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<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/16	<b>Next Review Date:</b> 11/17
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 09/09, 09/10, 07/11, 07/12, 05/13, 05/14, 01/15, 11/15, 11/16	

**Preauthorization is required.**

*The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: • Who are suspected of having facet joint pain	Interventions of interest are: • Diagnostic medial branch blocks	Comparators of interest are: • Clinical diagnosis	Relevant outcomes include: • Test accuracy • Other test performance measures • Symptoms • Functional outcomes
Individuals: • With facet joint pain	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Intra-articular Injection • Standard medical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use
Individuals: • With facet joint pain	Interventions of interest are: • Alternative methods of denervation • Therapeutic medial branch blocks	Comparators of interest are: • Intra-articular Injection • Standard medical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use

### Description

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.

### Summary of Evidence

The evidence for diagnostic medial branch blocks in individuals who are suspected of having facet joint pain includes one 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 the 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 suggests that there are relatively few patients who exhibit pain relief following two nerve blocks, but

that these select patients may have pain relief for several months following RF denervation. Other large series reported prevalence and false-positive rates following controlled diagnostic blocks, although there are issues with the reference standards used in these studies. 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for radiofrequency ablation to treat individuals with facet joint pain includes several randomized controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While evidence is limited to a few studies 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 appear to be reliable predictors of success. When RF facet denervation is successful, repeat treatments appear to have similar success rates and duration 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for therapeutic medial branch blocks and alternative methods of facet joint denervation in patients who have facet joint pain 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 nonpulsed 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. There is insufficient evidence to evaluate the effect of therapeutic medial branch blocks on facet joint pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Policy

Non-pulsed radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints is considered **medically necessary** when ALL of following criteria are met.

- No prior spinal fusion surgery in the vertebral level being treated; AND
- Disabling low back (lumbosacral) or neck (cervical) pain, suggestive of facet joint origin as evidenced by absence of nerve root compression as documented in the medical record on history, physical and radiographic evaluations; and the pain is not radicular; AND
- Pain has failed to respond to three (3) months of conservative management which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND
- There has been a successful trial of controlled medial branch blocks (see Policy Guidelines); AND
- If there has been a prior successful radiofrequency denervation, a minimum time of six (6) months has elapsed since prior RF treatment (per side, per anatomical level of the spine).

Radiofrequency denervation is considered **investigational** for the treatment of chronic spinal/back pain for all uses that do not meet the criteria listed above, including but not limited to treatment of thoracic facet joint pain.

All other methods of denervation are considered **investigational** for the treatment of chronic spinal/back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, chemodenervation (e.g., alcohol, phenol, or high-concentration local anesthetics), and cryodenervation.

Therapeutic medial branch blocks are considered **investigational**.

If there has been a prior successful radiofrequency (RF) denervation, additional diagnostic medial branch blocks for the same level of the spine are **not medically necessary**.

### Policy Guidelines

A successful trial of controlled diagnostic medial branch blocks consists of two separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or a placebo controlled series of blocks, under fluoroscopic guidance, that has resulted in at least a 50% reduction in pain for the duration of the local anesthetic used (e.g., three hours longer with bupivacaine than lidocaine). No therapeutic intra-articular injections (i.e., steroids, saline, or other substances) should be administered for a period of at least four weeks prior to the diagnostic medial branch block. The diagnostic blocks should involve the levels being considered for RF treatment and should not be conducted under intravenous sedation unless specifically indicated (e.g., the patient is unable to cooperate with the procedure). These diagnostic blocks should be targeted to the likely pain generator. Single level blocks lead to more precise diagnostic information, but multiple single level blocks require several visits and additional exposure to radiation.

### Medicare Advantage

These policy statements do not address sacral conditions or injections or neurotomies.

Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy may be considered **medically necessary** when all of the following indications are met:

- Patient must have history of at least three months of moderate to severe pain with functional impairment and pain is inadequately responsive to conservative care such as NSAIDs, acetaminophen, physical therapy (as tolerated).
- Pain is predominantly axial and, with the possible exception of facet joint cysts, not associated with radiculopathy or neurogenic claudication.
- There is no non-facet pathology that could explain the source of the patient's pain, such as fracture, tumor, infection, or significant deformity.
- Clinical assessment implicates the facet joint as the putative source of pain.

Thermal Medial Branch Radiofrequency Neurotomy (includes RF and microwave technologies) may be considered **medically necessary**:

- Only when dual MBBs provide greater than or equal to 80% relief of the primary or index pain and duration of relief is consistent with the agent employed may facet joint denervation with RF medial branch neurotomy be considered.
- Repeat denervation procedures involving the same joint will only be considered medically necessary if the patient experienced greater than or equal to 50% improvement of pain and improvement in patient specific ADLs documented for at least six months.

Non-thermal RF modalities for facet joint denervation including chemical, low grade thermal energy (less than 80 degrees Celsius), as well as pulsed RF are considered **investigational**.

### Medicare Advantage Policy Guidelines

General Procedure Requirements indicate that facet joint interventions (diagnostic and/or therapeutic) must be performed under fluoroscopic or computed tomographic (CT) guidance.

