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Dear Ms. Robinson:

The North American Neuromodulation Society (NANS) would like to thank the Medicare Administrative Contractor (MAC) Medial Directors for providing additional information and transparency regarding the Committee (CAC) Meeting Regarding Facet Joint and Medial Nerve Branch Procedures on May 28th, 2020. NANS is a multi-specialty association of more than 1,600 physicians dedicated to the development and promotion of the highest standards for the practice of neuromodulation procedures in the diagnosis and treatment of the nervous system, including neurosurgeons, orthopedic spine surgeons, anesthesiologists, physiatrists, psychologists, urologists, and neurologists. We are committed to working with Medicare Administrative Contractors and other stakeholders to promote the highest quality, most efficient, patient care for patients dealing with chronic neuromuscular pain.

We appreciate you providing insight and understanding as to the purpose of the meeting which as stated is to obtain advice from CAC members and subject matter experts (SMEs) regarding the strength of published evidence on Facet Joint and Medial Nerve Branch Procedures. NANS strongly believes that facet procedures represents one of the most important tools that pain physicians use to control chronic neck and back pain and it therefore it is critical that the MACs ensure proper coverage guidelines for this important conservative treatment modality.

As you are aware, interventional pain treatments significantly improve patients' pain and function and limit their need for opioid medications. For radiofrequency ablation for facet related pain, this was clearly demonstrated by the study conducted by Loh et al., which examined healthcare utilization in over 4,000 patients. The study demonstrated that healthcare utilization (e.g. additional procedures and office visits), was significantly reduced in the 12 months following radiofrequency ablation.¹ Furthermore, this study demonstrated that some patients eliminated opioid use. Patients who lose access to interventional modalities often turn to chronic opioid medications. If the goal is try and control overall costs related to these procedures, we would strongly recommend this be done by instituting measures to control abuse as we have suggested below rather than limiting patients access to medically necessary care. While CMS and private carriers have been reluctant to look at who is performing and billing these codes, one of the most important ways to control abuse and improve outcomes is to limit these procedures to those who are properly trained in their performance

• ¹ Loh E, Reid JN, Alibrahim F, Welk B. Retrospective cohort study of healthcare utilization and opioid use following radiofrequency ablation for chronic axial spine pain in Ontario, Canada. *Reg Anesth Pain Med.* 2019.

We have reviewed the questions in the document released last week and believe that most of these are addressed in the April 2020 publication entitled: The Consensus Practice Guidelines and Interventions for Lumbar Facet Joint Pain from a Multispecialty International Working Group.¹ These consensus guidelines involved representation from 14 organizations including the American Academy of Pain Medicine, American Pain Society, American Society of Anesthesiologists, American Society of Pain and Neuroscience, American Society of Regional Anesthesia and Pain Medicine, British Pain Society, Canadian Pain Society, International Neuromodulation Society, Korean Pain Society, North American Neuromodulation Society, Spine Intervention Society, US Department of Defense, US Department of Veteran Affairs, and World Institute of Pain. This multispecialty international working group addressed 17 questions surrounding lumbar facet joint pain and the associated interventions. The conclusions for each question utilized the United States preventive services task force grading of evidence guidelines, with levels of certainty rated as high, medium, or low.

We thought it would be helpful to address any questions not covered by the Consensus guidelines, provide references and also to provide an LCD coverage template for facet related procedures. The recommendations for this LCD template are based on the evidence contained within the literature and where gaps exist, consensus has been utilized to develop these recommendations; this represents the current standard of care in this country. NANS agrees with the MACs that it is equally as important to ensure coverage for patients who need this therapy as it is to help limit abuse of this treatment and in that regard we proactively wanted to provide advice on how this can be controlled.

Please find the following input broken out by sections of the 5-14-20 Evidence List and Questions.

Section One: Procedure Efficacy

1. What is your level of confidence there is robust clinical literature to support the use of diagnostic facet joint injections? Score (1-5): _____ ^[L]_[SEP]

*See page 12 of Cohen SP, et al. Reg Anesth Pain Med 2020;0:1–44. doi:10.1136/rapm-2019-101243: “IA facet joint injections meet criteria for diagnostic interventions for facet-mediated pain but are less predictive than MBB for response to medial branch RFA and are characterized by a high technical failure rate. As diagnostic tools, MBBs suffer from limitations related to aberrant lumbar facet joint innervation. Compared with saline controls, both IA and medial branch injections with LA provide better predictive information for medial branch RFA; **grade B recommendation.** “*

