

Medicare Administrative Contractors (MACs) will host a Multi-jurisdictional Contractor Advisory Committee (CAC) meeting regarding facet joint and medial nerve branch procedures. The purpose of this meeting is to obtain recommendations regarding zygapophyseal (aka facet) joint injection management of chronic, nonresponsive, and nonmalignant cervical, thoracic, and lumbar spinal pain of facet joint origin to relieve pain and improve functioning in Medicare beneficiaries.

Voting Questions:

For each voting question, please use the following scale identifying your level of confidence - with a score of 1 being low or no confidence and 5 representing high confidence.

1 — 2 — 3 — 4 — 5
Low Intermediate High
Confidence Confidence

Using this scale, please rate your confidence in the clinical literature for each question and cite the literature and rationale for your score. A score of ≥ 2.5 is considered intermediate confidence that there is robust clinical literature to support the question.

Section One: Procedure Efficacy

This section is to assess the evidence for the efficacy of the various facet joint interventions.

1. What is your level of confidence there is robust clinical literature to support the use of **diagnostic intra-articular** facet joint injections? Score (1-5): ____
2. What is your level of confidence; there is robust clinical literature to support the use of **therapeutic** facet joint injections to relieve pain and improve functioning? Score (1-5): ____
3. Does the clinical literature support the use of **therapeutic intra-articular** facet joint injections as robustly as **medial branch block** facet joint injections? Score (1-5): ____
4. Does the clinical literature support the safety of repeat facet joint injections ~~with steroids~~ beyond three injections per year? Score (1-5): ____ **please answer for both intraarticular injections and medial branch blocks/ based on beyond three injections per year.**
5. What is your confidence in the clinical literature to support the efficacy of **intra-articular** facet joint interventions in each of the following regions?
 - a. Cervical Facet (1-5): ____
 - b. Lumbar Facet (1-5): ____
 - c. Thoracic Facet (1-5): ____

Section 2: Patient Selection

The purpose of this section is to evaluate the evidence to determine who are the right patients for the procedures and criteria can help us determine if patients are selected appropriately.

1. Does the literature support the statement: rigorous beneficiary selection and inclusion criteria are necessary to reduce false-positive diagnoses and/or false-positive error rates when using facet joint injections and procedures?

YES NO

The following questions are to assess your level of confidence in the clinical literature for each of the following **inclusion criteria** for consideration of facet joint blocks for Medicare beneficiaries with chronic, axial, nonresponsive, nonmalignant cervical, thoracic, and lumbar spinal pain of facet joint origin:

2. The use of non-specific assessment of subjective "pain reduction" reported by a beneficiary with nonspecific chronic axial spine pain (not associated with radiculopathy or myelopathy) is a reliable and valid measure of improvement in pain following a facet injection or medial branch block injection? Score (1-5): _____

3. Do you have intermediate confidence (>2.5) that there is adequate clinical literature to support a minimal numeric "pain level" (Numerical Rating Scale [NRS], visual analog score [VAS] or similar) threshold (i.e., 6/10) to identify an individual's pain level before a Medicare beneficiary is eligible for a facet joint injection or procedure? YES NO

a. If Yes, what scoring system and the minimal score best supported by the literature?

4. If the answer to the above question is no, do you have at least intermediate confidence (≥ 2.5) the evidence support that inclusion criteria terminology indicate that the Medicare beneficiary's chronic, nonresponsive, and nonmalignant spinal pain be documented to be severe enough to cause some degree of moderate to severe functional deficit? YES NO

If yes, how does the evidence best define functional deficit?

