provided that the injection is performed utilizing a different approach or type of steroid.

Diagnostic Selective Nerve Root Block (DSNRB), also known as diagnostic transforaminal injection, is defined as the injection of anesthetic only, for the purpose of determining the need for surgical intervention.

DSNRB may be indicated in the evaluation and diagnostic work-up of radicular pain following consultation with a spine surgeon in ANY of the following scenarios:

- To confirm nerve root compression or spinal stenosis (central or foraminal) noted on an advanced imaging study (MRI or CT) and that is consistent with, and appears to be contributing to, the patient's symptoms.
- To determine or confirm the (or most) symptomatic level (i.e., site of compression) in the presence of multi-level involvement for which the primary symptomatic level is unclear.
- When radiculopathy is highly suspected but cannot be confirmed with advanced imaging studies.

Procedural Requirements and Restrictions:

- Injections must be performed under fluoroscopy or CT guidance.
- A maximum of four (4) therapeutic injection sessions may be performed in each spinal region (cervical or lumbosacral) in a 12-month period.
- If the initial injection achieves a suboptimal pain response in newly diagnosed patients, a one-time second injection may be performed no sooner than 2 weeks following the initial injection. This second injection is exclusive of the 12-month limit.
- No more than two (2) transforaminal injections may be performed at a single setting (e.g., single level bilaterally or two levels unilaterally). Injecting one level bilaterally would be considered two injections. Injecting two levels, each unilaterally, would also be considered two injections.
- For caudal or cervical/lumbar interlaminar injections, only one injection per session may be performed and NOT in conjunction with a transforaminal injection. A session is defined as all ESIs or spinal procedures performed on a single day.
- After three injections in the same region, the total cumulative dose of steroid must be documented and may not exceed 240 mg of methylprednisolone or triamcinolone or 36 mg of betamethasone or 45 mg of dexamethasone.

Contraindications and Risks

The following conditions should prompt further evaluation prior to considering ESI:

 New onset of low back pain or neck pain in the setting of established malignancy, or where there is a suspicion of malignancy based on the clinical presentation

- New onset of low back pain or neck pain in persons with risk factors for spinal infection
- Comorbid conditions associated with increased risk of bleeding due to coagulopathy or treatment with anticoagulants
- Back pain in the setting of trauma

Additional contraindications include the following conditions:

- Cauda equina syndrome
- Conus medullaris syndrome
- Epidural hematoma
- Subarachnoid hemorrhage
- Epidural mass
- Spinal cord ischemia
- Spinal fracture which occurred less than 6 weeks prior to injection
- Demyelinating disease or other CNS processes which predispose to transverse myelitis
- Systemic infection
- Local infection at the injection site
- Uncontrolled diabetes

Exclusions

Indications other than those addressed in this guideline are considered **not medically necessary**, including but not limited to the following:

- Thoracic level ESI performed for thoracic pathology
- Moderate to severe myelopathy on clinical exam
- Myelopathy associated with intramedullary cord signal change on T1 or T2 weighted MRI
- Isolated axial neck pain or low back pain

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CPT Codes

The following code list may not be all-inclusive. Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

*Note: Preauthorization is <u>required for notification purposes only (medical necessity review is not required)</u> when CPT 62320 and 62322 are used for postprocedural pain with any of the following ICD-10-CM diagnoses: G89.11 Acute pain due to trauma, G89.12 Acute post-thoracotomy pain, or G89.18 Other acute post procedural pain.

0228T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level
0229T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; each additional level (List separately in addition to code for primary procedure)
0230T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level
0231T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; each additional level (List separately in addition to code for primary procedure)
62320*	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance

62321 Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT) 62322* Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance 62323 Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT) 64479 Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level 64480 Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional level (List separately in addition to code for primary procedure) 64483 Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level 64484 Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (List separately in addition to code for primary procedure)

Status	Date	Action
Revised	10/29/2019	Independent Multispecialty Physician Panel (IMPP) review. Added physical therapy or
		home therapy and one complementary modality to conservative management
		requirements, aligns with spine and joint surgery guidelines. Added statement
		regarding adherence to procedural best practices established by FDA Safe Use
		Initiative. Clarified intent around requirement for advanced imaging for repeat
		<u>injections.</u>
Revised	05/18/2019	Reporting of symptom severity: expanded to include IADLs as functional impairment.
		Criteria: Updated time period of initial advanced imaging. Added definition and
		frequency of repeat therapeutic epidural steroid injection. Updated maximum
		number of annual injections. Added criteria for subsequent injection after suboptimal
		initial response.
Revised	01/01/2019	Added codes 0228T, 0229T, 0230T, and 0231T
Reviewed	09/12/2018	IMPP review
Revised	07/01/2018	Definitions, CPT Codes – Added Note stating preauthorization not required for CPT
		codes 62320 and 62322 for post-procedural pain with ICD-10 codes G89.11, G89.12,
		or G89.18. Criteria, Repeat Therapeutic ESI – Added clarification for therapeutic
		injections. Criteria, Procedural Requirements – Added clarifications for injection
		sessions and two levels unilaterally.
Reviewed	12/12/2017	IMPP review
Created	11/01/2017	Original effective date

