ABLATIVE TREATMENT FOR SPINAL PAIN

Policy Number: PAI003  Effective Date: March 1, 2019

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COVERAGE RATIONALE

Thermal Radiofrequency Ablation of facet joint nerves is proven and medically necessary for the following:

- Initial treatment of chronic cervical (C3 and below), thoracic and lumbar pain when:
  - Confirmed by documentation of analgesic response to Facet Nerve Blocks (i.e., medial branch blocks) at the specific side and level of the proposed ablation; and
  - The diagnostic procedure is not performed on the same day as the ablation procedure.

- Repeat treatment of chronic cervical (C3 and below), thoracic and lumbar pain when:
  - Performed at a frequency of six months or longer (maximum of 2 times over a 12 month period per side and level); and
  - There has been a 50% or greater documented reduction in pain for at least 10 weeks following the previous ablation.

Thermal Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary in the following circumstances due to insufficient evidence of efficacy:

- The source of back pain at the proposed ablation level is from a cause other than facet joint nerves that requires a different treatment approach. Examples include disc herniation, spinal stenosis, foraminal narrowing, vertebral fracture and spondylolisthesis; or
- ALL other pain indications, including, but not limited to sacroiliac pain or Complex Regional Pain Syndrome in the absence of spinal pain; or
- When using ANY of the following ablation techniques:
  - Pulsed Radiofrequency Ablation of the facet nerves of the cervical, thoracic, or lumbar region, sacral nerve root or dorsal root ganglion
  - Endoscopic radiofrequency ablation/endoscopic rhizotomy
  - Cryoablation (cryodenervation, cryoneurolysis, cryosurgery or cryoanesthesia)
  - Chemical ablation (including, but not limited to, alcohol, phenol or sodium morrhuate)
  - Laser ablation (including pulsed, continuous or low level).

Documentation Requirements for Aforementioned Procedures

- Temperature of procedure
- Duration of ablation
- Specific identification of side and level of medial branch blocks and ablation
- Percentage of pain relief with medial branch blocks or prior ablation if applicable
- Duration of improvement from medial branch blocks or prior ablation if applicable

DEFINITIONS

Chronic Pain (Nonmalignant): Pain lasting longer than 3 months (Qaseem et al., 2017; Chou et al., 2009).

Complex Regional Pain Syndrome (CRPS): A Chronic Pain condition that affects a limb (arm, hand, leg or foot) usually after an injury to a nerve. CRPS is divided into two types: CRPS-I and CRPS-II. Individuals without a confirmed nerve injury are classified as having CRPS-I (previously known as reflex sympathetic dystrophy syndrome).
CRPS-II (previously known as causalgia) is when there is an associated, confirmed nerve injury (National Institute of Neurological Disorders and Stroke, 2018).

**Facet Nerve Block**: For purposes of this policy, Facet Nerve Blocks are considered the same as medial branch blocks.

**Pulsed Radiofrequency Ablation**: Technique that delivers intermittent bursts of current, instead of continuous current, using a probe temperature of 42°-45° Celsius (Hayes, 2016a; updated 2017).

**Thermal Radiofrequency Ablation is defined as follows**:  
- Temperature ≥60° Celsius; and  
- Duration of ablation ≥40 seconds; and  
- Confirmation of needle placement by fluoroscopic guided imaging.

### APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

**Coding Clarification**:
- CPT codes 64633, 64634, 64635, and 64636 only apply to thermal (non-pulsed) radiofrequency ablation.  
- CPT code 64999 is to be used for pulsed radiofrequency ablation (CPT® Assistant, 2016).

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**DESCRIPTION OF SERVICES**

Radiofrequency ablation (RFA) is a percutaneous treatment that uses radiowave-induced heat to create a lesion in a spinal sensory nerve. Following a prognostic blockade to target the affected nerve(s), radiofrequency (RF) current is applied in a pulsed or continuous manner for several minutes via a needle electrode to the targeted nerves under image guidance. The goal of RFA is to relieve pain and symptoms by interrupting pain signal transmission from the sensory nerve to the brain (Hayes, 2016a; updated 2017).

