BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Treatment Modalities for Facetogenic Pain

Policy #: 141 | Latest Review Date: December 2020

Category: Surgery | Policy Grade: A

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after March 24, 2020:

For trigger point injections, see LCD L37635.

For facet joint injections, medial branch blocks, and facet joint radiofrequency neurotomy, see LCD L36471.

For injections of the spinal canal, see LCD L35148.

For diagnosis and treatment of sacroiliac joint pain, see Medical Policy 558.

Blue Advantage will treat **facet joint injections using ultrasound guidance** as a **non-covered benefit** and as **investigational**.

Effective for dates of service on February 26, 2018 through March 23, 2020:

For trigger point injections, see LCD L37635.

For facet joint injections, medial branch blocks, and facet joint radiofrequency neurotomy, see LCD L36471.

For injections of the spinal canal, see LCD L35148.

For diagnosis and treatment of sacroiliac joint pain, see Medical Policy 558.

For facet joint injections using ultrasound guidance refer to LCDs L34555 and L36471.

Effective for dates of service prior to February 26, 2018:

For lumbar facet blockade, see LCD 34293.

For trigger point injections, refer to L30066 and L34299.

For injections of the spinal canal, see LCD 32112.

For diagnosis and treatment of sacroiliac joint pain, see Medical Policy 558.

Cervical Facet/Zygapophysial Joint Injections

Blue Advantage will treat **cervical facet joint injections** as a **covered benefit** when all of the following criteria are met:

- Performed under radiographic guidance (i.e., fluoroscopy or CT); **and**
- Patient has a history of back pain that has failed to respond to three consecutive months of conservative therapy*; **and**
- Used as a diagnostic trial to help determine the origin of the patient's pain, establish effectiveness of facet injections in relieving pain, and to achieve a therapeutic effect; **and**

- A diagnostic block provided pain relief (at least 50% pain relief with the ability to perform previous painful maneuvers).

Blue Advantage will treat **up to 4 Cervical facet joint injection sessions per affected region (cervical) within a 12 month period** as a **covered benefit** once a diagnosis is established and the patient experiences symptom relief or functional improvement.

An injection session is defined as all Cervical facet injections administered per cervical region during a 24-hour period for a specified date of service.

Blue Advantage will treat **thoracic facet injections** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **subsequent cervical facet injections** as a **non-covered benefit** when the patient does not experience any symptom relief or functional improvement.

Blue Advantage will treat **facet joint injections using ultrasound guidance** as a **non-covered benefit**.

***Conservative therapy** is the use of structured physician-directed modalities which may include: prescription strength analgesics/anti-inflammatory medications if not contraindicated; participation in therapeutic physical medicine modality(ies) and/or manipulations when rendered by an eligible provider (including active exercise).

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Facet joints, located on either side of the vertebrae, give the spine its flexibility. They are paired (right and left) and are surrounded by a joint capsule. Like other joints, the facet joints can be a source of pain when they become irritated or inflamed. Facet joints may also be referred to as zygapophysial joints.

Facet injections, in the cervical and lumbar regions of the spine, are divided into 2 phases: the diagnostic phase and the therapeutic phase. In the diagnostic phase, an injection is given and if there is pain relief (positive block), additional injections are given as part of the therapeutic phase. If there is no pain relief after the diagnostic injection (negative block), the therapy is not continued. There are no historical, physical or imaging studies that are diagnostic of facet joint

pain. The diagnosis is one of exclusion that is facilitated by performing a diagnostic block of the facet joint or nerves (medial branch of the posterior primary ramus) innervating the joints.

If the patient feels pain relief immediately after intraarticular or medial branch blocks, this confirms that the facet joint was the source of pain. Pain may return after local anesthetic effect ends. Usually it takes about a week to reduce inflammation and pain. Pain relief can last up to several months.

Radiofrequency Facet Denervation
Percutaneous radiofrequency (RF) facet denervation is used to treat neck or back pain originating in facet joints with degenerative changes. Diagnosis of facet joint pain is confirmed by response to nerve blocks. The goal of facet denervation is long-term pain relief. However, the nerves regenerate, and repeat procedures may be required.

Radiofrequency (RF) facet denervation is performed under local anesthetic and with fluoroscopic guidance. A needle is directed to the median branch of the dorsal ganglion in the facet joint, where multiple thermal lesions are produced, typically by a radiofrequency generator. The procedure is usually performed with conscious sedation. A variety of terms may be used to describe radiofrequency (RF) denervation (e.g., rhizotomy, rhizolysis). In addition, the structures to which the RF energy is directed may be referred to as facet joint, facet nerves, medial nerve or branch, median nerve or branch, or dorsal root ganglion.

