Subject: Facet Joint/MBB Diagnostic Injections for Chronic Spinal Pain	Original Effective Date: 7/5/07
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MCPC Approval Date: 7/25/17, 3/8/18, 6/19/19, 3/19/20, 4/23/20, 4/5/21	

Contents

DISCLAIMER

This Molina Clinical Review (MCR) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Review (MCR) document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [49]

Facet joint syndrome is a condition that leads to chronic spinal pain due to unclear etiology. The classic findings of facet joint syndrome are pain in the cervical or low back radiating to the buttock and posterior thigh, pain due to hyperextension, pain on palpation of joint, and absence of both radiculopathy below the knee and neurologic deficits.

Facet blocks can be performed in cervical or lumbar segments of the spine and may be performed as a diagnostic or therapeutic procedure. Facet blocks using short or long-acting local anesthetics can be used to diagnose facet (zygapophyseal) joint syndrome as the cause of chronic back pain. Diagnostic injections involve the injection of a local anesthetic into the facet joints (intra-articular) or around the nerve supply to the joints (medial branches of the dorsal rami aka medial branch block [MBB]). Injections should be fluoroscopically guided. Pain relieved following the injection for the appropriate amount of time given the type of medication used, without definitive clinical or imaging findings, would suggest that the pain originated in the facet joint. A positive diagnostic block is the prerequisite for undergoing other treatments to alleviate facet joint pain such as *radiofrequency denervation of the facet joints.

INITIAL CRITERIA RECOMMENDATION [49-57]

1. **Diagnostic** facet joint injections/MBBs may be considered medically necessary for facet joint pain in adults who are age 18 years or older as part of a comprehensive pain management treatment program when all of the following criteria are met: [ALL]
   - ❑ Presence of chronic severe back pain (cervical, or lumbar) that is predominantly axial not associated with radiculopathy or neurogenic claudication present for a minimum of **3 months that is**: [ALL]
     - o resulting from disease, injury or surgery; and
     - o confirmed by provocative testing resulting in reproducible pain (i.e., hyperextension, rotation); and
   - ❑ Pain is affecting activity of daily living functional ability: > 4 on the NRS Pain Rating Scale*; and
     - ❑ Physical evaluation has ruled out that no non-facet pathology that could explain the source of the patient's pain, such as discogenic, sacroiliac joint pain, disc herniation, fracture, tumor, infection; and

       AND
   - ❑ Has tried and failed a minimum of 3 months of conservative therapy (i.e. for the <u>current episode of pain</u> that includes: [ALL]
     - o Physical therapy (PT) for a minimum of 4 weeks (3-4x per week for a total of 12 sessions); or
     - o There must be documentation submitted that explains why physical therapy is contraindicated:
       *<u>*Note:*</u> PT may be contraindicated if any of the following are present:
       - ➢ pain worsened with PT;
       - ➢ PT tried but was not able to be tolerated

         AND
     - o Activity or exercise modification; and
     - o Drug therapy (i.e. NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, or 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)

2. **Diagnostic Facet Joint Injection/Medial Branch Block (MBB) Criteria**
   The primary efficacy of diagnostic facet injections/MBBs is to determine the appropriateness for a radiofrequency neurotomy of painful segmental levels in order 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. All of the following criteria apply: **[ALL]**

- ❑ For each covered spinal region (cervical or lumbar), diagnostic facet joint injections/MBBs should be performed at no more than four (4) joints per session (e.g., two [2] bilateral levels or four [4] unilateral levels).
- ❑ A second diagnostic facet joint injection/medial branch block (i.e 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 of the following criteria are met:
    - Administered at the same level as the initial block
    - The initial diagnostic facet joint injection produced a positive response (i.e., at least 70% relief of facet mediated pain for at least the expected minimum duration of the effect of the local anesthetic)
    - A radiofrequency joint denervation/ablation procedure is being considered
- ❑ A maximum of six (6) facet joint procedural sessions per region (cervical or lumbar) may be performed in a 12-month period.
- ❑ More than two facet injections/medial branch blocks at the same level are considered to be therapeutic rather than diagnostic. Therapeutic facet injections/medial branch blocks are considered NOT medically necessary.

Definitions:

- ❑ A zygapophyseal (facet) joint level is defined as the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint.
- ❑ A session is defined as all injections/blocks procedures performed on one day and includes medial branch blocks (MBB), and facet intraarticular injections (IA)
- ❑ A region is defined as all injections performed in cervical/thoracic or all injections performed in lumbar (not sacral) spinal areas.

*Please refer to Radiofrequency Ablation MCR-085 for additional criteria

Note: Criteria recommendations are mainly obtained from the Official Disability Guidelines, AMR peer review and other professional society guidelines. [51 53-57]

LIMITATIONS [49-57]

- ❑ **Therapeutic** or subsequent facet injections/medial branch blocks 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/medial branch 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 *contraindications* 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

SUMMARY OF MEDICAL EVIDENCE [3-41]

There is a moderate amount of clinical reports and reviews of facet blocks for chronic back pain published in the peer reviewed medical literature consisting of systematic reviews, randomized controlled trials or controlled trials with ≥ 40 patients and uncontrolled trials with ≥ 100 patients. [3-37] Studies primarily addressed 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 of the studies that involved patients with low back pain persisting longer than 1 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. [38-39]

The 2015 AHRQ comparative effectiveness study on injection therapies for low back pain 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. [40]

PROFESSIONAL SOCIETY GUIDELINES [42-48]

American Society of Interventional Pain Physicians (ASIPP): [43]

An updated 2020 practice guideline states the following:

- **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

An updated 2013 practice guideline indicates 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 3 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. [43]

CODING INFORMATION: THE CODES LISTED IN THIS CLINICAL POLICY ARE FOR INFORMATIONAL PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE AND INCLUSION OR EXCLUSION OF ANY CODES DOES NOT GUARANTEE COVERAGE. PROVIDERS SHOULD REFERENCE THE MOST UP-TO-DATE SOURCES OF PROFESSIONAL CODING GUIDANCE PRIOR TO THE SUBMISSION OF CLAIMS FOR REIMBURSEMENT OF COVERED SERVICES.

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	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level
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)
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)

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REVISION HISTORY

7/17: 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.
3/8/18 & 6/19/19: Policy reviewed, no changes to criteria.
4/23/20: 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/medial branch blocks at the same level are considered to be therapeutic rather than diagnostic. Therapeutic facet injections/medial branch blocks are considered NOT medically necessary. Added additional criteria for a second diagnostic facet joint injection/medial branch block (i.e 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.
4/5/21: Policy reviewed, no changes to criteria. One new guideline found reference #43 American Society of Interventional Pain Physicians (ASIPP).