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

Note: This policy only addresses CPM in the home setting (i.e., not the hospital setting).

### Related Policies
- Autologous Chondrocyte Implantation and Other Cell-based Treatments of Focal Articular Cartilage Lesions
- Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

### Policy
Use of continuous passive motion (CPM) in the home setting may be considered medically necessary as an adjunct to physical therapy during the non-weight-bearing rehabilitation period following intra-articular cartilage repair procedures of the knee (e.g., microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures).

Use of CPM in the home setting for all other conditions is considered not medically necessary.

### Policy Guidelines
Following intra-articular cartilage repair procedures of the knee, CPM in the home setting will be allowable for up to 6 weeks during non-weight-bearing rehabilitation.

### Coding
There are specific HCPCS codes for the CPM device as listed below:
- **E0935**: Continuous passive motion exercise device for use on knee only
- **E0936**: Continuous passive motion exercise device for use other than knee
Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

Background

Physical therapy of joints following surgery focuses both on passive motion to restore mobility and active exercises to restore strength. While passive motion can be administered by a therapist, continuous passive motion (CPM) devices have also been used. CPM is thought to improve recovery by stimulating the healing of articular tissues and circulation of synovial fluid; reducing local edema; and preventing adhesions, joint stiffness or contractures, or cartilage degeneration. CPM has been most thoroughly investigated in the knee, particularly after total knee arthroplasty (TKA) or ligamentous or cartilage repair, but its acceptance in the knee joint has created interest in extrapolating this experience to other weight-bearing joints (i.e., hip, ankle, metatarsals) and non-weight-bearing joints (i.e., shoulder, elbow, metacarpals, interphalangeal joints). Use of CPM in stroke and burn patients is also being explored.

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

Literature Review

Most studies identified focused on the use of CPM in the knee. Therefore, the following discussion focuses on different surgical procedures for the knee, followed by a review of literature regarding CPM for other joints.

The original medical policy was based on a 1997 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment that concluded that CPM met the TEC criteria as an adjunct to physical therapy in patients undergoing TKA.(1) Early studies of CPM machines focused on their use in the hospital setting, in which the impact on length of stay was frequently considered a key clinical outcome, and the TEC Assessment did not specifically examine the place of service of CPM or the length of time that the CPM machines were used. For example, a critical study identified in the TEC Assessment was a randomized study by McInnes et al. that examined the use of CPM initiated in the immediate postoperative period and continued throughout the 7-day hospital stay.(2) At
6 weeks postoperatively, the most salient difference in the 2 groups was an increased incidence of arthrofibrosis requiring manipulation in the non-CPM group. However, this study did not focus on the use of CPM in the home. In the other articles reviewed for the TEC Assessment, CPM was typically used for 7 days or less. The 1997 TEC Assessment concluded that at the time of review, other applications of CPM did not meet the TEC criteria.

Over the past 10 to 20 years, hospital lengths of stay have progressively shortened, and in some cases, surgical repair may be done either 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 from an expensive in-hospital program to a less intensive outpatient program. Therefore, some providers may wish to continue CPM in the home as a means of duplicating the services offered with a longer (7-day) hospital stay. The focus of the current policy is to examine the literature regarding home use of CPM as it is currently being prescribed postoperatively. The most important comparisons will be treatment outcomes of CPM when used alone or in addition to conventional physical therapy, compared with conventional physical therapy alone.

