Molina Clinical Policy
Dynamic Exoskeletal Orthoses for Lower Extremity Injuries: Policy No. 352

Last Approval: 10/09/2024
Next Review Due By: October 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Foot and ankle injuries, including fractures, sprains/strains, and crush injuries, are common among military personnel. It is estimated that over 221,393 soldiers will seek medical assistance for ankle and foot injuries over the course of five years. Combat-related ankle and foot fractures frequently necessitate radical surgical procedures and, in some cases, amputation. A sports medicine approach is typically used in the military setting for rehabilitation, facilitating early strength and functional training with the goal of returning to high-level activities and, potentially, duty. Return-to-duty rates following lower leg, foot and ankle injuries continue to be remarkably low, with only 18% to 28% returning to duty after open tibial fractures, hindfoot injuries, and Lisfranc injuries (Mazzone et al. 2019).

The **Intrepid Dynamic Exoskeletal Orthosis (IDEO)** and a rehabilitation program, the Return to Run Clinical Pathway, were developed in 2009 by a multidisciplinary team of physical therapists, prosthetists, and orthopedic specialists from the Center for the Intrepid at Brooke Army Medical Center with the goal to enable service members with severe limb injuries to resume running, sports, and potentially military duty. The IDEO device is a custom-made dynamic response carbon fiber ankle-foot orthoses that stabilizes ankle support while reducing forefoot abduction or adduction. Initially designed for military personnel who had suffered massive tissue, nerve, and bone damage to the injured ankle to restore high-level physical function capabilities; it has since been rebranded as the **ExoSym** device for use in civilian population (Hanger Clinic 2019).

The dynamic exoskeletal orthoses are modular throughout the rehabilitation period to adapt to a patient's changes in strength and motion and are molded out of lightweight black carbon that includes a foot plate and a strut that runs up the back of the calf to a cuff that is situated just below the knee. As the individual steps down, it bends the foot plate, transferring energy forward by unloading body weight off the heel acting as a dynamic spring. Upon receiving their brace, patients are enrolled in a four-week Return to Run (RTR) physical training program where gait is analyzed through motion capture and force plates, so that exact data can be used to track their progress. Once the patient has progressed to an adequate level of recovery, the initial brace is replaced with a lighter, more dynamic, definitive exoskeletal orthosis system (Hanger Clinic date unknown).

COVERAGE POLICY

Dynamic exoskeletal orthoses (e.g., IDEO, ExoSym) for lower extremity injuries are considered **experimental, investigational, and unproven**. There is insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Overall, dynamic exoskeletal orthoses for lower extremity injuries have a low-quality body of evidence. Recent research suggests that these interventions may improve high-level function and return individuals to military duty rates and/or a high level of activity. There are no randomized controlled trials comparing the IDEO or ExoSym to other medical or surgical interventions. The available studies include systematic reviews, retrospective cohort studies, prospective reviews, and case series. Limitations of these reviews include the lack of a control or comparison group, a lack of randomization, a lack of objective outcome measures, a retrospective design, methodologies, or procedures that are not clearly reported, and baseline differences in disease severity between groups. Therefore, based on the paucity of data, there is currently insufficient evidence to support the use of the dynamic exoskeletal orthoses for lower extremity injuries.

Systematic Reviews and Meta-Analyses
Highsmith et al. (2016) conducted a systematic literature review to assess the available evidence and develop empirical evidence statements about the outcomes associated with IDEO utilization. Twelve studies were identified and rated. Subjects (n = 487, 6 females, mean age 29.4 years) were studied following limb trauma and salvage. All included studies had high external validity and internal validity was mixed because of reporting issues. Moderate evidence supported the development of four empirical evidence statements regarding IDEO use with specialized therapy. Following high-energy lower extremity trauma and limb salvage, use of IDEO with RTR therapy can enable return to duty, return to recreation and physical activity, and decrease pain in some high-functioning patients. In higher-functioning patients following limb salvage or trauma, IDEO uses improved agility, power, and speed, compared with no-brace or conventional bracing alternatives.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Feng et al. (2023) conducted a case series to evaluate the off-loading properties of the ExoSym device. Six civilian patients who had indications for treatment including arthritis foot or ankle conditions that were amenable to dynamic bracing were included in the study. Patients with neurologic or musculoskeletal disease in the contralateral leg, spinal cord injury or central nervous system pathology were excluded. Foot pressure analysis using F-Scan research software was used to calculate the maximal force, force*time integral, maximal contact area, maximal contact pressure, and pressure*time integral PTI for the forefoot and the heel. The ExoSym reduced forefoot maximal force by 66% and reduced contact pressure by 49%. Pain scores were significantly lower ($p<0.005$) with the ExoSym than without the ExoSym. Limitations of this study included a small sample size related to the low availability of ExoSym brace in the civilian population. The case series provides support of dynamic exoskeletal orthosis use beyond military personal; however additional study in larger patient populations is needed.

