LCD - Facet Joint Interventions for Pain Management (L33930)

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CMS National Coverage Policy

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IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*,
  - Chapter 15, Section 50 Drugs and Biologicals
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1,
  - Part 1, Section 30.3 for Acupuncture
  - Part 2, Section 150.7 for Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents
  - Part 4, Section 220.1 for Computed Tomography (CT)
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1861(s)(2)(K), medical or surgical services provided by a physician, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist;
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)[14], which are other than physicians' services described by section 1861(s)(2)(K)
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Code of Federal Regulations (CFR) References:

- CFR, Title 42, Volume 2, Chapter IV, Part 410.74 Physician assistants' services.
- CFR, Title 42, Volume 2, Chapter IV, Part 410.75 Nurse practitioners' services.
- CFR, Title 42, Volume 2, Chapter IV, Part 410.76 Clinical nurse specialists' services.
- CFR, Title 42, Volume 3, Chapter IV, Part 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.
- FR, Volume 65, Number 68, Page 18543. April 7, 2000, non-physician providers services, as defined

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

The spine is the most common source of chronic pain. Chronic axial spinal pain is one of the major causes of disability and accounts for a substantial U.S. health burden. Chronic spine pain poses a peculiar diagnostic and therapeutic challenge due to multiple pain sources, overlapping clinical features, and nonspecific radiological findings.

The facet joints can cause axial spinal pain and referred pain in the extremities. The pathology of the pain source is due to facet joints being richly innervated by the nerve fibers from the medial branch of the dorsal ramus of spinal nerves. Each facet has a dual nerve supply. One exception is at the C2–C3 zygapophysial joint, which has a singular nerve supply from the third occipital nerve (the superficial medial branch of C3 dorsal ramus).[1]

Facet joint interventions may be used in pain management for chronic cervical/thoracic and back pain arising from the paravertebral facet joints. The facet block procedure is an injection of a local anesthetic, with or without a steroid medication, either into the facet joint (intra-articular) or outside the joint space around the nerve supply to the joint (the medial branch nerve) known as medial branch block (MBB). Imaging guidance (fluoroscopy or CT per code descriptor) is used to assure accurate placement of the needle for the injection. Paravertebral facet joint denervation is a therapeutic intervention used to provide both long-term pain relief and reduce the likelihood of recurrence of chronic cervical/thoracic or back pain confirmed as originating in the facet joint's medial branch nerve.[1]

There are various methods that may be used in performing facet joint denervation. Percutaneous radiofrequency ablation (RFA) is a minimally invasive procedure done with imaging guidance (fluoroscopy or CT per code descriptor) and involves using energy in the radiofrequency range to cause necrosis of specific nerves (medial branches of the dorsal rami), preventing the neural transmission of pain. Conventional radiofrequency ablation (non-pulsed or continuous) applies thermal energy of typically 80 to 85 degrees Celsius. The terms RFA and radiofrequency neurotomy are used interchangeably. Both terms refer to a procedure that destroys the functionality of the nerve using radiofrequency energy. Non-thermal methods of denervation include chemical (chemodenervation), low-grade thermal energy (less than 80 degrees Celsius), pulsed RFA, laser neurolysis, and cryoablation.[1]

Throughout this document, societal recommendations with the grading of evidence are referenced. There are multiple systems to grade or rank the quality of medical evidence and develop evidence-based recommendations. Not all grading systems are equivalent, so while there are typically similarities in the grades or recommendations from various grading systems, they must be considered independent of the other. The references in this document refer to the following grading systems.

1. GRADE Guidelines used in some systematic reviews, the basis for NASS recommendations align with GRADE.
2. A Modified approach to the grading of evidence[2] and development of interventional pain management specific instrument[3] used in American Society of Interventional Pain Physicians (ASIPP) Guidelines and some systematic reviews.
3. The U.S. Preventive Services Task Force grading of evidence guidelines used by 2020 Consensus Guidelines by Cohen et al[4].
4. Levels of Evidence for Primary Research Question and Grades of Recommendation for Summaries or Review of Studies adopted by North American Spine Society (NASS).[5]

A Multi-MAC Subject Matter Expert (SME) Panel on Facet Joint and Medial Nerve Branch Procedures meeting was held on 5/28/2020.

Covered Indications

A. **Facet Joint Interventions:**

Facet Joint Interventions generally consist of four types of procedures: Intraarticular (IA) Facet Joint Injections, Medial Branch Blocks (MBB), Radiofrequency Ablations (RFA) and Facet cyst rupture/aspiration.

Facet Joint Interventions are considered medically reasonable and necessary for the diagnosis and treatment of chronic pain in patients who meet **ALL** of the following criteria:

1. Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale[11]; **AND***
2. Pain that has been present for a minimum of 3 months with documented failure to respond to noninvasive conservative care management (as tolerated)[4,12]; **AND**
3. Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by facet joint synovial cyst)[4,7]; **AND**
4. There is no non-facet pathology per clinical assessment or radiology studies that could explain the source of the patient's pain, including but not limited to fracture, tumor, infection, or significant deformity.[11]

*Pain assessment must be performed and documented at baseline, after each diagnostic procedure using the same pain scale for each assessment. A disability scale must also be obtained at baseline to be used for functional assessment (if patient qualifies for treatment).

B. **Diagnostic Facet Joint Injection Procedures (IA or MBB):**

The primary indication of a diagnostic facet joint procedure is to diagnose whether the patient has facet syndrome.[1,4,7,12,16] Intraarticular (IA) facet block(s) are considered medically reasonable and necessary as a diagnostic test only if MBB cannot be performed due to specific documented anatomic restrictions or there is an indication to proceed with therapeutic intraarticular injections. These restrictions must be clearly documented in the medical record and made available upon request.

Diagnostic procedures should be performed with the intent that if successful, a RFA procedure would be considered the primary treatment goal at the diagnosed level(s).[11]

A second diagnostic facet procedure is considered medically reasonable and necessary to confirm validity of the initial diagnostic facet procedure when administered at the same level. The second diagnostic procedure may only be performed a minimum of 2 weeks after the initial diagnostic procedure.[7]

1. An initial diagnostic facet joint procedure will be considered medically reasonable and necessary when the patient meets the criteria outlined under the indications for facet joint interventions.
2. A second confirmatory diagnostic facet joint procedure is considered medically reasonable and necessary in patients who meet **BOTH** of the following criteria:
    - The patient meets the criteria for the first diagnostic procedure; **AND**
    - After the first diagnostic facet joint procedure, there must be a consistent positive response of at least 80% relief of primary (index) pain (with the duration of relief being consistent with the agent

used).[11]

Frequency limitation: For each covered spinal region no more than four (4) diagnostic joint sessions will be considered medically reasonable and necessary per rolling 12 months, in recognition that the pain generator cannot always be identified with the initial and confirmatory diagnostic procedure.

C. **Therapeutic Facet Joint Injection Procedures (IA):**

Therapeutic facet joint procedures are considered medically reasonable and necessary for patients who meet **ALL** of the following criteria:

1. The patient has had two (2) medically reasonable and necessary diagnostic facet joint procedures with each one providing a consistent minimum of 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used); **AND**
2. Subsequent therapeutic facet joint procedures at the same anatomic site result in at least consistent 50% pain relief for at least three (3) months from the prior therapeutic procedure or at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale[11]; **AND**
3. Documentation of why the patient is not a candidate for radiofrequency ablation (such as established spinal pseudarthrosis, implanted electrical device) is in the medical record.[5,42,43,44]

Frequency limitation: For each covered spinal region no more than four (4) therapeutic facet joint injection (IA) sessions will be reimbursed per rolling 12 months.

D. **Facet Joint Denervation:**

An initial thermal RFA of cervical, thoracic, or lumbar paravertebral facet joint (medial branch) nerves is considered medically reasonable and necessary for patients who have had at least two (2) medically reasonable and necessary diagnostic MBBs, with each one providing a consistent minimum of 80% sustained relief of primary (index) pain (with the duration of relief being consistent with the agent used).

Repeat thermal[11] facet joint RFA at the same anatomic site is considered medically reasonable and necessary provided the patient had a minimum of consistent 50% improvement in pain for at least six (6) months **or** at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale.

Frequency limitation: For each covered spinal region no more than two (2) radiofrequency sessions will be reimbursed per rolling 12 months.

