Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Facet Radiofrequency Denervation is addressed separately in medical policy 00199.

Note: Spinal Cord Stimulation is addressed separately in medical policy 00260.

Note: Sacroiliac Joint Fusion is addressed separately in medical policy 00558.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers radiofrequency ablation of peripheral nerves to treat pain associated with knee osteoarthritis or planter fasciitis to be investigational.*

Based on review of available data, the Company considers cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty to be investigational.*

Based on review of available data, the Company considers radiofrequency ablation or cryoneurolysis of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache to be investigational.*

Based on review of available data, the Company considers diagnostic block performed before planned ablation to be investigational.*

Based on review of available data, the Company considers ablation of peripheral nerves to treat pain in all other conditions, with the exception of facet joint pain (see medical policy 00199) to be investigational.*
Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
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Background/Overview

Knee Osteoarthritis
Knee osteoarthritis (OA) is common, and often the cause of substantial disability. Prevalence increases with age, from about 24% among those 60 to 64 years of age to as high as 40% in those 70 to 74 years of age. Knee osteoarthritis is characterized by pain upon initiation of movement or walking. As osteoarthritis progresses, the pain becomes continuous and joint functionality is severely impaired.

Treatment
Treatment for OA of the knee aims to alleviate pain and improve function. However, most treatments do not modify the natural history or progression of OA and are not considered curative. Nonsurgical modalities used include: exercise; weight loss; various supportive devices; acetaminophen or nonsteroidal anti-inflammatory drugs (eg, ibuprofen); nutritional supplements (glucosamine, chondroitin); and intra-articular viscosupplements. Corticosteroid injection may be considered when relief from nonsteroidal anti-inflammatory drugs is insufficient, or the patient is at risk of gastrointestinal adverse events. If symptom relief is inadequate with conservative measures, invasive treatments may be considered. Total knee arthroplasty is an operative treatment for symptomatic OA of the knee.

Plantar Fasciitis
Plantar fasciitis is a common cause of foot pain in adults, characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some individuals the pain persists and can impede activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is unclear, although a repetitive injury is suspected. Heel spurs are a common associated finding, although it has never been proven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population.

Treatment
Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases.
Ablation of Peripheral Nerves to Treat Pain

Policy #   00503
Original Effective Date:  05/18/2016
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**Occipital Neuralgia**

Occipital neuralgia is a specific type of headache that is located on one side of the upper neck, back of the head, and behind the ears, and sometimes extending to the scalp, forehead, and behind the eyes. The pain, which may be piercing, throbbing, or electric-shock-like, follows the course of the greater and lesser occipital nerves. Occipital neuralgia is believed to occur due to pressure or irritation to the occipital nerves, which may result from injury, entrapment by tight muscles, or inflammation.

**Treatment**

Treatment may include massage and rest, muscle relaxants, nerve blocks, and injection of steroids directly into the affected area.

**Cervicogenic Headache**

Cervicogenic headache is a headache that is secondary to a disorder of the cervical spine. The pain may be referred from facet joints, intervertebral discs, or soft tissue. The pain is constant rather than throbbing, and may be aggravated by movements of the neck or pressure to certain areas on the neck. The first 3 cervical spinal nerves can refer pain to the head. The C1 suboccipital nerve innervates the atlanto-occipital joint; the C2 spinal nerve and the C3 dorsal ramus have close proximity to and innervate the C2-C3 facet joint. The C2-3 facet joint is the most frequent source of a cervicogenic headache. A diagnosis of a cervicogenic headache may be confirmed by an anesthetic block of the lateral atlanto-axial joint, the C2-3 facet joint, or the C3-4 facet joint.

**Treatment**

Treatment may include nerve blocks, physical therapy, and exercise.

**Nerve Radiofrequency Ablation**

Nerve radiofrequency ablation (RFA) is a minimally invasive method that involves the use of heat and coagulation necrosis to destroy tissue. A needle electrode is inserted through the skin and into the tissue to be ablated. A high-frequency electrical current is applied to the target tissue and a small sphere of tissue is coagulated around the needle by the heat generated. It is theorized that the thermal lesioning of the nerve destroys peripheral sensory nerve endings, resulting in the alleviation of pain. Cooled RFA is a variation of nerve RFA using a water-cooled probe that applies more energy at the desired location without excessive heat diffusing beyond the area, causing less tissue damage away from the nerve (see Table 1). The goal of ablating the nerve is the same.
Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023

RFA is also distinguished from pulsed radiofrequency (RF) treatment, which has been investigated for different types of pain. The mechanism of action of pulsed RF treatment is uncertain but it is thought not to destroy the nerve. It does produce some degree of nerve destruction but is thought to cause less damage than standard RFA. Some studies refer to pulsed RF treatment as ablation.