Paravertebral Facet Injection/Nerve Block/Neurolysis

Description

Paravertebral facet joints, also referred to as zygapophyseal joints or Z-joints, have been implicated as a source of chronic neck and low back pain with a prevalence of up to 70% in the cervical spine, and up to 30% in the lumbar spine. Neither physical exam nor imaging has adequate diagnostic power to confidently identify the facet joint as a pain source. Facet joint injection techniques have evolved primarily as a diagnostic tool for pain originating in these joints, but have been widely utilized to treat chronic pain shown to be of facet origin.

Injections may be performed at one of two sites, either the joint itself (intraarticular injection) or the nerve that supplies it (medial branch of the dorsal ramus of segmental spinal nerves). Diagnostic injections are performed with an anesthetic agent alone, while therapeutic injections involve administration of a corticosteroid, with or without an anesthetic. Following confirmation of facet pathology using a diagnostic medial branch block (MBB), select patients may undergo a radiofrequency nerve ablation procedure. Studies have validated the efficacy of this intervention in chronic pain of facet origin.

General Requirements

<u>Documentation supporting medical necessity should be submitted at the time of the request and must include the following components:</u>

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including but not limited to the following: requirements for physical therapy AND at least one complementary conservative management strategy.

Physical therapy requirement includes ANY of the following:

- Physical therapy
- Physician or physical therapist-supervised therapeutic home treatment exercise program which includes flexibility and muscle strengthening exercises or physical therapy
- Exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record

Complementary conservative management requirement includes ANY of the following:

- Complementary alternative medicine including, but not limited to, chiropractic care, acupuncture, cognitive behavioral or massage therapy
- Anti-inflammatory medications and analgesics
- Manual therapy or spinal manipulation
- Prescription strength anti-inflammatory medications and analgesics
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants
- Alternative therapies such as acupuncture
- Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate. Exceptions may be considered on a case by case basis.

Reporting of symptom severity – Severity of pain and its associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refer to pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least two (2) ADLs and/or IADLs.

Imaging studies – All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologyist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Criteria

Procedures must be performed with image guidance, either fluoroscopy or CT

Patients must meet ALL of the following criteria:

- Moderate to severe pain with functional impairment of at least 3 months' duration
- Predominant axial pain that is not attributable to radiculopathy (with the exception of synovial cysts),
 myelopathy, or neurogenic claudication
- Physical exam findings which are consistent with the facet joint as the presumed source of pain
- Absence of non-facet pathology that could explain the source of the patient's pain, such as fracture, tumor, or infection
- Absence of prior surgical fusion at the proposed level
- Lack of improvement or resolution following at least 6 weeks of conservative management

Diagnostic Medial Branch Blocks (MBB) with local anesthetic

The primary utility of MBBs is to determine the suitability of the patient for a radiofrequency neurotomy of painful segmental levels in order to achieve long-term pain management. A positive response is defined as at least 80% relief of the primary (index) pain, with the onset and duration of relief being consistent with the agent employed.

Note: The patient must be experiencing pain at the time of the injection (generally rated at least 3 out of 10 in intensity) in order to determine whether a response has occurred. Provocative maneuvers or positions which normally exacerbate index pain should also be assessed and documented before and after the procedure.

<u>Diagnostic MBBs are to be performed with local anesthetic agents only. The concurrent use of steroids are not medically necessary as they may compromise the integrity of the diagnostic test.</u>

- Dual MBBs, defined as injections performed in the same location(s) on two separate occasions at least one week apart, are necessary to confirm the diagnosis due to the unacceptably high false positive rate of single MBB injections.
- A confirmatory injection is indicated only if the first injection results in a positive response. If the second injection also results in a positive response, the target joint(s) is/are the confirmed pain generator(s).
- If the first session of diagnostic MBBs <u>are is negative</u>, a maximum of ONE (1) additional session may be performed to determine the primary levels of involvement prior to proceeding with confirmatory blocks.