E. **Facet Cyst Aspiration/Rupture**

Intra-articular facet joint injection performed with synovial cyst aspiration is considered medically reasonable and necessary when **BOTH** of the following criteria are met:

1. Advanced diagnostic imaging study (e.g., MRI/CT/myelogram) confirm compression or displacement of the corresponding nerve root by a facet joint synovial cyst; **AND**
2. Clinical and physical symptoms related to synovial facet cyst are documented in the medical record.

Frequency limitation: Cyst aspiration/rupture may be repeated once and only if there is 50% or more consistent improvement in pain for at least three (3) months.[11]

Limitations

1. Facet joint interventions done without CT or fluoroscopic guidance are considered not medically reasonable and necessary. This includes facet joint interventions done without any guidance, performed under ultrasound guidance,[4,11] or with Magnetic Resonance Imaging (MRI).[4]
2. General anesthesia is considered not medically reasonable and necessary for facet joint interventions. Neither conscious sedation nor Monitored Anesthesia Care (MAC) is routinely necessary for intraarticular facet joint injections or medial branch blocks and are not routinely considered medically reasonable and necessary. Individual consideration may be given on redetermination (appeal) for payment in rare, unique circumstances if the medical necessity of sedation is unequivocal and clearly documented in the medical record. Frequent reporting of these services together may trigger focused medical review.[4]
3. It is not expected that patients will present with pain in both cervical/thoracic and lumbar spinal regions. Therefore, facet joint interventions (both diagnostic and therapeutic) are limited to one spinal region per session.
4. It is not routinely necessary for multiple blocks (e.g., epidural injections, sympathetic blocks, trigger point injections, etc.) to be provided to a patient on the same day as facet joint procedures. Multiple blocks on the same day could lead to improper or lack of diagnosis. If performed, the medical necessity of each injection (at the same or a different level[s]) must be clearly documented in the medical record. For example, the performance of both paravertebral facet joint procedures and a transforaminal epidural steroid injection (TFESI) at the same or close spinal level at the same encounter would not be expected unless a synovial cyst is compressing the nerve root. In this situation, TFESI may provide relief for the radicular pain, while the facet cyst rupture allows nerve root decompression. Frequent reporting of multiple blocks on the same day may trigger a focused medical review.
5. Facet joint intraarticular injections and medial branch blocks may involve the use of anesthetic, corticosteroids, anti-inflammatories and/or contrast agents and do not include injections of biologicals or other substances not FDA designated for this use.
6. One to two levels, either unilateral or bilateral, are allowed per session per spine region. The need for a three or four-level procedure bilaterally may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal. A session is a time period, which includes all procedures (i.e., MBB, IA, facet cyst ruptures, and RFA ablations) that are performed during the same day.
7. If there is an extended period of time, two years or more, since the last RFA and/or there is a question as to the source of the recurrent pain then diagnostic procedures must be repeated.
8. Therapeutic intraarticular facet injections are not considered medically reasonable and necessary unless there is documentation explaining why RFA cannot be performed.[5,42,43,44]
9. Facet joint procedures in patients for the indication of generalized pain conditions (such as fibromyalgia) or chronic centralized pain syndromes are considered not medically reasonable and necessary. Individual consideration may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal.[56]
10. In patients with implanted electrical devices, providers must follow manufacturer instructions and extra planning as indicated to ensure safety of procedure.

The following are considered not medically reasonable and necessary:

1. Intraarticular and extraarticular facet joint prolotherapy [5,42,43,44]
2. Non-thermal modalities for facet joint denervation including chemical, low-grade thermal energy (less than 80 degrees Celsius), laser neurolysis, and cryoablation

3. Intra-facet implants[58]
4. Facet joint procedure performed after anterior lumbar interbody fusion (ALIF)
5. Definitive clinical and/or imaging findings pointing to a specific diagnosis other than facet joint syndrome
6. Diagnostic injections or MBB at the same level as the previously successful RFA procedure

Notice: Services performed for any given diagnosis must meet all the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

Provider Qualifications

Patient safety and quality of care mandate that healthcare professionals who perform facet injections/procedures are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program. If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure, and utilization of the required associated imaging modalities.

In addition to the above requirements, non-physician providers, such as certified nurse anesthetist, with certain exceptions, may certify, order and establish the plan of care as authorized by State law. (See Sections 1861[s][2] and 1862[a][14] of Title XVIII of the Social Security Act; 42 CFR, Sections 410.74, 410.75, 410.76 and 419.22; FR Vol. 65, No. 68 page18543, April 7, 2000). Each practitioner must provide only those services within the scope of practice for each state.

Definitions

Acute Pain: The temporal definition of pain persisting for up to 4 weeks after the onset of the pain.

Axial: Relating to or situated in the central part of the body, in the head and trunk as distinguished from the limbs, e.g., axial skeleton.

Biopsychosocial Model: Interdisciplinary model that looks at the interconnection between biology, pathology and socioenvironmental factors.

Central Neuropathic Pain: Pain, which is causally related to a lesion or disease of the central somatosensory nerves.

Centralized Pain: A neurological chronic pain syndrome of the central nervous system (brain, brainstem, and spinal cord) which commonly presents with widespread generalized allodynia which is causally related to the increased responsiveness of nociceptive nerves in the central nervous system to the normal threshold or subthreshold simulation from the afferent nerves. The condition has also been called "central sensitization," "central amplification," and "central pain syndrome." Fibromyalgia is considered one of the most common centralized pain syndromes.

Cervical Facet Pain: Pain located in the cervical spine, which may be characterized by chronic headaches, restricted motion, and axial neck pain, which may radiate sub-occipitally to the shoulders or mid-back.

Chronic Pain: The temporal definition of pain persisting for greater than or equal to 12 weeks after the onset of the pain.

Dual Diagnostic Blocks: The diagnostic technique of injecting the same spinal nerve on two separate occasions to be used as an efficacy comparison to increase diagnostic accuracy.

Epidural Steroid Injection: The administration via injection of steroid medicine into the potential epidural space in the spinal column to deliver steroids to the spinal nerves.

Facet Joint Intraarticular Injections, Diagnostic: The placement of local anesthetic and possibly a corticosteroid into the facet joint to diagnose facet joint pain.

Facet Joint Intraarticular Injections, Therapeutic: The placement of local anesthetic and possibly a corticosteroid into the facet joint to produce the beneficial effect of pain reduction.

Facet Joint: A diarthrodial joint in the spinal column (also called the zygapophysial joint or z-joint), producing the articulation of the posterior elements of one vertebra with its neighboring vertebra. There are bilateral superior and inferior articular surfaces at each spinal level. The terminology or nomenclature of the facet joint is classified by the specific vertebrae level that forms it (e.g., C4-5 or L2-3). There are two (2) facet joints, right and left, at each spinal level.

Facet Injection: (also called facet block) A general term used to describe the injection of local anesthetic and possibly a corticosteroid in the facet joint capsule or along the medial branch nerves supplying the facet joints.

Facet Joint Denervation or Radiofrequency Ablation (RFA): A general term used to describe the minimally invasive procedure that uses thermal energy generated by the radiofrequency current to deprive the facet joint of its nerve supply. The procedure is also known as a Medial Branch Radiofrequency Neurotomy (Ablation) because it is used to thermally remove the medial branch nerve by using electrical current to create thermal energy to coagulate the adjacent tissues around the targeted medial branch nerve.

Facet Joint Syndrome: A set of concurrent signs or symptoms to describe facet joint pain as the pain generator. The typical clinical signs or symptoms of a facet syndrome may include local paraspinal tenderness; pain that is brought about or increased on hyperextension, rotation, and lateral bending; low back stiffness; absence of neurologic deficit; absence of root tension signs (non-radiating below the knee, absence of paresthesia). Cervical facet pain is often characterized by chronic headaches, restricted motion, and axial neck pain, which may radiate sub-occipitally to the shoulders or mid-back.

Facet Level: Refers to the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint. Each level has a pair of facet joints: one on the right side and one of the left side of the spine.

Intra-Articular Injection (IA): The injection of local anesthetic and possibly a corticosteroid into the facet joint capsule.

Medial Branch: The dorsal ramus is the dorsal branch of a spinal nerve that forms from the dorsal root of the nerve after it emerges from the spinal cord.

Medial Branch Block (MBB): The placement of local anesthetic and possibly a corticosteroid near the medial

branch nerve which supplies the sensory innervation to a specific facet joint.

Neuropathic Pain: The pain which is caused by a lesion or disease of the somatosensory nerves.

Neurogenic Claudication: Intermittent leg pain from impingement of the nerves emanating from the spinal cord (also called pseuduoclaudication).