*In regard to intra-articular joint facet injections vs medial branch injections as diagnostic injections prior to RFA, IA is typically used for therapeutic effect and not diagnostic purposes. When dual blocks are done at least one should be with MBB. **See page 14 of Cohen SP, et al. Reg Anesth Pain Med 2020;0:1–44. doi:10.1136/rapm-2019-101243: “Overall, we conclude that MBB should be the prognostic screening test of choice before lumbar facet RFA”***

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): _____ ^[L]_[SEP]

*See page 19 of Cohen SP, et al. Reg Anesth Pain Med 2020;0:1–44. doi:10.1136/rapm-2019-101243: “We recommend against the routine use of therapeutic facet injections, although we acknowledge that in patients who may be at risk of adverse consequences from RFA (eg, young athletes, older individuals on anticoagulation therapy or with implant-able cardiac devices) or in whom there is a strong likelihood of success (eg, individuals who obtained prolonged relief from previous diagnostic injections with or without steroids), it may reasonable to add steroids to a block in the hope of deriving intermediate-term relief; **grade D, moderate level of certainty.** “*

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): _____

See page 14, table 6 of Cohen SP, et al. Reg Anesth Pain Med 2020;0:1–44. doi:10.1136/rapm-2019-101243; Comment: In regard to predictive value prior to RFA, the literature is more favorable for medial branch blocks vs intra-articular facet injections. Of note, therapeutic intra-articular facet injections and diagnostic medial branch blocks cannot be compared directly as one is a diagnostic test and the other is a therapeutic treatment.

4.Does the clinical literature support the safety of repeat facet joint injections with steroids beyond three injections per year? Score (1-5): _____

There is limited literature that evaluates safety of facet injections with steroids beyond three per year or what the optimal interval is for this particular intervention.

5.What is your confidence in the clinical literature to support the efficacy of facet joint interventions in each of the following regions? _____

a. Cervical Facet (1-5): _____

A randomized, double blinded, prospective study with one-year follow-up strongly support the therapeutic benefit of cervical facet interventions.

- 1) *Manchikanti L 1, Singh V, Falco FJ, Cash KM. Cervical medial branch blocks for chronic cervical facet joint pain: a randomized, double-blind, controlled trial with one- year follow. Spine. 2008 Aug 1;33(17):1813-20.*

b. Lumbar Facet (1-5): _____

Multiple Meta-analysis, RCT's, and prospective studies strongly support the efficacy of Lumbar facet joint interventions.

- 1) *Manchikanti L. A systematic review and best evidence synthesis of effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. J Pain physician. 2015;18:E535-E582.*
- 2) *Lee CH, Chung CK, Kim CH. The efficacy of conventional radiofrequency denervation in patients with chronic low back pain originating from the facet joints: a meta-analysis of randomized controlled trials. Spine J. 2017;17(11):1770-1780.*
- 3) *Lakemeier S, Lind M, Schultz W, et al. A comparison of intraarticular lumbar facet joint steroid injections and lumbar facet joint radiofrequency denervation in the treatment of low back pain: a randomized, controlled, double-blind trial. Anesth Analg. 2013;117(1):228-235.*
- 4) *Manchikanti L. A systematic review and best evidence synthesis of effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. J Pain physician. 2015;18:E535-E582.*
- 5) *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.*

c. Thoracic Facet (1-5): _____

Thoracic facet disease is much less prevalent than in the cervical and lumbar region. The available literature suggests that both thoracic facet and medial branch procedures are effective with 65% of the patients in the IA steroid injection group reported successful pain relief (pain relief \geq 50%), and 40% of the patients in the MBB group showed successful pain relief (1).

1) Lee DG, Ahn SH, Cho YW. Comparison of Intra-articular Thoracic Facet Joint Steroid Injection and Thoracic Medial Branch Block for the Management of Thoracic Facet Joint Pain. *Spine*. 2018 Jan 15;43(2):76-80. [SEP]

Section 2: Patient Selection

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? X YES ___NO.

Please refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al.

**Pg 6. Question 2: is there any correlation between radiological findings and a painful facet joint or*

radiofrequency ablation outcomes, and should imaging be required before prognostic blocks?

**Pg 7. Table 5: Studies evaluating the association between imaging pathology and facet joint block and treatment outcomes*

**Pg 23. Weighing false-positives versus false-negatives: “Two observational studies illustrate the high success rates that can be achieved with stringent selection.”*

**Pg 32. Patient Selection: “Similar to all treatments, patient selection for diagnostic facet blocks plays a critical role in determining the likelihood of a positive outcome.*

**Pg 33. Table 11. Failure of conservative treatment “Preferably 3 months, but may be less in certain circumstances (ego, incapacitating pain with strong suspicion of facetogenic origin, competitive athlete, military deployment)” with no recommendations for physical exam or diagnostic imaging.*

**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): 4**

Please refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al.

