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

Last Approval: 10/14/2026
Next Review Due By: October 2027

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. References included were accurate at the time of policy approval and publication.

OVERVIEW

The **ExoSym**, previously known as the **Intrepid Dynamic Exoskeletal Orthosis (IDEO)**, is a custom-made, passive dynamic response orthosis that is designed to store and return energy, improving gait and reducing pain for patients with severe lower limb injuries. The device and rehabilitation program were developed in 2009 by a multidisciplinary team of physical therapists, prosthetists, and orthopedic specialists from the Center for the Intrepid at the Brooke Army Medical Center with the goal to enable service members with severe limb injuries to resume running, sports, and potentially military duty. The device is a custom-made dynamic response carbon fiber ankle-foot orthosis that stabilizes ankle support while off-loading the affected joint. It was initially designed for military personnel who had suffered massive tissue, nerve, and bone damage from traumatic injuries (Hayes 2024).

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 physical rehabilitation program. 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 2019; Hayes 2024).

The **ReAktiv** brace, developed by Fabtech Systems, is a competing dynamic exoskeletal orthosis for lower limb injuries. It differentiates itself by its Posterior Dynamic Element, a modular carbon-fiber spring system designed for adaptability and individual patient needs. The spring system can be adjusted and swapped for different daily activities or when patient conditions change (Fabtech Systems date unknown).

Regulatory Status

The ExoSym, IDEO, and ReAktiv are orthotic devices, and unlike powered exoskeletons they do not contain electronic or motorized components and therefore do not fall under the FDA's classification for powered mobility devices. These devices are regulated as Class I medical devices and considered durable medical equipment. Class I devices typically do not require 510(k) premarket notification.

COVERAGE POLICY

Dynamic exoskeletal orthoses (e.g., Intrepid Dynamic Exoskeletal Orthosis [IDEO], ExoSym, ReAktiv) for lower extremity injuries are considered **experimental, investigational, and unproven** due to 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.

Molina Healthcare, Inc. ©2026 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

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 Intrepid Dynamic Exoskeletal Orthosis (IDEO), ExoSym, or ReAktiv devices 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, lack of randomization, lack of objective outcome measures, retrospective design, methodology limitations, procedures that are not clearly reported, and baseline differences in disease severity between groups. Based on the paucity of data, there is currently insufficient evidence to support the use of 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 Return to Run (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
Pierre et al. (2026) performed a retrospective cohort study to evaluate the long-term outcomes of treatment with IDO and RTR rehabilitation program. The study included 145 participants treated for traumatic lower limb injuries treated with an IDO at a military tertiary care hospital and rehabilitation center. The most common diagnoses were lower limb fractures involved the tibia, ankle, or hindfoot (54.5% of participants) and the most common mechanism of injury was from explosive devices (22.8%). Mean follow-up was 90.3 $\pm$ 32.9 months (range 24-157 months), which provides substantially longer follow-up than prior IDEO studies. 126 patients (86.9%) participated in the RTR program following IDEO prescription, for a mean of 4.9 weeks. Among the RTR participants, 79.4% (100 patients) reported an increased activity level after receiving the IDEO, while 15.1% (19 patients) reported no change, and 5.6% (7 patients) reported decreased activity following. Therefore, activity improvement was measured by self-report rather than any objective test. At final follow-up, 80 patients (55.2% of the cohort) had continued using the IDEO, and 113 patients (77.9%) returned to active duty or employment. The study did not include any objective measurements such as walking distance, pain, or functional scores to quantify long-term clinical improvement. Fourteen patients (9.7% of the cohort) ultimately elected amputation after a mean of 2.4 $\pm$ 2.1 years following IDEO use. Study limitations include the retrospective design, recall bias, self-selection or response bias, small sample size, and the absence of a control group. Additionally, because the majority of patients underwent RTR rehabilitation and received care within an extensive military and interdisciplinary support network, the relative contributions of the IDEO, rehabilitation, and broader support services could not be determined. The authors concluded that long-term IDEO use, when combined with the RTR rehabilitation program, was associated with positive long-term outcomes among patients with severe lower-extremity injuries. Prospective studies are needed to better understand which patients benefit, why IDEO use is discontinued, and which factors contribute to delayed amputation.

Lockwood et al. (2025) conducted a retrospective cohort study to evaluate the clinical outcomes after use of the IDEO for lower limb injury combined with a 4-week, high-intensity military rehabilitation program, the RTR in 41 patients with severe lower-extremity musculoskeletal injuries treated at the Center for the Intrepid. The most common traumatic injuries were related to motor vehicle accidents, falls, or sports. Clinical outcomes were measured using the Two Minute Walk Test (2MWT), taken before receiving the IDEO, immediately following receiving the IDEO, and after completion of the RTR. Mean 2MWT distance increased from 152 $\pm$ 40 m without IDEO to 179 $\pm$ 31 m with IDEO alone and 208 $\pm$ 29 m with IDEO and RTR, which was statistically significant ($p < 0.001$). Differences exceeded the study's Minimally Clinically Important Difference (37.2 m) and Minimal Detectable Change (34.3 m) threshold in the limb loss population. 61% of the IDEO + RTR group reached or exceeded the cited healthy age-matched normative 2MWT

Molina Healthcare, Inc. ©2026 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

distance of 202.1 m compared with 24% of the IDEO alone group and 0% of the group without IDEO. Study limitations include the retrospective design, absence of a true control group of IDEO participants without RTR, and a potential 2MWT learning effect (participants repeatedly performed the test and could benefit from more familiarity or actively attempt to exceed their previous distance). Additionally, there was no follow-up as the study ended at completion of the rehabilitation program. Therefore, it's unknown whether functional gains were maintained after patient discharge. The authors concluded that there is potential benefit of the combination of IDEO + RTR in improving walking in patients with lower limb musculoskeletal injuries.