Thermal (non-pulsed) and pulsed are two types of RFA. Thermal RFA involves the constant application of energy via an image-guided needle electrode inserted through the skin (percutaneously) to the affected nerve(s) under image guidance. The probe is placed, lesions or nerves are then targeted unilaterally or bilaterally for 40 to 90 seconds at temperatures of 60 to 90°C.

Pulsed RFA delivers intermittent bursts of current instead of continuous current, allowing the tissue to cool between bursts (Hayes, 2016a; updated 2017).

Endoscopic rhizotomy, a posterior endoscopic method, also known as dorsal endoscopic rhizotomy, has been developed as an alternative to percutaneous electrode RFA to target the medial, intermediate and lateral branches of the dorsal ramus using a modification of the Yeung Endoscopic Spinal Surgery (Y.E.S.S.) cannula and a specially designed Ellman radiofrequency bipolar electrode.

Cryoablation involves the use of extreme cold to destroy nerve tissue.
Relative or absolute contraindications to RFA mentioned in the reviewed literature include:

Definitive patient selection criteria for RFA as a treatment for chronic spinal pain have not been established. The evidence was reviewed for methodologic quality or risk of bias assessment utilizing the Quality Appraisal of Reliability Studies checklist for diagnostic interventions, and Cochrane review criteria and the Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment tool for therapeutic interventions. Evidence based on the review of the systematic assessment of controlled studies was graded utilizing a modified schema of qualitative evidence with best evidence synthesis, variable from level I to level V. Across all databases, 16 high quality diagnostic accuracy studies were identified. In addition, multiple studies assessed the influence of multiple factors on diagnostic validity. In contrast to diagnostic validity studies, therapeutic efficacy trials were limited to a total of 14 randomized controlled trials, assessing the efficacy of intraarticular injections, facet or zygapophysial joint nerve blocks and radiofrequency neurotomy of the innervation of the facet joints. The evidence for the diagnostic validity of lumbar facet joint nerve blocks with at least 75% pain relief with ability to perform previously painful movements was level I, based on a range of level I to V derived from a best evidence synthesis. 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 (>6 months), and level III evidence for lumbosacral zygapophysial joint injections for short-term improvement only. This review provides significant 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.

A systematic literature review of randomized controlled trials on radiofrequency ablation (RFA) procedures for spinal pain performed by Geurts et al. (2001) reported moderate evidence that radiofrequency lumbar facet denervation is more effective for chronic low back pain than placebo.

Nath et al. (2008) conducted a randomized controlled study of percutaneous radiofrequency neurotomy in 40 patients with chronic low back pain (20 active and 20 controls). All patients were examined by an orthopaedic surgeon before and 6 months after the treatment (sham or active). Inclusion criteria were 3 separate positive facet blocks. The active treatment group showed statistically significant improvement not only in back and leg pain but also back and hip movement as well as the sacroiliac joint test. There was significant improvement in quality of life variables, global perception of improvement and generalized pain. The improvement seen in the active group was significantly greater than that seen in the placebo group. The investigators concluded that radiofrequency facet denervation could be used in the treatment of carefully selected patients with chronic low back pain.

Van Wijk et al. (2005) conducted a randomized double-blind, sham lesion controlled trial of 81 patients with chronic low back pain who were randomized to undergo RFA (n=40) or sham treatment (n=41). Three months after treatment, combined outcome measure indicated no difference between RFA and sham treatment. The global perceived effect was in favor of RFA.

