Open Meeting: Facet Joint Interventions for Pain Management

Meeting Date and Time:	October 13, 2020 4:00 p.m. EST
Facilitator:	Dr. Meredith Loveless
Location:	Teleconference
Attendees:	Not to disclose

Dr. Loveless began the meeting at 4:00 pm ET for Facet Joint Interventions for Pain Management.

Overview

This policy will be replacing the existing policy and it has been updated to follow the 21st Century Cures Act format with recent assessment of evidence. This policy is a collaboration amongst the Medicare Administrative Contractors. The Multi-Jurisdictional CAC meeting was held in May and multiple topics of this policy was discussed with subject matter experts. Medical evidence, societal input, and the voting of our subject matter expert panel were used to help guide the decisions on the controversial areas of this policy.

Challenges with this procedure is the difficulty in diagnosis including difficult to diagnose by history, physical exam, or radiological studies. So, requires actual face joint injections to aid in the diagnosis if facet joint syndrome. Another challenge is the lack of consensus on some of the best practices. Literature and guidance were utilized to try to guide that process.

The policy includes an extensive definition section to prevent any confusion in terms of references throughout the policy.

Diagnostic Facet Injections

Diagnostic Facet Injections are necessary to confirm the diagnosis of facet syndrome. Once that is diagnosed it can help identify patients that may benefit from further intervention, typically radiofrequency ablation procedure.

In order to diagnose the syndrome, there should be a consistent positive response to the diagnostic injection, which is defined as 80% relief of pain or 50% improvement in function.

Our subject matter experts were very clear that the functional improvement is most important aspect of this improvement to we were sure to include that component in the policy.

There was some controversy over whether there should be a second confirmatory diagnostic facet procedure. It was supported by the medical literature and, therefore, the policy does require confirmation of a second diagnostic facet procedure for confirmation, and to identify patients.

We understand that sometimes the pain center is not identified on the first attempt. The policy is written to allow the provider to do separate diagnostic injections in a separate area if necessary to identify the pain generator. The KX will be used to distinguish the diagnostic

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injections from the therapeutic injection. This will help ensure that we don't deny appropriate diagnostic injection.

Therapeutic Facet Joint Procedures

The literature, the societal guidance, and the majority of the support lean towards radiofrequency ablation procedures as the preferred procedure with longer term benefits and outcomes. However, we understand that there are times where radiofrequency ablation cannot be performed. We wanted to make sure we included the therapeutic joint injections for patients who would not be good candidates for the radio frequency ablation.

These are limited to no more than four therapeutics facet joint session per rolling 12 months.

Facet Joint Denervation (RFA)

Regarding radiofrequency ablation, the radiofrequency ablation can be repeated after a patient has met the diagnostic criteria.

If the patient has consistent 50% improvement in pain for at least six months, allowing up to two sessions per rolling 12 months.

Facet Cyst Aspiration/Rupture

This requires the diagnostic study to confirm the diagnosis with clinical and physical symptoms.

It allows that a cyst rupture to be performed and repeated if there is improvement for at least three months.

Limitations

There are multiple limitations that are outlined in the policy and this is based on the evidence review.

We do require imaging to improve safety and success with the procedures.

Evidence did not support general anesthetic or sedation.

The policy allows 1 to 2 levels, unilateral or bilateral per session.

It does allow retreatment. It will not require that the patient has had success with the procedure in the past 24 months.

Documentation is required for therapeutic injection as to why they would not be a good candidate for the RFA procedure.

Facet Joint Interventions for Pain Management Summary

We want to ensure that this is not being utilized to treat generalized pain condition.

This policy isn't saying what the generalized pain condition couldn't have facet syndrome, but that we don't expect that this would treat a chronic or centralized pain syndrome. Therefore, they must demonstrate all criteria separate from their all criteria and that it's not trying to treat a generalized syndrome.

It's also not expected that patients would routinely present with:

- Pain in both cervical, the thoracic and the lumbar region
- Need for multiple blocks on the same day as the facet
- Three level procedures
- Routine performance of these could trigger focused medical review.

Comments

The comment period for this policy is open until December 12, 2020. Please submit comments as soon as possible with supporting literature. This will significantly help us in terms of reviewing your comments and evaluating them in terms of their terms of their impact on the policy. Comments should be sent to CMD.INQUIRY@cgsadmin.com.

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Presenters

Note: Presenters are to disclose any conflict of interest before their presentation

Dr. Cohen had no disclosure to provide.