New Onset of Spinal Pain: The new onset of the spinal pain must be materially and significantly different in location, type, duration and character from the previously treated spine pain.

Noninvasive Conservative Management: The use of nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, physical therapy, acupuncture (applies to only chronic low back pain), or spinal manipulation. This management should include the application of a biopsychosocial treatment technique.

Non-Radicular Back Pain: The radiating non-neuropathic pain which is not causally related to a spinal nerve root irritation and does not produce reproducible neuropathic symptoms in an objective dermatomal pattern.

Peripheral Neuropathic Pain: Pain, which is causally related to a lesion or disease of the peripheral somatosensory nerves.

Radicular Back Pain: The radiating neuropathic pain causally related to the spinal nerve root irritation which extends into the distal distribution, typically the lower extremity, producing neuropathic pain in a dermatomal pattern.

Radiculopathy: Radiating neuropathic pain causally related to the spinal nerve root irritation, which extends distal producing neuropathic pain in a dermatomal pattern.

Region: The segments of the back involved will be defined in this policy as two regions:

1. Cervical/Thoracic region = C1-C7/T1-T12
2. Lumbar/Sacral region = L1-L5/S1-S5

Session: A time period, which includes all procedures (i.e., MBB, IA, facet cyst ruptures, and RFA ablations) performed during one day.

Subacute Pain: The temporal definition of pain occurring during the 4-12-week time period.

Transforaminal Epidural Steroid Injection (TFESI): An epidural injection performed via a paramedian approach to enter the epidural space by placing the needle in the posterior-superior quadrant of the intervertebral foramen (neuroforamen) to inject near the dorsal root ganglion and exiting spinal nerve root (previously known as a selective nerve root block).

Summary of Evidence

Diagnostic Facet Joint Injections

Due to the lack of reliable history, physical exam, or imaging to predict response, providers must rely on facet

interventions diagnostic injections given for diagnostic purposes to determine if the facet joint is the source of suspected spinal pain. There is controversy over optimal patient selection for diagnostic injections, which measures successful response and type and number of diagnostic injections performed.

Numerous investigations have been undertaken to correlate symptoms and physical exam findings with facet pathology and have concluded conventional clinical findings are unreliable in identifying facet joint success.[4,6,7] A 2020 summary of the literature by Cohen et al "Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group" included 21 studies evaluating the association of physical exam findings with facet block results, and concluded there was no historical or physical exam findings that could reliably predict response to facet joint blocks, grade C evidence, low level of certainty.[4] This is consistent with ASIPP 2020 Comprehensive Evidence-Based Guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines (2020 ASIPP Guidelines) which rated accurate diagnosis of facet joint pain with physical examination and symptoms level IV with a weak strength of recommendation.[7] 2020 NASS Guidelines reported insufficient evidence to make a recommendation for or against patient reported reproduction of pain during a facet joint injection as a predictor of response to dual diagnostic blocks with a grade 1 recommendation.[5,7] A careful medical history and exam remain an important component to the evaluation of other etiologies of low back pain and raise suspicion of facet source.[7] Physical findings can help identify levels for blocks, and maneuvers can aid in the detection of radicular symptoms.[4]

Imaging studies have been investigated as a marker of painful lumbar facet joints. While degenerative changes can be found in imaging, they have not been correlated as a reliable predictor of success with facet interventions.[4,7] Nonetheless, imaging studies often play an important role in the exclusion of other etiologies of back and cervical/thoracic pain. Single-photon emission computed tomography (SPECT), a nuclear medicine imaging technique, can identify active inflammatory markers as seen in facet disease but have not shown consistent results in the prediction of facet joint intervention success. 2020 Consensus Guidelines reported on 12 studies and concluded moderate evidence for SPECT (grade C, moderate certainty) and weak evidence for scintigraphy, MRI, and CT with no to weak supporting evidence.[4] 2020 ASIPP Guidelines reported level III evidence for SPECT with weak strength of recommendation and level V evidence for other imaging modalities, weak recommendation.[7]

Conservative treatment, also called medical/interventional treatment, includes integrative treatments (such as acupuncture [see NCD 30.3] or spinal manipulation); physical treatments (physical therapy including exercise, heat and cold modalities, massage), medications (non-steroidal anti-inflammatory drugs [NSAIDS]/antidepressants), and lifestyle modifications (weight loss, sleep hygiene, nutrition, smoking cessation) are typically perused before interventional procedures. Facet joint pain is frequently accompanied by other pain etiologies, which may benefit from conservative modalities or combined therapy, and it is well accepted that some back pain will resolve spontaneously or with conservative or non-invasive measures over time. A few studies had a conservative arm, or investigated combined modalities that support a combined approach, but did not find a conservative approach alone consistently led to improvement.[5,8] The Agency for Healthcare Research released a systematic review of noninvasive nonpharmacological treatment for chronic pain, including cervical/thoracic and low back. Two-hundred and two trials that evaluated the spectrum of non-invasive treatment modalities concluded durable slight to moderate improvement in function and pain for specific chronic pain conditions and support clinical strategies that focus on non-pharmacological and non-invasive therapies.[9,10] 2015 NASS Guidelines recommend a failure of at least four weeks of non-invasive care[11], 2020 Consensus Guidelines recommend a 3-month trial of different non-invasive treatment[4], 2020 ASIPP Guidelines rated level of evidence II with a strong recommendation for three months after onset and failure of conservative management[7]; European Guidelines extend the period to 1 year.[12] Chronic pain may lead to stress, anxiety, poor sleep and depression, and other psychological sequelae and treatment beyond the pain symptoms may be necessary. Optimally a biopsychosocial model that promotes a multi-disciplinary team approach addressing physical pain and psychological factors are utilized.[13] Patients with chronic pain may also benefit from cognitive behavioral therapy, biofeedback, and other psychological interventions.[14]

Due to the lack of reliable history, physical exam, or imaging to predict response to facet interventions, diagnostic injections may be given for diagnostic purposes to determine if the facet joint is the source of suspected spinal pain.

The response pattern to diagnostic facet joint injections has become the gold standard for diagnosing facet syndrome. Temporary or prolonged abolition of the spinal pain suggests that facet joints were the source of the symptoms.[1] The possibility of false-positive and false-negative reporting is an inherent risk with facet blocks and challenges identifying the patients most likely to have a positive response to treatment.[4,7] Intra-articular (IA) and MBBs have been evaluated for predictive value for successful RFA. 2020 ASIPP Guidelines reported on ten studies in the lumbar spine and found prevalence rates ranged from 27% to 40% with false-positive rates of 27% to 47%, with ≥ 80% pain relief. They conclude level 1-2 evidence with moderate to strong strength of recommendation of lumbar, diagnostic facet nerve blocks.[7] While both IA and MBB blocks have been shown in studies to be predictive of success with RFA (2020 Consensus Guidelines grade B recommendation, low level of certainty)[4] five studies comparing lumbar MBB to IA injections, including two randomized studies[1,16] supports MBB as the preferred modality, largely due to high technical failure rate and pain associated with the IA injections. One randomized trial focusing on younger patients shows IA injection with steroids may play a role in patients in which MBB is contraindicated (Grade C evidence, moderate certainty).[4] The Greater Manchester EUR Policy Statement on Facet Injections no longer commissioned IA facet injections and recommended medial branches nerve blocks for diagnostic evaluation for RFA.[12] The Spinal Intervention Society (SIS) recommended that medial branch blocks replace intra-articular injections as a diagnostic indicator.[1]

In order to determine if a block is successful, there must be an assessment/measurement of pain and function. There are three points in which pain/function must be evaluated: 1. baseline; 2. after a diagnostic block; and 3. at each follow-up to evaluate long term relief. The definition of success lacks consistency, and there are different cut off values in the literature. Among the Multi-MAC SME panel, there was an agreement that subjective improvement in pain is a valid measurement of improvement in pain (average voting score of 3.8/5). However, there was not agreement on what the cut-off should be, if a tool should be used, and if so, which tool. There was also a consensus that function is the most important indicator of success. A study assessed the validity of subjective improvement rating improvement after one IA joint injection and compared subjective rating to use of Visual Analog Score (VAS) scoring and concluded that validity of pain provocation alone as criterion standards in patients undergoing diagnostic facet injections should be questioned with the positive predictive value of 16% for predicting facet joint as a source of pain.[17] Clinical trials and policy have used multiple standardized tools to measure pain, including the Numerical Rating Scale (NRS) and (VAS), with pre-set cut off values in an attempt to determine a specific measurement in which patient's may most benefit from intervention. Studies have evaluated if a specific cut-off value can predict outcomes of RFA and do report a high correlation between verbal rating scales, NRS and VAS scores in prediction of outcomes with RFA. However, the panel did not agree on a minimum value that can be used with these tools. The Multi-MAC SME panel did agree that measurement of function can provide valuable clinical input into improvement, such as the ability to stand, walk, and the ability to do activities of daily living and can predict success with future therapeutic procedures. There are multiple tools to measure function including the Pain Disability Assessment Scale (PDAS),[18] Oswestry Disability Index (ODI),[19] Oswestry Low Back Pain Disability Questionnaire (OSW), Quebec Back Pain Disability Scale (QUE),[20] Roland Morris Pain Scale,[21] Back Pain Functional Scale (BPFS),[22] and the easy to use Patient Reported Outcomes Measurement Information System (PROMIS) profile domains which have been found to correlate well with the ODI scale.[23]

