Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

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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 extracorporeal shockwave therapy (ESWT), using either a high-dose or low-dose protocol or radial extracorporeal shockwave therapy (rESWT), as a treatment of musculoskeletal conditions to be **investigational***, including but not limited to:

- Plantar fasciitis;
- Tendinopathies including tendinitis of the shoulder;
- Tendinitis of the elbow (lateral epicondylitis, tennis elbow);
- Achilles tendinitis;
- Patellar tendinitis;
- Spasticity;
- Stress fractures;
- Delayed union and non-union of fractures;
- Avascular necrosis of the femoral head.

Background/Overview

Chronic Musculoskeletal Conditions

Chronic musculoskeletal conditions (eg, tendinitis) can be associated with a substantial degree of scarring and calcium deposition. Calcium deposits may restrict motion and encroach on other structures, such as nerves and blood vessels, causing pain and decreased function. One hypothesis is that disruption of calcific deposits by shock waves may loosen adjacent structures and promote resorption of calcium, thereby decreasing pain and improving function.

Plantar Fasciitis

Plantar fasciitis is a common ailment 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 patients the pain persists, interrupting 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 repetitive injury is suspected. Heel spurs are a common associated finding, although it is unproven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population.

Tendinitis and Tendinopathies

Common tendinitis and tendinopathy syndromes are summarized in Table 1. Many tendinitis and tendinopathy syndromes are related to overuse injury.

Table 1. Tendinitis and Tendinopathy Syndromes

Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
Lateral epicondylitis ("tennis elbow")	Lateral elbow (insertion of wrist extensors)	Tenderness over lateral epicondyle and proximal wrist extensor muscle mass; pain with resisted wrist extension with elbow in full extension; pain with passive terminal wrist flexion with elbow in full extension	• Rest • Activity modification • NSAIDs • Physical therapy • Orthotic devices	Corticosteroid injections; joint débridement (open or laparoscopic)
Shoulder tendinopathy	Rotator cuff muscle tendons, most commonly supraspinatus	Pain with overhead activity	• Rest • Ice • NSAIDs • Physical therapy	Corticosteroid injections

Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
Achilles tendinopathy	Achilles tendon	Pain or stiffness 2-6 cm above the posterior calcaneus	• Avoidance of aggravating activities • Ice when symptomatic • NSAIDs • Heel lift	Surgical repair for tendon rupture
Patellar tendinopathy ("jumper's knee")	Proximal tendon at lower pole of patella	Pain over anterior knee and patellar tendon; may progress to tendon calcification and/or tear	• Ice • Supportive taping • Patellar tendon straps • NSAIDs	

NSAIDs: nonsteroidal anti-inflammatory drugs.

Fracture Nonunion and Delayed Union

The definition of a fracture nonunion remains controversial, particularly the duration necessary to define nonunion. One proposed definition is a failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months after the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing). The following criteria to define nonunion were used to inform this review:

- at least 3 months since the date of fracture;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is 1 cm or less; and
- the patient can be adequately immobilized and is of an age likely to comply with nonweight bearing.

The delayed union can be defined as a decelerating healing process, as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention. (In contrast, nonunion serial radiographs show no evidence of healing.)

Other Musculoskeletal and Neurologic Conditions
Other musculoskeletal conditions include medial tibial stress syndrome, osteonecrosis (avascular necrosis) of the femoral head, coccydynia, and painful stump neuromas. Neurologic conditions include spasticity, which refers to a motor disorder characterized by increased velocity-dependent stretch reflexes. It is a characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

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.

For tendinitis and tendinopathy syndromes, conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications (see Table 1).

Extracorporeal Shock Wave Therapy
Also known as orthotripsy, extracorporeal shock wave therapy (ESWT) has been available since the early 1980s for the treatment of renal stones and has been widely investigated for the treatment of biliary stones. ESWT uses externally applied shock waves to create a transient pressure disturbance, which disrupts solid structures, breaking them into smaller fragments, thus allowing spontaneous passage and/or removal of stones. The mechanism by which ESWT might have an effect on musculoskeletal conditions is not well-defined.

Other mechanisms are also thought to be involved in ESWT. Physical stimuli are known to activate endogenous pain control systems, and activation by shock waves may "reset" the endogenous pain receptors. Damage to endothelial tissue from ESWT may result in increased vessel wall permeability, causing increased diffusion of cytokines, which may, in turn, promote healing. Microtrauma induced by ESWT may promote angiogenesis and thus aid healing. Finally, shock waves have been shown to stimulate osteogenesis and promote callous formation in animals, which is the basis for trials of ESWT in delayed union or nonunion of bone fractures.