Chronic low back pain is a very common illness and there are a lot of treatments out there to treat back pain including: physical therapy, surgical options, medications, and conservative care. Some of these treatments can be expensive and a lot of them can be ineffective. It's really important to have an opportunity to treat the actual mechanism of action of pain. That's why facet joint interventions are very important. Dr. Loveless alluded to the fact that this an opportunity to actually prove or disprove the presence of joint syndrome by allowing an actual focused diagnostic block in that area of pathology.

If those patients presumably improved from the block then we could actually in conjunction with physical exam and imaging and other things get down to the real diagnosis of what's causing the back pain. This may allow for more effective and hopefully least expensive treatments. As when you have to do multiple treatments for something, if you don't have the right diagnosis, it accumulates more health care costs.

As pictured, you can see the normal facet joint and facet joint arthritis. The facet joint has a capsule around it and the joint can be seen inside. Those joints are needed for flection extension and different movements . Oftentimes, this type of pain translates chronic low back pain or tactical back pain. Back pain is the most common reason why people actually go visit a primary care physician

The distribution from the Facet Joint Intervention Guidelines that was published in Pain Physician with some of the pain distributions that you notice within the cervical, lumbar spine, and mapping of the thoracic spine.

Chronic low back pain treatments

- Somatic Pain-includes Facet joint pain, where a medial branch block is performed
- Radicular Pain- will be rated as Sciatica common one, pain in the back that doe down the leg

Surgical options for the treatment of back pain are expensive, but Facet Joint nerve blocks are significantly lower.

New LCD Suggestions

- The LCD states, 2nd diagnostic procedure may be performed a minimum of 2 weeks after the first"

Dr. Cohen is supportive of this two-week delay, but feels that others will see this as a problem for many reasons.

Problem: Why delay since the duration of local anesthetic is far less than 2 weeks?

Solution: 1 week

- General Comment-Page 4 B ii- "the 80% relief, or at least 50%, consistent with functional improvement metrics"
- Page 4.C-First line it states "median" branch
- Should be changed to "medial branch" to be consistent with accepted medial term
- Page 6, 6 (second #6) "diagnostic injections or MMB" is incorrect

Should be changed to (MBB for medical branch block)

Page 6, 6 (second #6) "MBB at the same level as previously successful RFA is not reasonable or necessary " yet #7 in the previous section, it states the RFA can be done if prior RFA within 24 months.

Reading this implies that it can't be done if the RFA was done greater than 24 months. If it says, it was done within 24 months, what if it's greater? Dr. Cohen doesn't know if that was the intent to limit it that way.

- Page 6, 2nd paragraph under provider qualification-change "healthcare professionals" to "physicians"

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Too many untrained for professionals may be able to perform be based on the LCD such as physician assistants or nurse practitioners. These professionals may not be consistence with the rules and law.

Dr. Alison Stout had not disclosures to provide.

Dr. Stout is presenting slides on behalf of the Spine Intervention Society and this information was been produced by the Health Policy Division of the Spine Intervention Society. Dr. Stout is a practicing clinician in Washington State and on the board of directors of Spine Intervention Society.

Diagnostic for Facet Joint Procedures

Dr. Stout agrees that a second diagnostic medial branch or facet diagnostic procedure is medically necessary, but the two-week delay is necessary.

This suspicion is brought forward from that a two-week delay between epidural steroid injections as long as it is a diagnostic procedure that doesn't require any steroids. Therefore, a two-week delay doesn't have any clear medical rationale.

As mentioned by Dr. Cohen, a potential delay of 7 to 10 days based on a global treatment time may create problems for traveling patients. Dr. Stout has patients that come from far distances and requiring that kind of delay could inhibit their ability to receive care for facet joint pain.

Criteria for Second Diagnostic Facet Joint Procedure

Dr. Stout agrees with the meeting the criteria for the first diagnostic procedure.

And yes, after the first diagnostic facet set procedure, there must be a consistent positive response, and at least 80% relief of their index pain with the duration of the relief being inconsistent with the anesthetic used.

The second part of the or at least 50% consistent objective improvement in our ability to perform previously painful movements, ADLs. Dr. Stout expressed that this requirement may be difficult to measure the reliably and could lead to risk of overutilization. Physicians could possibly be involved with more audits without a clear definition being listed.

Therapeutic Facet Joint Procedures

- It is not necessary to require two diagnostic needle branch blocks prior to a therapeutic intraarticular injection.

Intraarticular injection can include local anesthetic and a steroid. This will allow for both diagnostic and therapeutic at the same time.

There is a percentage of patients who obtain relief from a single intraarticular. In select patients, this really could result in significant cost savings over this three steps needed to perform a radiofrequency neurotomy.

