Facet Joint and Medial Nerve Branch SME Voting Results

The voting results are in from the May 28, 2020, Multi-jurisdictional Subject Matter Expert Advisory meeting regarding facet joint and medial nerve branch procedures. Total are for the 10-national panelist. View the results below.

Section One: Procedure Efficacy

S1.Q1. What is your level of confidence there is robust clinical literature to support the use of *diagnostic intra-articular* facet joint injections?

- Subject Matter Expert Average Score: 3.20

S1.Q2. 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?

- Subject Matter Expert Average Score: 2.70

S1.Q3. Does the clinical literature support the use of *therapeutic* intra-articular facet joint injections as robustly as medial branch block facet joint injections?

- Subject Matter Expert Average Score: 2.30

S1.Q4. Does the clinical literature support the safety of repeat facet joint injections beyond three injections per year? (Please answer for both intraarticular injections and medical branch blocks/ based on beyond three injections per year.)

- Subject Matter Expert Average Score: 2.80

S1.Q5. What is your confidence in the clinical literature to support the efficacy of intra-articular facet joint interventions in each of the following regions?

5a. Cervical Facet

- Subject Matter Expert Average Score: 3.50

5b. Lumbar Facet

- Subject Matter Expert Average Score: 4.00

5c. Thoracic Facet

- Subject Matter Expert Average Score: 2.70

Section 2: Patient Selection

S2.Q1. 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

- Subject Matter Expert Average Score: 0.90

NO

- Subject Matter Expert Average Score: 0.10

S2.Q2. The use of nonspecific 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?

- Subject Matter Expert Average Score: 3.80

S2.Q3. 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 individuals' pain level before a Medicare beneficiary is eligible for a facet joint injection or procedure?

YES

- Subject Matter Expert Average Score: 0.30

NO

- Subject Matter Expert Average Score: 0.70

3a. If Yes, what scoring system and the minimal score best supported by the literature?

- Subject Matter Expert Response 1: 5–10
- Subject Matter Expert Response 2: Pain assessment is insufficient; physical, emotional and social functional status
- Subject Matter Expert Response 3: 5
- Subject Matter Expert Response 4: There should not be a minimum score, though 4/10 is generally the cutoff for most clinical trials evaluating pain treatments

S2.Q4. 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

- Subject Matter Expert Average Score: 0.60

NO

- Subject Matter Expert Average Score: 0.40

4a. If yes, how does the evidence best define functional deficit?

- Subject Matter Expert Response 1: Apply to ADL
- Subject Matter Expert Response 2: PROMIS profile domains; an unvalidated but reasonable judgement might be 1 standard deviation from the population mean for the several functional domains
- Subject Matter Expert Response 3: Pain disability scale, Owestrey disability index
- Subject Matter Expert Response 4: Using ODI or Roland Morris

S2.Q5. Does the clinical literature support conservative treatment for a minimum of three (3) months as a prerequisite before facet injections and/or medial branch block injections? (Meaning conservative therapy in past [prior to injection].)

- Subject Matter Expert Average Score: 2.70

S2.Q6. Do you agree the following modalities are considered conservative treatment?

6a. Integrative treatments (such as acupuncture and spinal manipulation)

YES

- Subject Matter Expert Average Score: 1.00

NO

- Subject Matter Expert Average Score: 0.00

6b. Physical treatments (usually through physical therapy and include exercise, heat and cold modalities, massage)

YES

- Subject Matter Expert Average Score: 1.00

NO

- Subject Matter Expert Average Score: 0.00

6c. Medications (such as NSAIDs, antidepressants)

YES

- Subject Matter Expert Average Score: 1.00

NO

- Subject Matter Expert Average Score: 0.00

6d. Others (nutrition, weight loss, sleep hygiene)

YES

- Subject Matter Expert Average Score: 0.80

NO

- Subject Matter Expert Average Score: 0.20

S2.Q7. 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?