**Pg 19-20. Non-pain relief measures of benefit: “Because the limitations in using non-pain-related*

measures as the benchmark for designating a prognostic block as positive are related to the relatively short duration of action of LAs, should sustained-release or ultra-long-acting formulations of LA become standard of care, the use of objective measures of function (eg, use of a pedometer, medication reduction, functional capacity) to assess block success will become an area ripe for investigation.” LA=local anesthetic

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 individuals' pain level before a Medicare beneficiary is eligible for a facet joint injection or procedure? ___YES _X_NO

A minimal numeric "pain level" for patient selection is not readily found in the literature and may negate each individual's personal pain experience; however, please refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al.

**Pg 32. Patient Selection:* "Similar to all treatments, patient selection for diagnostic facet blocks plays a critical role in determining the likelihood of a positive outcome.

**Pg 33. Table 11.* Failure of conservative treatment "Preferably 3 months, but may be less in certain circumstances (eg, incapacitating pain with strong suspicion of facetogenic origin, competitive athlete, military deployment)" with no recommendations for physical exam or diagnostic imaging.

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

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 _X_NO

While some functional deficit may be useful for patient selection, this should include mild to severe functional deficits. Please also refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al.

**Pg 19-20. Non-pain relief measures of benefit.*

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

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): \rightarrow 5

Please refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al. and please refer to recommendations on page 10 under Question 3: Should physical therapy and/or prior conservative treatment be a requisite before prognostic facet blocks? If so, for how long should they be continued, and should they be concurrent?

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

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

___NO

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

c. Medications (such as NSAIDs, antidepressants) X YES ___NO

d. Others (nutrition, weight loss, sleep hygiene) X YES ___NO

Please refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al. and please see recommendations on page 10 under Question 3: Should physical therapy and/or prior conservative treatment be a requisite before prognostic facet blocks? If so, for how long should they be continued, and should they be concurrent? We agree with the above conservative treatments, but strongly feel that not all of the modalities need to be satisfied prior to prognostic block.

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): → 5

Please refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al. and please see Question 5: Are facet blocks ‘diagnostic’, ‘prognostic’ or both? On pages 10-13

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? X YES ___NO

Please refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al. and please see Question 1: Can history and physical exam be used to identify a painful facet joint, or to select for people for prognostic blocks? Pages 3 – 6. Please note that while history can be helpful in selecting patients for prognostic blocks, physical exam is much less reliable.

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

Please refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al. and please see Question 2: Is there any correlation between radiological findings and a painful facet joint or radiofrequency ablation outcomes, and should imaging be required before prognostic blocks. Pages 6 – 9.

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

As stated in the paper, there is moderate evidence to support the use of SPECT in identifying painful lumbar facet joints prior to MBB but this is not common in clinical practice and the cost benefit analysis for this modality has not been studied.

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? X YES ___NO

Objective documentation may not necessarily require pain diary but other methods such as described in the literature. For example, in Younger, J., McCue, R. & Mackey, S. (2009). Pain outcomes: A brief review of instruments and techniques. 2009: Current Science Inc 13; 39–43.

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?

For question 12, we would refer the medical directors to section of the Consensus Guidelines entitled Question 10: what should the cut-off be (i.e., percent relief) for designating a block as 'positive 'and is there any benefit in using non-pain score outcome measures? starting on page 19 The Committee recommended a greater than or equal to 50% reduction pain to be considered a positive block. As far as permanent pain relief, pain relief is not expected with radiofrequency ablation. The results with radiofrequency ablation are durable but time-limited and the treatment needs to be repeated to maintain efficacy.

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 X NO

**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. X YES
___NO**

If yes, what criteria are supported?

The selection criteria would be similar to patients without widespread pain symptoms. Essentially, the focus of the pain would be on the area being treated and outcome measures and pain scores should be focused on the area being treated. Moreover, the article below outlines methods to recognize and reduce co-morbid conditions prior to spine procedures in order to improve outcomes.

Please see Brummett, C. M., Goesling, J., Tsodikov, A., Meraj, T. S., Wasserman, R. A., Clauw, D. J., & Hassett, A. L. (2013). Prevalence of the fibromyalgia phenotype in patients with spine pain presenting to a tertiary care pain clinic and the potential treatment implications. 2013: Arthritis and rheumatism, 65(12);3285–3292. <https://doi.org/10.1002/art.38178>

14. Is there clinical evidence to support additional inclusion or exclusion criteria? X YES ___NO

Please refer to the following sections of the 2020 International, Multi-Specialty, Multi-Society Consensus Guidelines by Cohen et al. and please refer to recommendations Question 1: Can history and physical exam be used to identify a painful facet joint, or to select for people for prognostic blocks? Pages 3 – 6. Specifically, those with radicular signs and/or non-axial pain would be excluded from facet joint procedures.

