Policy Replaced with LCDs L34555 & L36471 Effective February 26, 2018

BlueCross BlueShield of Alabama

For Trigger Point Injections see LCD L30066
For Lumbar Facet Blockade see LCD 34293
For injections of the Spinal Canal see LCD 34291
Diagnosis and Treatment of Sacroiliac Joint Pain see Medical Policy 558

Name of Blue Advantage Policy:

Treatment Modalities for Cervical or Thoracic Facetogenic Pain

Policy #: 141
Category: Surgery

Latest Review Date: November 2017
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).*

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.

Policy:

Effective for dates of service on or after February 26, 2018 refer to LCDs L34555 & L36471

Effective for dates of service on or after April 2, 2017 and prior to February 26, 2018:

Cervical Facet/Zygapophysial Joint Injections

Blue Advantage will treat **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.

Key Points:

Facet Joint Injections

Although the history and physical examination may suggest that the facet joint is the cause of spine pain, no noninvasive pathognomonic findings distinguish facet joint-mediated pain from other sources of spine pain. Fluoroscopically guided facet joint injections are commonly considered the gold standard for isolating or excluding the facet joint as a source of spine or extremity pain. Intra-articular, fluoroscopic-guided, contrast-enhanced facet injections are considered critical for proper diagnosis and can be instrumental in the treatment of facet joint arthropathies. A patient can be examined both pre-injection and post-injection to determine what portion of his or her pain can be attributed to the joints injected.

Typically, small amounts of anesthetic and or corticosteroid are injected directly into the joint. The rationale is that the anesthetic will supply short-acting pain relief, and the steroid will decrease local inflammation and result in sustained pain relief. Fluoroscopic guidance with confirmation of needle placement via injection of radiopaque contrast is mandatory as a significantly improved outcome results in intraarticular placement of corticosteroid as opposed to local extra-articular injection. Efficacy of injections has been shown in uncontrolled trials to range from 18 to 63%. In addition, there have been reports of sustained relief after injection of anesthetic and saline alone. Nevertheless, because of the suspicion of local inflammation and the low side-effects profile, the practice of instilling corticosteroid is widely practiced. In the only randomized placebo-controlled trial that utilized diagnostic injection as inclusion criteria, results showed a trend to improvement at one month with corticosteroid compared to placebo. However, this difference was not statistically significant.

Because most acute low back pain improves in several weeks, injection should be reserved for patients who have had persistent symptoms despite conservative therapy for 4 to 6 weeks. Injections should not be used in patients with neurologic impairment as this suggests additional pathology. Other contraindications include bleeding diathesis, local infection, spinal malignancy, pregnancy (because of the teratogenic effects of radiation), or severe allergy to any of the medications. Potential complications include bleeding, infection, thecal sac puncture with headache, post-procedure radicular or back pain, and allergic and vasovagal reactions. Injections should be used in conjunction with a physical therapy program as the main goal of the injection is to afford the patient enough pain relief to allow participation in a strengthening program. Repeat injections should be reserved for patients who had significant symptom improvement.

In 2009, Manchikanti and colleagues issued updated comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. The guideline recommends diagnostic facet joint nerve block for individuals with pain that has lasted at least 3 months with failure to respond to conservative therapy, including chiropractic care, physical therapy modalities with exercises, and non-steroidal anti-inflammatory agents.

A technology assessment published by the Agency for Healthcare Research and Quality (AHRQ, 2015) conducted a systematic review of injection therapies for lower back pain which included 13 trials for facet joint injections. The publication concluded:

> Studies found no clear differences between various facet joint corticosteroid injections (intra-articular, extra-articular [peri-capsular], or medial branch) and placebo interventions. There was insufficient evidence from one very small trial to determine effects of peri-articular sacroiliac joint corticosteroid injections.

Diagnostic medial branch blocks have been established as the standard for diagnosing facetogenic pain. In a prospective multicenter study Cohen and colleagues (2013) evaluated optimal cutoff threshold for diagnostic lumbar facet blocks. A positive diagnostic block was defined as pain relief of 50% or more during the injection procedure with the individual being able to carry out previously painful maneuvers. The authors concluded that employing more stringent selection criteria would likely result in withholding treatment from a substantial number of individuals, without improving success rate.

<u>Therapeutic Facet Joint Nerve Blocks</u>
Medial branch nerve blocks have also been evaluated as a therapeutic intervention. However, no RCTs were identified that compared anesthetic nerve blocks with placebo injections. Placebo-controlled studies are important for treatments for which the primary outcome is a measurement of pain in order to account for the potential placebo effect of an intervention.