Alternative methods of denervation include pulsed RF, laser, chemodenervation, and cryoablation. Pulsed RF consists of short bursts of electric current of high voltage in the RF range but without heating the tissue enough to cause coagulation. It is suggested as a possibly safer alternative to thermal RF facet denervation. Temperatures do not exceed 42°C at the probe tip versus temperatures in the 60°C range reached in thermal RF denervation, and tissues may cool between pulses. It is postulated that transmission across small unmyelinated nerve fibers is disrupted but not permanently damaged, while large myelinated fibers are not affected. With chemical denervation, injections with a diluted phenol solution, a chemical ablating agent, are injected into the facet joint nerve.

KEY POINTS:
This policy has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through September 18, 2020.

Summary of Evidence
For individuals who have suspected facet joint pain who receive diagnostic medial branch blocks, the evidence includes a systematic review of 17 diagnostic accuracy studies, a small randomized trial, and several large case series. Relevant outcomes are test accuracy, other test performance measures, symptoms, and functional outcomes. There is considerable controversy about the role of these blocks, the number of positive blocks required, and the extent of pain relief obtained. Studies have reported use of single or double blocks and at least 50% or at least 80% improvement in pain and function. This evidence has suggested that there are relatively few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have

pain relief for several months following radiofrequency (RF) denervation. Other large series have reported prevalence and false-positive rates following controlled diagnostic blocks, although there are issues with the reference standards used in these studies because there is no criterion standard for diagnosis of facet joint pain. There is level I evidence for the use of medial branch blocks for diagnosing chronic lumbar facet joint pain and level II evidence for diagnosing cervical and thoracic facet joint pain. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false-positive rate. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive radiofrequency ablation, the evidence includes a systematic review of randomized controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While evidence is limited to a few randomized controlled trials with small sample sizes, RF facet denervation appears to provide at least 50% pain relief in carefully selected patients. Diagnosis of facet joint pain is difficult. However, response to controlled medial branch blocks and the presence of tenderness over the facet joint appears to be reliable predictors of success. When RF facet denervation is successful, repeat treatments appear to have similar success rates and durations of pain relief. Thus, the data indicate that, in carefully selected individuals with lumbar or cervical facet joint pain, RF treatments can result in improved outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive alternative methods of facet joint denervation or therapeutic medial branch blocks, the evidence includes uncontrolled case series and randomized trials without a sham control. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. Pulsed RF does not appear to be as effective as conventional RF denervation, and there is insufficient evidence to evaluate the efficacy of other methods of denervation (e.g., alcohol, laser, cryodenervation) for facet joint pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
Agency for Healthcare Research and Quality (AHRQ)
The Agency for Healthcare Research and Quality issued an evidence-based practice center systematic review protocol in 2014. Pain Management Injection Therapies for Low-Back Pain states that between 1994 and 2001, the "use of epidural injections increased by 271 percent and facet joint injections increased by 231 percent among Medicare beneficiaries. Despite these dramatic increases, use of injection therapies for low back pain remains controversial. Systematic reviews of injection therapies have come to conflicting conclusions regarding the benefits of injection therapies, and clinical practice guidelines provide discordant recommendations regarding their use. Important challenges in conducting a review of this topic include sparse data from randomized trials for most injection therapies (with the exception of epidural steroids), inconsistency of results across trials, as well as variability across studies in the methods used to select patients for inclusion, the specific techniques used, the comparisons evaluated, and the outcomes assessed."
American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS)

In 2014, the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) published updated guidelines on the treatment of degenerative disease of the lumbar spine. AANS/CNS recommended to use a double-injection technique with an improvement threshold of 80% or greater to establish a diagnosis of lumbar facet-mediated pain (Grade B), that this is an option for predicting a favorable response to facet medial nerve ablation by thermocoagulation (Grade C), and that there is no evidence to support the use of diagnostic facet blocks as a predictor of lumbar fusion outcome in patients with chronic low-back pain from degenerative lumbar disease (Grade I: Inconclusive). AANS/CNS gave Grade B recommendations that 1) intraarticular injections of lumbar facet joints are not suggested for the treatment of facet-mediated chronic low back pain; 2) medial nerve blocks are suggested for the short-term relief of facet-mediated chronic low back pain; and 3) lumbar medial nerve ablation is suggested for the short-term (3- to 6-month) relief of facet-mediated pain in patients who have chronic lower back pain without radiculopathy from degenerative disease of the lumbar spine.