• For each covered spinal region (cervical or lumbar), diagnostic MBBs should be performed at no more than four (4) joints per session (e.g., two (2) bilateral levels or four three (43) unilateral levels per session).

Therapeutic Intraarticular (IA) Facet Joint Injections

Patients must meet BOTH of the following criteria:

- Evidence of nerve root compression due to a facet synovial cyst when seen on an advanced imaging study (MRI or CT) performed within the previous 12 months that correlates with the clinical findings
- Associated moderate to severe radicular pain and functional limitations
- Therapeutic IA injections may be repeated every 6 months only if the prior injection results in significant pain relief (at least 50%).
- For each covered spinal region (cervical or lumbar), IA facet joint injections should be performed at no more than four (4) joints per session (e.g., two [2] bilateral levels or four [4] unilateral levels).
- The patient continues to receive conservative treatment between injections.

Thermal Medial Branch Radiofrequency Neurotomy (RFN)

- RFN may be offered to patients if dual diagnostic MBB injections each produce ≥ 80% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed.
- RFN may be performed at the same level no more than twice annually and only if the initial radiofrequency lesion results in significant pain relief (at least 50%) and improvement in patient specific ADLs for at least 6 months.
- For each covered spinal region (cervical or lumbar), RFN should be performed at no more than four (4) joints per session (e.g., two (2) bilateral levels or four three (43) unilateral levels).
- Repeat RFN to treat recurrent facet joint pain in a patient who has failed other conservative
 measures may be covered without repeating diagnostic MBB injections if the patient has
 experienced significant and prolonged relief of pain (at least 50% reduction for at least 5-6
 months) and improvement of function in the past following RF ablation.
- RFN may not be performed at C0-C1 or at C1-C2.

Procedural Limitations (MBB, IA)

- A maximum of six (6) facet joint procedural sessions per region (cervical or lumbar) may be performed in a 12-month period, regardless of type or indication.
- One additional diagnostic block may be indicated prior to a repeat neurotomy when there is diagnostic uncertainty about the source of pain.

Exclusions

Indications other than those addressed in this guideline are considered **not medically necessary**, including but not limited to the following:

- Diagnostic intraarticular facet joint injection
- Therapeutic medial branch block
- Therapeutic intraarticular facet joint injection for any other indication not listed above
- Use of corticosteroid with diagnostic MBB
- Diagnostic or therapeutic IA injection, medial branch block, or radiofrequency ablation in the thoracic region with the exception of C7-T1 and T12-L1
- Use of MBB or RFN in the setting of moderate to severe spondylolisthesis (grade 2 or higher)
- Use of MBB or RFN in the setting of an isolated pars defect
- Use of MBB or RFN at the level of a posterolateral fusion or posterior instrumentation prior fusion
- Use of chemical neurolysis for medial branch ablation
- Use of laser neurolysis for medial branch ablation
- Use of cryodenervation (cryoablation) for medial branch ablation
- Use of cooled radiofrequency denervation for medial branch ablation
- Use of pulsed radiofrequency denervation for medial branch ablation
- Any facet joint interventions performed under ultrasound guidance
- Intraarticular or extra-articular facet joint prolotherapy
- Radiofreguency neurolysis for sacroiliac (SI) joint pain

Selected References

- Boswell MV, Manchikanti L, Kaye AD, et al. A Best-Evidence Systematic Appraisal of the Diagnostic Accuracy and Utility of Facet (Zygapophysial) Joint Injections in Chronic Spinal Pain. Pain physician. 2015;18(4):E497-533.
- 2 Centers for Medicare and Medicaid Services, Local Coverage Determinations: Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy, (2016) Baltimore MD, 62 pgs.
- 3 Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine. 2009;34(10):1066-77.
- 4 COST B13 Working Group on Guidelines for Chronic Low Back Pain, Airaksinen O, Brox JI, et al. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. Eur Spine J. 2006;15 Suppl 2:S192-300.
- 5 Falco FJ, Manchikanti L, Datta S, et al. Systematic review of the therapeutic effectiveness of cervical facet joint interventions: an update. Pain physician. 2012;15(6):E839-68.
- 6 Lee CHL, J.; Kang, J. D. et al. . Laminoplasty versus laminectomy and fusion for multilevel cervical myelopathy: a meta-analysis of clinical and radiological outcomes. J Neurosurg Spine. 2015;22(6):589-95.
- Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain physician. 2013;16(2 Suppl):S49-283.
- 8 Manchikanti LB, R. M.; Falco, F. J.; Kaye, A. D.; Hirsch, J. A. Do Epidural Injections Provide Short- and Long-term Relief for Lumbar Disc Herniation? A Systematic Review. Clin Orthop. 2015;473(6):1940-56.
- 9 North American Spine Society, Facet Joint Interventions NASS Coverage Policy Recommendations, (August 2016) Burr Ridge IL, 16 pgs.