There are 2 types of ESWT: focused and radial. Focused ESWT sends medium- to high-energy shockwaves of single pressure pulses lasting microseconds, directed on a specific target using ultrasound or radiographic guidance. Radial ESWT (RSW) transmits low- to medium-energy

shockwaves radially over a larger surface area. The Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Currently, 6 focused ESWT devices have been approved by FDA through the premarket approval process for orthopedic use (see Table 2). FDA product code: NBN.

Table 2. FDA-Approved Extracorporeal Shock Wave Therapy Devices

Device Name	Approval Date	Delivery System Type	Indication
OssaTron®‡ device (HealthTronics)	2000	Electrohydraulic delivery system	Chronic proximal plantar fasciitis, ie, pain persisting >6 mo and unresponsive to conservative management Lateral epicondylitis
Epos™‡ Ultra (Dornier)	2002	Electromagnetic delivery system	Plantar fasciitis
Sonocur®‡ Basic (Siemens)	2002	Electromagnetic delivery system	Chronic lateral epicondylitis (unresponsive to conservative therapy for >6 mo)
Orthospec™‡ Orthopedic ESWT (Medispec)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients ≥18 y
Orbasone™‡ Pain Relief System (Orthometrix)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients ≥18 y
Duolith®‡ SD1 Shock Wave Therapy Device (Storz Medical AG)	2016	Electromagnetic delivery system	Chronic proximal plantar fasciitis in patients ≥18 y with history of failed alternative conservative therapies >6 mo

FDA: Food and Drug Administration.

Both high-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high-energy shock waves (1300 mJ/mm2). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which lower dose shock waves are applied. This protocol does not require anesthesia. The FDA-labeled indication for the OssaTron®‡ and Epos™‡ Ultra devices specifically describes a high-dose protocol, while the labeled indication for the Sonocur®‡ device describes a low-dose protocol.

In 2007, Dolorclast®‡ (EMS Electro Medical Systems), a radial ESWT, was approved by FDA through the premarket approval process. Radial ESWT is generated ballistically by accelerating a bullet to hit an applicator, which transforms the kinetic energy into radially expanding shock waves. Radial ESWT is described as an alternative to focused ESWT and is said to address larger treatment areas, thus providing potential advantages in superficial applications like tendinopathies. The FDA-approved indication is for the treatment of patients 18 years and older with chronic proximal plantar fasciitis and a history of unsuccessful conservative therapy. FDA product code: NBN.

Rationale/Source

Extracorporeal shock wave therapy (ESWT) is a noninvasive method used to treat pain with shock or sound waves directed from outside the body onto the area to be treated, (eg, the heel in the case of plantar fasciitis). Shock waves are generated at high- or low-energy intensity, and treatment protocols can include more than 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

For individuals who have plantar fasciitis who receive ESWT, the evidence includes3 recent systematic reviews, each analyzing 9 RCTs, for a total of 21 randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. While several of the same trials were included in multiple meta-analyses, pooled results were inconsistent. One 2017 meta-analysis reported that ESWT was beneficial in reducing pain, while another reported non-significant findings in pain reduction. The most recent trial (2018) compared ESWT to corticosteroid injections (CSIs) and found that high-energy ESWT is more effective than CSI and low-energy ESWT is not. Reasons for the differing results include lack of uniformity in the definitions of outcomes, and heterogeneity in ESWT protocols (focused vs radial, high-energy vs low-energy, number and duration of shocks per

