MEDICAL POLICY

POLICY TITLE	**APOS THERAPY SYSTEM**
POLICY NUMBER	**MP 8.014**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	**6/1/2026**

POLICY

AposTherapy System, inclusive of the product, education/training on use, and calibration and adjustment of the system's pods, may be considered **medically necessary** when ALL of the following criteria are met:

- A diagnosis of moderate or advanced knee joint disease, supported by clinically appropriate (radiographic or MRI) imaging and clinical diagnosis of osteoarthritis
- Documentation of persistent pain that is not controlled despite optimal, conservative pain management:
  - To include a description of the pain (onset, character, aggravating, duration, and relief factors), analgesics and the treatment modalities used; and
- Documentation of functional limitations that interfere with activities of daily living (ADLs):
  - To include the specific limitation of ADLs; and
  - To include an evaluation of safety issues (i.e. fall risk); and
- Documentation of a history of conservative medical therapy that has been tried and failed including but not limited to ONE OR MORE of the following;
  - Activity modification; or
  - Structured land-based programs including strengthening and/or cardio and/or balance training/neuromuscular exercise; or
  - Mind-body exercise including Tai Chi or Yoga; or
  - Physical therapy that includes flexibility and muscle strengthening exercises; or
  - NSAIDS; or
  - Therapeutic intra-articular (knee) injections as appropriate; or
  - Weight loss efforts as appropriate.
- Individual does not have a planned surgery to treat the osteoarthritis of the knee at the time of initiation onto the Apos biomechanical shoe system
- Individual has the ability to ambulate and is not at risk for falls based upon an evaluation by a Physical Therapist

Use of AposTherapy System not meeting the criteria above will be considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

AposTherapy System is considered **contraindicated** with the presence of following:

- Active infection of the knee joint (i.e. active septic arthritis) or an active infectious process anywhere in the body (i.e. systemic bacteremia); or
- Individual requires a cane or walker both indoors and outdoors; or
- Individual has a history of two (2) or more unexplained falls within the last 12 months; or
- Individual has severe neurological, psychiatric, or comprehension issues preventing an understanding of how to use the device; or
- Individual has peripheral neuropathy; or
- Individual has severe osteoporosis
- Individual has severe balance or vertigo issues

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP medical policy manual. The FEP medical policy manual can be found at: fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

DESCRIPTION/BACKGROUND

The Apos® (formerly AposTherapy) System is a home-based exercise program utilizing a customized shoe-like device claimed to be a noninvasive biomechanical treatment for osteoarthritis (OA) of the knee (Apos® US Management Inc., New York, NY). It is purported adjustable external spacers (i.e., pods) placed in the sole of the custom shoe aim to correct gait patterns and re-training of the neuromuscular system. Apos® is initiated by a physical therapist using computerized gait analysis software to analyze the walking pattern. The physical therapist calibrates the pods which provide perturbation on the bottom of the Apos® shoes based on these analyses. It is claimed that the device works to retrain muscles around the knee by adjusting the offload pressure from painful joints, thereby changing the way one's foot interacts with the ground, with the ultimate goal of relieving pain. In theory, the pod causes an imbalance requiring one to realign the weight placed on joints and correct abnormal walking patterns, thereby correcting back, hip and knee alignment during ambulation. The Apos® System is comprised of convex adjustable biomechanical elements placed under the hind-foot and fore-foot regions of each foot. The elements are attached via a platform in the form of a shoe.

The device is proposed as an addition to or alternative to nonsurgical standard care. Other nonsurgical comparators for treatment of OA include but are not limited to physical therapy, splints, supports, braces, and intra-articular joint injections.

Regulatory Status

On November 16, 2018, US Food and Drug Administration (FDA) granted 510K approval for AposTherapy System to be used by trained professionals for adjusting the distribution of

weight/force(s) that is being applied to a lower limb. The AposTherapy System is intended for patients with knee osteoarthritis, to help temporarily reduce knee pain and improve lower extremity function during activities of daily living.

RATIONALE

SUMMARY OF EVIDENCE

In evaluation of the available literature, the evidence base for the Apos® System consists of a small, controlled comparative study, uncontrolled, prospective studies, case series, and multiple publications from a large observational registry.

Bar-Ziv et al (2010) evaluated clinical symptoms of knee osteoarthritis (pain, function and gait patterns) in a prospective, controlled, double-blind trial (n=57) with 8-week follow-up. Participants from two comparative groups reported changes in self-evaluation questionnaires (Western Ontario and McMaster Osteoarthritis Index [WOMAC], secondary outcome measures: SF-36, Knee society score) and in aggregated locomotor function (ALF) tests.

This study demonstrated promising data, as the active group (n= 31) when compared to the control group (n=26), resulted in significant differences between the groups for WOMAC pain score and function score at the 8-week endpoint (< 0.001). The active group reported significant pain relief after 8 weeks of treatment with a mean difference of 3.5 cm (64.8%) (95% CI; 2.7-4.4). In contrast, the control group reported no pain relief, having a mean increase of 0.4 cm (8%) with a (95% CI; -1.7-0.8). On the WOMAC function scale, the active group reported significant improvement with a mean decrease of 3.2 cm (62.7%) after 8 weeks (95% CI; 2.5-4.1) compared to the control group, which reported no function improvement, having a mean increase of 0.5 cm (9.8%) (95% CI; -1.4-0.5). The ALF final mean score values demonstrated significant differences between the groups over time. The active group showed significant improvement in function with a mean decrease of 11.6 sec. (31.4%) (95% CI; 8.7-14.5) on the ALF scale after 8 weeks, while the control group had limited improvements resulting in a mean decrease of 0.7 sec (1.8%) (95% CI; -0.9-2.1) after 8 weeks (p < 0.001).The authors report improved pain and physical function with the biomechanical footwear system compared with the control footwear. The individuals in the treatment group reported a significant improvement in their levels of pain and function as well as improvement in their quality of life but no significant changes were observed in the control group. However, this publication was limited by lack of randomization, small sample size and short follow-up time period. Additional studies are required to demonstrate replication of these results.

