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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

Low back pain (LBP) is reported by over 80% of adults in their lifetime. While long-term outcomes are favorable, millions of individuals have persistent symptoms. Subacute LBP has a duration of 4 to 12 weeks and chronic LBP continues for 12 weeks or more (Chou, 2021) but less than six months (Hayes, 2022). Globally LBP impacts approximately 10% of individuals – 17% of patients have severe chronic LBP without lower extremity pain while 26% have back and leg pain. The condition can cause severe pain Patients with chronic, nonresponsive pain at any spinal level will present with constant pain that can limit mobility, the ability to work and/or perform activities of daily living (ADLs), cause depression and other psychosocial impairments, and reduce quality of life. (Hayes, 2022).

Facet joints are pairs of joints located near the bony spine and not near the spinal cord; the joints provide stability to the spine and improve motion. Facet joint injections (FJIs) are used to treat chronic nonmalignant spinal pain originating with a facet joint in the lumbar, thoracic, or cervical spine. A FJI is performed by injecting local anesthetic (with or without a corticosteroid) into one or more facet joint(s).

A medial branch block (MBB) is used to treat chronic nonmalignant spinal pain of facet joint origin in the lumbar, thoracic, or cervical spine (Hayes, 2021). An MBB is performed by injecting local anesthetic (with or without a corticosteroid) into the vicinity of the medial branch nerves of the dorsal rami (which innervate the facet joints of the spine). (Hayes, 2022 & 2021).

COVERAGE POLICY

Please refer to Radiofrequency Ablation for Chronic Back Pain (MCP-085) for related criteria.

Diagnostic facet joint injections / MBBs **may be considered medically necessary** for facet joint pain in adults ages >18 years as part of a comprehensive pain management treatment program when **ALL** the following are met:

- 1. Presence of chronic severe back pain (cervical or lumbar) that is predominantly axial and not associated with radiculopathy or neurogenic claudication and has been present for a minimum of 3 months that is:
 - Resulting from disease, injury, or surgery; AND
 - Confirmed by provocative testing resulting in reproducible pain (e.g., hyperextension, rotation).

AND

- 2. Pain is affecting activity of daily living functional ability (> 4 on the NRS Pain Rating Scale*); AND
- 3. Physical evaluation has ruled out that no non-facet pathology to explain the source of the patient's pain (e.g., discogenic, sacroiliac joint pain, disc herniation, fracture, tumor, infection); **AND**

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- 4. Has tried and failed a minimum of 3 months of conservative therapy for the current episode of pain that includes:
 - Physical therapy (PT) for a minimum of 4 weeks (3-4x per week for a total of 12 sessions); OR
 - Submitted documentation to explain why PT is contraindicated note that PT may be contraindicated if any of the following are present:
 - i. Pain worsened with PT: OR
 - ii. PT tried but was not able to be tolerated.

AND

- Activity or exercise modification; AND
- Drug therapy (e.g., NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, opiates).
 - * The Numeric Rating Scale (NRS-11): Rating Pain Level. 0: No Pain, 1 3: Mild Pain (nagging, annoying, interfering little with ADLs), 4 6: Moderate Pain (interferes significantly with ADLs), 7 10: Severe Pain (disabling; unable to perform ADLs).

Additional Criteria

The primary efficacy of diagnostic facet injections / MBBs is to determine the appropriateness for a radiofrequency neurotomy of painful segmental levels to achieve long-term pain management. A positive response is defined as at least 70% relief of the primary (index) pain with the onset and duration of relief being consistent with the local anesthetic employed and measured by a decrease in pain medication and increase in functional ability.

- 1. For each covered spinal region (cervical or lumbar), diagnostic facet joint injections / MBBs should be performed at <u>no more than four (4) joints per session</u> (e.g., two [2] bilateral levels or four [4] unilateral levels).
- 2. A second diagnostic facet joint injection / MBB (e.g., dual), performed to confirm the validity of the clinical response to the initial facet joint injection performed in the same location(s) on two separate occasions at least one week apart, **are considered medically necessary** to confirm the diagnosis due to the unacceptably high false positive rate of single MBB injections when **ALL** the following criteria are met:
 - Administered at the same level as the initial block; AND
 - Initial diagnostic facet joint injection produced a positive response (e.g., at least 70% relief of facet mediated pain for at least the expected minimum duration of the effect of the local anesthetic); **AND**
 - Radiofrequency joint denervation / ablation procedure is being considered.
- 3. A maximum of six (6) facet joint procedural sessions per region (cervical or lumbar) may be performed in a 12-month period.
- 4. More than two facet injections / MBBs at the same level are considered therapeutic rather than diagnostic. Therapeutic facet injections / MBBs are considered NOT medically necessary.