**Total Knee Arthroplasty**

**Early Postoperative Period**: Efficacy in the early postoperative period has been cited to support the continued use of these devices in the home setting following early discharge. CPM after TKA was the subject of a 2003 Cochrane review.(3) This review reported that CPM combined with physical therapy was found to statistically significantly increase active knee flexion and decrease length of stay. However, the analysis suggests that the benefits of CPM in a hospital setting may be small and only short term.(4) This Cochrane review was updated in 2010 and 2014.(5,6) The updated review included 24 randomized trials with 1445 participants and examined short-term (<6 weeks), medium-term (6 weeks-6 months), and long-term (>6 months) effects of CPM. Most of the included studies examined short-term effects. CPM was applied for 1.5 to 24 hours a day, over 1 to 17 days. The review found that there was moderate-quality evidence that CPM increases passive and active knee flexion range of motion (ROM; mean difference, 2°), but the effects were too small to be clinically worthwhile. Low-quality evidence indicated that CPM does not have clinically important short-term effects on pain (-0.4 points on a 10-point scale), and moderate-quality evidence indicated that CPM does not have clinically important medium-term effects on function or quality of life. Very low-quality evidence indicated that CPM may reduce the need for manipulation under anesthesia (25 fewer manipulations per 1000; risk ratio [RR], 0.3), and low-quality evidence suggested that CPM reduced the risk of adverse events (13 fewer adverse events per 1000, RR=0.9). The review concluded that CPM does not have clinically important effects on active knee flexion ROM, pain, function, or quality of life to justify its routine use. It may reduce the risk of manipulation under anesthesia and risk of adverse events, although the quality of evidence supporting these findings was very low and low, respectively.

Earlier studies in the hospital setting focused on whether the use of CPM is safe (i.e., whether it has an impact on healing of tissues), what ROM can be tolerated at what point in the postoperative recovery, and whether the use of CPM permits earlier hospital discharge by accelerating the recovery of ROM. For example, Yashar et al. reported on a trial that randomly assigned 178 patients undergoing TKA to CPM immediately in the postoperative period or to CPM 1 day after surgery. A small but statistically significant improvement in flexion was found at the time of discharge in those started on early CPM, but this difference did not persist at 4 weeks.(7) MacDonald et al. reported on a randomized trial focusing on immediate postoperative versus no postoperative CPM in a
group of patients undergoing TKA. (8) Patients received a maximum of 24 hours with CPM. There were no differences in the treatment groups regarding ROM, length of stay, or analgesic requirements. In a trial reported by Pope et al., 53 patients were randomly assigned either to 2 different schedules of CPM versus no CPM. The use of CPM was not associated with improved function or ROM. (9) Kumar et al. randomly assigned 73 patients who had undergone TKA to receive either CPM in the immediate postoperative period versus protocol of early passive flexion referred to as the “drop and dangle” technique. (10) Patients assigned to the drop and dangle technique were discharged from the hospital earlier and also had a statistically better extension range at 6 months compared with the CPM group.

More recent randomized controlled trials (RCTs) find that 2 to 4 hours of daily CPM in the hospital after total knee replacement does not improve postoperative outcomes at discharge or follow-up. (11-14) For example, Bruun-Olsen et al. randomly assigned 67 patients undergoing TKA to receive active physiotherapy exercises with or without CPM to assess whether there was short-term benefit on pain or function. (11) In both groups, exercises were performed daily for 30 minutes, starting 1 day after surgery until discharge at 1 week. For the experimental group, CPM was provided for 4 hours on the day of surgery, followed by 6 hours daily in addition to therapist-guided exercises. Blinded assessment at 1 week and 3 months after surgery showed similar results for pain and function in the 2 groups; at 1 week, both groups had visual analog scale (VAS) pain ratings of 40 and flexion scores that were within 2° of each other. Functional testing at 3 months showed no benefit of adjunctive CPM. The lack of improvement with CPM in recent studies may be due to the current practice of permitting patients to mobilize or commence flexion immediately following surgery. (13) A 2014 study of 150 patients undergoing TKA found no benefit of CPM when used over a 2-day postoperative hospital stay. (14)