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. ExoSym reduced forefoot maximal force by 66% and reduced contact pressure by 49%. Pain scores were significantly lower ($p < 0.005$) with ExoSym than without ExoSym. Limitations of this study included a small sample size related to the low availability of ExoSym 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.

Mazzone et al. (2019) completed a retrospective review evaluating the effectiveness of the RTR Clinical Pathway in military service members with lower extremity fractures. The Study included 30 unilateral IDEO users completed the RTR program at naval Medical Center San Diego. The primary outcome was improvement in high level mobility, assessed using the Comprehensive High Level Activity Mobility Predictor (CHAMP), which includes subtests such as the T test (ability to change direction, including acceleration, deceleration, and lateral movement), single legged stance, Edgren sidestep test and Illinois agility test. Secondary outcomes included individual subtest performance and overall functional mobility. Statistical analysis using an analysis of covariance revealed significant improvements in the T test (mean change faster by 5.3 seconds, 95% CI: 3.6 to 7.1 seconds, P = .03) and total CHAMP score (mean change: 4.2 points, 95% CI: 3.0 to 5.3 points P < .05). No significant changes were noted in the single legged stance, Edgren sidestep, or Illinois agility sub tests. The authors concluded that the RTR pathway facilitated meaningful gains in high level, multidirectional mobility among IDEO users with a history of lower extremity fracture. Limitations of this study include a sample of convenience, absence of a control group, and potential selection bias favoring individuals who successfully completed the RTR pathway. The study was classified as level 4 evidence (therapy), and the authors emphasize that broader applicability of the intervention requires further validation before widespread use.

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.

National and Specialty Organizations

The **American Academy of Orthopaedic Surgeons (AAOS)** (2019) published an evidence-based clinical practice guideline for limb salvage or early amputation. The guideline states that all lower extremity limb salvage patients with residual deficits should be evaluated for an appropriate orthosis. However, "the impact of including a dynamic orthosis as part of the rehabilitation strategy requires more investigation."

Molina Healthcare, Inc. ©2026 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

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
L1960	Ankle-foot orthosis (AFO), posterior solid ankle, plastic, custom fabricated
L2755	Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only
L2220	Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint
L2780	Addition to lower extremity orthosis, noncorrosive finish, per bar
L2250	Addition to lower extremity, foot plate, molded to patient model, stirrup attachment

** 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

10/14/2026	Policy reviewed. No change to coverage criteria. Added information about the ReAktiv device.
10/08/2025	Policy reviewed. No changes to coverage criteria.
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.
12/14/2022	Policy reviewed. No changes to coverage criteria.
12/08/2021	Policy reviewed. No changes to coverage criteria.
12/09/2020	Policy reviewed. No changes to coverage 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.

REFERENCES

1. American Academy of Orthopaedic Surgeons (AAOS). Limb salvage or early amputation: Evidence-based clinical practice guideline. Published December 6, 2019. Accessed September 1, 2026. https://www.aaos.org.
2. Bedigrew KM, Patzkowski JC, Wilken JM, et al. Can an integrated orthotic and rehabilitation program decrease pain and improve function after lower extremity trauma? Clin Orthop Relat Res. 2014 Oct;472(10):3017-25. doi: 10.1007/s11999-014-3609-7.
3. Fabtech Systems. ReAktiv brace vs. Exosym/IDEO brace: What's the difference? [date unknown]. Accessed September 1, 2026. https://fabtechsystems.com/news/reaktiv-brace-vs-exosym-ideo-brace-whats-the-difference/#
4. Feng J, Weiss J, Thompson A, Meeker JE. Passive Dynamic Ankle Foot Orthoses Use in Civilian Patients with Arthritic Conditions of the Foot and Ankle. Foot Ankle Orthop. 2023 Mar 13;8(1):24730114231157734. doi: 10.1177/24730114231157734. PMID: 36937807; PMCID: PMC10014983.
5. Hanger Clinic. Featured Technology: Hanger Clinic ExoSym (formerly IDEO). Published October 30, 2019. Accessed August 5, 2025. https://hangerclinic.com/blog/featured-technology/hanger-clinic-exosym/.
6. Hayes. ExoSym Care Program (Hanger Clinic) for Treatment of Lower Extremity Conditions. Evidence Analysis Research Brief. Published April 25, 2024. Accessed August 27, 2026. https://evidence.hayesinc.com.
7. Highsmith MJ, Nelson LM, Carbone NT, et al. Outcomes associated with the Intrepid Dynamic Exoskeletal Orthosis (IDEO): A systematic review of the literature. Mil Med. 2016 Nov;181(S4):69-76. doi: 10.7205/MILMED-D-16-00280.
8. Lockwood MD, Hovorka CF, Baumann ME, Childers WL. Clinical outcome of Two Minute Walk Test after return to run program in IDEO users: a retrospective study. Front Rehabil Sci. 2025 Oct 8;6:1602110. doi: 10.3389/fresc.2025.1602110. PMID: 41133255; PMCID: PMC12540400.
9. Mazzone B, Farrokhi S, Depratti A. High-level performance after the return to run clinical pathway in patients using the Intrepid Dynamic Exoskeletal Orthosis. J Orthop Sports Phys Ther 2019;49(7):529–535. Epub 13 Feb 2019. doi:10.2519/jospt.2019.8763.
10. Pierrie SN, Lockwood MD, Cagle TJ, Fergason JR, Childers WL. Long-term outcomes after intrepid dynamic exoskeletal orthosis treatment coupled with advanced rehabilitation. OTA Int. 2026 Apr 10;9(2):e477. doi: 10.1097/OI9.0000000000000477. PMID: 41969764

Molina Healthcare, Inc. ©2026 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*