For the diagnostic block, the pain relief achieved is temporary and used as a predictor of success for subsequent RFA. The objective is to reduce false-positives that would not be predictive of success with RFA and avoid false-negative patients who could benefit but would not be offered treatment. Most studies have used a cut-off of pain relief greater than 80% to consider MBB as positive. Ten studies assessing the prevalence of lumbar facet joint pain using a cut-off value of 80% relief reported a prevalence rate of 27% to 40% with false-positive rates of 27% to 47% receiving a moderate to a strong recommendation from 2020 ASIPP Guidelines.[7] One paper reports dual comparative blocks are advocated as a means of identifying true-positive cases and excluding placebo responders and have been shown to have a sensitivity of 100% and a specificity of 65%.[24]

As stated in the 2020 Consensus Guideline: "the cut-off designating an MBB as positive is one of the most controversial areas in pain medicine".[4] Cohen et al in 2013, in a prospective study to evaluate predictive values reported no difference in the predictive value of ≥ 50% to <80% pain reduction vs. ≥80% pain reduction.[25] The

guidelines advocate for using ≥50% for clinical trials and clinical practice. The guidelines acknowledge that the existing evidence does not adequately address the 50-80% group and that this cut-off was selected to maximize access to care given lack of reliable alternative treatment options in this population and potential benefit of treatment in this group.[4] On the contrary, there are studies that show patients with ≥80% relief are more likely to show a positive response to RFA. 2020 ASIPP Guidelines report Level I to II evidence based on ten diagnostic accuracy studies (using ≥75% and ≥80% criterion) and offer moderate to strong strength of recommendation. They cite the literature using the 50% cut-off is conflicting due to internal inconsistencies.[7]

There is controversy regarding the number of diagnostic blocks needed to ensure an accurate diagnosis before proceeding with RFA. Derby et al evaluated the correlation of lumbar MBB with diagnostic MBB cutoff values to optimize therapeutic outcomes and a failure of single MBB and conclude with a dual block protocol a 70% cut-off value was acceptable. With a single block, 80% or higher was optimal.[26,27] Three systematic reviews also showed significantly better improvement with dual MBB with 80% cut off value.[28-30] Two randomized controlled trials (RCTs) (one in the cervical region) demonstrated positive results with dual blocks.[31,32] SIS and ASIPP advocate for dual diagnostic blocks, and diagnostic accuracy is reduced if lower cut-off criteria are used. In contrast, the 2020 Consensus Guidelines advocate for single blocks using a 50% cut-off. One RCT compares outcomes of stratified by different prognostic values and reported the success rate in those who underwent RFA in the zero (no block), single and double block groups were 33%, 39%, and 64%, respectively.[33] Another study reporting on success rates of RFA based on the number of blocks concludes no difference in outcomes based on the number of blocks.[34] A meta-analysis of five RCTs using zero or one block favored RFA.[35] However, a meta-analysis is challenging given the high heterogenicity of the literature. The 2020 Consensus Guidelines suggest the number of blocks depends on the goals with dual blocks preferable for research where diagnostic accuracy is critical while single (or no) blocks reduce the number of procedures and access to care. Balancing these factors, they recommend a single block reporting moderate evidence that dual blocks result in higher success with RFA, but zero-block results in the highest number of patients with a positive response to RFA.[4] The result of voting from the Multi-MAC SME Panel was a score of 3.2/5, stating confidence in the clinical literature to support two MBB needed to diagnose facet pain. NASS Guidelines recommend dual MBB blocks on two separate occasions and second block administered only if >80% relief with the first block due to an unacceptably high false-positive rate of single diagnostic injection.[11] In the 2020 NASS Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care, they state a single diagnostic IA injection with 50% pain relief provides no clinically meaningful improvement at six months (Grade of Recommendation B) and insufficient evidence to make a recommendation for or against the use of RFA (Grade of Recommendation I [Insufficient]).[5]

The literature and societal guidance report that diagnostic injections should be medial branch blocks, not intraarticular injections. This is agreed upon in the 2020 Consensus Guidelines, 2020 ASIPP Guidelines, and NASS Guidelines. NASS Guidelines state IA facet injections have not been validated for diagnostic use, and the false positive rate is unknown as well as lack of effectiveness studies comparing IA vs. MBB in the cervical spine.[11] The exceptions in the case of the occipitoatlantal and atlantoaxial joints, since there are no medial branch or other intervention to block readily. In these cases, dual blocks with 80% relief are supported by most guidelines.[5]

Therapeutic Joint Injections

Intra-articular injections into the facet joint have been used as a treatment modality for facet related pain and remains controversial. Therapeutic injections typically include a corticosteroid as there would not be anticipated long-acting pain relief from a short-term local anesthetic. Among the Multi-MAC SME panel, the average voting was 2.70, with a range from 1-4. There is clinical evidence against the use of IA therapeutic facet joint injection. Lilius et al conducted an RCT including 109 patients who failed to show a difference between saline, steroids, and anesthetic injected around two facet joints.[36] Carette et al conducted an RCT including 101 patients with IA lumbar facet pain which showed a non-significant difference between the injection of saline and depo-corticosteroid with 22% in the steroid group compared to 5% in the saline group reporting benefit at six months.[37] A small RCT, including 41 patients, reported return of pain in 3 days after IA steroid injection compared to 3.5 days in the control.[38] Kennedy et al performed a small RCT comparing IA facet injections with a steroid to saline and did not find a change in need

for RFA.[39] In the FACTS study, a double-blinded RCT, Cohen et al found no significant difference for pain relief or functional outcome change between lumbar facet IA injection with steroid or anesthetic or MBB with steroid, anesthetic or saline for up to 6 months post-injection. Five patients made it to the 6-month follow-up, of which two had RFA. The FACTS study also found that MBB for anesthetic or steroids did not perform better than saline.[12]

On the contrary, a systematic review by Manchikanti et al (2014) using a modified approach to the grading of evidence[2] and reported 20 RCTs assessed with moderate to high-quality methodological criteria. For therapeutic interventions, the evidence was variable from level II to III, with level II evidence for lumbar facet joint nerve blocks and radiofrequency neurotomy for long-term improvement (greater than six months), and level III evidence for lumbosacral zygapophysial joint injections for short-term improvement only. This review provides evidence for the diagnostic validity of facet joint nerve blocks, and moderate evidence for therapeutic radiofrequency neurotomy and therapeutic facet joint nerve blocks in managing chronic low back pain.[6] These two studies have been criticized for a high proportion of patients taking opioids and prior back surgery, lack of control groups, and the absence of blinding.[4] Schneider et al reported in rigorously selected patients, 56% of patients had 100% pain relief at six months.[40] A systematic review by Engel reported sustained relief of 6 months, and 1/3 had relief at one year.[29]

This is in contrast with another systematic review during the same period that looked at the evidence supporting the use of therapeutic IA facet joint injections for patients with suspected facet joint pain. The review focused on IA facet joint injections with active drug or placebo/inactive injection are more effective in reducing back pain and back pain-related disability than conservative treatment. A total of 391 records were screened, and six trials were included. The trials included were small (range 18 -109 participants), and overall in terms of pain and disability outcomes, most were inconclusive. Only two of the trials report any significance between the group's differences in pain or disability outcomes. The authors addressed the limitations and flaws in these trials that were clinically diverse and precluded any meta-analysis. Several methodological issues were identified. The positive results are interpreted with caution and suggest that there is a need for further high-quality work in this area.[41]

Many societal recommendations that do not support the use of therapeutic facet joint injections include:

- The 2020 Consensus Guidelines developed by a multispecialty international working group recommend against the routine use of therapeutic facet injections giving it a grade D, moderate level of certainty.[4]
- National Institute for Health and Care Excellence (NICE) guideline on Low back pain and sciatica in over 16s: assessment and management[42] recommendations are based on systematic reviews of best available evidence and explicit consideration of cost effectiveness. The NICE recommendation for image-guided facet joint injections "Do not offer spinal injections for managing low back pain. The Guideline Development Group (GDG) agreed that health-related quality of life, pain severity, function, and psychological distress were the outcomes that were critical for decision making. Responder criteria (greater than 30% improvement in pain or function), adverse events, and healthcare utilization were also considered as important. Evidence was reported for all the outcomes except for psychological distress and healthcare utilization. For image-guided facet joint injections, evidence was only available for pain, function, and responder criteria. There was no evidence for any of the other outcomes." The NICE summary concludes: "Overall, the GDG agreed that there was no consistent good quality evidence to recommend the use of spinal injections for the management of low back pain. There was minimal evidence of benefit from injections, and reason to believe that there was a risk of harm, even if rare. The GDG consequently agreed that it was appropriate to recommend against the use of spinal injections for people with low back pain."
- The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) 2014 Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine: Part 13: injection therapies, low-back pain, and lumbar fusion. Lumbar intraarticular facet injections are not recommended for the treatment of chronic lower-back pain. The literature does suggest the use of lumbar medial nerve blocks for short-term relief of facet-mediated chronic lower-back pain without radiculopathy.[43]
- The North American Spine Society (NASS) Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis 2nd Edition (2016) reports that there is

insufficient evidence to make a recommendation for or against the use of injections for the treatment of degenerative lumbar spondylolisthesis. Grade of Recommendation: I (Insufficient Evidence).[11] The 2020 NASS Low Back Pain Guidelines state there is insufficient evidence to make a recommendation for or against the use of steroid injections for suspected facet-mediated pain (Grade 1 Recommendation) nor sufficient evidence for or against the use of 50% reduction in pain following MBB for diagnosis of facet joint pain (Grade 1 Recommendation). The guidelines also state that the outcomes of RFA become more reliable when more stringent diagnostic criteria are used, and relief is durable for at least six months following procedure (Grade B Recommendation).[5] NASS Guidelines state while there is some evidence in the literature when compared to RFA, RFA offers longer-term pain relief, and long-term outcomes have not been reported in adequately designed trials. They state that if therapeutic IA injections are used, they should be used in patients whose initial injections resulted in pain relief >50% for at least three months and should not be repeated more than three times annually. The guidelines address concern of the majority of research on therapeutic MBBs comes from a single-center, reports on prospective studies and one RCT which had unspecified intervals and cannot determine the true duration of treatment and concern with lack of studies comparing therapeutic MBBs to medical branch RFA.[5,11]

- Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program: Pain Management Injection Therapies for Low Back Pain (2015) authors used predefined criteria and selected randomized trials of patients with lumbosacral radiculopathy, spinal stenosis, nonradicular back pain, or chronic postsurgical back pain that compared effectiveness or harms of the epidural, facet joint, or sacroiliac corticosteroid injections versus placebo or other interventions. Also included were randomized trials that compared different injection techniques and large (sample sizes greater than 1,000) observational studies of back injections that reported harms. Seventy-eight randomized trials of epidural injections, 13 trials of facet joint injections, and one trial of sacroiliac injections were included. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain and that facet joint corticosteroid injections are not effective for presumed facet joint pain.[44]
- A 2009 American Pain Society guideline recommends against the use of corticosteroids into the facet joint.[14]

Some societal recommendations supporting the use of therapeutic facet joint injections include:

- 2020 ASIPP Guidelines[7]: Therapeutic Facet Joint Interventions in Lumbar Spine states:
    - The level of evidence is II with moderate strength of recommendation for therapeutic lumbar facet joint nerve blocks with the inclusion of 3 relevant randomized controlled trials with long-term improvement.
    - The level of evidence is IV with a weak strength of recommendation for lumbar facet joint intraarticular injections with inclusion of 9 relevant randomized controlled trials, with most of them showing lack of effectiveness without the use of local anesthetic.

The American Society of Anesthesiologists (ASA) Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine (ASRA) Practice Guidelines for Chronic Pain Management (2010)[45]:

- Recommendations for joint blocks: RCTs report equivocal findings regarding the efficacy of facet joint steroid injections compared with facet saline injections regarding pain relief for patients with low back pain (LBP). However, studies with observational findings for facet joint injections indicate that pain scores are improved over baseline scores for assessment periods of 1-6 months. Intraarticular facet joint injections may be used for symptomatic relief of facet-mediated pain. Medial branch blocks may be used for the treatment of facet-mediated spine pain.

The American Association of Neurological Surgeons (AANS) and the CNS 2014 Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: injection therapies, low-back pain, and lumbar fusion states lumbar intraarticular facet injections are not recommended for the treatment of chronic lower-back pain. The literature does suggest the use of lumbar medial nerve blocks for short-term relief of facet-mediated

chronic lower-back pain without radiculopathy.[43]

Radiofrequency Ablation

Radiofrequency neurotomy is described as radiofrequency lesioning performed utilizing either a heat lesion or pulsed mode radiofrequency. A thermal radiofrequency neurotomy lesion for facet denervation is performed at 80° to 85°C. Clinically, a higher temperature allows for a larger lesion to be made. The size of the lesion is influenced by the vascularity of the surrounding tissue: the greater the vascularity of the tissue, the smaller the lesion. Overall, the mechanism of radiofrequency neurotomy is described as denaturing of the nerves. Consequently, with radiofrequency, the pain returns when the axons regenerate, requiring repetition of the radiofrequency procedure. The pulsed mode radiofrequency is an application of a strong electric field to the tissue that surrounds the electrode, and the temperature of the tissue surrounding the tip of the electrode does not exceed 42°C and heat is dissipated during the silent period.[7]

The effectiveness of radiofrequency ablation to improve pain and function for facet joint mediated back pain in carefully selected individuals has been explored in the medical literature. Clinical trials report conflicting data on the effectiveness of RFA. Most clinical trials defined success with RFA as 50% pain relief at six months.

A 2015 Cochrane review by Maas et al, including 23 RCTs (n=1,309), evaluated patients who had a positive response to diagnostic block and underwent RFA found moderate evidence on the effectiveness of RFA compared to placebo for pain management of facet origin over the short term (mean difference [MD] -1.47, 95% confidence interval [CI] -2.28 to -0.67). Low-quality evidence that facet joint RFA is more effective than placebo for function over the short term (MD -5.3, 95% CI -8.66 to -.20) and over the long term (MD -3.9, 95% CI -6.94 to 0.47). RFA for disc pain did not show effects compared to placebo over the short or long term (MD -1.63, 95% CI -2.58 to -.68). They concluded no high-quality evidence to suggest RFA procedure provides pain relief for patients with chronic low back pain.[46]

Juch et al reported on 125 patients in the treatment arm and 126 in the control arm (exercise). Patients had a single diagnostic block with at least 50% or more pain reduction before RFA. The mean difference for the primary outcome pain intensity at three months was −0.18 (95% CI, −0.76 to 0.40). The mean difference for functional status at three months was −2.45 (95% CI, −5.53 to 1.03); the RR for global perceived recovery at three months was 1.35 (95% CI, 0.81 to 2.05). This study has been challenged, stating that the lack of efficacy was due to the treatment arm using the perpendicular technique.[47] Perpendicular electrode placement has been questioned with concern it may fail to reach the target nerve or only capture a segment, while parallel electrode placement reliably captures the target nerve and does so along a substantial length of the nerve. Those who challenge these studies report there are three studies (1999-2008) that utilized the parallel technique that would result in positive outcomes and report support for RFA from these trials.[47] There are no recent trials that address this controversy.