CPT Codes

The following code list may not be all-inclusive. Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

0213T Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure) 0214T Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (List separately in addition to code for primary procedure) 0215T Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure) Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating 0216T that joint) with ultrasound guidance, lumbar or sacral; single level 0217T Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (List separately in addition to code for primary procedure) 0218T Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure) 64490 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophysial) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level 64491 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophysial) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level (List separately in addition to code for primary procedure) 64492 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure) 64493 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level 64494 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for primary procedure) 64495 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure) 64625 Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or

Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT);

computed tomography)

cervical or thoracic, single facet joint

64633

Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)

Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint

Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)

Destruction by neurolytic agent; other peripheral nerve or branch

Status	Date	Action
Revised	10/29/2019	Independent Multispecialty Physician Panel (IMPP) review. Added physical therapy or
		home therapy and one complementary modality to conservative management
		requirements, aligns with spine and joint surgery guidelines. Removed indication for 4
		unilateral medial branch blocks per session. Limited use of intra-articular steroid
		injection to mechanical disruption of a facet synovial cyst.
Revised	01/01/2020	2020 Annual CPT Code Update. Added CPT code 64625.
Revised	05/18/2019	Reporting of symptom severity: expanded to include IADLs as functional impairment.
		Updated injection frequency limitations.
Revised	01/01/2019	Added exclusion for radiofrequency neurolysis for sacroiliac joint pain.
		Added codes 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 64640.
Reviewed	09/12/2018	IMPP review
Revised	07/01/2018	Criteria, Predominant axial pain – Moved exception of synovial cysts from note to
		second bullet. Criteria, Diagnostic MBB – Replaced bullet specifying maximum of 2
		levels in a single session with additional levels (2 bilateral or 4 unilateral) and sessions
		(max 4 joints per session). Criteria, Therapeutic IA Facet Joint Injections – Added
		bullet specifying maximum of 4 joints per session (2 bilateral or 4 unilateral levels)
		and sessions (max 4 joints per session). Added bullet requiring conservative
		treatment between injections. Exclusions – Added five exclusions for medial branch
		ablation. Removed exclusion for non-thermal radiofrequency modalities.
Reviewed	12/12/2017	IMPP review
Created	11/01/2017	Original effective date

Regional Sympathetic Nerve Block

Description

Sympathetic blockade includes procedures that temporarily obstruct the local function of the sympathetic nervous system. Anesthetic is injected directly into sympathetic neural structures that serve affected limb(s), such as the stellate ganglion or the lumbar sympathetic chain. Radiologic guidance (fluoroscopy or CT scan) is utilized to ensure accuracy.

Regional sympathetic nerve block has been utilized primarily for treatment of complex regional pain syndrome. Despite limited evidence supporting its efficacy, it has also been investigated in treating a number of other pain syndromes thought to be sympathetically mediated.

This and other interventional procedures should be considered only when the full spectrum of noninvasive management strategies has not provided sufficient relief of symptoms.

General Requirements

<u>Documentation supporting medical necessity should be submitted at the time of the request and must include the following components:</u>

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including but not limited to the following: requirements for physical therapy AND at least one complementary conservative management strategy.

Physical therapy requirement includes ANY of the following:

- Physical therapy
- Physician or physical therapist-supervised therapeutic home treatment exercise program which includes flexibility and muscle strengthening exercises or physical therapy
- Exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record

Complementary conservative management requirement includes ANY of the following:

- Complementary alternative medicine including, but not limited to, chiropractic care, acupuncture, cognitive behavioral or massage therapy
- Anti-inflammatory medications and analgesics
- Manual therapy or spinal manipulation
- Prescription strength anti-inflammatory medications and analgesics
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants
- Alternative therapies such as acupuncture
- Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate. Exceptions may be considered on a case by case basis.

Reporting of symptom severity – Severity of pain and its associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors in determining the need for intervention. For purposes of this

guideline, significant pain and functional impairment refer to pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least two (2) ADLs and/or IADLs.

