Continuous Passive Motion (CPM)

Policy # 00020
Original Effective Date: 05/26/1993
Current Effective Date: 08/01/2021

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: Dynamic Range of Motion Devices is addressed in medical policy 00193.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of continuous passive motion (CPM) in the home setting to be **eligible for coverage**.**

Patient Selection Criteria

The use of continuous passive motion in the home setting may be considered **eligible for coverage**** as an adjunct to physical therapy when initiated within the first 48 hours following surgery in the following situations:

- Under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a total knee arthroplasty (TKA) or total knee arthroplasty revision. This may include patients with complex regional pain syndrome (reflex sympathetic dystrophy); extensive arthrofibrosis or tendon fibrosis; or physical, mental, or behavioral inability to participate in active physical therapy; OR
- During the non-weight-bearing rehabilitation period following articular cartilage repair procedures of the knee (eg, microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures).

Note:
Following total knee arthroplasty, continuous passive motion in the home setting will be allowed for up to 21 days after surgery while patients are immobile or unable to bear weight.

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Following articular cartilage repair procedures of the knee, continuous passive motion in the home setting will be allowed for up to 6 weeks during non-weight-bearing rehabilitation.

When 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 continuous passive motion (CPM) when patient selection criteria are not met to be **investigational.***

The use of continuous passive motion in the home setting for all other conditions is considered **investigational***, including but not limited to use for other joints, temporomandibular joint (TMJ), treatment of degenerative joint disease, or chronic contractures.

Continuous passive motion (CPM) is considered to be **investigational*** for any of the following:

- For use longer than 21 days from the date of first application following total knee arthroplasty; OR
- For use longer than 6 weeks from the date of first application following articular cartilage repair procedure.

Policy Guidelines

Synthetic sheepskin pad (E0188) and lamb's wool sheepskin pad (E0189) are included in the rental fee of the CPM device and are not separately payable.

Background/Overview

Physical therapy of joints following surgery focuses both on passive motion to restore mobility and on active exercises to restore strength. While passive motion can be administered by a therapist, continuous passive motion devices have also been used. Continuous passive motion is thought to improve recovery by stimulating the healing of articular tissues and the circulation of synovial fluid; reducing local edema; and preventing adhesions, joint stiffness or contractures, or cartilage degeneration. Continuous passive motion has been investigated primarily in the knee, particularly after total knee arthroplasty or ligamentous or cartilage repair. Acceptance of its use in the knee joint

has created interest in continuous passive motion use for other weight-bearing joints (ie, hip, ankle, metatarsals) as well as non-weight-bearing joints (ie, shoulder, elbow, metacarpals, interphalangeal joints). Use of continuous passive motion in stroke and burn patients is also being explored.

The device used for the knee moves the joint (eg, flexion and extension) without patient assistance, continuously for extended periods of time (ie, up to 24 h/d). An electrical power unit is used to set the variable range of motion and speed. The initial settings for range of motion are based on a patient's level of comfort and other factors assessed intraoperatively. The range of motion is increased by 3 to 5 per day, as tolerated. The speed and range of motion can be varied, depending on joint stability. The use of the device may be initiated in the immediate postoperative period and then continued at home for a variable period of time.

Over time, hospital lengths of stay have progressively shortened and in some cases, surgical repair is done as an outpatient or with a length of stay of 1 to 2 days. As a result, there has been a considerable shift in the rehabilitation regimen, moving range of motion an intensive in-hospital program to a less intensive outpatient program. Some providers may want patients to continue continuous passive motion in the home setting as a means of duplicating services offered with a longer (7-day) hospital stay.

The focus of the current review is to examine the literature on the use of continuous passive motion in the home setting as it is currently being prescribed postoperatively. Relevant comparisons are treatment outcomes of continuous passive motion when used alone or with physical therapy, compared with physical therapy alone.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Continuous passive motion devices are considered class 1 devices by the U.S. FDA and are exempt range of motion 510(k) requirements. This classification does not require submission of clinical data on efficacy but only notification of the FDA prior to marketing. FDA product code: BXB.

Rationale/Source

Description

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Continuous passive motion devices are used to keep a joint in motion without patient assistance. Continuous passive motion is being evaluated for treatment and postsurgical rehabilitation of the upper- and lower-limb joints and for a variety of musculoskeletal conditions.