For the indications assessed in this medical policy, nerve RFA should be distinguished from RF energy applied to areas other than the nerve to cause tissue damage. Some individuals have been treated for plantar fasciitis with a fasciotomy procedure using an RF device. This procedure does not ablate a specific nerve.

Table 1. Types of Radiofrequency Ablation

<table>
<thead>
<tr>
<th>Type</th>
<th>Procedure</th>
<th>Tissue Temperature</th>
<th>Key Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard RFA</td>
<td>Electrode tip provides thermal energy for 90–130 seconds</td>
<td>70 – 90°C</td>
<td>Longer term pain relief but with more adjacent thermal tissue injury and limitation in size and shape of lesion.</td>
</tr>
<tr>
<td>Pulsed RFA</td>
<td>Non-ablative - provides 20 ms pulses every 30 seconds</td>
<td>42°C</td>
<td>Limits tissue damage but results in shorter duration of pain relief.</td>
</tr>
<tr>
<td>Cooled RFA</td>
<td>Water circulates through RF electrode to cool the tip</td>
<td>60°C</td>
<td>Larger lesion with limited thermal injury to tissue. Longer term pain relief.</td>
</tr>
</tbody>
</table>

RF: radiofrequency; RFA: radiofrequency ablation
Adapted from Oladeji et al (2019)

Cryoneurolysis
Cryoneurolysis is being investigated to alleviate pain. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction but maintenance of the perineural and epineural elements of the nerve bundle. Wallerian degeneration allows complete regeneration and recovery of nerve function in about 3 to 5 months. The iovera cryoablation system is a portable handheld device that applies percutaneous and targeted delivery of cold to superficial peripheral nerves.
Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023

**FDA or Other Governmental Regulatory Approval**

**U.S. Food and Drug Administration (FDA)**

A number of RF generators and probes for the peripheral nervous system have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are listed in Table 2.

In 2017, the COOLIEF Cooled Radiofrequency Probe (Avanos, previously known as Halyard Health) was cleared for marketing by the FDA through the 510(k) process to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue (K163461). One of the indications is specifically for "creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥ 50% reduction in pain) to a diagnostic genicular nerve block."

**Table 2. Radiofrequency and Cryoneurolysis Devices**

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance</th>
<th>Date</th>
<th>FDA Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>SInergy®‡/Bayless Pain Management Probe</td>
<td>Kimberly-Clark/Baylis</td>
<td>K053082</td>
<td>2005</td>
<td>GXD</td>
</tr>
<tr>
<td>NeuroTherm®‡ NT 2000</td>
<td>NeuroTherm</td>
<td>K111576</td>
<td>2011</td>
<td>GXD</td>
</tr>
<tr>
<td>iovera</td>
<td>Pacira (formerly Myoscience)</td>
<td>K133453</td>
<td>2014</td>
<td>GXH</td>
</tr>
<tr>
<td>COOLIEF®‡ Cooled Radiofrequency Kit</td>
<td>Avanos (formerly Halyard Health)</td>
<td>K163236</td>
<td>2016</td>
<td>GXI</td>
</tr>
<tr>
<td>COOLIEF®‡ Cooled RF Probe</td>
<td>Avanos (formerly Halyard Health)</td>
<td>K163461</td>
<td>2017</td>
<td>GXI</td>
</tr>
</tbody>
</table>
Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023

| Rulo(TM) Radiofrequency Lesion Probe | Epimed International | K190256 | 2019 | GXI |

**Rationale/Source**
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Radiofrequency ablation (RFA) and cryoneurolysis of nerves have been proposed as treatments for several different types of pain. RFA has been used to treat a number of clinical pain syndromes such as trigeminal neuralgia as well as cervical and lumbar pain. This review evaluates the application of RFA and cryoneurolysis in peripheral sites distant from the spine.

