Anthem

Clinical UM Guideline

Subject: Biomechanical Footwear Therapy
Guideline #: CG-DME-53
Status: New

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Description

This document addresses biomechanical footwear therapy for individuals with knee, back or hip pain. The treatment program consists of use of biomechanical footwear that is custom fitted on the first visit and recalibrated every several months. Treatment programs are personalized and generally last about 12 months.

Note: Please see the following related documents for additional information:

- CG-DME-19 Therapeutic Shoes, Inserts or Modifications for Individuals with Diabetes
- CG-DME-20 Orthopedic Footwear

Clinical Indications

Not Medically Necessary:

Biomechanical footwear therapy is considered **not medically necessary** for all indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services are Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

CPT

	For the following CPT codes **when specified as a gait test, fitting and calibration for a biomechanical foot orthotic**:
96000	Comprehensive computer-based motion analysis by video-taping and 3D kinematics
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies) and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
97799	Unlisted physical medicine/rehabilitation service or procedure

HCPCS

	For the following HCPCS codes **when specified as a biomechanical footwear therapy system**
L2999	Lower extremity orthoses, not otherwise specified
L3649	Orthopedic shoe, modification, addition or transfer; not otherwise specified
T1999	Miscellaneous therapeutic items and supplies, retail purchases, not otherwise classified; identify product in “remarks” [Medicaid HCPCS code]

ICD-10 Diagnosis

	All diagnoses including, but not limited to the following:
M16.0-M16.9	Osteoarthritis of hip
M17.0-M17.9	Osteoarthritis of knee
M19.071-M19.079	Primary osteoarthritis ankle and foot
M25.551-M25.579	Pain in hip, knee, ankle and joints of foot
M54.50-M54.9	Low back pain, pain in thoracic spine, other dorsalgia

Discussion/General Information

Apos® (AposHealth® New York, NY) footwear is a home-use device designed to treat chronic knee, hip, or back pain. The device looks similar to a shoe and has adjustable pods built into the soles. It is worn at home for 1 hour per day while conducting normal activities. An Apos device is custom fitted at the first visit using a computerized gait test, and its pods are recalibrated by a trained physical therapist every few months. According to the manufacturer, “Apos® is designed to address the underlying causes of pain by temporarily shifting pressure from affected areas. The neuromuscular re-education of the muscles results in a healthier walking pattern, even when not actively wearing the device.” Treatment programs are personalized and last for an average of 12 months.

In 2018, the Food and Drug Administration (FDA) cleared the Apos Therapy System for marketing as a type of limb orthosis. The intended use/indications for use, according to the FDA document, is:

> The AposTherapy System is intended 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.

The commercially available biomechanical footwear therapy system, Apos, has primarily been studied for treatment of knee pain. Knee osteoarthritis is a common health condition in the United States. Approximately 10% of men and 13% of women over 60 years old in the United States are affected by symptomatic knee osteoarthritis (Zhang, 2010).

Two randomized controlled trials (RCTs) evaluating Apos therapy for treatment of individuals with knee osteoarthritis were identified. No RCTs were identified that evaluated Apos therapy for foot or hip pain. In addition, no RCTs were identified that evaluated delay in surgery or reduction in the rate of surgery associated with Apos device use.

Debbi (2019) included 50 individuals who had total knee arthoplasty (TKA) surgery for knee osteoarthritis. Participants were randomized 6 weeks after TKA to an Apos therapy group or a sham footwear control group. Primary outcomes were not specified. A number of clinical outcomes including pain, quality of life and walk distance were assessed. The statistical analysis did not control for multiple comparisons, $p<0.05$ was considered to be statistically significant for each comparison. Findings were mixed. At 6 months, scores on 5 of 11 clinical variables were significantly better in the treatment than control group at the $p<0.05$ level, and at 12 months, scores on 6 of 11 clinical variables significantly favored the treatment group.

Reichenbach (2020) was a blinded study that randomized 220 individuals diagnosed with knee osteoarthritis to treatment with an Apos device or a control footwear (a sham comparison). The pre-specified primary outcome was pain at 24 weeks as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscore which ranged from 0 (no symptoms) to 10 (extreme symptoms). There were a number of secondary outcomes. For the primary outcome, the investigators found a statistically significantly greater improvement in pain at 24 weeks in the Apos therapy group (mean score, 1.3) compared with the sham group (mean score, 2.6). The difference between groups was 1.3 (95% confidence interval [CI], 0.9 to 1.8). Findings were similar for secondary WOMAC outcomes at 24 weeks. Although statistically significant, the clinical significance of the degree of difference between groups for the WOMAC outcome measures, 1.3 points for the primary outcome and 1.1 to 1.4 for other measures at 24 weeks, is unclear. The authors stated, “minimal clinically important differences [MCID] were not considered when planning the trial”. Scores on the secondary outcomes related to the SF-36, self-reported health care use, self-reported pain medication use, and gait velocity did not differ significantly between groups.

An earlier, 2010, study by Bar-Ziv and colleagues that evaluated the Apos system in individuals with knee osteoarthritis was a controlled trial but did not randomize participants. Participants were allocated to a treatment group or comparison group (sham device) based on the day of the week it was convenient for them to go to the study clinic. A total of 57 individuals were included in the study, 31 in the treatment group and 26 in the comparison group. Primary outcomes were improvement in pain and function as assessed by the WOMAC and the Aggregated Locomotor Function score (ALF). The ALF is a sum of timed scores on three locomotive measures. Outcomes were assessed at baseline and then 4 and 8 weeks after beginning treatment. The study was not randomized, and groups might have differed at baseline on characteristics that affected outcomes. At the final 8-week follow-up, there was statistically significant improvement in the treatment versus comparison group on all five primary outcome measures ($p<0.001$ for each). The study was limited by its short follow-up and lack of randomization, which could have led to confounding.