Summary of Evidence
For individuals who have total knee arthroplasty who receive continuous passive motion in the home setting, the evidence includes randomized controlled trials (RCTs), case series, and systematic reviews. Relevant outcomes are symptoms and functional outcomes. Early trials generally used continuous passive motion in the inpatient setting and are less relevant to today's practice patterns of short hospital stays followed by outpatient rehabilitation. Current postoperative rehabilitation protocols differ considerably from when the largest body of evidence was collected, making it difficult to apply available evidence to the present situation. For use of continuous passive motion after total knee arthroplasty, recent studies have suggested that institutional and home use of continuous passive motion has no benefit compared with standard physical therapy (PT). There were no studies evaluating continuous passive motion in patients who could not perform standard PT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have articular cartilage repair of the knee who receive continuous passive motion in the home setting, the evidence includes nonrandomized studies, case series, and studies with nonclinical outcomes (eg, histology), and systematic reviews of these studies. Relevant outcomes are symptoms and functional outcomes. Systematic reviews of continuous passive motion for this indication have cited studies reporting better histologic outcomes in patients following continuous passive motion. A few studies have reported clinical outcomes but inadequacies of these studies do not permit conclusions on efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring PT who receive continuous passive motion in the home setting, the evidence includes RCTs for some conditions and case series for others. Relevant outcomes are symptoms and functional outcomes. Three small RCTs of continuous passive motion after rotator cuff surgery showed some evidence that continuous passive motion after this shoulder surgery improved short-term pain and range of motion; however, the trials were not high-quality, and the small differences in outcomes may not be clinically important. Two trials reported short-term

improvements in range of motion for patients undergoing continuous passive motion, and one reported a short-term reduction in pain. None reported long-term improvements, and there are no reported benefits in functional status. Therefore, the clinical significance of the short-term improvements reported is uncertain. In addition, there is uncertainty about the optimal PT regimen following shoulder surgery such that the optimal treatment comparator for continuous passive motion is unclear. Two small RCTs compared continuous passive motion with conventional PT for treatment of adhesive capsulitis. One of the trials focused on diabetic patients with adhesive capsulitis. Both reported comparable improvements in range of motion and functional ability between treatment groups. For other musculoskeletal conditions, RCTs do not exist; case series either did not show efficacy of continuous passive motion or had important methodologic flaws. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had a stroke requiring PT who receive continuous passive motion in the home setting, the evidence includes a small RCT. Relevant outcomes are symptoms and functional outcomes. This trial reported a trend toward improved shoulder joint stability but no statistical difference between continuous passive motion plus PT and PT alone. The trial was small and treatment lasted only 20 days. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

2010 Input

For patients unable to tolerate exercise regimens following total knee arthroplasty, continuous passive motion is an alternative modality. However, there is no evidence to support its use in this situation. Clinical input obtained in 2010 supports the use of continuous passive motion under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a total knee arthroplasty or total knee arthroplasty revision.

2016 Input

Despite a lack of published evidence, clinical input obtained in 2016 supports the use of continuous passive motion after articular cartilage repair of the knee.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input Range of Motion Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2016 Input
In response to requests, input was received range of motion 2 physician specialty societies and 1 academic medical center while this policy was under review in 2016. Input considered continuous passive motion (continuous passive motion) medically necessary as an adjunct to physical therapy during the non-weight-bearing rehabilitation period following articular cartilage repair procedures of the knee. One reviewer referred to the American Academy of Orthopaedic Surgery (2015) guidelines on the surgical management of osteoarthritis of the knee, which concluded that there was strong evidence that continuous passive motion after knee arthroplasty does not improve outcomes.

2010 Input
In response to requests, input was received range of motion 2 physician specialty societies and 5 academic medical centers while this policy was under review in 2010. Overall, input supported the use of continuous passive motion under conditions of low postoperative mobility or inability to comply with rehabilitation exercises after total knee arthroplasty or total knee arthroplasty revision or during the non-weight-bearing rehabilitation period following articular cartilage repair procedures of the knee. Support was limited for use of continuous passive motion in joints other than the knee or in situations or conditions other than those described in this evidence review.

2008 Input
In response to requests, input was received range of motion 1 physician specialty society and 2 academic medical centers while this policy was under review in 2008. The 3 reviewers interpreted the existing literature as supporting the use of continuous passive motion for the knee for at least 7

days post operatively, whether in the hospital or home, and suggested that longer use of continuous passive motion would be warranted for special conditions.

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
In 2015, the American Academy of Orthopaedic Surgeons (AAOS) published evidence-based guidelines on the surgical management of osteoarthritis of the knee. The AAOS identified 2 high-quality studies and 5 moderate-quality studies that evaluated the use of continuous passive motion. In one high-quality study, continuous passive motion was used for about 2 weeks after discharge. The AAOS concluded that "the combined results provide strong evidence that the surgical outcomes for those who used continuous passive motion are not better than for those who did not use continuous passive motion."