- Subject Matter Expert Average Score: 3.60

S2.Q8. 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

- Subject Matter Expert Average Score: 0.20

NO

- Subject Matter Expert Average Score: 0.80

S2.Q9. Does the clinical literature support with at least intermediate confidence (≥ 2.5) a requirement for imaging before prognostic blocks?

YES

- Subject Matter Expert Average Score: 0.30

NO

- Subject Matter Expert Average Score: 0.70

9a. If yes, what imaging studies are best supported in the literature?

- Subject Matter Expert Response 1: MRI, CT
- Subject Matter Expert Response 2: Imaging is not supported in the literature based on guidelines

S2.Q10. 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

- Subject Matter Expert Average Score: 0.60

NO

- Subject Matter Expert Average Score: 0.40

S2.Q11. 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

- Subject Matter Expert Average Score: 0.80

NO

- Subject Matter Expert Average Score: 0.20

S2.Q12. Is there clinical evidence to support additional inclusion or exclusion criteria?

- Subject Matter Expert Response 1: Yes

- Subject Matter Expert Response 2: No Research is geared to measures outcomes, for the study requirements. Not real life conditions.
- Subject Matter Expert Response 3: Not completely sure I understand the question
- Subject Matter Expert Response 4: If one is referencing assessment of long lasting and permanent pain relief, then the assessment should include domains of physical, emotional and social functioning and use of health care resources
- Subject Matter Expert Response 5: Yes
- Subject Matter Expert Response 6: No
- Subject Matter Expert Response 7: Yes, literature supports being able to do spine movements or function that was previously painful or prohibitive because of pain
- Subject Matter Expert Response 8: Yes
- Subject Matter Expert Response 9: Patient specific functional limitations
- Subject Matter Expert Response 10: Absence of predominant radicular signs or symptoms as an exclusion criterion

S2.Q13. Does the clinical literature support the definitions for the following terms?

13a. 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

- Subject Matter Expert Average Score: 0.40

NO

- Subject Matter Expert Average Score: 0.60

If NO, what percentage would the literature recommend?

- Subject Matter Expert Response 1: 30
- Subject Matter Expert Response 2: The LCD for JN has been 50% for a decade. Most literature supports 50%. Using 80% provides limited gain.
- Subject Matter Expert Response 3: 50%
- Subject Matter Expert Response 4: "Therapeutic" outcomes are supported by much lower than 80%, this would be different than "diagnostic" cut-offs
- Subject Matter Expert Response 5: 50% relief – 80% relief is inconsistent with the IMMPACT guidelines and current FDA responder analyses

13b. 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

- Subject Matter Expert Average Score: 0.80

NO

- Subject Matter Expert Average Score: 0.20

If NO, what duration of weeks would the literature support?

- Subject Matter Expert Response 1: >/= to 6 weeks.
- Subject Matter Expert Response 2: Medial branch blocks should only last the duration of the anesthetic. RF should last longer than 12 weeks.

13c. 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

- Subject Matter Expert Average Score: 0.80

NO

- Subject Matter Expert Average Score: 0.20

If NO, what duration of weeks would the literature support?

- Subject Matter Expert Response 1: >/= 2 years
- Subject Matter Expert Response 2: > 50% is OK, but 26 weeks is not "permanent"

S2.Q14. Please rank your confidence in the clinical literature to support exclusion criteria for facet joint procedures:

14a. 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

- Subject Matter Expert Average Score: 0.60

NO

- Subject Matter Expert Average Score: 0.40

14b. 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

- Subject Matter Expert Average Score: 0.40

NO

- Subject Matter Expert Average Score: 0.60

14c. 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

- Subject Matter Expert Average Score: 0.60

NO

- Subject Matter Expert Average Score: 0.40

14d. If yes, what criteria are supported?

- Subject Matter Expert Response 1: I would exclude this answer b/c I am not following how it relates to 16 having answered yes but am required to answer
- Subject Matter Expert Response 2: The validated criteria for facet denervation, dual comparative medial branch blocks
- Subject Matter Expert Response 3: Could be the fibromyalgia impact questionnaire

S2.Q15. Is there clinical evidence to support additional inclusion or exclusion criteria?