Hill et al. (2016) conducted a retrospective review describing the demographics, presenting diagnosis and patterns of amputation in patients prescribed an IDEO at the Center for the Intrepid (CFI). The study population was comprised of 624 service members who were treated at the CFI and prescribed an IDEO between 2009 and 2014. Data were extracted from the Expeditionary Medical Encounter Database, Defense Manpower Data Center, Military Health System Data Repository, and CFI patient records for demographic and injury information as well as an amputation outcome. The most common injury categories that received an IDEO prescription were injuries at or surrounding the ankle joint (25%), followed by tibia injuries (17.5%) and nerve injuries below the knee (16%). Over 80% of the sample avoided amputation within a one-year period using this treatment modality. Future studies should track IDEO users for a longer term to determine the long-term viability of the device. The authors cited paucity of research outlining the demographics, patterns of injury and patient outcomes of amputation in those who have been prescribed an IDEO.

Bedigrew et al. (2014) conducted a prospective review of 84 service members who enrolled in the 8-week RTR program. There were 58 fractures, 53 nerve injuries with weakness, and 6 cases of arthritis (there was some overlap in the patients with fractures and nerve injuries, which resulted in a total of > 84). Four weeks of physical therapy were completed without the orthosis, followed by 4 weeks with it. Testing was conducted at Weeks 0, 4, and 8. Validated physical performance tests and patient-reported outcome surveys were used, as well as questions regarding whether patients were considering an amputation. Patients improved in all physical performance measures and all relevant patient-reported outcomes by 8 weeks. Patients who were injured less than 2 years ago and those who were injured more than 2 years ago improved similarly. After 8 weeks, 41 of 50 patients who were considering amputation preferred

limb salvage. Efforts are underway to determine whether the RTR clinical pathway with the IDEO can be successfully implemented in additional military centers in patients more than two years post-injury while maintaining similar improvements in patient outcomes.

The PRIORITI-MTF study (NCT0215888) is a multicenter before-after program evaluation where participants at least one year out from a traumatic lower extremity injury serve as their own controls. Participants are evaluated before receiving the IDEO, immediately after four weeks of physical therapy with the IDEO and at six and twelve months after the completion of physical therapy. Primary outcomes include functional performance, measured using well-validated assessments of speed, agility, power, and postural stability and self-reported functioning using the Short Musculoskeletal Function Assessment and the Veterans Health Survey (VR-12). Secondary outcomes include pain, depression, posttraumatic stress, and satisfaction with the IDEO (Clinical Trials 2019).

National and Specialty Organizations

No guidelines have been published by professional organizations that include the IDEO brace or ExoSym for lower extremity injuries.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
L1945	Ankle-foot orthosis (AFO), plastic, rigid anterior tibial section (floor reaction), custom fabricated
L2755	Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only

** According to CMS, CGS Administrators, only HCPCS codes L1945 and L2755, in combination, may be used to bill for this type of brace. Use of the Not Otherwise Classified (NOC) HCPCS code L2999 is incorrect coding.*

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/09/2024	Policy reviewed. No changes to coverage criteria. IRO Peer Review on August 1, 2024, by a practicing physician board-certified in Physical Medicine and Rehabilitation, Pain Medicine.
12/13/2023	Policy reviewed. No changes to criteria. Title changed from *IDEO (Intrepid Dynamic Exoskeletal Orthosis) for Lower Extremity Injuries.* Updated policy to include ExoSym. Updated references and Summary of Medical Evidence.
12/14/2022	Policy reviewed. No changes to criteria. Updated references.
12/08/2021	Policy reviewed. No changes to criteria. Updated references.
12/09/2020	Policy reviewed. No changes to criteria.
12/10/2019	New policy. IRO Peer Review. October 3, 2019, by a practicing, board-certified physician in the areas of Physical Medicine, Rehabilitation and Pain Management.

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