Leggett et al (2014) conducted a systematic review to determine the efficacy of RFA for chronic low back pain associated with lumbar facet joints, sacroiliac joints, discogenic low back pain, and the coccyx. Included articles were sham-controlled RCTs, that assessed the efficacy of RFA, reported at least one month of follow-up, and included participants who had experienced back pain for at least three months. Eleven sham controlled RCTs were included: three studies involving discogenic back pain, six studies involving lumbar facet joint pain, and two studies involving sacroiliac joint pain. No studies were identified assessing the coccyx. The evidence supports RFA as an efficacious treatment for lumbar facet joint and sacroiliac joint pain, with five of six and both of the RCTs demonstrating statistically significant pain reductions, respectively. The evidence supporting the RFA for the treatment of discogenic pain is mixed. Future studies should examine the clinical significance of the achieved pain reduction and the long-term efficacy of RFA.[48]

The systematic review (2014) by Manchikanti et al looked at both therapeutic injections, and RFA in lumbar, cervical and thoracic regions evaluated 21 RCTs and five observational trials, using a modified approach to the grading of evidence,[3] reported Level II evidence[2] for RFA in the lumbar and cervical spine, and level IV in the thoracic region.[28] A systematic review by Engel et al 2016, which serves as the basis for NASS recommendations, "The

Effectiveness and Risks of Fluoroscopically-Guided Cervical Medial Branch Thermal Radiofrequency Neurotomy: A Systematic Review with Comprehensive Analysis of the Published Data" using the GRADE system for rating. They conclude the majority of patients were pain-free at six months and over a third pain-free at one year.[29] In 2017, Lee et al conducted a meta-analysis that included seven trials with 454 patients comparing RFA (n=231) to sham or epidural (n=223) and reported greater improvement in the RFA group.[35]

2020 ASIPP consensus guidelines[7] reports on 11 studies on RFA effectiveness and concludes:

- Lumbar Spine: The level of evidence is II with moderate strength of recommendation for lumbar radiofrequency ablation with the inclusion of 11 relevant RCTs with two negative studies and four studies with long-term improvement.

The American Society of Anesthesiologists (ASA) Task Force on Chronic Pain Management and the ASRA Practice Guidelines for Chronic Pain Management (2010) Recommendations for Ablative Techniques (ASA 2010)[45]: The Task Force notes that other treatment modalities should be attempted before consideration of the use of ablative techniques.

- Chemical denervation: Chemical denervation (e.g., alcohol, phenol, or high-concentration local anesthetics) should not be used in the routine care of patients with chronic non-cancer pain.
- Cryoablation: Cryoablation may be used in the care of selected patients (e.g., post-thoracotomy pain syndrome, low back pain [medial branch], and peripheral nerve pain).
- Radiofrequency ablation: Conventional (e.g., 80°C) or thermal (e.g., 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief. Conventional radiofrequency ablation may be performed for neck pain. Conventional or thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of lumbar radicular pain.

National Institute for Health and Care Excellence (NICE) guideline on Low back pain and sciatica in over 16s: assessment and management (2017) Evidence Statement[49]:

- Radiofrequency denervation compared with placebo/sham for low back pain: Evidence from four studies demonstrated clinical benefit in pain for radiofrequency denervation compared to placebo/sham at both the short and long-term follow-ups of less than and greater than four months (low to moderate quality, n=160). In contrast, there was no difference in function between treatments at any time point. Conflicting evidence from one study for quality of life at less than four months follow-up showed clinical benefit for radiofrequency denervation compared to placebo/sham for the SF-36 domains of general health and vitality. Radiofrequency denervation was inferior to sham for the domains of mental health, pain, and social function. There was no difference between treatments for the physical domain (low quality, n= 81).
  Evidence from a single study reporting adverse events at less than four months follow-up demonstrated an increase in adverse effects for radiofrequency denervation in terms of the number of patients with moderate or severe treatment-related pain (low quality, n = 79). There was no difference in other adverse events (change of sensibility and loss of motor function) at short term follow-up when radiofrequency denervation was compared to placebo/sham in the same study (very low quality). Additionally, when compared with placebo/sham, a benefit for radiofrequency denervation in responders to pain reduction measured by global perceived effect was demonstrated by two studies at both the less than and greater than four months follow-up time points. However, this was not seen for pain reduction measured by VAS at less than four months reported by a single study (low quality, n equal to 111).
- Radiofrequency denervation versus medial branch block:
  Evidence from a single study demonstrated clinical benefit in terms of pain for radiofrequency denervation compared to medial branch blocks at both the short- and long-term follow-ups of less than and greater than 4

months (very low quality, n = 100). Radiofrequency denervation has evolved as a treatment for spinal pain over the last 40 years and is a minimally invasive and percutaneous procedure performed under local anesthesia or light intravenous sedation. Radiofrequency energy is delivered along an insulated needle in contact with the target nerves. This focused electrical energy heats and denatures the nerve. This process may allow axons to regenerate with time, requiring the repetition of the radiofrequency procedure.

- The duration of pain relief following radiofrequency denervation is uncertain. Data from randomized controlled trials suggests relief is maintained for at least 6-12 months, but no study has reported longer-term outcomes. Pain relief for more than 2 years would not be an unreasonable clinical expectation.
- The de novo economic model undertaken for this guideline for radiofrequency denervation suggested that the treatment is likely to be cost-effective, provided the duration of effect exceeds 16 months.
- If radiofrequency denervation is repeated, we do not know whether the outcomes and duration of these outcomes are like the initial treatment. If repeated radiofrequency denervation is to be offered, we need to be more certain that this intervention is both effective and cost effective.

NASS Guidelines state that therapeutic medial branch RFA is a validated treatment for facet mediated pain, and repeat procedures are equally successful if the response to the initial RFA lasted at least three months. These guidelines advocate dual diagnostic MBB with ≥80% relief of the primary (index pain), and the onset, and minimum duration of relief is consistent with the agent employed. Also, RFA should be performed at the same level no more than twice annually, and only if the initial radiofrequency lesion results in significant pain relief (> 50%) for at least six months. In those situations, a repeat procedure in that year is appropriate.[15] 2020 NASS Low Back Pain Guidelines states there is insufficient evidence to make recommendations for or against the use of cryodenervation for treatment of zygapophyseal (facet) joint pain.[5]

The American Association of Neurological Surgeons (AANS) and the CNS 2014 Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: injection therapies, low-back pain, and lumbar fusion. Lumbar intraarticular facet injections are not recommended for the treatment of chronic lower-back pain. The literature does suggest the use of lumbar medial nerve blocks for short-term relief of facet-mediated chronic lower-back pain without radiculopathy. Lumbar medial nerve ablation is suggested for 3–6 months of relief for chronic lower-back pain without radiculopathy. Diagnostic medial nerve blocks by the double-injection technique with an 80% improvement threshold are an option to predict a favorable response to medial nerve ablation for facet-mediated chronic lower-back pain without radiculopathy. Still there is no evidence to support the use of diagnostic medial nerve blocks to predict the outcomes in these same patients with lumbar fusion.[43]

Cervical and Thoracic Spine

Most of the literature focuses on the lumbar region regarding interventional facet joint diagnosis, and the 2020 Consensus Guidelines are specific for the lumbar region. The 2020 ASIPP Guidelines include the cervical and thoracic regions. The 2020 ASIPP Guidelines report level I-II with moderate to strong strength of recommendation for lumbar, diagnostic blocks report ten diagnostic accuracy studies to support the recommendation. ASIPP report level II evidence for the cervical spine with moderate strength or recommendation citing ten diagnostic accuracy studies. Two systematic reviews support reliance on dual diagnostic blocks with 100% relief of the index pain to select patients for the procedure reporting more than 60% selected using this stringent criterion had 100% relief of index pain. They were pain-free at six months and nearly 40% pain free at one year with functional improvement in neck pain.[29,30]

ASIPP (2020)[7] Therapeutic Facet Joint Intervention Cervical Spine:

- The level of evidence is II with moderate strength of recommendation for therapeutic cervical facet joint nerve blocks with the inclusion of one relevant randomized controlled trial and three observational studies, with long-term improvement.
- The level of evidence is V with weak strength of recommendation for cervical intraarticular facet joint injections

with the inclusion of 3 relevant randomized controlled trials, with two observational studies, the majority showing lack of effectiveness. In contrast, one study with a 6-month follow-up showed a lack of long-term improvement.
- The level of evidence is II with moderate strength of recommendation for cervical radiofrequency ablation with the inclusion of one randomized controlled trial with positive results and two observational studies with long-term improvement.

ASIPP (2020)[7] Therapeutic Facet Joint Interventions Thoracic Spine:

Evidence to support use in the thoracic region is sparse. ASIPP reports level II evidence with moderate strength recommendation for thoracic spine, citing three diagnostic accuracy studies.

- The level of evidence is II with moderate strength of recommendation for thoracic therapeutic facet joint nerve blocks with the inclusion of 2 randomized controlled trials and one observational study with long-term improvement.
- The level of evidence is III with weak to moderate strength of recommendation for thoracic intraarticular facet joint injections with the inclusion of one randomized controlled trial with a six-month follow-up, with emerging evidence.
- Thoracic Spine: The level of evidence is III with weak to moderate strength of recommendation with emerging evidence for thoracic radiofrequency ablation with the inclusion of one relevant randomized controlled trial and three observational studies.