A non-randomized study with longer (2-year) follow-up was published by Bar-Ziv and colleagues in 2013. Inclusion criteria were symptomatic knee osteoarthritis for at least 6 months and varus knee alignment. A total of 40 individuals were included in the active treatment group and 16 individuals were in the comparison group. Groups did not differ significantly on age, sex, and Kellgren & Lawrence (K&L) scores at baseline. At the 2-year follow-up, 38 (95%) individuals remained in the active treatment group and 8 (50%) remained in the comparison group. There was statistically significant improvement in the treatment versus comparison group on all 4 primary outcome measures (WOMAC pain, WOMAC stiffness, WOMAC function and ALF) at 2 years ($p<0.001$ for each). The study is limited by the small number of participants, large amount of loss to follow-up in the comparison group and lack of randomization.

In 2022, Drew and colleagues published results of a retrospective uncontrolled study in a cohort of 237 individuals with knee osteoarthritis. Study participants were deemed eligible for TKA and elected to undergo Apos Therapy. The primary outcome of the study was avoidance of TKA surgery at the end of 2 years. Over 2 years, 203 of the 237 (86%) individuals who chose the Apos intervention avoided TKA. The authors compared this rate with 294 individuals who chose to proceed directly to TKA; over 2 years, 259 of them (88%) actually underwent TKA. Individuals who chose to receive Apos therapy may differ from those who wanted a TKA; for example, they may have been in less pain or may have had less favorable opinions of surgery. The study was not randomized and did not compare Apos Therapy to another active intervention such as a structured exercise program.

According to a 2021 clinical practice guideline from the American Academy of Orthopaedic Surgeons (AAOS), moderately or strongly recommended non-surgical treatments for knee osteoarthritis are supervised exercise, weight loss for obese individuals, canes and braces, topical NSAIDS and oral acetaminophen. The AAOS guideline did not address use of biomechanical footwear therapy. It included a strong recommendation against the use of lateral wedge orthotics.

Osteoarthritis management guidelines from the American College of Rheumatology and Arthritis Foundation (2021) did not address biomechanical footwear therapy. The guidelines conditionally recommend against the use of modified shoes and lateral and medical wedge orthotics for treatment of knee or hip osteoarthritis.

Definitions

Osteoarthritis: A progressive disorder of the joints caused by gradual loss of cartilage. Also known as osteoarthrosis or degenerative joint disease.

Minimal clinically important difference (MCID): The smallest change in an outcome variable that an individual would identify as clinically important.

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): A set of validated questionnaires used objectively to assess the condition of individuals with osteoarthritis of the knee or hip. The result is reported as a total score, pain score, stiffness score, and physical functioning score. Higher scores indicate worse pain, stiffness or physical functioning.

References

Peer Reviewed Publications:

1. Bar-Ziv Y, Beer Y, Ran Y et al. A treatment applying a biomechanical device to the feet of patients with knee osteoarthritis results in reduced pain and improved function: a prospective controlled study. BMC Musculoskelet Disord. 2010; 11:179.
2. Bar-Ziv Y, Debbi EM, Ran Y et al. Long-term effects of AposTherapy in patients with osteoarthritis of the knee: A two-year followup. Arthritis. 2013; 2013:689236.
3. Debbi EM, Bernfeld B, Herman A et al. A biomechanical foot-worn device improves total knee arthroplasty outcomes. J Arthroplasty. 2019; 34(1):47-55.
4. Drew IS, Hoffing M, Lim C et al. Avoidance of total knee replacement in a population health setting: Introducing a noninvasive

biomechanical intervention for patients with knee osteoarthritis. Popul Health Manag. 2022; 25(5):601-607.
5. Reichenbach S, Felson DT, Hincapié CA et al. Effect of biomechanical footwear on knee pain in people with knee osteoarthritis: The BIOTOK Randomized Clinical Trial. JAMA. 2020; 323(18):1802-1812.
6. Zhang Y, Jordan JM. Epidemiology of osteoarthritis. Clin Geriatr Med. 2010; 26(3):355-369.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Orthopaedic Surgeons (AAOS). Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline. 2021. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf. Accessed on December 12, 2023.
2. AposHealth®. Available at: https://www.aposhealth.com/. Accessed on December 12, 2023.
3. Buelt A, Narducci DM. Osteoarthritis management: Updated guidelines from the American College of Rheumatology and Arthritis Foundation. Am Fam Physician. 2021; 103(2):120-121.
4. Food and Drug Administration (FDA). 510(k) SUMMARY – K182090: APOS Medical Assets Ltd.'s AposTherapy System. 2018. Available at https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182090.pdf. Accessed on December 12, 2023.

Websites for Additional Information

1. American Academy of Orthopaedic Surgeons (AAOS). Osteoarthritis Available at:https://orthoinfo.aaos.org/en/diseases--conditions/osteoarthritis/. Accessed on November 28, 2023.
2. Arthritis Foundation. Osteoarthritis of the Knee. Available at:https://www.arthritis.org/diseases/more-about/osteoarthritis-of-the-knee. Accessed on November 28, 2023.
3. National Institute of Arthritis and Musculoskelatal and Skin Diseases (NIAMS). Back Pain: Diagnosis, Treatment, and Steps to Take. Available at: https://www.niams.nih.gov/health-topics/back-pain/diagnosis-treatment-and-steps-to-take. Accessed on November 28, 2023.

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Apos Therapy

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.