5. Does the clinical literature support conservative treatment for a minimum of 3 months as a prerequisite before facet injections and/or medial branch block injections? Score (1-5): _____

Meaning conservative therapy in past (prior to injection)

6. Do you agree the following modalities are considered conservative treatment?

a. Integrative treatments (such as acupuncture and spinal manipulation) YES NO

b. Physical treatments (usually through physical therapy and include exercise, heat and cold modalities, massage) YES NO

c. Medications (such as NSAIDs, antidepressants) YES NO

d. Others (nutrition, weight loss, sleep hygiene) YES NO

7. Does the clinical literature support the use of inclusion criteria for facet blocks for with subjective chronic axial spine pain of greater than three months duration? Score (1-5): _____
8. Does the clinical literature support at least intermediate confidence (≥ 2.5) that history and physical examination can be used to identify a painful facet joint as the primary source of pain?
 YES NO
9. Does the clinical literature support with at least intermediate confidence (≥ 2.5) a requirement for imaging before prognostic blocks? YES NO
If yes, what imaging studies are best supported in the literature?
10. Does the clinical literature support with at least intermediate confidence (≥ 2.5) objective documentation (e.g., a daily pain diary) should be required to measure the sustained percentage of improvement following facet joint injections to relieve pain and improve function? YES NO
11. I am confident that there is at least intermediate confidence (≥ 2.5) in the clinical literature to support the terminology of temporary pain relief, long-lasting pain relief, and permanent pain relief is a reasonable, reliable, and meaningful health outcome terms to provide an objective clinical assessment for facet-mediated pain relief? YES NO
12. Does the clinical literature support the definitions for the following terms?
- a. Temporary pain relief is defined as pain relief greater than 80% based on the minimum duration of action/relief consistent with the local anesthetic agent employed during the therapeutic zygapophyseal joint injection procedure and/or medial branch blocks? YES NO
If NO, what percentage would the literature recommend?
- b. Long-lasting pain relief is defined as pain relief consistent greater than 50% pain relief for at least twelve (12) weeks from the prior therapeutic zygapophyseal joint injection procedure and/or medial branch blocks YES NO
If NO, what duration of weeks would the literature support?
- c. Permanent pain relief is defined as pain relief consistent greater than 50% pain relief for at least twenty-six (26) weeks from the prior therapeutic zygapophyseal joint injection procedure and/or medial branch blocks YES NO
If NO, what duration of weeks would the literature support?
13. Please rank your confidence in the clinical literature to support exclusion criteria for facet joint procedures:
- a. I have at least intermediate confidence (≥ 2.5) that there is clinical literature to support that a Medicare beneficiary with mild pain or mild functional deficits should not be treated with facet joint procedure? YES NO

b. I have at least intermediate confidence (≥ 2.5) that there is **not sufficient** clinical literature to support the use of zygapophyseal joint injection procedures for the management of spinal pain in Medicare beneficiaries with clinical findings of centralized pain syndrome(s) with widespread diffuse pain? YES NO

c. If no, I have at least intermediate confidence (≥ 2.5) that there is clinical literature to support that a physician must include a rigorous beneficiary evaluation and apply selection criteria to those Medicare beneficiaries with centralized pain syndrome(s) with widespread diffuse pain before the use of providing zygapophyseal joint injection procedures for the management of chronic, axial, nonresponsive, and nonmalignant spinal pain. YES NO

If yes, what criteria are supported?

14. Is there clinical evidence to support additional inclusion or exclusion criteria? (Deborah Tracy)

Section 3: Procedure Related Questions

1. What is your level of confidence (1-5) based on the clinical literature to support that the following procedures should not be used in the same or close location and in conjunction with a zygapophyseal joint injection procedure to reduce false-positive diagnoses and/or false-positive error rates in Medicare beneficiaries with spinal pain of facet joint origin? (Keith Barnhill)

- a. Trigger point injections Score (1-5): _____
- b. Epidural injections Score (1-5): _____
- c. SI joint injections Score (1-5): _____
- d. Selective nerve root blocks Score (1-5): _____
- e. Sympathetic ganglion blocks Score (1-5): _____
- f. Other injections, celiac plexus blocks, trigeminal nerve blocks, etc. Score (1-5): _____