Imaging studies – All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologyist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Criteria

Complex Regional Pain Syndrome (Type I or Type II)

Diagnostic criteria for Complex Regional Pain Syndrome (CRPS) must be met:

- Continuing pain that is disproportionate to any inciting event
- At least 1 symptom reported in at least THREE (3) of the following categories:
 - Sensory: Hyperesthesia or allodynia
 - Vasomotor: Temperature asymmetry, skin color changes, skin color asymmetry
 - Sudomotor/edema: Edema, sweating changes, or sweating asymmetry
 - Motor/trophic: Decreased range of motion, motor dysfunction (eg, weakness, tremor, dystonia), or trophic changes (eg, hair, nail, skin)
- At least ONE (1) sign at time of evaluation in at least TWO (2) of the following categories:
 - Sensory: Evidence of hyperalgesia (to pinprick), allodynia (to light touch, temperature sensation, deep somatic pressure, or joint movement)
 - Vasomotor: Evidence of temperature asymmetry (>1°C), skin color changes or asymmetry
 - Sudomotor/edema: Evidence of edema, sweating changes, or sweating asymmetry
 - Motor/trophic: Evidence of decreased range of motion, motor dysfunction (eg, weakness, tremor, dystonia), or trophic changes (eg, hair, nail, skin)
 - No other diagnosis better explaining the signs and symptoms
- In addition, ALL of the following are required:
 - Level of pain and disability in the moderate to severe range
 - o Failure of at least 2 weeks of conservative management
 - Documentation of ongoing participation in a comprehensive pain management program

The performance of an initial diagnostic regional sympathetic block is considered medically necessary to establish the presence or absence of sympathetically mediated complex regional pain syndrome. A positive response is defined as a significant reduction in pain (at least 80% reduction) and improvement in function with the duration of relief being consistent with agent employed, and objective evidence that the block was physiologically effective.

For procedures that target pain in a limb, there must be documentation of a rise in temperature from baseline of the ipsilateral limb. A sensory exam is required to confirm absence of spread to adjacent nerve roots.

Following a positive response to the initial diagnostic block, additional diagnostic and therapeutic regional sympathetic blocks, up to maximum of six (6) total blocks, performed at a frequency of no more than two (2) per week, may be considered medically necessary when ALL the following criteria have been met:

- Benefit has been demonstrated by prior blocks as evidenced by ALL of the following:
 - Decreased use of pain medication
 - Improved level of function (e.g., increased range of motion, strength, and use of extremity in activities of daily living)
 - Improved tolerance to touch (e.g., decreased allodynia) or other objective measures
- The intervention is being provided as part of a comprehensive pain management program (physical therapy, patient education, psychosocial support, and oral medication).
- If there is no sustained benefit in pain and function after three (3) sympathetic blocks from baseline (pre block) pain and function, then additional blocks are not warranted.
- If there is sustained benefit after the first three (3) sympathetic blocks then up to three (3) additional blocks may be performed.

Exclusions

Indications other than those addressed in this guideline are considered **not medically necessary**, including but not limited to the following:

- Use of intravenous phentolamine (Regitine) as a diagnostic test for CRPS
- Intravenous regional sympathetic block utilizing guanethidine
- Intrapleural analgesia for treatment of CRPS

Selected References

- Harden RN, Oaklander AL, Burton AW, Perez RS, Richardson K, Swan M, Barthel J, Costa B, Graciosa JR, Bruehl S; Reflex Sympathetic Dystrophy Syndrome Association. Complex regional pain syndrome: practical diagnostic and treatment guidelines, 4th edition. Pain Med. 2013 Feb;14(2):180-229. doi: 10.1111/pme.12033. Epub 2013 Jan 17.
- 2 O'Connell NEW, B. M.; Gibson, W., et al. . Local anaesthetic sympathetic blockade for complex regional pain syndrome. Cochrane Database Syst Rev. 2016;7:CD004598.
- 3 Zernikow BW, J.; Brehmer, H.; Hirschfeld, G.; Maier, C. Invasive treatments for complex regional pain syndrome in children and adolescents: a scoping review. Anesthesiology. 2015;122(3):699-707.