Inpatient Rehabilitation Hospital: In a 2014 randomized trial by Herbold et al., 141 TKA patients were assigned to either 3 hours of CPM daily or to 2 hours total CPM during their inpatient rehabilitation stay. (15) After an average length of stay of 8 days for both groups, there were no significant differences between the CPM and no CPM groups for active ROM, Timed Up and Go test, knee girth, Functional Independence Measure scores, ambulation device at discharge, or on the self-reported Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). A retrospective comparative study by the same group evaluated use of CPM in 61 matched pairs of patients admitted to a rehabilitation hospital. (16) Outcomes following use of CPM were compared with those from a cohort of 61 inpatients who also had poor initial ROM, defined as less than 75° of active knee flexion at the time of admission, and matched for postoperative day at admission, age, length of stay, and Health Insurance Prospective Payment System (HIPPS) code. Use of CPM (2 hours/day) was determined primarily by the referring physician and was used in 29% of the pool of 633 patients who had poor initial ROM. The average length of stay was 7.85 days. There were no significant differences in outcomes at discharge, including knee flexion or extension, discharge to the community, need for home care services, need for an assistive device, or functional scores on the HIPPS.

Chen et al. randomly assigned 51 patients in an inpatient rehabilitation service who had undergone TKA to receive conventional active physical therapy or physical therapy plus CPM. (17) Referral to the rehabilitation center was made 5 to 6 days after surgery, and most had received CPM as part of the initial hospitalization. Knee flexion was the principal outcome. No significant difference was noted in range of passive motion between the 2 groups, as measured on admission, on the third and seventh days, and at the time of discharge (8 days after admission). Thus, the use of CPM in the rehabilitation
hospital offered no added benefit. While a rehabilitation service does not duplicate the home environment, it does reflect the use of CPM beyond the initial acute hospitalization.

**Home Setting:** A study by Worland et al. was the only identified controlled study that compared the use of CPM and active physical therapy in the home setting. In this study, 80 patients undergoing TKA were randomly assigned to receive, at discharge, home CPM (3 hours/day for 10 days) versus active physical therapy, as offered by professional physical therapists.(18) Most studies have examined CPM as an adjunct to active physical therapy; therefore, this study is unique in that CPM is proposed as an alternative. At 2 weeks, knee flexion was similar in the 2 groups, but a flexion contracture was noted in 1 patient in the CPM-only group. At 6 months, no differences were found in knee scores or knee flexion.

In another study, 60 patients with limited flexion ROM (<80°) at the time of hospital discharge were assigned to standard physical therapy alone or in combination with CPM in the home (4 hours per day) until assessment on postoperative day 17.(19) Blinded assessment showed a trend for an increase in ROM for the CPM group (e.g., 89° vs 84°, respectively, p=0.07), with no differences in function between the groups, as measured by the Knee Society Score (function subscore 43 vs 40, respectively) or the WOMAC difficulty score (49 vs 45, respectively). No differences were observed between groups in ROM or function at the 6-week or 3-month assessment. No differences were observed for the secondary outcome measures (perceived effect, medication use, satisfaction with treatment, adherence) at any of the assessment times. Because benefit for long-term ROM or functional recovery was not detected, the authors questioned whether routine use of CPM following hospital discharge should be continued.

**Section Summary**
Numerous RCTs have been performed comparing CPM as an adjunct to physiotherapy for patients undergoing TKA. Early trials generally used CPM in the inpatient setting and are less relevant to today’s practice patterns of short hospital stays followed by outpatient rehabilitation. Some of these trials report an improvement in ROM for patients receiving CPM, but these improvements are short term, of small magnitude, and of uncertain clinical significance. No RCTs have reported clinically meaningful improvements in important clinical outcomes such as functional status and/or quality of life. As a result, the evidence is not sufficient to determine that the use of CPM improves outcomes for most patients undergoing TKA.