2. I am confident that there is clinical literature to support the use of a series of **two** (2) medial branch blocks [MBBs] are needed to diagnose facet pain and establish consistency of test results due to high false-positive rate of a single MBB injection? Score (1-5): _____ (Steve Cohen)

a. What is your level of confidence the clinical literature supports the use of two (2) medial branch blocks [MBBs] test results need to have objective documentation (e.g., a **pain diary**) to support the Medicare beneficiary had a minimum of 80% temporary pain relief of first and second MBB pain levels (with the duration of relief being consistent with the agent used) or objective documentation (i.e., a pain diary) to support a minimum of at least 50% sustained improvement in pain and the ability to perform previously painful movements and ADLs? Score (1-5): _____

3. What is your level of confidence based on the clinical literature to support **subsequent** therapeutic intraarticular injections or medial branch blocks at the previously injected facet joints or medial branch blocks (i.e., the same anatomic site) are effective to reduce pain and improve function? Score (1-5): ____ (Micheal Creamer)
 - a. What is your level of confidence based on the clinical literature if the **subsequent** facet joint intraarticular injections or medial branch blocks need to have objective documentation (e.g., a pain diary) to show a minimum of 80% sustained relief of the first and second MBB pain levels (with the duration of relief being consistent with the agent used)? Score (1-5): ____
 - b. What is your level of confidence based on the clinical literature if the **subsequent** facet joint intraarticular injections or medial branch blocks need to have objective documentation (e.g., a pain diary) to support a minimum of at least 50% sustained improvement in pain and in the ability to perform previously painful movements and ADLs for at least three months? Score (1-5): ____
4. What is your level of confidence based on the clinical literature regarding the frequency of repeat injections? (Laxmaiah Manchikanti)
 - a. Diagnostic injections should be a minimum of 28 days apart? Score (1-5): ____
 - b. Therapeutic injections should be a minimum of 3 months apart? Score (1-5): ____
 - c. Interventional procedures at different regions should be performed a minimum of 2 weeks apart? Score (1-5): ____
 - d. In the treatment phase, interventional procedures should be repeated only if medically necessary and not to exceed four times in one year? Score (1-5): ____
 - e. For facet joint neurolysis frequency would be only of medically necessary at a minimum of 6 months apart? Score (1-5): ____
5. What is your confidence in the clinical literature to support facet injection or medial branch blocks being allowed for three (3) spinal levels per anatomic regions (diagnostic or therapeutic) in one session? Score (1-5): ____ (David Kennedy)
6. What is your level of confidence (1-5) the clinical literature supports that when **subsequent thermal medial branch radiofrequency neurotomies** at the same anatomic site are considered medically reasonable and necessary if the facet joint denervation has objective documentation (e.g., a pain diary) to show a minimum of 80% from diagnostic injections (with the duration of relief being consistent with the agent used) or objective documentation (e.g., a pain diary) to show a minimum of at least 50% sustained

- improvement in pain and in the ability to perform previously painful movements and ADLs for at least six months. Score (1-5): ____ (Laxmiaiah Manchikant)
- a. Does the literature support repeat imaging for repeat thermal medial branch radiofrequency neurotomies? Score (1-5): ____
 - b. Does the literature support a requirement to have repeat diagnostic injections prior to repeating thermal medial branch radiofrequency neurotomies? Score (1-5): ____
7. Are there any evidence-based strategies to improve the safety and reduce complications associated with facet joint injections and procedures? YES NO YES NO (Timothy Maus)
8. What is your confidence in the clinical literature to support a limitation of injection volume <0.5 ml for medial branch block and volumes <1.5ml for intraarticular injections? Score 1-5 _____ (Thomas Simopoulos)
9. What is your confidence in the clinical literature to support that facet joint interventions (diagnostic or therapeutic) must be performed under fluoroscopic or CT guidance? Score 1-5 _____ (Ben Schwachman)
10. What is your confidence that there is sufficient clinical literature to support facet joint interventions (diagnostic or therapeutic) can be performed under ultrasound guidance? Score 1-5 _____ (Deborah Tracy)
11. What is your confidence based on the clinical literature to support to use of a facet joint cyst rupture to provide facet mediated pain relief? Score 1-5 _____ (Keith Barnhill)
12. What is your confidence based on existing literature in the placement of intrafacet implants? Score 1-5 _____ (Steve Cohen)