Gofeld et al. (2007) conducted a prospective audit of 174 patients with complaints of low back pain for more than 6 months. Patients were asked to estimate total perceived pain reduction (on a scale from 0% to 100%) at 6 weeks and at 6, 12 and 24 months after the procedure. Fifty-five reported no benefit from the procedure and 119 reported good (>50%) to excellent (>80%) pain relief lasting from 6 to 24 months. The authors concluded that radiofrequency denervation of the lumbar zygapophysial joints provides long-term pain relief.

Definitive patient selection criteria for RFA as a treatment for chronic spinal pain have not been established.

Relative or absolute contraindications to RFA mentioned in the reviewed literature include:

- Neurologic abnormalities
- Definitive clinical and/or imaging findings
Thermal Radiofrequency Ablation for Sacroiliac Pain

The sacroiliac (SI) joint has been identified as a primary source of chronic low back pain. Studies provide limited evidence regarding the efficacy and safety of thermal RFA for individuals with SI joint pain, and contain insufficient data that allows for definitive conclusions. Further high quality controlled trials are needed that compare this procedure in defined populations with placebo and with alternative treatments.

A Hayes report concluded that the overall quality of the evidence regarding the use of thermal RFA for treating chronic SI joint pain is low. There is positive but inconsistent evidence suggesting that thermal RFA of the SI joint is safe and may improve symptoms of pain over the short to intermediate term compared with sham therapy or alternative therapies. The lack of a standard RF denervation technique for RFA prevents definitive conclusions regarding the efficacy and safety of the procedure. An inherent challenge to the efficacy of RFA is the variable anatomy of targeted lateral branch nerves in the SI joint. Questions remain regarding patient selection criteria, long-term outcomes and the comparative efficacy versus alternative therapies (Hayes, 2017).

In a randomized, double-blind multicenter study; van Tilburg et al. (2016) compared percutaneous RFA with a sham procedure in 60 patients with SI joint pain. The treatment group received RFA to the lateral branches of S1, S2, S3 and S4 nerve roots and the posterior dorsal ramus of L5. Primary outcome was pain reduction. The authors found that pain was significantly reduced in both the conventional RFA and sham groups, with no statistically significant difference between the mean pain scores in the RFA treatment group versus the sham treatment group at 1-month follow-up. The pooled mean score for pain in both groups decreased significantly by 1 month. Study limitations include small sample size, short-term follow-up and presence of placebo effect.

Hansen et al. (2012) performed a systematic review of therapeutic interventions for sacroiliac joint pain. The primary outcome measure was pain relief (short-term relief = up to 6 months and long-term > 6 months). Secondary outcome measures were improvement in functional status, psychological status, return to work and reduction in opioid intake. Fifty-six studies were considered for inclusion. Of these, 6 randomized trials and 5 non-randomized studies met inclusion criteria for methodological quality assessment. The authors concluded that the evidence for conventional and pulsed RFA is poor. The limitations of this review include a paucity of literature on therapeutic interventions, variations in technique and variable diagnostic standards for sacroiliac joint pain.

Aydin et al. (2010) conducted a meta-analysis to assess the effectiveness of RFA of the SI joint for pain relief. While it appears that patients had > 50% pain relief at both 3 and 6 months post-treatment, the study was limited by variability between each study and lack of randomized controlled trials to evaluate the use of RFA of the SI joint. The authors concluded that further studies are needed, preferably randomized controlled studies, to evaluate whether RFA improves health outcomes in patients with SI joint pain.

Cohen et al. (2008) conducted a randomized placebo-controlled study in 28 patients with injection-diagnosed SI joint pain. Patients were randomized equally to receive both a L4-L5 primary dorsal rami and S1-S3 lateral branch radiofrequency denervation using cooling-probe technology after a local anesthetic block, or local anesthetic block followed by placebo denervation. Patients who did not respond to placebo injections crossed over and were treated with radiofrequency denervation using conventional technology. At 1, 3 and 6 months after the procedure, 11 (79%), 9 (64%) and 8 (57%) radiofrequency-treated patients experienced pain relief of 50% or greater and significant functional improvement. In contrast, only 2 patients (14%) in the placebo group experienced significant improvement at their 1-month follow-up, and none experienced benefit 3 months after the procedure. In the crossover group (n = 11), 7 (64%), 6 (55%) and 4 (36%) experienced improvement 1, 3 and 6 months after the procedure. One year after treatment, only 2 patients (14%) in the treatment group continued to demonstrate persistent pain relief. The authors concluded radiofrequency denervation may provide intermediate-term pain relief and functional benefit in selected patients with suspected SI joint pain; however, larger studies are needed to confirm these results and to determine the optimal candidates and treatment parameters for this disorder.