CPT Codes

The following code list may not be all-inclusive. Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

64510 Injection, anesthetic agent; stellate ganglion (cervical sympathetic)

Injection, anesthetic agent; lumbar or thoracic (paravertebral sympathetic)

Status	Date	Action
Revised	10/29/2019	Independent Multispecialty Physician Panel (IMPP) review. Added physical therapy or
		home therapy and one complementary modality to conservative management
		requirements, aligns with spine and joint surgery guidelines.
Revised	05/18/2019	Reporting of symptom severity: expanded to include IADLs as functional impairment.
Reviewed	09/12/2018	IMPP review
Created	11/01/2017	Original effective date

Sacroiliac Joint Injection

Description

Non-inflammatory sacroiliac (SI) joint complex pain may be traumatic, degenerative, or due to adjacent segment disease (after lumbar fusion or total hip replacement). Sacroiliitis is associated with inflammatory spondyloarthropathies. Pain arising from the sacroiliac joint complex typically radiates to the gluteal area and posterior hip. In addition to localized tenderness over the sacroiliac joint, there are additional examination maneuvers which suggest the diagnosis.

General Requirements

<u>Documentation supporting medical necessity should be submitted at the time of the request and must include the following components:</u>

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including but not limited to the following: requirements for physical therapy AND at least one complementary conservative management strategy.

Physical therapy requirement includes ANY of the following:

- Physical therapy
- Physician or physical therapist-supervised therapeutic home treatment exercise program which includes flexibility and muscle strengthening exercises or physical therapy
- Exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record

Complementary conservative management requirement includes ANY of the following:

- Complementary alternative medicine including, but not limited to, chiropractic care, acupuncture, cognitive behavioral or massage therapy
- Anti-inflammatory medications and analgesics
- Manual therapy or spinal manipulation
- Prescription strength anti-inflammatory medications and analgesics
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants
- Alternative therapies such as acupuncture
- Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate. Exceptions may be considered on a case-by-case basis.

Reporting of symptom severity – Severity of pain and its associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refer to pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least two (2) ADLs and/or IADLs.

Imaging studies – All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologyist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Criteria

Procedures must be performed with image guidance, either fluoroscopy or CT.

Patients must meet ALL of the following inclusion criteria to be able to proceed with diagnostic intraarticular sacroiliac joint injections, therapeutic intraarticular sacroiliac joint injections, or diagnostic lateral branch blocks.

- There is persistent typically unilateral non-radicular pain that is predominantly below the lumbar spine (L5) and is primarily localized over the region of the sacroiliac joint and has been present for at least 3 months.
- Examination shows localized tenderness with palpation over the sacral sulcus just inferior to the posterior superior iliac spine (PSIS) in the absence of tenderness of equal severity elsewhere (e.g., lumbar spine, greater trochanter, hip, coccyx)
- At least ONE of the following provocative tests is positive: pelvic distraction test, lateral iliac compression test, sacral compression/thrust test, thigh thrust test, FABER (Patrick's test), and Gaenslen's test.
- There is no evidence of acute or subacute radicular pain/radiculopathy or neurogenic claudication. If there is evidence of radicular pain/radiculopathy or neurogenic claudication the condition must be fixed and stable and have been maximally addressed through comprehensive treatment.
- Lack of adequate improvement following 6 weeks of conservative management.

Diagnostic Intraarticular Sacroiliac Joint Injections

The primary utility of diagnostic intraarticular sacroiliac joint injections is to determine if the sacroiliac joint is the primary pain generator for the patient's low back pain.

- Dual intraarticular sacroiliac joint injections, defined as injections performed in the same joint on two separate occasions, are necessary to confirm the diagnosis due to the unacceptably high false positive rate of single intraarticular sacroiliac joint injections.
- A second confirmatory injection is indicated only if the first injection produces greater than or equal to 75% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed. This confirmatory block confirms the tested sacroiliac joint as the source if the index pain is reduced by greater than or equal to 75% and the onset and minimum duration of relief is consistent with the agent employed.
- Anesthetic volume must be limited to 1.5 cc to maximize the anatomic specificity of the procedure. Concurrent injection of steroid is not appropriate for diagnostic sacroiliac joint injection.
- The day of the procedure, the patient's pain must be at least 3/10 severity at rest or during a
 consistently provocative maneuver, which will allow accurate monitoring of the response to the
 injection.

Therapeutic Intraarticular (IA) Sacroiliac Joint Injections

• Therapeutic IA sacroiliac joint injections are performed with the use of corticosteroid with or without the use of anesthetic.

 Total injection volume should be limited to 2.0 cc to minimize extravasation of the injectate outside of the sacroiliac joint.

Repeat Therapeutic Intraarticular Sacroiliac Joint Injections

- Repeat injection is considered medically necessary if symptoms recur and the patient has
 demonstrated at least 50% pain relief, and improvement in patient-specific ADLs, for at least 6 weeks
 after a previous injection.
- Injections may not be repeated at intervals of less than 3 months, with a maximum of three (3) injections in a 12-month period.
- Treatment with therapeutic injections should be accompanied by participation in an ongoing active rehabilitation program, home exercise program, or functional restoration program.