Limitations and Exclusions

- Therapeutic or subsequent facet injections / MBBs at the same level are considered experimental, investigational, or unproven as there is insufficient data to support the effectiveness of these interventions.
- Facet joint injections in the thoracic region are considered experimental, investigational, and unproven.
- The performance of facet joint injections / MBBs blocks in the presence of an untreated radiculopathy is considered not medically necessary.
- The performance of injections/blocks no more than four (4) joints per session (e.g., two [2] bilateral levels or four
 [4] unilateral levels) on the same day is considered not medically necessary.
- The following are considered <u>contraindications</u> to the procedure and require physician documentation of medical necessity in the presence of any the following:
 - Previous history of spinal fusion in the area treated
 - Unstable medical conditions or psychiatric illness
 - Current anticoagulation treatment
 - Current systemic infection or infection over the injection site

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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

Baroncini et al. (2021) performed a systematic review comparing results of injections obtained with different compounds in the management of LBP originating from facet joints. A literature search conducted in October 2020 that identified data from 587 patients; mean follow-up was 12.4 ± 10.5 months, mean age was 51.3 ± 9.6 years old, and 57% patients were women. The authors reported that steroids reduced the numeric rating scale by 28% - there was also an improvement of Oswestry Disability Index (ODI) by 13%. Local anesthetics promoted an improvement of the ODI by 9.8%. Sarapin resulted in a reduction of NRS by 44% and an improvement the ODI by 15%; combined with steroids, sarapin promoted a reduction of NRS by 47% and an improvement of the ODI by 12%.

Perolat et al. (2018) analyzed LBP and lumbar facet joints, a common source of pain for 15-45% of adults; facet arthrosis is the most common form of facet pathology. The authors explore specific interventional facet joint management. Diagnostic positive facet joint block can specify facet joints as the source of a patient's pain and may benefit from facet joint neurolysis (especially radiofrequency or cryoablation). Diagnostic blocks are important for diagnosing facet syndrome. If diagnostic blocks supplying specific facet joints can relieve pain, denervation procedure lesioning of the same nerves can be performed for long term outcomes. Radiologists are particularly important in the management of patients with LBP with respect to pain management from diagnosis to interventional management.

Manchukonda et al. (2007) performed a retrospective review with the objective of evaluating the occurrence of facet joint pain in chronic spinal pain of cervical, thoracic, and lumbar origin by using controlled, comparative local anesthetic blocks and evaluation of false-positive rates of single blocks in the diagnosis of chronic spinal pain of facet joint origin. Facet joints are clinically important sources of chronic cervical, thoracic, and lumbar spine pain. Previous studies show the value and validity of controlled, comparative local anesthetic blocks in the diagnosis of FJ pain (prevalence of 15-67% in lumbar, thoracic, and cervical regions). False-positive rates of single diagnostic blocks ranged from 17% to 63%. A total of 500 consecutive patients were analyzed; all had received controlled, comparative local anesthetic blocks of medial branches for the diagnosis of facet or zygapophysial joint pain. Diagnostic blocks used 0.5 mL of 1% lidocaine per nerve; patients with lidocaine-positive results were further studied using 0.5 mL of 0.25% bupivacaine per nerve on a separate occasion. Positive responses included patients with at least 80% pain relief from a block of at least 2 hours in duration when lidocaine was used, and at least 3 hours than the duration of relief with lidocaine when bupivacaine was used. Patients were also evaluated in terms of their ability to perform movements that were previously painful. In conclusion, 438 patients were included. Facet joint prevalence was 39% in the cervical spine; 34% in the thoracic pain; and 27% in the lumbar spine. The false-positive rate with a single block in the cervical region was 45%, 42% in the thoracic region, and 45% in the lumbar region.

Studies primarily address the diagnosis and/or treatment of patients with chronic low (lumbar) back pain and involved patients with cervical or thoracolumbar pain. Outcome measures varied among studies but generally included assessment of pain, assessment of ability to perform functions of daily living and to return to previous work, use of pain medication, and patient satisfaction. The randomized controlled trials reported a relatively large placebo effect, with improvement in all groups, but no difference in clinical response between local anesthetic block and placebo (saline injection). One study reported some improvement in lumbar mobility but no greater improvement in pain or disability when facet injections were added to an exercise program compared with exercise alone. The uncontrolled studies reported conflicting results regarding the accuracy of facet blocks for identifying facet joint syndrome as a cause of chronic back pain, but all reported relief of pain in some patients following facet block. The Cochrane systematic review analyzed 21 randomized trials and found that there was no convincing evidence for the therapeutic efficacy of facet joint blocks in patients with lower back pain. The primary outcome measure was pain relief, and all studies that involved patients with LBP persisting longer than one month were reviewed. The overall body of evidence regarding facet injections as a treatment for chronic neck and back pain shows that while facet blocks are associated with some pain relief; most studies suggest that the effects are attributable to the anesthetic or placebo effect. (Staal et al., 2008; Nelemans et al., 2000).