**Anterior Cruciate Ligament Repair**

The literature review did not identify any additional RCTs of CPM in the home setting after repair of the anterior cruciate ligament (ACL). Therefore, the studies of CPM after ACL repair in the immediate postoperative period may possibly be relevant to the home setting for patients who are discharged with an abbreviated hospital stay. The 1997 TEC Assessment concluded that CPM in the immediate postoperative period as an adjunct to conventional physical therapy offered no demonstrable advantage over conventional physical therapy alone.(1) In a 2008 systematic review of ACL reconstruction rehabilitation, Wright et al. discussed 6 RCTs on CPM that had been published before 1996; no RCTs published after the 1997 TEC Assessment were identified.(20) The review found no substantial advantage for CPM use and concluded that CPM for ACL rehabilitation could not be justified. Wright et al. also noted that most current ACL rehabilitation protocols initiate early motion within the first postoperative week.
Cartilage Repair of the Knee

Although no RCTs were identified that compared health outcomes with or without the use of CPM, CPM is routinely used as a part of the rehabilitation protocol for as long as 6 weeks when weight bearing is restricted following autologous chondrocyte implantation (ACI).(21-23) Basic research is cited that supports greater healing of articular cartilage of full-thickness defects that penetrate the subchondral bone than either immobilization or intermittent mobilization.(24,25)

In 2010, Fazalare et al. published a systematic review of CPM following knee cartilage defect surgery.(26) The review found use of CPM following ACI, microfracture, osteochondral autografts and osteochondral allografts in numerous studies in the previous 5 years. Four level III (cohort) studies with 262 patients were identified that specifically compared CPM with no CPM; no RCTs were identified. Procedures in these 4 studies included microfracture, periosteal transplant of the patella, and high tibial osteotomy with either diagnostic arthroscopy or abrasion arthroplasty. CPM regimens ranged from 6 days to 8 weeks. Heterogeneity in the studies and outdated surgical techniques limit conclusions from these trials. Karnes et al. conducted a 2013 review of CPM protocols following ACI, microfracture, marrow stimulation, mosaicplasty osteochondral autograft or osteochondral allograft.(27) They identified 107 studies that described the use of CPM following cartilage repair surgery. Although reporting of CPM parameters was poor, the most commonly prescribed protocol was for 6 to 8 hours daily over 6 weeks.

Hip

The literature search did not identify any controlled studies focusing on CPM of the hip after surgical intervention. One pilot study looked at the use of CPM of the hip in patients with osteoarthritis in the absence of surgical intervention.(28) This uncontrolled study examined the use of CPM for 1 to 7 hours daily for a 12-week trial. While improvements were noted in the patient’s assessment of pain, a controlled trial is needed to validate this treatment effect, particularly in comparison with a program of regular walking.

Rotator Cuff

Passive shoulder motion has been studied after shoulder surgery, particularly after repair of the rotator cuff. Du Plessis et al. published a systematic review of CPM following rotator cuff repair in 2011, with a literature review performed in 2009.(29) Three RCTs with a total of 113 patients were included in the review. A meta-analysis could not be conducted due to heterogeneity in populations studied, outcome measurements and tools, interventions and comparisons. Two of the RCTs included in this review were the studies by Lastayo et al. and Raab et al. discussed next.(30,31) The third study included in the systematic review was a German language report that found a significant reduction of 12 days in the time to reach 90° abduction compared with a physical therapy control group, with no significant difference in pain between the 2 groups.

The 2 RCTs included in the systematic review were small. Lastayo et al. reported the results of a trial that randomly assigned 31 patients undergoing rotator cuff repair to 1 of 2 types of postoperative management: a 4-week home program of CPM (average of 3 hours/day) or manual passive elevation and rotation exercises.(30) No significant difference in outcomes was observed between the 2 approaches. Raab et al. conducted a trial that randomly assigned 26 patients to undergo postoperative physical therapy alone or CPM in addition to physical therapy.(31) Patients were evaluated with
pre- and 3-month postoperative shoulder scores that incorporated pain, function, muscle strength, and ROM. A significant improvement was found in the subscore of ROM, although there was no significant improvement in overall shoulder score in the CPM group compared with the control group. Both of these RCTs were likely underpowered to show differences on important clinical outcomes.