Three randomized double-blind controlled trials were identified from Manchikanti et al in 2010 that compared the therapeutic effect of medial branch blocks with bupivacaine alone to bupivacaine and steroid (betamethasone). Patients included had a diagnosis of facet joint pain (cervical, thoracic, and lumbar) with an 80% reduction in pain following 2 diagnostic anesthetic blocks of the medial branches. Patient outcomes were measured at 3, 6, 12, 18, and 24 months with a Numeric Rating Scale for pain and with the ODI. Significant pain relief was considered to

be a decrease of 50% or greater on the Numeric Rating Scale. Opioid intake and work status were also evaluated.

Cervical
One of the randomized trials included 120 patients meeting the diagnostic criteria for cervical facet joint pain. The 2 groups were further subdivided, with half of the patients in each group receiving Sarapin. Patients were followed at 3-month intervals, and the cervical medial branch blocks were repeated only when reported pain levels decreased to below 50%, with significant pain relief after the previous block. Injections were repeated an average of 5.7 times over a period of 2 years. Sarapin did not affect the outcome, and the data were reported only for the 2 main conditions. At 2-year follow-up, 85% of patients in the bupivacaine group and 93% of patients in the steroid group were reported to have significant pain relief, based on intent-to-treat analysis. The average duration of pain relief with each procedure was 17 to 19 weeks. At least 50% improvement in the Neck Disability Index was seen in 70% of patients in the bupivacaine group and 75% of patients in the bupivacaine plus steroid group. There was no significant change in the intake of opioids. There was a loss of 38% of data for the 24-month evaluation. Sensitivity analysis using the last follow-up score, best case scenario, and worst case scenario were not significantly different, and intent-to-treat analysis with the last follow-up visit was utilized.

Thoracic
One-year results were reported in 2010 and 2-year results reported in 2012 from the randomized double-blind trial of the efficacy of thoracic medial branch blocks performed under fluoroscopy. The 100 patients in this study received an average of 3.5 treatments per year. Intent-to-treat analysis at 12 months showed a decrease in average pain scores from 7.9 at baseline to 3.2 in the bupivacaine group and from 7.8 to 3.1 in the bupivacaine plus steroid group. At least 50% improvement in the ODI was observed in 80% and 84% of participants, respectively. In both groups, 90% of participants showed significant pain relief (≥50%) at 12 months. The average relief per procedure was 16 weeks for bupivacaine and 14 weeks for bupivacaine plus betamethasone. There was no significant change in the intake of opioids. Efficacy remained the same at 2 years' follow-up, with 80% of patients in the bupivacaine group and 84% of patients in the bupivacaine plus steroid group continuing to show improvement in the ODI by 50% or more. The average number of procedures over the 2 years was 5.6 for bupivacaine and 6.2 for bupivacaine plus steroids.

The longer-term outcomes from these 3 randomized double-blind trials are intriguing, given the apparent long duration of efficacy of this short-acting anesthetic and the lack of a known mechanism. However, placebo-controlled studies are important for treatments in which the primary outcome is a measurement of pain. No trials were identified that compare medial branch nerve blocks with placebo. RCTs that compare therapeutic nerve blocks with placebo injections and with the current standard of care (RF denervation) are needed to fully evaluate this treatment approach.

Section Summary: Therapeutic Facet Joint Nerve Blocks
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Following is a summary of key studies to date.

Patient Selection
Patient selection for facet joint interventions, and particularly the utility of diagnostic blocks, is discussed in a number of articles. Evidence is presented for use of dual blocks with a threshold of 50%, 75%, or a threshold of 80% pain relief.

In 2015, Boswell et al reported a systematic review of the accuracy and utility of facet joint injections for the diagnosis of facet joint pain. Co-authors included Manchikanti, who is primary author of most of the studies included in the systematic review. Of the 13 studies on diagnosis of lumbar facet joint pain that used a criterion standard of at least 75% pain relief, 11 were conducted by the same group of authors, and all 3 studies on diagnosis of thoracic facet joint pain were also conducted by the same group. Study quality was rated by reviewers who were not authors on these primary studies. Using the Quality Appraisal of Diagnostic Reliability (QAREL) checklist, evidence was rated as level I for controlled lumbar facet joint blocks, level II for cervical facet joint blocks, and level II for thoracic facet joint blocks. However, in none of the studies were raters blinded to clinical information or to the reference standard. In addition, there is no gold standard test for diagnosis of facet joint pain, which creates difficulties in determining test accuracy.

The review included 17 studies on lumbar facet joint pain that utilized controlled blocks with a diagnostic criterion of at least 75% pain relief. Prevalence was reported to be 16% to 41%, with false positive rates of 25% to 44%. For cervical facet joint pain, 11 controlled diagnostic studies were included, reporting a variable prevalence ranging from 36% to 67% and false-positive rates ranging from 27% to 63%. For thoracic facet joint pain, 3 studies were included that used a criterion standard of 80% or higher pain relief, reporting a prevalence from 34% to 48% and false-positive rates ranging from 42% to 48%. The systematic review did not specify the reference standard that was used to determine the prevalence and false-positive rates. Four studies were identified in the review that evaluated the influence of diagnostic blocks on therapeutic outcomes. Three of these are described next.