Evidence to support the use of intraarticular facet joint interventions in the thoracic region is further supported by one 2012 systematic review reporting evidence for diagnostic accuracy of the thoracic facet joint injection, and one 2018 study comparing thoracic IA vs. MBB reporting significant pain relief with thoracic joint injection.[50,51] NASS guidelines state that there is a lack of supporting literature for the use of IA injections for thoracic pain, however, also states that "there is no medical literature that suggests any other effective alternative therapy for this patient population."[11]

Imaging

Image guidance has become standard care for facet blocks and RFA procedures, allowing accurate needle placement, monitor contrast and anesthetic spread, and improved safety by direct visualization of bony elements and avoiding surrounding structure. Studies dating back to the 1980s comparing "blind" injections to image-guided concluded that the procedure should not be performed without radiographical imaging. Fluoroscopy is considered the gold standard for facet block procedures, and most studies were conducted with fluoroscopic guidance and consistent with societal recommendations. The U.S. Department of Health and Human Services OIG report in 2008 asserted radiographic guidance is recommended.[52] One cadaveric study showed improved accuracy with fluoroscopy over CT.[53] 2020 Consensus Guidelines recommend CT or preferably fluoroscopy for lumbar MBB (grade B recommendation), CT scanning for IA placement (grade C recommendation), and fluoroscopy for medial branch RFA (grade B recommendation, low level of evidence). The Guidelines state fluoroscopy is preferred to CT due to lower cost, faster times, and less radiation exposure than CT.[4]

The use of ultrasound has been explored as an alternative imaging modality. Cadaveric, retrospective studies, and reviews of RCTs and non-RCTs suggest that there is little difference between ultrasound and fluoroscopy guided procedures; however, there are no well-designed studies to report the safety of this approach. Limitations for ultrasound guidance include reduced visibility in obese patients, more challenging to target the proper segment, and not being able to visualize facet joint.[4] The NASS Guidelines state insufficient evidence to support use of ultrasound guidance.[11] Subject matter experts score low confidence that the facet joint procedures can be performed under ultrasound guidance (score 1.7/5).

Facet Joint Cyst Rupture

Facet joint cysts have been found to have a prevalence of 6.5% and are thought to play a role in facet mediated pain. In these cases, nerve root compression or irritation is associated with radicular pain like other neuro-compressive lesions. Rupture of the cysts have been associated with pain improvement and may potentially avoid more invasive open surgical procedures. In these cases, IA injection is used and often with TFESI to treat radicular pain.[11] A systematic review of 870 patients report cyst resolution to be 58% for the percutaneous procedure, and 90% for decompressive procedures concluding advantage of surgical intervention as compared to percutaneous procedures and pain relief with surgical management is estimated 83.5%. Shuang et al systematic review of 29 studies reported overall the satisfactory results (after short- or long-term follow-up) were achieved in 55.8% [49.5, 62.08] (pooled mean and 95% CI) of the 544 patients subjected to percutaneous lumbar facet joint cyst resolution procedures. 38.67% [33.3, 43.95] of this population underwent surgery subsequently to achieve durable relief.[54] However, the analysis consisted largely of small retrospective studies and case reports with low-quality evidence. In one prospective, non-randomized study, 120 patient's satisfaction was reported as 75%, with 25% requiring repeat surgery.[55] NASS Guidelines address the concern of cyst reoccurrence, which occurs about 50% of the time and does not recommend repeating the procedure more than once and only if the first procedure produces satisfactory results, which they define as 50% improvement for at least three months.[11] The subject matter expert panel voted 3.9/5 in support of facet joint cyst rupture for pain relief.

Centralized Pain Syndrome

Facet procedures by nature treat a local pain condition, while a centralized pain syndrome, such as fibromyalgia, is a generalized pain condition. Patients with centralized pain syndromes are thought to have alterations in central neurotransmission. A prospective study with 548 patients diagnosed with primary spine pain was also evaluated for fibromyalgia criteria before spinal interventions. 42% of the patients meet diagnostic criteria for fibromyalgia. They determined a profound phenotypic difference in those with fibromyalgia as compared to those with spinal pain alone associated with more neuropathic pain descriptors, anxiety, greater pain interference and lower physical function. The authors concluded that the phenotypical factors found in the fibromyalgia group may be predictive of poor outcomes in spine intervention procedures.[56] Exploration of factors associated with poor outcomes from lumbar RFA and long duration pain was correlated with treatment failure. There is insufficient literature that addresses if facet joint procedures are beneficial for centralized pain conditions.

Intrafacet Implants

Intrafacet implants have been proposed as an alternative technique to surgical fusion. They involve the placement of an allograft dowel made from bone (from femur or tibia) and placed surgically or via the minimally invasive procedure. The allografts, which are processed by licensed tissue banks, which must be compliant with FDA requirements for tissue processing, are not subject to FDA 510K clearance and can be marketed. There are no clinical trials that address the efficacy and safety of these implants. The report on 6 cases did not indicate efficacy.[58]

Nonthermal modalities

Several alternatives to percutaneous radiofrequency denervation have been proposed, including pulsed radiofrequency, cryoablation, laser ablation, and chemical ablation, in which a neurolytic substance (e.g., alcohol, phenol, glycerol) is injected into the affected nerve root. An alternative method of denervation using an endoscopic approach (i.e., endoscopic dorsal ramus rhizotomy) has also been proposed.[59] The literature on these modalities is largely limited to case reports or small series with mixed results.[60-63] One RCT (n=80) comparing pulsed radiofrequency ablation to steroid injections concluded it may be more effective than steroids.[64] A RCT (n=50) compared study of continuous to pulsed radiofrequency ablation and did not report significant differences.[65] Long term safety and efficacy data is lacking. The American Society of Anesthesiologists (ASA) Task Force on Chronic Pain Management and the ASRA Practice Guidelines for Chronic Pain Management (2010) Recommendations for Ablative Techniques: The Task Force notes that other treatment modalities should be attempted before consideration of the

use of ablative techniques.[45]

Analysis of Evidence (Rationale for Determination)

Facet joint procedures are a challenging area due to variability in the literature, lack of consensus among experts, differences in societal guidelines and a historical pattern that demonstrates high risk for over utilization. When there is a lack of consensus on best practices, careful evaluation of the medical literature and utilization of the best available evidence serves as the basis for our determinations in coverage and guidelines. This is supplemented with the knowledge shared from our subject matter expert panel.

The literature and consensus of the expert panel and societal guidelines agree that there is no specific history, physical exam findings, or imaging studies that can diagnose facet joint mediated pain and predict response to treatment. For this reason, diagnostic facet joint injections are indicated. Medial branch blocks are the preferred technique for these injections, which are validated and supported by literature as compared to the IA injections, which lack validation, are technically more difficult, and more painful. There is consensus that all facet procedures should be performed under image guidance, CT or fluoroscopy, with a preference for fluoroscopy.

The controversial areas are the number of blocks and the percentage of pain relief required to consider a block successful. For the diagnostic block, the pain relief achieved is temporary and used as a predictor of success for subsequent RFA. The objective is to reduce false-positives that would not be predictive of success with RFA and avoid false-negative patients who could benefit but would not be offered treatment. Many studies have used a cut-off of pain relief greater than 75-80% to consider a diagnostic block as positive. Ten studies assessing the prevalence of lumbar facet joint pain using a cut-off value of 80% relief reported with a prevalence rate of 27% to 40% with false-positive rates of 27% to 47% received a moderate to a strong recommendation from 2020 ASIPP Guidelines.[7]

The 2020 Consensus Guideline advocates for using single blocks with ≥50% for clinical trials and clinical practice while acknowledging that the existing evidence does not adequately address the 50-80% group and that this cut-off was selected to maximize access to care given lack of reliable alternative treatment options in this population and potential benefit of treatment in this group.[4] On the contrary, there are studies that show patients with dual blocks using ≥80% relief are more likely to show a positive response to RFA. This aligns with ASIPP and NASS guidelines.[1,11,] Given the lack of clear evidence, the consensus among experts and societies is that there is uncertainty regarding the cut off values and number of blocks. Most of the evidence and societal guidance supports the use of a more stringent diagnostic cut off. Once a patient begins treatment, the treatments often continue without repeat diagnostic studies, so the correct diagnosis initially is important. The existing evidence is clear there is a high risk of false positives with a single block and 50% cut off and that a dual block and higher cut-off (75-80%) improves diagnostic accuracy. The evidence also supports that improved diagnostic accuracy predicts greater improvement with RFA treatments. While this must be balanced against excluding some patients for treatment who may potentially benefit, given the lack of supporting literature to define this population, current evidence supports dual blocks at 75-80% improvement is more strongly supported than the alternative less stringent approach.