In 2010, Garofalo et al. reported another randomized study on the effects of CPM after rotator cuff repair.(32) All of the 100 patients underwent passive self-assisted ROM exercise, with additional use of CPM in roughly half of the patients for 2 hours per day (4 sessions of 30 minutes each) over 4 weeks. The physical therapist-supervised exercises included pendulum movements and progressive passive abduction, forward flexions, and external rotation. Otherwise, the shoulder was immobilized in a sling brace for 4 weeks after surgery. From the 5th to the 28th week, all patients underwent the same physical therapy protocol. ROM and VAS for pain were measured at 2.5, 6, and 12 months by an independent examiner. In the CPM group, VAS was slightly better at 2.5-month follow-up (7.5 vs 9.1), but not at the 6-month (0.5 vs 0.6) or 12-month (0.2 vs 0.2 – all respectively) evaluation. Use of pain medication was not examined. ROM was significantly better in the group of patients who used CPM at 2.5-month follow-up (e.g., forward flexion of 133.0 vs 120.7) and 6 months (158.1 vs 151.7), but not at 12 months (165.2 vs 158.0 – all respectively).

Section Summary
Three small RCTs of CPM post rotator cuff surgery have been identified in the English language literature. Two of these trials report short-term improvements in ROM for patients undergoing CPM, and 1 reports a short-term reduction in pain. None of the trials report long-term improvements, nor are there any reported benefits in functional status or quality of life. Therefore, the clinical significance of the short-term improvements reported is uncertain. In addition, there is uncertainty about the optimal physical therapy regimen post shoulder surgery such that the optimal comparison for CPM is not clear. Larger RCTs with longer follow-up are required to determine whether CPM following rotator cuff surgery results in clinically meaningful improvements in health outcomes.

Adhesive Capsulitis of the Shoulder
Dundar et al. compared CPM with physical therapy in a randomized trial of 57 patients with adhesive capsulitis (frozen shoulder).(33) CPM or physical therapy was provided for 1 hour per day (5 days/week) for 4 weeks. Pain and function were similar in the 2 groups at baseline, with VAS scores for pain ranging from 5.44 (at rest) to 6.34 (with movement). Assessments at baseline, 4, and 12 weeks showed improvements in pain and function in both groups. CPM resulted in better pain reduction than physical therapy (at rest; 47% vs 25% with movement, 35% vs 21% and at night, 36% vs 19% all respectively). There were no differences between groups in ROM or functional ability. Although this unblinded study provides some support for the inclusion of CPM in a physical therapy program, additional studies are needed to evaluate CPM when provided at home.

Stroke
CPM is also being studied as a means to aid recovery of motor skills following stroke. One study randomly assigned 35 patients to daily sessions of CPM (25 minutes) or daily group therapy sessions consisting of self-range motion for poststroke rehabilitation.(34) All patients also received standard poststroke therapy for 3.5 hours/day. Following 20 days of therapy, there was a trend for greater shoulder joint stability in the passive motion group (n=17, p=0.06) compared with the control group (n=15). No statistically significant differences were found for measures of motor impairment. This study is limited by the...
small sample size and the short follow-up period; additional studies are needed to determine whether treatment with passive motion over a longer duration could aid in the recovery of motor skills following stroke.

**Elbow**

Postoperative management of open elbow contracture release with CPM was assessed in a matched cohort study by Lindenhovius et al. (35) Sixteen patients who had used CPM after open contracture release and 16 patients who had not used CPM after surgery were matched for age, gender, diagnosis, ROM, and radiographic appearance. Chart review was used when possible; patients who had insufficient follow-up in the medical record were invited back for follow-up and radiograph. Twenty-three patients (72%) were evaluated by an investigator who was not involved in their care. Improvements in ROM were not different between the 2 groups for either early (4-10 months) or final (10-56 months) evaluations.