French Physical Medicine and Rehabilitation Society
In 2007, clinical practice guidelines range of motion the French Physical Medicine and Rehabilitation Society concluded that evidence is not sufficient to recommend substituting continuous passive motion for other rehabilitation techniques aimed at early mobilization after total knee arthroplasty. The evidence review did not find a positive effect of continuous passive motion over intermittent early mobilization, at short- or long-term follow-up.

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

Medicare National Coverage
In 2005, the Centers for Medicare & Medicaid Services issued a national coverage determination on durable medical equipment reference, which stated:
"Continuous passive motion devices are devices covered for patients who have received a total knee replacement. To qualify for coverage, use of the device must commence within 2 days following

surgery. In addition, coverage is limited to that portion of the 3-week period following surgery during which the device is used in the patient's home. There is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Actual Enrollment	Completion Date
Unpublished			
NCT01420887	Preservation of Joint Function Using Postoperative Continuous Passive Motion (continuous passive motion): A Pilot Study	6 0	May 2020

NCT: national clinical trial.

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Policy History

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08/16/2001	Medical Policy Committee review
08/27/2001	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
02/20/2003	Medical Policy Committee review
04/14/2003	Managed Care Advisory Council approval
06/01/2004	Medical Director review
06/15/2004	Medical Policy Committee review
06/28/2004	Managed Care Advisory Council approval
03/01/2005	Medical Director review
03/15/2005	Medical Policy Committee review
04/04/2005	Managed Care Advisory Council approval
04/05/2006	Medical Director review

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05/17/2006	Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Patient Selection criteria revised to correct redundant criterion. Coverage eligibility unchanged.
05/02/2007	Medical Director review
05/23/2007	Medical Policy Committee approval. Coverage eligibility unchanged. Rationale revised.
06/13/2007	Medical Director review
06/20/2007	Medical Policy Committee approval. Rationale updated. Coverage eligibility unchanged.
10/01/2008	Medical Director review
10/22/2008	Medical Policy Committee approval. No change to coverage eligibility.
10/01/2009	Medical Policy Committee approval
10/14/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
10/14/2010	Medical Policy Committee review
10/20/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2012	Medical Policy Committee review
12/19/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/12/2013	Medical Policy Committee review
12/18/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/04/2014	Medical Policy Committee review
12/17/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/18/2015	Coding update.
12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. No change to coverage.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. No change to coverage.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. No change to coverage.
05/07/2020	Medical Policy Committee review
05/13/2020	Medical Policy Implementation Committee approval. No change to coverage.
05/06/2021	Medical Policy Committee review
05/12/2021	Medical Policy Implementation Committee approval. Patient selection criteria revised to track BCBSA. New investigational statement added. The use of continuous passive motion in the home setting for all other conditions is considered investigational*, including but not limited to use for other joints, temporomandibular joint (TMJ), treatment of degenerative joint disease, or chronic contractures.

Next Scheduled Review Date: 05/2022

Coding

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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	No codes
HCPCS	E0935, E0936
ICD-10 Diagnosis	M12.561-M12.569, M15.0-M15.9, M16.0-M16.12, M17.0-M17.12, M17.9, M18.0-M18.12, M19.011-M19.079, M19.111-M19.119, M19.131-M19.139, M19.211-M19.219, M19.231-M19.239, M19.90-M19.93, M23.50, M24.10, M24.111-M24.176, M24.30, M24.311-M24.376, M25.161-M25.169, M25.731-M25.739, M25.741-M25.749, M25.751-M25.759, M25.761-M26.769, M25.771-M25.776, M25.861-M25.869, M70.10-M70.12, M70.040-M70.042, M70.50-M70.52, M70.60-M70.62, M70.70-M70.72, M75.00-M75.02, M76.00-M76.9, M77.20-M77.22, M77.40-M77.42, M77.8, M93.20, M93.211-M93.29, S72.401A-S72.401C, S72.402A-S72.402C, S72.409A-S72.409C, S72.411A-S72.411C, S72.412A-S72.412C, S72.413A-S72.413C, S72.414A-S72.414C, S72.415A-S72.415C, S72.416A-S72.416C, S72.421A-S72.421C, S72.422A-S72.422C, S72.423A-S72.423C, S72.424A-S72.424C, S72.425A-S72.425C, S72.426A-S72.426C, S72.431A-S72.431C, S72.432A-S72.432C, S72.433A-S72.433C, S72.434A-S72.434C, S72.435A-S72.435C, S72.436A-S72.436C, S72.441A-S72.441C,