Ultrasound-guidance

Ultrasound is the only imaging-guidance appropriate for use during pregnancy

Exclusions

Indications other than those addressed in this guideline are considered **not medically necessary**, including but not limited to the following:

- Intraarticular sacroiliac joint injections performed on the same day as other spine injection procedures.
- Use of corticosteroid with diagnostic intraarticular sacroiliac joint injections

Selected References

- 1 Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine. 2009;34(10):1066-77.
- 2 COST B13 Working Group on Guidelines for Chronic Low Back Pain, Airaksinen O, Brox JI, et al. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. Eur Spine J. 2006;15 Suppl 2:S192-300.
- 3 Hansen H, Manchikanti L, Simopoulos TT, et al. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. Pain physician. 2012;15(3):E247-78.
- 4 Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain physician. 2013;16(2 Suppl):S49-283.
- 5 Muheremu AN, X.; Wu, Z.; et al. . Comparison of the short- and long-term treatment effect of cervical disk replacement and anterior cervical disk fusion: a meta-analysis. Eur. 2015;25 Suppl 1:S87-100.
- 6 North American Spine Society, Sacroiliac Joint Injections NASS Coverage Policy Recommendations, (2015), Burr Ridge IL, 11 pgs.
- 7 Zaidi HAM, A. J.; Dickman, C. A. Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. J Neurosurg Spine. 2015;23(1):59-66.

CPT/HCPCS Codes

The following code list may not be all-inclusive. Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

- 27096 Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed
- G0260 Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

Status	Date	Action	
Revised	10/29/2019	Independent Multispecialty Physician Panel (IMPP) review. Added physical therapy or	
		home therapy and one complementary modality to conservative management	
		requirements, aligns with spine and joint surgery guidelines.	
Revised	05/18/2019	Reporting of symptom severity: expanded to include IADLs as functional impairment.	
		Lowered threshold in demonstrated pain reduction from the initial injection.	
Reviewed	09/12/2018	IMPP review	
Revised	07/01/2018	Added HCPCS code G0260	
Created	11/01/2017	Original effective date	

Spinal Cord and Nerve Root Stimulators

Description

Spinal cord stimulators, also known as dorsal column stimulators ("stimulators"), are implantable devices used to treat chronic pain. Electrodes are surgically placed within the dura mater via laminectomy, or by percutaneous insertion into the epidural space. Low voltage electrical signals are delivered to the dorsal column of the spinal cord in order to override or mask sensations of pain.

The patient's pain distribution pattern determines the level at which the stimulation lead is placed. The lead may incorporate 4 to 8 electrodes, with 8 electrodes typically used for complex pain patterns, such as bilateral pain or pain extending from the limbs to the trunk.

Implantation is typically a two-step process. Initially, the electrode is temporarily implanted in the epidural space, allowing a trial period of stimulation. Once treatment effectiveness is confirmed (defined as at least 50% reduction in pain), the electrodes and radio receiver/ transducer are permanently implanted.

Extensive programming of the neurostimulators is often required to achieve optimal pain control.

General Requirements

<u>Documentation supporting medical necessity should be submitted at the time of the request and must include the following components:</u>

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including but not limited to the following: requirements for physical therapy AND at least one complementary conservative management strategy.

Physical therapy requirement includes ANY of the following:

- Physical therapy
- Physician or physical therapist-supervised therapeutic home treatment exercise program which includes flexibility and muscle strengthening exercises or physical therapy
- Exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record

Complementary conservative management requirement includes ANY of the following:

- Complementary alternative medicine including, but not limited to, chiropractic care, acupuncture, cognitive behavioral or massage therapy
- Anti-inflammatory medications and analgesics
- Manual therapy or spinal manipulation
- Prescription strength anti-inflammatory medications and analgesics
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants
- Alternative therapies such as acupuncture
- Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate. Exceptions may be considered on a case by case basis.

Reporting of symptom severity – Severity of pain and its associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refer to pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least two (2) ADLs and/or IADLs.