**Hand**

The 1997 TEC Assessment reviewed a multicenter study of CPM in patients who had undergone flexor tendon repair. (36) The TEC Assessment concluded that data were inadequate to permit scientific conclusions regarding these applications. Ring et al. examined the role of CPM in 15 hands (60 joints) undergoing silicone interposition arthroplasty of the metacarpophalangeal joint secondary to rheumatoid arthritis. (37) Patients were randomly assigned to receive a 6-week protocol CPM plus the standard dynamic splint protocol versus the dynamic splint protocol alone. The authors did not identify any clear advantages of adding CPM to the standard protocol. A retrospective chart review compared 15 patients who had received CPM after tenolysis with 21 who did not. (38) The patients who received CPM improved total active motion 40° (from 137° to 177°), while patients who did not receive CPM improved motion 32° (from 152° to 184°). This was not significantly different. Although the CPM users had more therapy visits, it was not known why some patients had been prescribed CPM and others had not. Interpretation of this uncontrolled study is limited.

**Foot**

One study compared passive motion versus immobilization following surgical treatment of idiopathic club foot in 38 infants (50 feet). (39) The infants were randomly assigned to CPM (4 hours/day) or casting during days 10 to 42 following surgery. Blinded analysis showed improvements in the Dimeglio clubfoot score (9.7 to 3.1) that were significantly greater than in the control group (10.3 to 4.2, respectively) through 12 months (97% follow-up). Between 12 and 18 months, this trend reversed and by 48 months after surgery, there was no significant difference between the 2 groups. Compliance with this treatment may be low. (40)

**Summary**

Most research on continuous passive motion (CPM) has been as a postoperative treatment for total knee arthroplasty (TKA). Studies conducted in a controlled hospital setting suggest that CPM can improve rehabilitation when postoperative mobility is restricted. However, current postoperative rehabilitation protocols are considerably different than when the largest body of evidence was collected, making it difficult to apply the available evidence to the present situation. Recent literature suggests that institutional and home use of CPM has minimal benefit when combined with standard physical therapy after TKA. In the situation following intra-articular cartilage repair
procedures of the knee, CPM may be considered medically necessary for patients in the non-weight-bearing period.

For joints other than the knee, there is limited published evidence. There is some evidence that use of CPM following rotator cuff repair of the shoulder improves short-term pain and ROM; however, this is not high-quality evidence, and the small differences in outcomes may not be clinically important. Use of CPM in the home under all other conditions has not been shown to improve health outcomes and is thus considered not medically necessary.

**Practice Guidelines and Position Statements**

Clinical practice guidelines from the French Physical Medicine and Rehabilitation Society conclude that evidence is not sufficient to recommend substituting CPM for other rehabilitation techniques aimed at early mobilization after TKA.(41) The evidence review found no positive effect of CPM over intermittent early mobilization, at short- or long-term follow-up.

**U.S. Preventative Services Task Force Recommendations**

The use of continuous passive motion devices is not a preventive service.

**Medicare National Coverage**

Medicare National Coverage Determinations-Durable Medical Equipment Reference List (280.1) Manual 100-3:

“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 three 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."(42)

**References**

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Continuous Passive Motion as an Adjunct to Physical Therapy for Joint Rehabilitation. TEC Assessments 1997; Volume 12, Tab 20.


Documentation Required for Clinical Review

- History and physical and/or consultation report including:
  - Operative report(s)
  - Treatment plan including length of time for CPM use
  - Physical therapy report

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/NMN

The following services may be considered medically necessary when policy criteria are met. Services are considered not medically necessary when policy criteria are not met.

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<tr>
<th>Type</th>
<th>Code</th>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<th>Effective Date</th>
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<th>Reason</th>
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<tr>
<td>6/8/1994</td>
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<td>Medical Policy Committee</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.
Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.