## Background

Percutaneous 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. Patients generally are sedated for the RF procedure. The goal of facet denervation is long-term pain relief. However, the nerves regenerate, and repeat procedures may be required.

Facet joint denervation is performed under local anesthetic and with fluoroscopic guidance. A needle or probe is directed to the median branch of the dorsal ganglion innervating the facet joint, where multiple thermal lesions are produced, typically by a RF generator. A variety of terms may be used to describe 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.

## Regulatory Status

A number of RF generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SInergy® (Kimberly Clark/Baylis), a water-cooled single-use probe, was cleared by FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is with a RF generator to create RF lesions in nervous tissue. FDA product code: GXD.

## Related Protocols

Diagnosis and Treatment of Sacroiliac Joint Pain

Facet Arthroplasty

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Chou R, Atlas SJ, Stanos SP, et al. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. *Spine (Phila Pa 1976)*. May 1, 2009; 34(10):1078-1093. PMID 19363456
2. Falco FJ, Datta S, Manchikanti L, et al. An updated review of the diagnostic utility of cervical facet joint injections. *Pain Physician*. Nov-Dec 2012; 15(6):E807-838. PMID 23159977
3. Falco FJ, Manchikanti L, Datta S, et al. Systematic review of the therapeutic effectiveness of cervical facet joint interventions: an update. *Pain Physician*. Nov-Dec 2012; 15(6):E839-868. PMID 23159978
4. Falco FJ, Manchikanti L, Datta S, et al. An update of the systematic assessment of the diagnostic accuracy of lumbar facet joint nerve blocks. *Pain Physician*. Nov-Dec 2012; 15(6):E869-907. PMID 23159979
5. Falco FJ, Manchikanti L, Datta S, et al. An update of the effectiveness of therapeutic lumbar facet joint interventions. *Pain Physician*. Nov-Dec 2012; 15(6):E909-953. PMID 23159980
6. Boswell MV, Manchikanti L, Kaye AD, et al. A best-evidence systematic appraisal of the diagnostic accuracy and utility of facet (zygapophysial) joint injections in chronic spinal pain. *Pain Physician*. Jul-Aug 2015; 18(4):E497-533. PMID 26218947
7. Cohen SP, Strassels SA, Kurihara C, et al. Randomized study assessing the accuracy of cervical facet joint nerve (medial branch) blocks using different injectate volumes. *Anesthesiology*. Jan 2010; 112(1):144-152. PMID 19996954
8. Cohen SP, Stojanovic MP, Crooks M, et al. Lumbar zygapophysial (facet) joint radiofrequency denervation success as a function of pain relief during diagnostic medial branch blocks: a multicenter analysis. *Spine J*. May-Jun 2008; 8(3):498-504. PMID 17662665
9. Pampati S, Cash KA, Manchikanti L. Accuracy of diagnostic lumbar facet joint nerve blocks: a 2-year follow-up of 152 patients diagnosed with controlled diagnostic blocks. *Pain Physician*. Sep-Oct 2009; 12(5):855-866. PMID 19787011
10. Manchikanti L, Pampati S, Cash KA. Making sense of the accuracy of diagnostic lumbar facet joint nerve blocks: an assessment of the implications of 50% relief, 80% relief, single block, or controlled diagnostic blocks. *Pain Physician*. Mar-Apr 2010; 13(2):133-143. PMID 20309379
11. Manchikanti L, Kaye AD, Boswell MV, et al. A systematic review and best evidence synthesis of the effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. *Pain Physician*. Jul-Aug 2015; 18(4):E535-582. PMID 26218948
12. Civelek E, Cansever T, Kabatas S, et al. Comparison of effectiveness of facet joint injection and radiofrequency denervation in chronic low back pain. *Turk Neurosurg*. 2012; 22(2):200-206. PMID 22437295
13. Lakemeier S, Lind M, Schultz W, et al. A comparison of intraarticular lumbar facet joint steroid injections and lumbar facet joint radiofrequency denervation in the treatment of low back pain: a randomized, controlled, double-blind trial. *Anesth Analg*. Jul 2013; 117(1):228-235. PMID 23632051
14. Nath S, Nath CA, Pettersson K. Percutaneous lumbar zygapophysial (facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain: a randomized double-blind trial. *Spine (Phila Pa 1976)*. May 20, 2008; 33(12):1291-1297; discussion 1298. PMID 18496338
15. van Wijk RM, Geurts JW, Wynne HJ, et al. Radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain: a randomized, double-blind, sham lesion-controlled trial. *Clin J Pain*. Jul-Aug 2005; 21(4):335-344. PMID 15951652
16. Lord SM, Barnsley L, Wallis BJ, et al. Percutaneous radio-frequency neurotomy for chronic cervical zygapophysial-joint pain. *N Engl J Med*. Dec 5 1996; 335(23):1721-1726. PMID 8929263