- Subject Matter Expert Response 1: Yes
- Subject Matter Expert Response 2: Exclusion = Radiation exposure, Infection, acute myelopathy
- Subject Matter Expert Response 3: Not sure what clinical evidence means therefore answering no
- Subject Matter Expert Response 4: No
- Subject Matter Expert Response 5: Yes
- Subject Matter Expert Response 6: No
- Subject Matter Expert Response 7: To the best of the literature, facet joint interventions have not been studied in wide-spread pain. This does not mean that they cannot be used if facet joint pain is suspected.
- Subject Matter Expert Response 8: Yes
- Subject Matter Expert Response 9: No
- Subject Matter Expert Response 10: Again, predominant radiculopathy as an exclusion criterion

Section 3: Procedure Related Questions

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S3.Q1. 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?

1a. Trigger point injections

- Subject Matter Expert Average Score: 1.90

1b. Epidural injections

- Subject Matter Expert Average Score: 1.90

1c. SI joint injections

- Subject Matter Expert Average Score: 1.30

1d. Selective nerve root blocks

- Subject Matter Expert Average Score: 1.80

1e. Sympathetic ganglion blocks

- Subject Matter Expert Average Score: 1.90

1f. Other injections, celiac plexus blocks, trigeminal nerve blocks, etc.

- Subject Matter Expert Average Score: 1.70

S3.Q2. 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?

- Subject Matter Expert Average Score: 3.20

2b. 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?

- Subject Matter Expert Average Score: 3.30

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S3.Q3. 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?

- Subject Matter Expert Average Score: 3.40

3a. 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)?

- Subject Matter Expert Average Score: 2.90

3b. 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?

- Subject Matter Expert Average Score: 3.50

S3.Q4. What is your level of confidence based on the clinical literature regarding the frequency of repeat injections?

4a. Diagnostic injections should be a minimum of 28 days apart?

- Subject Matter Expert Average Score: 1.80

4b. Therapeutic injections should be a minimum of 3 months apart?

- Subject Matter Expert Average Score: 3.50

4c. Interventional procedures at different regions should be performed a minimum of 2 weeks apart?

- Subject Matter Expert Average Score: 3.10

4d. In the treatment phase, interventional procedures should be repeated only if medically necessary and not to exceed four times in one year?

- Subject Matter Expert Average Score: 3.40

4e. For facet joint neurolysis frequency would be only of medically necessary at a minimum of 6 months apart?

- Subject Matter Expert Average Score: 3.90

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S3.Q5. 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?

- Subject Matter Expert Average Score: 3.80

S3.Q6. 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.

- Subject Matter Expert Average Score: 3.70

6a. Does the literature support repeat imaging for repeat thermal medial branch radiofrequency neurotomies?

- Subject Matter Expert Average Score: 2.10

6b. Does the literature support a requirement to have repeat diagnostic injections prior to repeating thermal medial branch radiofrequency neurotomies?

- Subject Matter Expert Average Score: 2.30

S3.Q7. Are there any evidence-based strategies to improve the safety and reduce complications associated with facet joint injections and procedures?

YES

- Subject Matter Expert Average Score: 0.90

NO

- Subject Matter Expert Average Score: 0.10

S3.Q8. What is your confidence in the clinical literature to support a limitation of injection volume <0.5 ml for medical branch block and volumes <1.5ml for intraarticular injections?

- Subject Matter Expert Average Score: 4.00

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S3.Q9. 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?

- Subject Matter Expert Average Score: 4.90

S3.Q10. What is your confidence that there is sufficient clinical literature to support facet joint interventions (diagnostic or therapeutic) can be performed under ultrasound guidance?

- Subject Matter Expert Average Score: 1.70

S3.Q11. 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?

- Subject Matter Expert Average Score: 3.90

S3.Q12. What is your confidence based on existing literature in the placement of intrafacet implants?

- Subject Matter Expert Average Score: 1.20