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?

Based on the published literature and specific patient scenarios we agree that most of the listed procedures would not be indicated concomitantly with lumbar facet joint procedures, however, in highly exceptional circumstances there may be clinical scenarios which require selective nerve root block and/or sacroiliac joint injection to be performed during the same day of service e.g. clinical presentation encompassing two distinct pathologies namely facet joint juxtaarticular cyst and lumbar radiculopathy secondary to nerve root compression by the cyst. We do endorse using appropriate modifiers to specify delineated services rendered during the same day of service.

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?

After a comprehensive review of the available literature and input from expert guidance on best practice from members of the society, NANS believes that a uniform policy in regards to diagnostic medial branch blocks of the cervical, thoracic, and lumbar regions should be adopted. Our society's strong consensus is as follows. We understand the recommendation from the consensus guidelines for the use of at least 50% relief from a single diagnostic block as an appropriate threshold to select patients and in specific instances this would be recommended. However, if the goal of the MAC medical directors is to prioritize treatment success then dual blocks would be the preferred method. The use of dual blocks reduces false positive rates which can be as high as 25 to 45% with a single block.

After a comprehensive review of the available literature and input from expert guidance on best practice from members of the society, NANS believes that a uniform policy in regards to diagnostic medial branch blocks of the cervical, thoracic, and lumbar regions should be adopted. Our society's strong consensus is as follows.

-At least 50% relief from dual diagnostic blocks in the cervical, thoracic, and lumbar regions.

We believe this uniform policy is the best synthesis of the available literature and results in the best clinical scenario in which patients are selected for radiofrequency ablation of the medial branches of the spine. Greater than 80% pain relief from dual diagnostic blocks is likely too restrictive, and many patients with 50-79% pain relief would be excluded who would likely receive significant benefit from RFA. Additionally, we feel a policy that recommends 50% relief from a single block would ultimately lead to an over utilization of RFA due to the false positive rate.

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):

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?

NANS recommend following consensus statements for question 3 and 4 based on reviewed literature and expert guidance.

For Diagnostic Facet Joint Injections

- Dual MBBs (a series of two MBBs) are necessary to diagnose facet pain due to the high false positive rate of single MBB injections.*
- A second confirmatory MBB is necessary if documentation indicates the first MBB produced \geq 50% relief of*

primary (index) pain and duration of relief is consistent with the pharmacological agent employed.

For Therapeutic Injections:

- *Either intra-articular or medial branch blocks may provide temporary or long-lasting or permanent relief of facet-mediated pain. Injections may be repeated if the first injection results in significant pain relief (> 50%) for at least 3 months.*
- *Recurrent pain at the site of previously treated facet joint may be treated without additional diagnostic blocks if > 50% pain relief from the previous block(s) lasted at least 3 months.*

For Thermal Medial Branch Radiofrequency Neurotomy (includes RF and microwave technologies):

- *Facet joint denervation with RF medial branch neurotomy can be considered when dual MBBs provide $\geq 50\%$ relief of the primary or index pain and duration of relief is consistent with the pharmacological agent employed.*
- *Repeat denervation procedures involving the same joint are medically necessary if the patient experienced $\geq 50\%$ improvement of pain and improvement in patient specific ADLs documented for at least 6 months.*

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): ____

a. Does the literature support repeat imaging for repeat thermal medial branch radiofrequency neurotomies? Score (1-5): ____

The literature does not support repeating imaging for repeat thermal medial branch radiofrequency neurotomies

b. Does the literature support a requirement to have repeat diagnostic injections prior to repeating thermal medial branch radiofrequency neurotomies? Score (1-5): ____

The literature does not support a requirement to have repeat diagnostic injections prior to repeating thermal medial branch radiofrequency neurotomies. Refer to question 17 page 33.

7. Are there any evidence-based strategies to improve the safety and reduce complications associated with facet joint injections and procedures? ____ YES ____ NO

There are evidence-based strategies to improve the safety and reduce complications associated with facet joint injections and procedures. Please refer to question 15 in the consensus guidelines starting on page 28.

8. 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? Score (1-5): ____

The ideal volume for facet blocks recommended by the consensus guidelines are the following:

- 1. lumbar medial branch block should be performed with a volume of less than or equal to 0.5 mL to prevent spread to adjacent structures.*
- 2. Intra-articular injection should be done with a volume of less than 1.5 mL to prevent aberrant spread and capsular rupture.*

Please refer to question eight page 17.