**Summary of Evidence**
For individuals who have knee OA who receive RFA of peripheral nerves, the evidence includes systematic reviews of randomized controlled trials (RCTs), RCTs with 24 to 200 individuals (including 4 with a minimum of 6-month follow-up), and prospective observational studies with 12 to 24 months of follow-up. Relevant outcomes include symptoms, functional outcomes, and quality of life (QOL). Knee osteoarthritis (OA) is a common disorder in older adults. RFA of the genicular nerves has the potential to alleviate pain and improve function in this population, and might also delay or eliminate the need for total knee arthroplasty (TKA). At this time, there is high heterogeneity in methods and comparators. The 2 multi-center trials conducted in the U.S. used anesthetic nerve block under fluoroscopic guidance and compared the efficacy of cooled RFA to either steroid injection or hyaluronic acid injection. Both studies reported a responder rate of approximately 70% at 6 months, which was significantly greater than the control conditions. Given that OA of the knee is a common condition; study in a larger number of individuals, preferably blinded with active and sham controls and follow-up of at least 12 months, is needed to determine the benefits and potential harms of this treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023

For individuals who have knee OA or TKA who receive cryoneurolysis of peripheral nerves, the evidence includes an RCT with 180 individuals and a retrospective comparative study. Relevant outcomes include symptoms, functional outcomes, and QOL. Cryoneurolysis in individuals with knee OA resulted in a greater decrease in Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) pain score, WOMAC total score, and visual analog scale (VAS) score at 30 days compared with sham-treated controls. However, subsequent measurements showed no significant benefit of cryoneurolysis on WOMAC score at 60 days or VAS score at 60 or 90 days. Perioperative cryoneurolysis was shown in a retrospective comparison to reduce the length of stay and opioid use in individuals undergoing TKA. These results need to be confirmed in an RCT. Several technical issues including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula have not been resolved. The most effective method for determining probe insertion location (eg, ultrasound-guided or based on anatomic landmarks) also need to be established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have plantar fasciitis who receive RFA of peripheral nerves, the evidence includes 2 RCTs. Relevant outcomes include symptoms, functional outcomes, and QOL. One of the randomized trials only evaluated 17 individuals, and assessment of randomized outcomes was limited to 4 weeks post-treatment. A second RCT evaluated 36 individuals out to 12 weeks. Both trials found RFA associated with pain reduction, but to be more confident in the efficacy of this treatment, controlled trials with larger samples and longer follow-up would be necessary. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have occipital neuralgia or cervicogenic headache who receive RFA or cryoneurolysis of peripheral nerves, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. No RCTs of RFA for chronic occipital neuralgia have been identified. Three RCTs of RFA for a cervicogenic headache have been published, none of which were high quality. Pain is a subjective, patient-reported measure that is particularly susceptible to a placebo effect. Randomized trials with sham or active-controls are needed to evaluate the efficacy of this treatment. One controlled trial found a temporary benefit of cryoneurolysis for cervicogenic headache, but the effect was not significantly better than injection of corticosteroid and local anesthetic. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
Ablation of Peripheral Nerves to Treat Pain

Policy #  00503
Original Effective Date:  05/18/2016
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Supplemental Information
Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons et al
In 2021, the American Academy of Orthopaedic Surgeons published a clinical practice guideline, endorsed by the American Association of Hip and Knee Surgeons and the American Physical Therapy Association, on management of osteoarthritis (OA) of the knee. The guideline did not specifically address RFA or cryoneurolysis, but did include a guideline statement on denervation therapy that included various ablation techniques (e.g., RFA, cryoneurolysis, thermal ablation and chemical ablation). The guideline stated, "denervation therapy may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee" (strength of recommendation: limited).

American College of Rheumatology and Arthritis Foundation
The 2019 Guidelines from the American College of Rheumatology and the Arthritis Foundation gave a conditional recommendation for radiofrequency ablation for the treatment of knee OA. The recommendation was based on evidence of a potential analgesic benefit, but the studies used heterogeneous techniques and there was a lack of long-term safety data.

American College of Foot and Ankle Surgeons
The American College of Foot and Ankle Surgeons (2018) issued consensus guidelines on the diagnosis and treatment of acquired infracalcaneal heel pain. The safety and efficacy of bipolar radiofrequency were listed as uncertain (neither appropriate nor inappropriate).

American Society of Pain and Neuroscience
The American Society of Pain and Neuroscience (2021) issued consensus guidelines using U.S. Preventive Services Task Force (USPSTF) grading criteria on the use of RFA to treat various pain conditions. The guidelines stated that genicular RFA may be used for the treatment of osteoarthritis-
Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023

related and post-surgical knee joint pain (Grade B), and may be selectively offered for the treatment of occipital neuralgia pain when greater or lesser nerves have been identified as the etiology of pain via diagnostic blocks (Grade C).