Pulsed Radiofrequency Ablation

There is insufficient evidence in the published clinical literature to determine the safety and efficacy of pulsed RFA for the treatment of spinal pain.

A Hayes report concluded that the overall quality of the evidence regarding the use of pulsed RFA for treating chronic low back pain is low. There is a paucity of studies evaluating this technology as the primary intervention. There is
Lee et al (2011) noted that recently, clinical reports using pulsed RFA have shown favorable effects in the treatment of a variety of focal pain areas, including non-nervous system tissues; however, the mechanism of effect underlying this treatment to non-nervous system tissue remains unclear.

A prospective study by Vallejo et al. (2006) evaluated the effect of pulsed RFA in 126 patients with chronic low back pain due to SI joint syndrome. The main outcome measures were visual analog scale (VAS) and quality of life (QOL) questionnaire performed prior to and after the treatment. Of the 126 patients who underwent arthrographically confirmed steroid/local anesthetic SIJ injection, 52 patients (41.3%) had > 75% pain relief after conservative treatment, while 22 patients failed to respond to the treatment. The 22 patients who failed conservative treatment underwent pulsed RFA of the medial branch of L4, posterior primary rami of L5, and lateral branches S1 and S2. Results showed that 16 patients (72.7%) experienced good (> 50% reduction in VAS), or excellent (> 80% reduction in VAS) pain relief following pulsed RFA. Duration of pain relief range was 6-9 weeks in four patients, 10-16 weeks in five patients, and 17-32 weeks in seven patients. In addition, QOL scores improved significantly in all measured categories. Six patients (26.1%) did not respond to PRFD and had less than 50% reduction in VAS and were considered failures. The authors concluded that pulsed RFA may be an effective treatment for some patients with SIJ pain that has been unresponsive to other forms of treatment. This study is limited by small sample size and the uncontrolled study design.

Simopoulos et al. (2008) conducted a prospective study of 76 patients to evaluate the safety and efficacy of pulsed RFA in a prospective, randomized, double-blinded study of 50 patients with lumbar back pain. Target facet joints were identified with oblique radiographic views. Continuous radiofrequency thermocoagulation was delivered at 80°C for 75 seconds, while PRF was delivered at 42°C with a pulse duration of 20 ms and pulse rate of 2 Hz for 120 seconds. No significant differences in the relative percentage improvement were noted between groups in either VAS or Oswestry Low Back Pain and Disability Questionnaire (OSW) scores. Within the PRF group, comparisons of the relative change over time for both VAS and OSW scores were not significant. However, within the CRF group, VAS and OSW scores showed significant improvement. The investigators concluded that although there was no significant difference between CRF and PRF therapy in long-term outcome in the treatment of lumbar facet syndrome, there was a greater improvement over time noted within the CRF group.

Abejon (2007) completed a retrospective analysis of the effectiveness of pulsed RFA applied to the lumbar dorsal root ganglion in 54 patients who underwent 75 PRF procedures. The patients were divided into three groups according to the etiology of the lesion herniated disc, spinal stenosis, and failed back surgery syndrome. The efficacy of the technique was assessed using a 10-point Numeric Rating Scale (at baseline and, along with the Global Perceived Effect (GPE) at 30, 60, 90, and 180 days. The reduction in medications and the number of complications associated with the technique were assessed although not reported. Pain reduction was noted in all groups except for those with failed back surgery syndrome. No complications were noted. The authors concluded that PRF was effective in herniated disc and spinal stenosis, but not failed back surgery syndrome. The flaws of this study include the retrospective design, subjective outcome measures and short term follow-up.