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): ____

Facet intervention should be performed with radiographic imaging. Please refer to question four page 10. Preferably fluoroscopic guidance should be utilized. CT scanning may be utilized with intra-articular injections to enhance accuracy. For radiofrequency ablation, fluoroscopic guidance should be utilized.

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): ____

Although ultrasound guidance can be used for medial branch blocks and intra-articular facet procedures there are limitations and therefore fluoroscopic guidance remains the initial choice. Question 4 page 11.

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): ____

Synovial cysts of the lumbar zygapophysial joints can be treated by percutaneous injection of corticosteroids, with distension and/or rupture of the cyst. Bureau et al have reported complete regression of the symptomatic cyst in 67% of their patients who underwent percutaneous procedures. We strongly support continuation of coverage for image guided facet joint cyst rupture procedure.

Please see the following article.

- 1. Bureau NJ, Kaplan PA, Dussault RG. Lumbar facet joint synovial cyst: percutaneous treatment with steroid injections and distention--clinical and imaging follow-up in 12 patients. Radiology. 2001;221(1):179-185. doi:10.1148/radiol.2211010213*

**12. What is your confidence based on existing literature in the placement of intrafacet implants?
Score (1-5):**

Please see the following article. There does not appear to be enough research to support intrafacet implants.

1. Cook, D.J., Yeager, M.S., et al. Lumbar Intrafacet Bone Dowel Fixation. *Neurosurgery*, 2015 Apr; 76(4):470-8. PMID: 25621985

References:

1. 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. Campos WK, Linhares MN, Sarda J, et al. CATASTROPHIZING PREDICTS THE PAIN RECURRENCE AFTER LUMBAR FACET JOINT INJECTIONS. *J Frontiers in Neuroscience*. 2019;13:958.
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4. Do KH, Ahn SH, Cho YW, Chang MC. Comparison of intra-articular lumbar facet joint pulsed radiofrequency and intra-articular lumbar facet joint corticosteroid injection for management of lumbar facet joint pain: A randomized controlled trial. *Medicine (Baltimore)*. 2017;96(13):e6524.
5. Juch JN, Maas ET, Ostelo RW, et al. Effect of radiofrequency denervation on pain intensity among patients with chronic low back pain: the mint randomized clinical trials. *J Jama*. 2017;318(1):68-81.
6. Kennedy DJ, Fraiser R, Zheng P, et al. Intra-articular Steroids vs Saline for Lumbar Z-Joint Pain: A Prospective, Randomized, Double-Blind Placebo-Controlled Trial. *Pain Med*. 2019;20(2):246-251.
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8. Kim BR, Lee JW, Lee E, Kang Y, Ahn JM, Kang HS. Intra-articular facet joint steroid injection-related adverse events encountered during 11, 980 procedures. *J European Radiology*. 2020;30(3):1507-1516.
9. Kwak DG, Kwak SG, Lee AY, Chang MC. Outcome of intra-articular lumbar facet joint corticosteroid injection according to the severity of facet joint arthritis. *Exp Ther Med*. 2019;18(5):4132-4136.
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11. Lee CH, Chung CK, Kim CH. The efficacy of conventional radiofrequency denervation in patients with chronic low back pain originating from the facet joints: a meta-analysis of randomized controlled trials. *Spine J*. 2017;17(11):1770-1780.

12. Manchikanti L. A systematic review and best evidence synthesis of effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. *J Pain physician*. 2015;18:E535-E582.
13. Manchikanti L, Hirsch JA, Falco FJ, Boswell MV. Management of lumbar zygapophysial (facet) joint pain. *World J Orthop*. 2016;7(5):315-337.
14. Manchikanti L, Hirsch JA, Kaye AD, Boswell MV. Cervical zygapophysial (facet) joint pain: effectiveness of interventional management strategies. *Postgrad Med*. 2016;128(1):54-68.
15. Manchikanti L, Sanapati MR, Pampati V, et al. Update of Utilization Patterns of Facet Joint Interventions in Managing Spinal Pain from 2000 to 2018 in the US Fee-for-Service Medicare Population. *Pain Physician*. 2020;23(2):E133-E149.
16. Rambaransingh B, Stanford G, Burnham R. The effect of repeated zygapophysial joint radiofrequency neurotomy on pain, disability, and improvement duration. *Pain Med*. 2010;11(9):1343-1347.
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Thank you for your time and attention to this matter. We look forward to answering any questions and engaging in follow up with the panel.

Sincerely,



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