17. Haspelslagh SR, Van Suijlekom HA, Lame IE, et al. Randomised controlled trial of cervical radiofrequency lesions as a treatment for cervicogenic headache [ISRCTN07444684]. *BMC Anesthesiol.* 2006; 6:1. PMID 16483374
18. Husted DS, Orton D, Schofferman J, et al. Effectiveness of repeated radiofrequency neurotomy for cervical facet joint pain. *J Spinal Disord Tech.* Aug 2008; 21(6):406-408. PMID 18679094
19. Schofferman J, Kine G. Effectiveness of repeated radiofrequency neurotomy for lumbar facet pain. *Spine (Phila Pa 1976).* Nov 1 2004; 29(21):2471-2473. PMID 15507813
20. Rambaransingh B, Stanford G, Burnham R. The effect of repeated zygapophysial joint radiofrequency neurotomy on pain, disability, and improvement duration. *Pain Med.* Sep 2010; 11(9):1343-1347. PMID 20667024
21. Smuck M, Crisostomo RA, Trivedi K, et al. Success of initial and repeated medial branch neurotomy for zygapophysial joint pain: a systematic review. *PM R.* Sep 2012; 4(9):686-692. PMID 22980421
22. Hashemi M, Hashemian M, Mohajerani SA, et al. Effect of pulsed radiofrequency in treatment of facet-joint origin back pain in patients with degenerative spondylolisthesis. *Eur Spine J.* Sep 2014; 23(9):1927-1932. PMID 24997616
23. Van Zundert J, Patijn J, Kessels A, et al. Pulsed radiofrequency adjacent to the cervical dorsal root ganglion in chronic cervical radicular pain: a double blind sham controlled randomized clinical trial. *Pain.* Jan 2007; 127(1-2):173-182. PMID 17055165
24. Tekin I, Mirzai H, Ok G, et al. A comparison of conventional and pulsed radiofrequency denervation in the treatment of chronic facet joint pain. *Clin J Pain.* Jul-Aug 2007; 23(6):524-529. PMID 17575493
25. Kroll HR, Kim D, Danic MJ, et al. A randomized, double-blind, prospective study comparing the efficacy of continuous versus pulsed radiofrequency in the treatment of lumbar facet syndrome. *J Clin Anesth.* Nov 2008; 20(7):534-537. PMID 19041042
26. Iwatsuki K, Yoshimine T, Awazu K. Alternative denervation using laser irradiation in lumbar facet syndrome. *Lasers Surg Med.* Mar 2007; 39(3):225-229. PMID 17345622
27. Joo YC, Park JY, Kim KH. Comparison of alcohol ablation with repeated thermal radiofrequency ablation in medial branch neurotomy for the treatment of recurrent thoracolumbar facet joint pain. *J Anesth.* Jun 2013; 27(3):390-395. PMID 23192698
28. Haufe SM, Mork AR. Endoscopic facet debridement for the treatment of facet arthritic pain--a novel new technique. *Int J Med Sci.* 2010; 7(3):120-123. PMID 20567612
29. Manchikanti L, Singh V, Falco FJ, et al. Comparative outcomes of a 2-year follow-up of cervical medial branch blocks in management of chronic neck pain: a randomized, double-blind controlled trial. *Pain Physician.* Sep-Oct 2010; 13(5):437-450. PMID 20859313
30. Manchikanti L, Singh V, Falco FJ, et al. Evaluation of lumbar facet joint nerve blocks in managing chronic low back pain: a randomized, double-blind, controlled trial with a 2-year follow-up. *Int J Med Sci.* 2010; 7(3):124-135. PMID 20567613
31. Manchikanti L, Singh V, Falco FJ, et al. Comparative effectiveness of a one-year follow-up of thoracic medial branch blocks in management of chronic thoracic pain: a randomized, double-blind active controlled trial. *Pain Physician.* Nov-Dec 2010; 13(6):535-548. PMID 21102966
32. Manchikanti L, Singh V, Falco FJ, et al. The role of thoracic medial branch blocks in managing chronic mid and upper back pain: a randomized, double-blind, active-control trial with a 2-year followup. *Anesthesiol Res Pract.* 2012; 2012:585806. PMID 22851967

33. Watters WC, 3rd, Resnick DK, Eck JC, et al. 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. *J Neurosurg Spine*. 2014; 21(1):79-90. 2014/07/02: <http://thejns.org/doi/abs/10.3171/2014.4.SPINE14281>. Accessed September, 2014.
34. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician*. Apr 2013; 16(2 Suppl):S49-283. PMID 23615883
35. American Society of Anesthesiologists Task Force on Chronic Pain Management, American Society of Regional Anesthesia and Pain Medicine. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology*. Apr 2010; 112(4):810-833. PMID 20124882
36. National Institute for Health and Clinical Excellence (NICE). Early management of non-specific low back pain. Clinical guideline 88 2009; <http://www.nice.org.uk/nicemedia/live/11887/44343/44343.pdf>. Accessed July, 2014.
37. California Technology Assessment Forum (CTAF). Percutaneous radiofrequency neurotomy for treatment of chronic pain from the upper cervical (C2-3) spine. A Technology Assessment 2007; <http://www.ctaf.org/content/assessment/detail/742>. Accessed July, 2014.