- Medial branch blocks are diagnostic procedures only.
    - There's no anatomical basis of putting steroids on the medial branch nerve
    - The use of steroids on the medial branch nerves has not shown to produce long term effects
- The proposed new criteria of at least 50% consistent improvement in the ability to perform previously painful movements and ADLs
    - Could lead to risk overutilization.
- If a patient obtains at least 50% relief from a therapeutic face joint injection, why require documentation that they are not a candidate for radiofrequency neurotomy?
- Therapeutic intraarticular facet injections may be appropriate to perform as an initial treatment and appropriate to repeat in patients that obtain at least 50% relief from their index pain for at least 3 months.
- If patients do not obtain at least 3 months improvement from a therapeutic facet injection, then it would be appropriate to perform diagnostic MBBs to evaluate if they have face pain that may be amendable to RFN.
    - This can lead to cost savings

Facet Joint Denervation (Radiofrequency Ablation/Neurotomy)

- Dr. Stout agrees that coverage decision of at least two medically reasonable unnecessary diagnostic medical branch blocks each providing a minimum 80% relief of their primary index pain consistent with the agent or anesthetic used.
- At least 50% improvement in painful movements in ADLs
  - » Could lead to risk overutilization

Limitations

- Repeating MMB after the diagnostic procedures after 24 months of pain relief from RFN is not necessary. There are patients who experience more than 24 months really from a radio frequency neurotomy
  - » As long as it is documented that it is the same pain with a visit with pain, diary, and or documentation of the physical exam showing that it's in the same location. Requiring another set of medial branch blocks prolongs the pain and adds additional procedures that may not be necessary.
- Requiring documentation of why RFN should not be performed with patients being treated with therapeutic intraarticular facet injections creates unnecessary work or the physician that will not result in improved patient care. (e.g. edematous joint/surrounding bone and whiplash injuries).

Provider Qualifications

- Consider replacing "healthcare professionals" with "physicians"
  - » Facet Joint procedures requires extensive knowledge of the anatomy and physiology performing a radio frequency.

Questions

Please contact Belinda (Senior Director of Policy and Practice Spine Innervation Society) at bduzynski@SpineIntervention.org

Dr. Loveless requested that Dr. Stout and any other presenters provide recommendations as a modality to measure functional improvement.

Dr. Laxmaiah Manchikanti disclosed no conflicts of interest

Dr. Manchikanti reviewed the Medicare Program Integrity Manual details regarding LCDs.

- It has to target Medicare population.
- In conducting a review, MACs shall use the available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines.
- MACs are to explain the rational that supports their coverage
- Medical necessity
  - » Safe and effective
  - » Not experimental or investigational
  - » Appropriate, including the duration and frequency that is considered appropriate for the item or service

Facet joint injections, therapeutic medial branch blocks, and radio frequency neuropathy are appropriate based on their duration relief. Procedures may only be eliminated with overwhelming negative evidence.

Issues with Proposed Rule

- The language is vague and confusing
- Deviates from existing LCD-not supported by evidence
- Utilizing guidance from the following societies

- NASS
- AANS
- AHRQ-Choc

Specific Issues

Diagnostic Facet Joint Procedures

- At least 50% consistent objective improvement in the ability to perform previously painful movements and activities of daily living (ADLs) may be confusing to some
  - The following recommendation should be at least 50% consistent objective improvement in the ability to perform previously painful movements or provocative maneuvers

Therapeutic Face Joint Procedures

- **Option I:** Restriction only when patient is not a candidate for radiofrequency should be removed and return to old language
- **Option III:** Expand indications

Limitations

- 6. The number of levels, either unilateral or bilateral are allowed, are allowed per session per the spine region. The need for a three-level procedure may be considered under unique circumstances with sufficient documentation of medical necessity on appeal.
  - **Suggestion:** Two joints for bilateral procedures and 4 joints unilateral area allowed per session per spine region.
- 7. Repeat MBB after 24 months of pain relief from therapeutic face joint injections or RFA is not necessary
- Consider deletion or change to if there is no change in the symptomatology, or physical examination, there is no requirement for repeat medial branch blocks
  - Not Reasonable and Necessary
- 4. Face joint procedure performed at a fused posterior spinal motion segment
  - Not much literature is available, consider deletion

Closing

Presenters are to include the supporting literature with your comments to ensure that CGS is referencing the literature specific to your recommendations and suggestions.

The comment period will be open through December 12th, 2020 to stakeholders within CGS's jurisdiction.