treatment, number of treatments, and different comparators). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lateral epicondylitis who receive ESWT, the evidence includes small RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Overall, although some RCTs have demonstrated benefits in pain and functional outcomes associated with ESWT, the limited amount of high-quality RCT evidence precludes conclusions about the efficacy of ESWT for lateral epicondylitis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have shoulder tendinopathy who receive ESWT, the evidence includes 2 network meta-analyses as well as several systematic reviews and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The network meta-analyses focused on 3 outcomes: pain reduction, functional assessment, and change in calcific deposits. One network meta-analysis separated trials using high-energy focused ESWT (H-FSW), low-energy ESWT, and radial ESWT (RSW). This analysis reported the most effective treatment for pain reduction was ultrasound-guided needling, followed by RSW and H-FSW. The only treatment showing a benefit in functional outcomes was H-FSW. For the largest change in calcific deposits, the most effective treatment was ultrasound-guided needling, followed by RSW, then H-FSW. Many of the RCTs were judged of poor quality. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Achilles tendinopathy who receive ESWT, the evidence includes systematic reviews of RCTs, an RCT published after the systematic review, and nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In the most recent systematic review, a pooled analysis found that ESWT reduced both short- and long-term pain compared with non-operative treatments, although reviewers warned that results were inconsistent across the RCTs and that there was heterogeneity across studies (eg, patient populations, treatment protocols). An RCT published after the systematic review compared ESWT with hyaluronan injections and reported improvements in both treatment groups, although the improvements were significantly higher in the injection group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have patellar tendinopathy who receive ESWT, the evidence includes systematic reviews of small studies, an RCT not included in the systematic reviews, and a nonrandomized study. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The studies reported inconsistent results. Many had methodologic deficiencies such as small numbers, short follow-up periods, and heterogeneous treatment protocols. Results from a nonrandomized study suggested that the location of the patellar tendinopathy might impact the response to ESWT (patients with retropatella fat extension did not respond to RSW compared with patients with tendon involvement). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have medial tibial stress syndrome who receive ESWT, the evidence includes a small RCT and a small nonrandomized cohort study. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT reported no difference in self-reported pain between study groups. The cohort study reported improvements with ESWT, although selection bias impacted the strength of the conclusions. The available evidence is limited and inconsistent; it does not permit conclusions about the benefits of ESWT for medial tibial stress syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteonecrosis of the femoral head who receive ESWT, the evidence includes three systematic reviews of small, mostly nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. While many of the studies have suggested that ESWT might be effective in improving motor function and reducing pain, particularly in patients with early-stage osteonecrosis, the studies were judged of low quality based on lack of blinding, lack of comparators, small sample sizes, short follow-up, and variations in treatment protocols. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes a systematic review of an RCT and several case series, as well as 2 RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Reviewers concluded that the evidence was inconsistent and of poor quality. Data pooling was not possible due to the heterogeneity of outcome

definitions and treatment protocols. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spasticity who receive ESWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. As a treatment for spasticity, several small studies have demonstrated ESWT provides short-term improvements in Modified Ashworth Scale scores, but direct evidence on the effect of ESWT on more clinically meaningful measures (eg, pain, function) are lacking. Differences in treatment parameters among studies, including energy dosage, method of generating and directing shock waves, and use or absence of anesthesia, limit generalizations about the evidence base. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

American College of Foot and Ankle Surgeons

Thomas et al (2010) revised guidelines on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons. The guidelines identified extracorporeal shock wave therapy (ESWT) as a third tier treatment modality in patients who have failed other interventions, including steroid injection. The guidelines recommended ESWT as a reasonable alternative to surgery. In an update to the American College of Food and Ankle Surgeons clinical consensus statement, Schneider et al (2018) stat that ESWT is a safe and effective treatment for plantar fasciitis.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence has published guidance on ESWT for a number of applications.

A guidance issued in 2003 stated that current evidence on safety and efficacy for treatment of calcific tendonitis of the shoulder "appears adequate to support the use of the procedure."

The 2 guidance documents issued in 2009 stated that current evidence on the efficacy of ESWT for refractory tennis elbow and plantar fasciitis "is inconsistent."

A guidance issued in 2011 stated that evidence on the efficacy and safety of ESWT for refractory greater trochanteric pain syndrome "is limited in quality andquantity."

A guidance issued in 2016 stated that current evidence on the efficacy of ESWT for Achilles tendinopathy "is inconsistent and limited in quality and quantity."

Canadian Agency for Drugs and Technologies in Health
A 2007 summary by the Canadian Agency for Drugs and Technologies in Health (CADTH) noted that results from randomized trials of ESWT for plantar fasciitis have been conflicting. The report noted that the "lack of convergent findings from randomized trials of ESWT for chronic plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed … does not support the use of this technology for this condition."

Similarly, a 2007 report by CADTH on ESWT for chronic lateral epicondylitis noted conflicting results from randomized trials (RCTs), with half showing no benefit over placebo for any outcome measures. The report noted that "the lack of convincing evidence regarding its effectiveness does not support the use of ESWT for CLE [chronic lateral epicondylitis]."

A third 2007 summary by CADTH concluded that "the current evidence supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis that is recalcitrant to conventional conservative treatment, although more high-quality RCTs with larger sample sizes are required to provide more convincing evidence."

A 2016 update from CADTH addressed the use of shockwave therapy for pain associated with upper-extremity orthopedic disorders. Based on results from 7 systematic reviews (with overlapping randomized controlled trials), the Agency concluded the following (see Table 3).