	S72.442A-S72.442C, S72.443A-S72.443C, S72.444A-S72.444C, S72.445A-S72.445C, S72.446A-S72.446C, S72.451A-S72.451C, S72.452A-S72.452C, S72.453A-S72.453C, S72.454A-S72.454C, S72.455A-S72.455C, S72.456A-S72.456C, S72.461A-S72.461C, S72.462A-S72.462C, S72.463A-S72.463C, S72.464A-S72.464C, S72.465A-S72.465C, S72.466A-S72.466C, S72.471A, S72.472A, S72.479A, S72.491A-S72.491C, S72.492A-S72.493C, S72.499A-S72.499C, S79.101A, S79.102A, S79.109A, S79.111A, S79.112A, S79.119A, S79.121A, S79.122A, S79.129A, S79.131A, S79.132A, S79.139A, S79.141A, S79.142A, S79.149A, S79.191A, S79.192A, S79.199A, S82.001A-S82.001C, S82.002A-S82.002C, S82.009A-S82.009C, S82.011A-S82.011C, S82.012A-S82.012C, S82.013A-S82.013C, S82.014A-S82.014C, S82.015A-S82.015C, S82.016A-S82.016C, S82.021A-S82.021C, S82.022A-S82.022C, S82.023A-S82.023C, S82.024A-S82.024C, S82.025A-S82.025C, S82.026A-S82.026C, S82.031A-S82.031C, S82.032A-S82.032C, S82.033A-S82.033C, S82.034A-S82.034C, S82.035A-S82.035C, S82.036A-S82.036C, S82.041A-S82.041C, S82.042A-S82.042C, S82.043A-S82.043C, S82.044A-S82.044C, S82.045A-S82.045C, S82.046A-S82.046C, S82.091A-S82.091C, S82.092A-S82.092C, S82.099A-S82.099C, S82.101A-S82.101C, S82.102A-S82.102C, S82.109A-S82.109C, S82.111A-S82.111C, S82.112A-S82.112C, S82.113A-S82.113C, S82.114A-S82.114C, S82.115A-S82.115C, S82.116A-S82.116C, S82.121A-S82.121C, S82.122A-S82.122C, S82.123A-S82.123C, S82.124A-S82.124C, S82.125A-S82.125C, S82.126A-S82.126C, S82.131A-S82.131C, S82.132A-S82.132C, S82.133A-S82.133C, S82.134A-S82.134C, S82.135A-S82.135C, S82.136A-S82.136C, S82.141A-S82.141C, S82.142A-S82.142C, S82.143A-S82.143C, S82.144A-S82.144C, S82.145A-S82.145C, S82.146A-S82.146C, S82.151A-S82.151C, S82.152A-S82.152C, S82.153A-S82.153C, S82.154A-S82.154C, S82.155A-S82.155C, S82.156A-S82.156C, S82.191A-S82.191A, S82.192A-S82.192C, S82199A-S82.199C, S86.001A, S86.002S, S86.009A, S86.091A,

	S86.092A, S86.099A, S86.101A, S86.102A, S86.109A, S86.191A, S86.192A, S86.199A, S86.201A, S86.202A, S86.209A, S86.291A, S86.292A, S86.299A, S86.301A, S86.302A, S86.309A, S86.391A, S86.392A, S86.399A, S86.801A, S86.802A, S86.809A, S86.891A, S86.892A, S86.899A, S86.901A, S86.902A, S86.909A, S86.991A, S86.992A, S86.999A, S89.001A, S89.002A, S89.009A, S89.011A, S89.012A, S89.019A, S89.021A, S89.022A, S89.029A, S89.031A, S89.032A, S89.039A, S89.041A, S89.042A, S89.049A, S89.091A, S89.092A, S89.099A, S89.80XA, S89.81XA, S89.82XA, S89.90XA, S89.91XA, S89.92XA, S96.001A, S96.002A, S96.009A, S96.091A, S96.092A, S96.099A, S96.101A, S96.102A, S96.109A, S96.191A, S96.192A, S96.199A, S96.201A, S96.202A, S96.209A, S96.291A, S96.292A, S96.299A, S96.801A, S96.802A, S96.809A, S96.891A, S96.892A, S96.899A, S96.901A, S96.902A, S96.909A, S96.991A, S96.992A, S96.999A, S99.811A, S99.812A, S99.819A, S99.821A, S99.822A, S99.829A, S99.911A, S99.912A, S99.919A, S99.921A, S99.922A, S99.929A, Z47.1, Z96.651, Z96.652, Z96.653, Z96.659 Added codes eff 10/01/2020: M24.19, M24.29, M24.39, M24.49, M24.59, M24.69, M24.89, M25.39, M25.59, M25.69

*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:

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Policy # 00020
Original Effective Date: 05/26/1993
Current Effective Date: 08/01/2021

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.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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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.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.