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The 2015 AHRQ comparative effectiveness study on injection therapies for LBP concluded that the studies found no clear differences between various facet joint corticosteroid injections (intraarticular, extra-articular [peri-capsular], or medial branch) and placebo interventions (Chou et al., 2015).

National and Specialty Organizations

The American College of Radiology (ACR) (2021) published *Appropriateness Criteria: Low Back Pain* which provides evidence-based guidelines that are reviewed annually by a multidisciplinary expert panel. The ACR recommends imaging for patients with up to six weeks of medical management and PT but had minimal or no improvement in their back pain. Imaging is also recommended for patients that present with symptomology for a serious underlying condition (e.g., cauda equina syndrome, malignancy, fracture, or infection).

An updated 2020 practice guideline published by the **American Society of Interventional Pain Physicians (ASIPP)** states the following (Manchikanti et al., 2020; ¹⁻² Manchikanti et al., 2013):

- Lumbar Spine Diagnosis: The level of evidence is I to II with moderate to strong strength of recommendation for lumbar diagnostic facet joint nerve blocks; ten relevant diagnostic accuracy studies with 4 of 10 studies utilizing controlled comparative local anesthetics with concordant pain relief criterion standard of ≥ 80% were included; the prevalence rates ranged from 27% to 40% with false-positive rates of 27% to 47%, with ≥ 80% pain relief
- Cervical Spine: The level of evidence is II with moderate strength of recommendation; ten relevant diagnostic accuracy studies, 9 of the 10 studies with either controlled comparative local anesthetic blocks or placebo controls with concordant pain relief with a criterion standard of ≥ 80% were included, the prevalence and false-positive rates ranged from 29% to 60% and of 27% to 63%, with high variability.
- Thoracic Spine: The level of evidence is II with moderate strength of recommendation; three relevant diagnostic accuracy studies, with controlled comparative local anesthetic blocks, with concordant pain relief, with a criterion standard of ≥ 80% were included; the prevalence varied from 34% to 48%, whereas false-positive rates varied from 42% to 58%.

*Note: Level I evidence is strong evidence obtained from multiple relevant high quality randomized controlled trials or evidence obtained from multiple high quality diagnostic accuracy studies Level II is moderate evidence obtained from at least one relevant high quality randomized controlled trial or multiple relevant moderate or low quality randomized controlled trials or evidence obtained from at least one high quality diagnostic accuracy study or multiple moderate or low quality diagnostic accuracy studies.

Guidelines also indicate that diagnostic cervical facet joint nerve blocks are recommended in patients with somatic or non-radicular neck pain or headache and upper extremity pain, with duration of pain of at least three months, without preponderance of evidence of discogenic pain, disc herniation, or evidence of radiculitis. Diagnostic lumbar facet joint nerve blocks are recommended in patients with suspected facet joint pain. (1-2 Manchikanti et al, 2013).

Qaseem et al. (2017) published a clinical practice guideline from the **American College of Physicians (ACP)** on *Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain.* Using data from a systematic review of randomized, controlled trials and systematic reviews, the ACP developed recommendations regarding noninvasive pharmacologic and nonpharmacologic treatments for LBP. Outcomes analyzed included: reduction or elimination of LBP, improvement in back-specific and overall function, improvement in health-related quality of life, reduction in work disability and return to work, global improvement, number of back pain episodes or time between episodes, patient satisfaction, and adverse effects. The following recommendations were made by the ACP:

- Nonpharmacologic treatment should include superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). If pharmacologic treatment is needed, the Provider and should discuss options with their patients including nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants (moderate-quality evidence).
- Initial nonpharmacologic treatment should include exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation (low-quality evidence).

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3. For patients who had an inadequate response to nonpharmacologic therapy, Providers should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as a first-line therapy, or tramadol or duloxetine as second-line therapy. Opioids should only be considered in patients who have failed the previously mentioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients.

The **Department of Veterans Affairs and Department of Defense** (2022) published the *VA/DoD Clinical Practice Guideline: Diagnosis and Treatment of Low Back Pain.* The guidelines offer an evidence-based approach for patients with acute, subacute, or chronic LBP (with or without neurological symptoms) to improve clinical outcomes. This includes how providers can assess a patient's condition while collaborating with the patient and their caregiver(s) to determine the best approach to care; how to highlight the use of patient-centered care and shared decision making; minimizing preventable complications and morbidity; and optimizing the patient's health outcomes and quality of life. Recommendations are also made regarding:

- Evaluation and Diagnostic Approach
- Patient Education and Self-Care
- Non-Pharmacologic and Non-Invasive Therapy
- Pharmacotherapy
- Dietary Supplements
- Non-surgical Invasive Therapy

The **National Institute for Health and Clinical Excellence (NICE)** (2020) published a guideline for *Low Back Pain and Sciatica* which addresses patients over age 16. The guideline covers physical, psychological, pharmacological, and surgical treatments to manage LBP and sciatica by promoting the most effective forms of care for LBP and sciatica. Recommendations are also included for pharmacological management of sciatica as well as serve as supplemental information for existing recommendations on the assessment as well as invasive and non-invasive treatments of LBP and sciatica. Guidance is also being developed by NICE for the use of opioids for non-cancer pain. Guidance includes patient education about safe opioid prescribing and withdrawal management.