Table 3. Conclusions on the Use of ESWT for Upper-Extremity Pain

Condition	Evidence	Comparator	Conclusions
Shoulder			
Calcific tendonitis	Systematic reviews	Placebo	Effective in reducing pain

Noncalcific tendonitis	Systematic reviews	Placebo or other treatments	No significant benefit
Tendonitis	Single RCTs	Exercise or radiotherapy	No significant benefit
Tendonitis	1 RCT	Transcutaneous electric nerve stimulation	Effective in reducing pain
Elbow			
Lateral epicondylitis	Systematic reviews	Placebo	Inconclusive
Lateral epicondylitis	Single RCTs	Physical therapy or percutaneous tenotomy	No significant benefit
Lateral epicondylitis	Single RCTs	Corticosteroid injections	Inconclusive

ESWT: extracorporeal shockwave treatment; RCT: randomized controlled trial.

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 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02424084	Effects of Extracorporeal Shock Wave Therapy in Bone Microcirculation	80	Dec 2020
NCT02668510	A Randomized Controlled Trial Comparing Extracorporeal Shock Wave Therapy with Platelet Rich Plasma versus Extracorporeal Shock Wave Therapy in a High Demand Cohort with Resistant Plantar Fasciitis	30	Dec 2018 (unknown)
NCT03472989	The Effectiveness of Radial Extracorporeal Shockwave Therapy (rESWT), Sham-rESWT, Standardized Exercise Program or Usual Care for Patients With Plantar Fasciopathy. Study Protocol for a Double-blind, Randomized Sham-Controlled Trial	200	Mar 2022
NCT04365478	Effects of an Early Radial Shock Waves Therapy on Spasticity of the Upper Limb and on Functional Outcome in Patients With Stroke in Subacute Phase	28	Aug 2020
NCT04332471	Treatment of Plantar Fasciitis With Radial Shockwave Therapy vs. Focused Shockwave Therapy: a Randomized Controlled Trial	104	Oct 2021
Unpublished			
NCT02613455	Prospective Randomized Trial Comparing Corticosteroid Injection to High Energy	80	Dec 2016 (unknown)

	Extracorporeal Shock Wave Therapy for Lateral Epicondylitis		
NCT02757664	Shock Wave Therapy, Associated to Eccentric Strengthening Versus Isolated Eccentric Strengthening for Treating Insertional Achilles Tendinopathy: Double Blinded Randomized Clinical Trial	119	Jun 2020
NCT02546128	LEICSTES=LEICeSter Tendon Extracorporeal Shock Wave Studies Assessing the Benefits of the Addition of Extracorporeal Shock Wave Treatment to a Home-Rehabilitation Programme for Patients with Tendinopathy	720	Jun 2020
NCT03779919	The Therapeutic Effect of the Extracorporeal Shock Wave Therapy on Shoulder Calcific Tendinitis	90	May 2020
NCT03399968	Extracorporeal Shockwave Therapy (ESWT) in Patients Suffering From Complete Paraplegia at the Thoracic Level	25	May 2020

NCT: national clinical trial.

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Policy History

Original Effective Date: 08/27/2001
Current Effective Date: 04/12/2021

08/16/2001	Medical Policy Committee review
08/27/2001	Managed Care Advisory Council approval
03/21/2002	Medical Policy Committee review. Coverage eligibility changed to reflect current literature.
03/25/2002	Managed Care Advisory Council approval
02/03/2004	Medical Director Review

02/17/2004	Medical Policy Committee review. Format revision. Coverage eligibility change to reflect the investigational status of the technology identified in current literature.
02/23/2004	Managed Care Advisory Council approval. Claims Processing effective date based on revised policy will be 4/1/04.
02/01/2006	Medical Director review
02/15/2006	Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
02/23/2006	Quality Care Advisory Council approval
02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee approval. No change to coverage eligibility.
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010	Medical Director review
02/17/2010	Medical Policy Committee approval. Title changed to Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions.
02/03/2011	Medical Policy Committee review
02/16/2011	Medical Policy Implementation Committee approval. No change to coverage statement.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. No change to coverage statement.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2013	Coding revised
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2015	Medical Policy Committee review
03/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

03/04/2016	Medical Policy Committee review
03/16/2016	Medical Policy Implementation Committee approval. Added additional indications into coverage statement. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2018	Medical Policy Committee review
03/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2019	Coding update
03/07/2019	Medical Policy Committee review
03/20/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/10/2019	Coding update
03/05/2020	Medical Policy Committee review
03/11/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/10/2020	Coding update
03/04/2021	Medical Policy Committee review
03/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