Imaging studies – All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologyist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Criteria

Spinal Cord Stimulation (including burst, high frequency, and traditional stimulation methods)

Stimulator Trial may be indicated when ALL of the following criteria are met:

- The patient has chronic intractable neuropathic pain of the trunk and/or limbs associated with at least ONE (1) of the following conditions:
 - Lumbosacral arachnoiditis as documented by high levels of protein in the cerebrospinal fluid and/or imaging (MRI or myelography)
 - Nerve root injuries that are post-surgical or post-traumatic, including post-laminectomy syndrome (failed back syndrome)
 - Complex regional pain syndrome (CRPS), type I or type II (formerly known as reflex sympathetic dystrophy or causalgia)
- Severe pain and disability with documented pathology or an objective basis for the pain
- Dorsal column stimulation is being used as a late or last resort after documented failure of at least 6 consecutive months of physician-supervised conservative management.
- There is no evidence of existing untreated drug addiction.
- The patient has been evaluated by a pain management specialist prior to implantation.
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient must be available.
- At least one surgical opinion has been obtained to ensure that the patient does not have a surgically correctable lesion.
- Documentation of an evaluation by a mental health provider (e.g., a face-to-face assessment with or
 without psychological questionnaires and/or psychological testing) that confirms no evidence of an
 inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression,
 psychosis) that would negatively impact the success of a spinal cord stimulator or contraindicate its
 placement.

Stimulator Implantation (Permanent) may be indicated when ALL of the following criteria are met:

- The patient meets all of the criteria for a stimulator trial
- A stimulator trial of at least three (3) days duration has been performed
- Documented pain reduction and functional improvement following the stimulator trial with at least a 50% reduction of target pain or analgesic medication use, and specific evidence of improved function

Stimulator Revision or Removal may be indicated when ANY of the following criteria are met:

- Stimulator hardware complication including
 - Lead migration
 - Infection
 - Painful generator site

- Stimulator response complications including
 - Loss of effectiveness
 - Patient intolerance
 - Development of new neurologic deficits
- Planned procedure where stimulators are contraindicated including
 - Magnetic resonance imaging (MRI)
 - Automatic implantable cardioverter defibrillator (AICD)

Dorsal Root Ganglion (DRG) Stimulation may be indicated as an alternative to dorsal column stimulation in patients with moderate to severe chronic intractable pain of the lower limbs from complex regional pain syndrome (CRPS) types I or II and who otherwise meet above criteria for spinal cord stimulator trial or implantation.

Exclusions

Indications other than those addressed in this guideline are considered **not medically necessary**, including but not limited to the following:

- Use of spinal cord stimulation for the treatment of critical limb ischemia to forestall amputation, refractory angina pectoris, heart failure, and cancer-related pain.
- Dorsal root ganglion neurostimulation for any non-CRPS lower extremity indication
- Dorsal root ganglion neurostimulation in patients with CRPS lower extremity who currently have a spinal cord stimulator or who have previously failed spinal cord stimulation therapy
- Simultaneous placement of a dorsal column and dorsal root ganglion stimulator
- Replacement of a conventional spinal cord stimulator with a burst, high frequency, or DRG stimulator in the absence of an indication for stimulator removal

Selected References

- 1 Centers for Medicare and Medicaid Services, National Coverage Determination for Electrical Nerve Stimulators, (1995) Baltimore MD, 3 pgs.
- 2 Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine. 2009;34(10):1066-77.
- 3 COST B13 Working Group on Guidelines for Chronic Low Back Pain, Airaksinen O, Brox JI, et al. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. Eur Spine J. 2006;15 Suppl 2:S192-300.
- 4 Lewis RAW, N. H.; Sutton, A. J., et al. . Comparative clinical effectiveness of management strategies for sciatica: systematic review and network meta-analyses. Spine J. 2015;15(6):1461-77.
- Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain physician. 2013;16(2 Suppl):S49-283.

CPT Codes

The following code list may not be all-inclusive. Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

63650 Percutaneous implantation of neurostimulator electrode array, epidural

63655 Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural

63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Status	Date	Action
Revised	10/29/2019	Independent Multispecialty Physician Panel (IMPP) review. Added physical therapy or
		home therapy and one complementary modality to conservative management
		requirements, aligns with spine and joint surgery guidelines. New indication for dorsal
		root ganglion stimulation. Clarified exclusions for spinal cord and dorsal root ganglion
		stimulation.
Revised	05/18/2019	Reporting of symptom severity: expanded to include IADLs as functional impairment.
		Added criteria for revision/removal of spinal cord stimulator. Separated criteria of
		trial stimulation and permanent stimulator implantation. Added exclusion of dorsal
		root ganglion stimulation.
Revised	01/01/2019	Added codes C1767, C1820, C1822, L8679, L8680, L8682, L8683, L8685, L8686, L8687,
		and L8688
Reviewed	09/12/2018	IMPP review
Created	11/01/2017	Original effective date