American Society of Interventional Pain Physicians (ASIPP)
In 2020, the American Society of Interventional Pain Physicians published guidelines on use of facet joint interventions for management of chronic spinal pain. Use of facet joint nerve blocks for diagnosis of facet joint pain is recommended with a moderate to strong strength of recommendation for the lumbar spine (evidence level I to II), moderate strength for the cervical spine (evidence level II), and moderate strength for the thoracic spine (evidence level II); a criterion standard of ≥80% pain relief was included for these recommendations. Radiofrequency ablation is recommended for treatment of pain in the lumbar spine (moderate strength recommendation; evidence level II), cervical spine (moderate strength recommendation; evidence level II), and thoracic spine (weak to moderate strength recommendation; evidence level III). Facet joint nerve blocks are recommended for treatment of pain in the lumbar spine (moderate strength recommendation; evidence level II), cervical spine (moderate strength recommendation; evidence level II), and thoracic spine (weak to moderate strength recommendation; evidence level III). Treatment of facet joint pain with intraarticular injections is a weak strength recommendation with lower levels of evidence (level III, IV, and V evidence for the thoracic, lumbar, and cervical spine respectively).

American Society of Anesthesiologists Task Force on Chronic Pain Management and American Society of Regional Anesthesia and Pain Medicine
Practice guidelines for chronic pain management by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine were published in 2010. The guidelines include the following recommendations:

- 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.
- 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.

American Pain Society

A 2009 American Pain Society Clinical Practice Guideline on nonsurgical interventions for low back pain states that "there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate" a number of interventions including facet denervation.

International Working Group consensus Guidelines
International consensus guidelines from 13 different pain societies (2020) provide recommendations regarding interventions for lumbar facet joint pain specifically. When used for diagnosis, the guidelines suggest that intra-articular injections are more diagnostic than medial branch blocks, but note that intra-articular injections have a high technical failure rate and provide less predictive value when administered prior to radiofrequency ablation (grade B evidence, low level of certainty). For therapeutic treatment of lumbar facet pain the guideline recommends against use of medial branch blocks or intra-articular injections (grade D evidence, moderate level of certainty), although acknowledges certain clinical scenarios which may warrant these techniques, such as a contraindication to radiofrequency ablation.

National Institute for Health and Clinical Excellence (NICE)
The National Institute for Health and Clinical Excellence (NICE) published guidance in 2016 entitled "Low back pain and sciatica in over 16s: assessment and management." NICE recommended that RF denervation can be considered for patients with chronic low back pain "when other non-surgical treatment has not worked for them and the main source of pain is thought to come from structures supplied by the medial branch nerve and they have moderate or severe levels of localized back pain". RF denervation should only be performed after a positive response to a diagnostic medial branch block. NICE cautioned that the length of pain relief after RF denervation is uncertain, and that results from repeat RF denervation procedures are also uncertain.

California Technology Assessment Forum
In 2001, the California Technology Assessment Forum published a review of the evidence for percutaneous RF neurotomy of cervical and lumbar zygapophysial joints for chronic neck and low back pain and concluded that the technology met their criteria for efficacy and safety for treatment of lower cervical (C3 and below) and for lumbar pain but not for treatment of upper (C2-C3) levels. In 2007, the California Technology Assessment Forum reviewed the evidence for treatment of C2-3 joints and did not reverse its position.

Dutch Society of Anesthesiologists
In 2016, the Dutch Society of Anesthesiologists, in collaboration with the Dutch Orthopedic Association and the Dutch Neurosurgical Society issued a guideline for invasive treatment of lumbosacral spine pain. For facet joint pain, the guideline concludes that there is evidence that RF has a beneficial effect on functionality for 3 to 6 months. The guideline also concludes that "pulsed RF has no place in the treatment of lumbar facet pain."

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Facet joint injections, percutaneous radiofrequency facet denervation, radiofrequency facet denervation, zygapophyseal joint, radiofrequency ablation, neurotomy, therapeutic medial nerve branch block, radiofrequency denervation, pulsed radiofrequency denervation, laser denervation, cryodenervation, chemodenervation, SIngery®, medial branch block, Dorsal root ganglion, Non pulsed radiofrequency ablation

APPROVED BY GOVERNING BODIES:
A number of radiofrequency generators and probes have been cleared for marketing through the FDA 510(k) process.

One device, the SInergy® by Kimberly Clark/Baylis, is a water-cooled single-use probe that received FDA clearance in 2005, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT codes:

64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) withy image guidance (fluoroscopy or CT), cervical or thoracic; second level (List separately in addition to code for primary procedure)
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or

	nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for primary procedure)
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	; each additional facet joint (List separately in addition to code for primary procedure)
64635	; lumbar or sacral, single facet joint
64636	; lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)
64999	Unlisted procedure, nervous system. (should be used for pulsed radiofrequency ablation as opposed to specific codes.
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level
0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (List separately in addition to code for primary procedure)
0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level
0217T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level(s) (List separately in addition to code for primary procedure)
0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; additional level(s)

	(List separately in addition to code for primary procedure)

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