In 2010, Cohen et al reported a multicenter randomized cost-effectiveness trial comparing 0, 1, or 2 diagnostic blocks before lumbar facet RF denervation. Included in the study were 151 patients with predominantly axial low back pain of 3 months or more in duration, failure to respond to conservative therapy, paraspinal tenderness, and absence of focal neurologic signs or symptoms. Of the 51 patients who received RF denervation without undergoing diagnostic blocks, 17 (33%) obtained a successful outcome. Of the 16 patients (40%) who had a single diagnostic block followed by RF denervation, 8 (50% of 16) were considered successful. Of the 14 patients (28%) who went on to have RF denervation after 2 medial branch blocks, 11 (79% of 14) were considered successful. Three patients were successfully treated after medial branch blocks alone. The cost-effectiveness of proceeding to RF denervation without diagnostic blocks

was discussed. The same group of investigators compared lumbar zygapophysial joint RF denervation success rates between the conventional at least 50% pain relief threshold and the more stringently proposed at least 80% cutoff in a retrospective multicenter study with 262 patients. A total of 145 patients had greater than 50% but less than 80% relief after medial branch block, and 117 obtained at least 80% relief. In the greater than 50% group, success rates were 52% and 67% on pain relief and global perceived effect (GPE), respectively, after RF. Among those who had at least 80% relief from diagnostic blocks, 56% achieved at least 50% relief from RF and 66% had a positive GPE. The study concluded that the more stringent pain relief criteria are unlikely to improve success rates.

Manchikanti et al compared outcomes of 110 patients who underwent facet nerve blocks after meeting positive criteria of 50% relief and had 2 years of follow-up. At the end of 1 year, the diagnosis of lumbar facet joint pain was confirmed (by sustained relief of pain and improved function) by 75% of patients in the group with 50% relief from diagnostic blocks versus 93% in the group with 80% relief. At 2 years, the diagnosis was sustained in 51% of patients in the group with 50% relief, and sustained in 89.5% of patients who reported 80% relief from diagnostic blocks.

Section Summary: Patient Selection

Literature on the effect on health outcomes following the use of nerve blocks for patient selection includes 1 small randomized trial and several large case series. This evidence suggests that there are relatively few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have relief of pain for several months following RF denervation. A 2015 systematic review identified a number of other large series that reported prevalence and false positive rates following controlled diagnostic blocks, although there are questions about the reference standard used in these studies. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false positive rate.

Summary of Evidence

The evidence for diagnostic medial branch blocks in individuals who are suspected of having a facet joint pain includes one small randomized trial and several large case series. Relevant outcomes include symptoms, functional outcomes, quality of life, and medication use. There is considerable controversy about the role of the blocks, the number of positive blocks required, and the extent of pain relief obtained. Reported studies have used single or double blocks and at least 50% or at least 80% improvement in pain and function. This evidence suggests that there are relatively few patients who exhibit pain relief following two nerve blocks, but that these select patients may have relief of pain for several months following RF denervation. Other large series reported prevalence and false positive rates following controlled diagnostic blocks, although there are questions about the reference standard used in these studies. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false positive rate. Evidence is sufficient to determine qualitatively that the technology result in a meaningful improvement in the net health outcome. Based on review of the evidence and clinical input, the statement in the Policy Guidelines section states that at least 50% improvement on two positive blocks (or a placebo-controlled series of blocks) is required.

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)

Updated guidelines on interventional techniques in the management of chronic spinal pain from the American Society of Interventional Pain Physicians (ASIPP) were published in 2013. Diagnostic lumbar facet joint nerve blocks were recommended in patients with suspected facet joint pain, based on good evidence for diagnostic lumber facet joint nerve blocks with 75% to 100% pain relief as criterion standard. For the treatment of facet joint pain, evidence was considered to be good for conventional radiofrequency, limited for pulsed radiofrequency, fair to good for lumbar facet joint nerve blocks and limited for intra-articular injections. Based on the evidence review, ASIPP recommends treatment with conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks.

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.

National Institute for Health and Clinical Excellence (NICE)
The United Kingdom's National Institute for Health and Clinical Excellence (NICE) 2009 guidelines on the early management of nonspecific low back pain states that people should not be referred for radiofrequency facet joint denervation.

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.

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

Key Words:
Facet joint injections, therapeutic medial nerve branch block, medial branch block, Dorsal root ganglion,

Approved by Governing Bodies:
Steroids are not FDA approved for use as epidural injections, such use represents off-label use of an FDA approved medication. The specific preparations used for epidural injections are steroids added to a sterile saline solution, which are prepared by a compounding pharmacy.

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)
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)

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This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.