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

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02915120</td>
<td>Ultrasound-Guided Pulsed Radiofrequency Of The Genicular Nerves In The Treatment Of Patients With Osteoarthritis Knee Pain: Randomized, Double-Blind, Placebo-Controlled Trial</td>
<td>142</td>
<td>Jul 2022</td>
</tr>
<tr>
<td>NCT03774121</td>
<td>Cryoneurolysis for the Management of Chronic Pain in Patients With Knee Osteoarthritis; A Randomized Controlled Study</td>
<td>90</td>
<td>Mar 2023</td>
</tr>
<tr>
<td>NCT04145011</td>
<td>A Prospective, Multi-center, Randomized, Single Blind Clinical Trial Comparing COOLIEF* Cooled Radiofrequency to Conventional Radiofrequency Ablation of the Genicular Nerves in the</td>
<td>153</td>
<td>Aug 2022</td>
</tr>
</tbody>
</table>
Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Study Title</th>
<th>Number of Participants</th>
<th>Study Start Date</th>
<th>Study End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02294864</td>
<td>A Controlled Comparison of Pulsed Radiofrequency Vs Physical Therapy on Treating Chronic Knee Osteoarthritis</td>
<td>50</td>
<td>Apr 2017</td>
<td>(unknown)</td>
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<tr>
<td>NCT02260869</td>
<td>Efficacy of Cooled and Monopolar Radiofrequency Ablation of the Geniculate Nerves for the Treatment of Chronic Osteoarthritic Knee Pain</td>
<td>78</td>
<td>Jun 2019</td>
<td>(terminated due to finances)</td>
</tr>
<tr>
<td>NCT02925442(^a)</td>
<td>Comparison Between Cooled (C-RFA) and Standard (t-RFA) Radiofrequency Ablation, and Control for Pain Management Following Unilateral Knee Arthroplasty: A Double-Blinded, Parallel-Grouped, Placebo-Controlled Randomized Clinical Trial</td>
<td>150</td>
<td>Feb 2020</td>
<td></td>
</tr>
<tr>
<td>NCT03818022</td>
<td>Effectiveness of Preoperative Cryoneurolysis (Iovera) for Postoperative Pain Control in Total Knee Arthroplasty</td>
<td>100</td>
<td>Dec 2020</td>
<td>(unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
\(^a\) Industry sponsored or partially sponsored.

References
Ablation of Peripheral Nerves to Treat Pain

Policy #  00503
Original Effective Date:  05/18/2016
Current Effective Date:  05/08/2023

Ablation of Peripheral Nerves to Treat Pain

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Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023


Ablation of Peripheral Nerves to Treat Pain

Policy #  00503
Original Effective Date:  05/18/2016
Current Effective Date:  05/08/2023


Policy History
Original Effective Date:  05/18/2016
Current Effective Date:  05/08/2023
05/05/2016    Medical Policy Committee review
05/18/2016    Medical Policy Implementation Committee approval. New policy.
11/01/2016    Coding update
01/01/2017    Coding update: Removing ICD-9 Diagnosis Codes
05/04/2017    Medical Policy Committee review

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Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023

05/17/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/03/2018 Medical Policy Committee review
05/16/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/08/2018 Medical Policy Implementation Committee approval. Title changed from “Radiofrequency Ablation of Peripheral Nerves to Treat Pain” to “Ablation of Peripheral Nerves to Treat Pain”. Added four investigational statements as follows: cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis (OA) or total knee arthroplasty is considered to be investigational; radiofrequency ablation (RFA) of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered to be investigational; diagnostic block performed before radiofrequency ablation (RFA) is considered to be investigational; and ablation of peripheral nerves to treat pain in all other conditions, with the exception of facet joint pain is considered to be investigational.
11/07/2019 Medical Policy Committee review
11/13/2019 Medical Policy Implementation Committee approval. Replaced “radiofrequency ablation” with “planned ablation”, so that diagnostic block before any ablation is investigational.
04/02/2020 Medical Policy Committee review
04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/01/2021 Medical Policy Committee review
04/14/2021 Medical Policy Implementation Committee approval. Cryoneurolysis was added to the investigational statement on occipital neuralgia or cervicogenic headache.
05/24/2021 Coding update
10/01/2021 Coding update
11/29/2021 Coding update
12/20/2021 Coding update
04/07/2022 Medical Policy Committee review
04/13/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023 Medical Policy Committee review
Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/08/2023

04/12/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 04/2024

Coding
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>64405, 64450, 64454, 64624, 64640</td>
</tr>
<tr>
<td>HCPCS</td>
<td>Delete codes effective 1/1/2022: C9752, C9753</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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