Van Zundert (2007) studied the effect of pulsed RFA on patients with cervical radicular pain in a prospective audit that showed satisfactory pain relief for a mean period of 9.2 months. Then a randomized sham controlled trial of 23 patients out of 256 screened, met the inclusion criteria and were randomly assigned in a double blind fashion to receive either pulsed RFA for 120 seconds or sham intervention. The evaluation was done by an independent observer. At 3 months the pulsed RFA group showed a significantly better outcome with regard to the global perceived effect.
Cryoablation has been proposed as an option for relief of spinal pain; however, there is a lack of published data to support the safety and efficacy of this technique.

Endoscopic Radiofrequency Ablation/Endoscopic Rhizotomy

There is insufficient evidence in the published clinical literature to determine the safety and efficacy of endoscopic RFA for the treatment of spinal pain.

Clinical outcomes from a pilot study evaluating endoscopic RFA were presented as a professional society conference abstract (Yeung et al., 2011).

Li et al. (2014) evaluated the effectiveness of surgical dorsal endoscopic rhizotomy in 58 patients with lumbar facetogenic chronic low back pain. Forty-five patients who experienced >80% relief of pain with two comparative lumbar medial branch blocks received dorsal endoscopic rhizotomy. The remaining 13 patients received conservative treatment. The authors reported that percentage of pain relief in the operation group at any time point postoperatively were significantly higher than that in the conservative group. Further studies with larger sample sizes and longer follow-up are needed to further validate the efficacy of this technique.

Cryoablation

Cryoablation has been proposed as an option for relief of spinal pain; however, there is a lack of published data to support the safety and efficacy of this technique.
Birkenmaier et al. (2007) conducted a prospective clinical case series to examine the effects of medial branch cryodenervation (cryoablation) in the treatment of lumbar facet joint pain. Patient selection was based on medical history, physical examination and positive medial branch blocks. Percutaneous medial branch cryodenervation was performed using a Lloyd Neurostat 2000. Target parameters were low back pain (by means of VAS, limitation of activity (McNab) and overall satisfaction. A total of 50 patients were recruited, and 46 completed the study. The follow-up time was 1 year. At 6 weeks, 33 patients (72 %) were pain-free or had major improvement of low back pain; 13 (28 %) had no or little improvement. Including failures, mean low back pain decreased significantly from 7.7 pre-operatively to 3.2 at 6 weeks, 3.3 at 3 months, 3.0 at 6 months and 4.2 at 12 months. However, the authors noted that at the 12 month follow-up period the failure rate rose to 43%.

A prospective study by Staender et al. (2005) evaluated the therapeutic effect of computerized tomography (CT)-guided cryorhizotomy in the treatment of 76 patients with lumbar facet joint syndrome (LFJS). All of the patients received one treatment after confirmation with a medial branch block using a 1.3cm size needle. Twenty-six patients required 2-4 additional treatments and a 2.0cm needle was used. The VAS was used as an evaluation tool along with reports of return to work and pain med use. Success was determined to be 50% reduction in VAS scores. Pre-treatment the median score was 6.7 and post-treatment was 3.2 for up to 6 months. Individual scores pre- and post-treatment were not reported. Patients without prior back surgery had a better result than post-surgical patients. The authors concluded the CT-guided treatment was effective. The intervening variable of the medial branch blocks has to be taken into account as part of the pain relief response which the authors acknowledge. Fifty percent of patients had 50% pain relief for at least up to a year in the reported aggregate data. Six percent of patients failed treatment. Although the results are promising, further study is needed to identify the placebo effect of the medial branch blocks.