Code Type	Code
CPT	0101T, 0102T, 0512T, 0513T, 20999, 28890
HCPCS	No codes
ICD-10 Diagnosis	M48.40XA-M48.48XA, M62.40-M62.49, M62.831, M62.838, M72.2, M76.50-M76.52, M76.60-M76.62, M77.10-M77.12, M77.10-M77.12, M80.00XK, M80.011K-M80.019K, M80.021K-M80.029K, M80.031K-M80.039K, M80.041K-M80.049K, M80.051K-M80.059K, M80.061K-M80.069K, M80.071K-M80.079K, M80.08XK, M80.80XK, M80.811K-M80.819K, M80.821K-M80.829K, M80.831K-M80.839K, M80.841K-M80.849K, M80.851K-M80.859K, M80.861K-M80.869K, M80.871K-M80.879K, M80.88XK, M84.30XA, M84.30XK, M84.311A, M84.311K, M84.312A, M84.312K, M84.319A, M84.319K, M84.321A, M84.321K, M84.322A, M84.322K, M84.329A, M84.329K, M84.331A, M84.331K, M84.332A, M84.332K, M84.333A, M84.333K, M84.334A, M84.334K, M84.339A, M84.339K, M84.341A, M84.341K, M84.342A, M84.342K, M84.343A, M84.343K, M84.344A, M84.344K, M84.345A, M84.45K, M84.346A, M84.346K, M84.350A, M84.350K, M84.351A, M84.351K, M84.352A, M84.352K, M84.353A, M84.353K, M84.359A,

	M84.359K, M84.361A, M84.361K, M84.362A, M84.362K, M84.363A, M84.363K, M84.364A, M84.364K, M84.369A, M84.369K, M84.371A, M84.371K, M84.372A, M84.372K, M84.373A, M84.373K, M84.374A, M84.374K, M84.375A, M84.375K, M84.376A, M84.376K, M84.377A, M84.377K, M84.378A, M84.378K, M84.379A, M84.379K, M84.38XA,M84.38XK, M84.40XK-M84.48XK, M84.50XK-M84.58XK, M84.60XK-M84.68XK, M84.80, M84.811-M84.879, M84.8, M84.9, M85.10, M85.111-M85.179, M85.18-M85.19, M85.80, M85.811-M85.879, M85.88-M85.89, M87.051-M87.859, M89.20, M89.211-M89.279, M89.28-M89.30, M89.311-M89.379, M89.38-M89.39, M89.50, M89.511-M89.579, M89.58-M89.59, M89.8X0-M89.8X9, M90.551-M90.559, M94.1, M94.351-M94.359, M94.8X0-M94.8X9, S02.0XXK, S02.210XK, S02.110K-S02.119K, S02.19XK, S02.2XXK-S02.3XXK, S02.400K-S02.402K, S02.411K-S02.413K, S02.42XK, S02.5XXK, S02.600K, S02.609K, S02.61XK-S02.69XK, S02.8XXK, S02.91XK-S02.92XK, S12.00K, S12.001K, S12.01XK-S12.02XK, S12.030K-S12.031K, S12.040K-S12.041K, S12.090K-S12.091K, S12.100K-S12.101K, S12.110K-S12.112K, S12.110K-S12.191K, S12.200K-S12.2291K, S12.34XK, S12.350K-S12.351K, S12.390K-S12.391K, S12.400K-S12.401K, S12.430K-S12.431K, S12.44XK, S12.450K-S12.451K, S12.490K-S12.491K, S12.500K-S12.501K, S12.530K-S12.531K, S12.54XK, S12.550K-S12.551K, S12.590K-S12.591K, S12.600K-S12.691K, S22.000K-S22.9XXK, S32.000K-S32.9XXK, S42.001K-S42.92XK, S49.001K-S49.199K, S52.001K-S52.92XN, S59.001K-S59.299K, S62.001K-S62.92XK, S72.001K-S72.92XN, S79.001K-S79.199K, S82.001K-S82.92XN, S89.032K-S89.399K, S92.001K-S92.919K Added codes eff 1/1/2020: S02.121A-S02.129S, S02.831A-S02.839S, S02.841A-S02.841S, S02.842A-S02.842S, S02.849A-S02.849S, S02.85XA-S02.85XS Added codes eff 10/1/2020: M80.0AXA-M80.0AXS, M80.8AXA-M80.8AXS

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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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