Bar Ziv (2013) performed a longer-term (2 years) follow-up study utilizing the AposHealth shoe compared to a control arm that did not receive the biomechanical elements. The control group (2-years) did not receive balanced follow-up at the same time-intervals as in the active group (six-months, 12-months, 2 years) leading to confounders and biases. The population size (n = 47; only 9 in control group available for longer-term follow-up at 2 years) was not adequate to draw firm conclusion on the long-term effects of using the system. As a result, analyses were not included in this evidence review.

In a recent publication, Reichenbach et al (2020) largely assessed pain scores on the WOMAC pain scale in a single-center, single-blinded, randomized, sham controlled clinical trial (n=220) that followed participants for 6 months. In this study, each arm received footwear devices, the treatment arm (n= 111) wore a device consisting of 2 shoes with 2 convex adjustable rubber pods screwed to the outsole at the heel and forefoot, while the control footwear group (n=109) had a similar visibly appearing design to that of the biomechanical footwear, but their shoe did not create a convex walking surface. Investigators do acknowledge that the trial could be considered potentially deceptive according to international guidelines.

The primary outcome was pain at 24-week follow-up in the index knee assessed with the WOMAC pain subscore (visual analog version). Several secondary outcomes were investigated, including subscores of the WOMAC for global score and WOMAC physical function and stiffness subscores at 12 and 24 weeks. Additional analyses of WOMAC pain subscores were performed at 4, 8, 12, and 16 weeks. The physical and mental component summary scores of SF-36 at 12 and 24 at week follow-up; gait velocity, step length, and single limb support measured by 2-dimensional computerized gait analysis when walking barefoot at five specified timepoints during the study; self-reported time spent wearing the footwear per day; self-reported health care use; and self-reported analgesic use were all evaluated as secondary outcomes.

Assessing the primary outcome, the authors report the biomechanical footwear group had a significantly larger decrease in standardized WOMAC pain subscore at 24 weeks than the control footwear group (mean score, 1.3 vs 2.6, respectively; between-group difference, −1.3 [95% CI, −1.8 to −0.9]; $P < .001$. The authors did not consider the minimal clinically important difference when conducting the study and did not define the metrics of a clinically significant reduction in the pain subscore. In evaluating the secondary outcomes, the biomechanical footwear group resulted in larger declines of WOMAC physical function and stiffness subscores and WOMAC global score at 24 weeks of follow-up. Observations for the same secondary outcomes did not produce similar declines at 12 weeks.

At 12 and 24 weeks, all functional secondary outcomes, such as gait velocity, step length, and single limb support failed to reach statically significance between groups, as well as, both SF-36 scales (PCS or MCS), analgesic use, or for health care use were not significantly different when comparing treatment groups. Wear time was significantly different between the intervention group compared to the control group (70.3 min/day, during past week to 209.2 min/day/past week vs 58.1 to 173.5 hours at 4 weeks and 24 weeks, respectively) group during the treatment duration.

The authors acknowledge study limitations, including, but not limited to the following: non-generalizability, narrow study population, short follow-up. Results from the RANGER registry aims to remediate the small sample sizes and shorter-term data limitations. Additionally, the reports demonstrate differences in wear time which could possibly influence outcomes potentially indicating that the greater benefit observed in the biomechanical footwear group was due to longer wear time, and most importantly failed to provide clinical relevance.

The participants were asked to discontinue their regular pain medication and advised that other interventions, such as physical therapy, should be avoided during the trial. Although, these self-

reported survey responses did not differ between groups, confounders may be present within the data and should be carefully considered when reviewing for efficacy.

Benn (2023) report on a retrospective audit of 571 individual from a national registry who met the clinical criteria for total knee replacement and received Apos® non-surgical intervention between October 2015 and March 2020. The authors state that eighty-nine percent of eligible TKR patients did not require secondary care consultation over a treatment period of up to 6 years. The registry data indicate participants had a significant reduction in pain and improved function was observed in individuals after 3 months of user, and the improved were sustained for up to 3 years. Related to progression to additional procedures, referral rates to secondary care consultation were reported as 11.4% with an average follow-up of 3.5 years.

Based on the larger-term data, out to seven-year follow-up, observation of utilizing the Apos® System and the ability for use to delay the user's progression to more invasive treatment options, the safety and efficacy of the system has been established.

DEFINITIONS/BACKGROUND

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes							
97799							

POLICY TITLE	APOS THERAPY SYSTEM
POLICY NUMBER	MP 8.014

ICD-10-CM Diagnosis Code	Description
M17.32	Post-traumatic osteoarthritis of left knee
M17.0	Bilateral primary osteoarthritis of knee
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.9	Osteoarthritis of knee, unspecified
M17.5	Other unilateral secondary osteoarthritis of knee

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POLICY HISTORY

MP 8.014	**05/28/2025 New Policy.**