The **North American Spine Society (NASS)** (2020) published the *Clinical Guideline for the Diagnosis and Treatment of Low Back Pain* to provide evidence-based recommendations for the diagnosis and treatment of adults with nonspecific LBP. Goals of the guideline recommendations focus on the delivery of optimum, efficacious treatment and functional recovery from nonspecific LBP. Recommendations are provided for:

- Diagnosis
- Imaging
- Medical and Psychological Treatment
- Physical Medicine and Rehabilitation
- Interventional Treatment
- Surgical Treatment
- Cost-Utility

The **Institute for Clinical Systems Improvement (ICSI)** (2018) published a guideline on *Low Back Pain, Adult Acute and Subacute* for adults over age 18 who present with symptoms of LBP or radiculopathy. This pain may be acute (pain for up to 4 weeks) and subacute (pain for between 4 and 12 weeks); the guideline does not address chronic pain (after 12 weeks).

The ICSI (2017) also published a guideline on *Pain: Assessment, Non-Opioid Treatment Approaches and Opioid* Management which is a combination ICSI's *Acute Pain Assessment/Opioid Prescribing Protocol* and the *Assessment and Management of Chronic Pain* guidelines. The guideline also addresses the entire continuum for acute, sub-acute, and chronic non-cancer pain in adults. A major aim of the guideline is to assist primary care clinicians on how to provide effective assessment, treatment, and ongoing management of patients with pain.

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SUPPLEMENTAL INFORMATION

Definitions

- Zygapophyseal (facet) Joint Level or the two medial branch nerves that innervate the zygapophyseal joint.
- Session includes all injections or block procedures performed on one day, including MBBs and facet intraarticular injections.
- Region includes all injections performed in the cervical or thoracic region, or all injections performed in lumbar (not sacral) spinal areas.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) 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 (zygapophyseal) 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)
0213T 0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves
	innervating that joint) with ultrasound guidance, cervical or thoracic; single level
02141	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)
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves
	innervating 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)

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.

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APPROVAL HISTORY

4/13/2023 Policy reviewed, no changes to criteria, updated Summary of Medical Evidence sections.

4/13/2022 Policy reviewed, no changes to coverage criteria, updated Summary of Medical Evidence section and References.

4/5/2021 Policy reviewed, no changes to criteria. One new guideline found reference #43 American Society of Interventional Pain Physicians

(ASIPP).

4/23/2020 Policy reviewed, criteria updated based on current standard of care medical guidelines that include ODG and InterQual; eviCore

and other guidelines. The entire criteria was changed under initial recommendation #2: changed improvement scale from 50% to 70%, levels restricted to no more than four (4) joints per session (e.g., two [2] bilateral levels or four [4] unilateral levels), sessions restricted to a maximum of six (6) facet joint procedural sessions per region (cervical or lumbar) may be performed in a 12-month period and more than two facet injections / MBBs at the same level are considered to be therapeutic rather than diagnostic. Therapeutic facet injections / MBBs are considered NOT medically necessary. Added additional criteria for a second diagnostic facet joint injection/medial branch block (e.g., dual), performed to confirm the validity of the clinical response to the initial facet joint injection performed in the same location(s). Revised conservative therapy to tried and failed a minimum of 3 months that includes PT for a minimum of 4 weeks. These changes are consistent with ODG, eviCore and other current guidelines and vetted

by AMR reviewer.

6/19/2019

Policy reviewed, no changes to criteria.

3/8/2018 Policy reviewed, no changes to criteria.

7/2017 Reduced PT requirement from 20 sessions to 10-12 sessions over 8 weeks, changed improvement scales from significant

functional improvement of 80% to significant functional pain relief of 50% measured by a decrease in pain medication and increase in functional ability, changed diagnostic injection criteria from 3 levels to 2 levels, removed significant narrowing of the vertebral canal or spinal instability as a contraindication, added that thoracic region injections are considered experimental, investigational and unproven and removed the requirement for a comprehensive psychosocial assessment. Changes are based on 2017 ODG

Guidelines per AMR review.

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Other Authoritative Publications

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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.