**Chemical Ablation**

Chemical facet injections have been proposed as an option for relief of spinal pain; however, there is a lack of published data to support the safety and efficacy of this technique.

Joo et al. (2013), compared alcohol ablation with RFA in a randomized study of 40 patients with recurrent thoracolumbar facet joint pain after thermal RFA treatment. Patients were randomly allocated to two groups, receiving either the same repeated RFA (n=20) or alcohol ablation (n=20). At 24-month follow-up, three patients in the alcohol ablation group had recurring pain compared to 19 in the RFA group. The median effective periods were 10.7 months (range 5.4 to 24) for RFA and 24 months (range 16.8 to 24) for alcohol ablation. No significant complications were observed.  This study is limited by small sample size and short-term follow-up.

**Laser Ablation**

Laser ablation has been proposed as an option for relief of spinal pain; however, there is a lack of published data to support the safety and efficacy of this technique.

Iwatsuki (2007) reported treatment of facet syndrome by laser neurolysis in 21 study participants including 5 who had undergone previous spinal surgery. One year after laser denervation, 17 participants experienced pain reduction of at least 70%. Of the 5 individuals who had previously undergone spinal surgery, 4 did not have a successful outcome from laser denervation at 1-year follow-up. This study is limited by small sample size, short-term follow-up and lack of a control group.

**Professional Societies**

**American Society of Interventional Pain Physicians (ASIPP)**

ASIPP clinical practice guidelines review the evidence for several interventional techniques for managing chronic spinal pain. The guidelines recommend that patient selection for RFA rely on response to controlled diagnostic blocks (Manchikanti et al., 2013).

ASIPP guidelines state that the suggested therapeutic frequency for medial branch neurotomy should remain at intervals of at least 6 months or longer per each region (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 10 to 12 weeks. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely (Manchikanti et al., 2013).

**American Society of Anesthesiologists (ASA)**

ASA clinical practice guidelines (2010) review the evidence for chronic pain management techniques. The guidelines state that neuroablative procedures should be used as part of a comprehensive pain management regimen, performed only as a last resort when pain is refractory to other therapies. Recommendations for ablative therapies include the following:

- **RFA**
Conventional (e.g., 80°C) or thermal (e.g., 67°C) RFA of the medial branch nerves to the facet joint should be performed for low back pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief. Category A1 evidence – based on multiple, randomized controlled trials.

- RFA may be performed for neck pain. Category A3 evidence – based on a single randomized controlled trial.
- Conventional or thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of lumbar radicular pain. Category C2 evidence – insufficient or inconsistent findings.

- Cryoablation may be used in the care of selected patients, including those with low back pain (medial branch). Category B2 evidence – based on noncomparative observational studies.
- Chemical ablation (e.g., alcohol, phenol or high-concentration local anesthetics) should not be used in the routine care of patients with chronic non-cancer pain. Category B2 and B3 evidence – based on noncomparative observational studies or case reports.

### U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Radiofrequency ablation (RFA) for spinal pain is a procedure and, therefore, not subject to regulation by the FDA. However, the FDA regulates RFA devices, and there are numerous devices listed in the FDA 510(k) database approved for use in performing RFA for neurosurgical procedures. Three product codes are used to represent these devices: radiofrequency lesion generators (GXD), radiofrequency lesion probes (GXI) and electrosurgical cutting and coagulating device and accessories (GEI). See the following website for more information:


Products for other types of spinal ablation therapies can be searched at the following website:


(Accessed September 4, 2018)

### CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for ablative treatments for spinal pain. Local Coverage Determinations (LCDs) exist; see the LCDs for Destruction of Paravertebral Facet Joint Nerve(s), Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy and Nerve Blockade for Treatment of Chronic Pain and Neuropathy.

(Accessed April 19, 2018)

### REFERENCES


### POLICY HISTORY/REVISION INFORMATION

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Corporate Medical Affairs Committee

### INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.