The effectiveness and clinical utility of therapeutic facet blocks is another controversial area. In this case, we are referring to injections with corticosteroids as injections as local anesthetic would not be expected to have any sustained effect. There is support for the use of therapeutic injections in the form of a systematic review and societal guidelines. Most of this support is from a single center that utilizes a published, modified grading criterion they developed. Grading from one grading criteria to another often have similarities but cannot be extrapolated to another so we must consider each grading criteria individually. There is some additional literature from other sites and societal support for therapeutic injections offered by ASA and ASRA. The overwhelming majority of other guidelines and evidence do not support therapeutic IA injections, and this includes multiple studies, systematic reviews, and guidelines by 2020 Consensus Guidelines, NASS, NICE, AHRQ, AANS, and CNS. Their use received a “D” rating from 2020 Consensus Guidelines. The current consensus is that diagnostic injections are to select patients who may be candidates for RFA, and not for therapeutic injections. Clinically since the reported efficacy of therapeutic injections (if a true benefit exists) would be around three months compared to six months or longer for RFA, so there is an

obvious benefit for selection of RFA as a treatment over injections. The Multi-MAC SME panel voting was 3.4/5 that subsequent therapeutic IA or MBB are effective. The evidence does support several special circumstances when RFA cannot be performed, and therapeutic injections may be appropriate. Therefore, the LCD allows therapeutic injections in circumstances when RFA is not feasible.

The goal procedure for facet joint interventions is radiofrequency ablation. The strongest available data related to facet interventions is to support the use of RFA for facet joint pain. Still, even that is mixed and lacks a clear consensus on proper patient selection and effectiveness. A 2015 Cochrane review showed a moderate benefit for RFA for pain, but lack of benefit for function.[46] However, the patient selection used the less stringent criteria of a single block with a 50% reduction in pain. Other studies have shown this criterion is associated with a higher false-positive rate and less success with RFA procedures, so this conclusion may not be represented if the stricter criteria were used. The FACTS study, a RCT that compared outcomes stratified by different prognostic values and reported the success rate in those who underwent RFA in the zero (no block), single and double block groups were 33%, 39%, and 64%, respectively.[33] While this served as the basis for recommending a single block at 50% in the 2020 Consensus Guidelines, it also demonstrates the improved success rate for the dual block group, which increased to 64%.[20] A systematic review that used the GRADE system for rating which is a more standardized grading system and allows both RCTs and observational studies to be evaluated, concluded the majority of patients were pain free at six months and over a third pain free at one year.[29] This conclusion was supported by a 2017 meta-analysis.[35] The overall societal consensus is in support of the use of RFA with ASIPP, ASA/ASRA, NICE, 2020 Consensus Guidelines, and AANS/CNS, all having guidelines that support RFA use. Even the NASS Guidelines that report insufficient evidence for RFA provided guidelines for use. There remain concerns as the clinical studies of RFA for chronic low back pain have significant methodological limitations that can affect the interpretation of the data. Uncertainties regarding several aspects of RFA for spinal pain necessitate additional research. The validation of radiofrequency for chronic spinal pain management relies upon the resolution of these technical issues, as well as issues regarding patient selection and long-term efficacy.[48] While the literature is not complete in terms of efficacy and patient selection for RFA facet procedures, the procedure offers the potential to avoid more invasive surgery. It may potentially reduce opioid use, justifying maintaining RFA as an option in the management of back pain in properly selected patients despite these limitations.

Limitations, such as number of levels and frequency, are challenging as there is little evidence on these factors. Lack of consensus in the medical community about frequency of injections has been a challenge.[52] Societies have begun to offer recommendations on frequency. The NASS Coverage Recommendations recommends dual blocks, does not recommend therapeutic procedures, and recommends limiting RFA to maximum of twice per year and procedures for facet joint cyst rupture to be repeated not more than once.[11] The 2020 Consensus Guidelines report recommends single diagnostic blocks, does not recommend therapeutic injections and recommends limiting RFA to no more than two times per year.[4] The Multi-MAC SME panel also provided input on frequency. The panel voted 1.8/5 that diagnostic injections should be a minimum of 28 days apart and recommended allowing sooner may be beneficial. The panel voted 3.5/5 that therapeutic injections should be a minimum of 3 months apart, and during treatment phase interventional procedures should be repeated only if medically necessary, and not to exceed four times per year was scored as 3.4/5. The panel voted RFA should be repeated only if medically necessary at minimum of 6 months apart with score of 3.9/5. The panel supported allowing three levels (diagnostic or therapeutic) in one session with score of 3.8/5, however prevalence data demonstrates that three diagnostic levels are not routine and would be under unusual circumstances.

Several alternatives to percutaneous radiofrequency denervation have been proposed, including pulsed radiofrequency, cryoablation, laser ablation, and chemical ablation, in which a neurolytic substance (e.g., alcohol, phenol, glycerol) is injected into the affected nerve root. An alternative method of denervation using an endoscopic approach (i.e., endoscopic dorsal ramus rhizotomy) has also been proposed. There is insufficient evidence in the published medical literature to determine the safety and efficacy of these emerging alternative modalities or approaches compared to thermal radiofrequency denervation for the treatment of spinal pain.

General Information

Associated Information

Please refer to the related Local Coverage Article: Billing and Coding: Facet Joint Interventions for Pain Management A57787 for documentation requirements, utilization parameters and all coding information as applicable.

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
04/25/2021	R6	LCD revised and published on 06/10/2021 effective for dates of service on and after 04/25/2021. This revision to section "D. Facet Joint Denervation:" was to remove the language, "**or** at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale." for an Initial thermal RFA. Minor corrections in typographical and formatting made throughout the LCD.	• Other (Clarification)
04/25/2021	R5	LCD revised and published on 04/22/2021 effective for dates of service on and after 04/25/2021. This revision was to add a superscript citation for the Cohen 2013 reference.	• Other (Clarification)
04/25/2021	R4	LCD posted for notice on 03/11/2021. LCD becomes effective for dates of service on and after 04/25/2021. 10/29/2020 DL33930 Draft LCD posted for comment.	• Other (Clarification)
01/08/2019	R3	Revision Number: 3 Publication: April 2020 Connection LCR B2020-008 Explanation of Revision: Based on CR 10901, the LCD was revised to remove CPT codes 64490, 64491, 64492, 64493, 64494 and 64495 from the "Coverage Indications" section. The effective date of this revision is for claims processed on or after January 8, 2019, for dates of service on or after October 3, 2018.	• Other
01/08/2019	R2	Revision Number: 2 Publication: November 2019 Connection LCR B2019-031 Explanation of Revision: Based on Change Request (CR) 10901, the LCD was revised to remove all billing and coding and all language not related to reasonable and necessary provisions ("Bill Type Codes," "Revenue Codes," "CPT/HCPCS Codes," "ICD-10 Codes that Support Medical Necessity," "Documentation Requirements" and "Utilization Guidelines" sections of the LCD) and place them into a newly created billing and coding article. During the process of moving the ICD-10-CM diagnosis codes to the billing and coding article, the ICD-10-CM diagnosis code ranges were broken out and listed individually. In addition, the	• Other (Revision based on CR 10901)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		Social Security Act and IOM reference sections were updated. The effective date of this revision is for claims processed on or after January 8, 2019, for dates of service on or after October 3, 2018. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this LCD.	
03/01/2018	R1	Revision Number: 1 Publication: March 2018 Connection LCR B2018-006 Explanation of Revision: Based on an annual review of the LCD, it was determined that the language in the "Indications and Limitations of Coverage and/or Medical Necessity" section of the LCD does not represent direct quotation from the CMS sources; therefore, this LCD is being revised to assure consistency with the manual language. The effective date of this revision is based on date of service. 03/01/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (Revisions based on annual review completed on 12/07/2017.)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A58668 - (MCD Archive Site)

A57787 - Billing and Coding: Facet Joint Interventions for Pain Management

LCDs

DL33930 - (MCD Archive Site)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
06/04/2021	04/25/2021 - N/A	Currently in Effect (This Version)
04/16/2021	04/25/2021 - N/A	Superseded
03/05/2021	04/25/2021 - N/A	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A