DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members. ¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

The Intrepid Dynamic Exoskeletal Orthosis (IDEO, TechLink) is a custom high-level floor reaction ankle-foot orthosis (AFO) and a high intensity, progression-oriented rehabilitation program developed to return severely injured patients back to a high level of activity. This AFO was designed specifically for the war limb salvage military population. Prosthetist Ryan Blanck designed the Intrepid Dynamic Exoskeletal Orthosis (IDEO) at the Center for the Intrepid, Brooke Army Medical Center in 2009. Goals were to reduce pain and restore mobility to active-duty and retired service members with limb salvage conditions as a way to avoid amputation. Hanger Clinic in Washington State continues to support the military in these goals, and is now expanding bringing this technology to civilians. According to the Hanger Clinic, the ExoSym device has helped patients with limb salvage injuries as well as foot and ankle fusions, partial-foot amputations, heel fractures, tarsal coalitions, arthritis and other lower extremity dysfunctions.

The IDEO device is modular throughout the rehabilitation period to adapt to a patient’s changes in strength and motion and is 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. Purportedly, when force is applied to the foot plate, the strut bends. As the individual steps down, it bends the foot plate, transferring energy forward by unloading body weight off of the heel and using 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 correlated to their progress. Once the patient has progressed to an adequate level of recovery, the initial modular IDEO is replaced with a lighter, more dynamic, definitive IDEO system that has enabled dozens of wounded soldiers to return to duty.

**RECOMMENDATION**

The Intrepid Dynamic Exoskeletal Orthosis (IDEO) brace for lower extremity injuries is considered experimental, investigational and unproven because its effectiveness has not been established in the peer reviewed literature.

**SUMMARY OF MEDICAL EVIDENCE**

Overall, there is a low-quality body of evidence regarding the Intrepid Dynamic Exoskeletal Orthosis (IDEO) brace for lower extremity injuries. Recent research suggests, 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 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 lack of a control or comparison group, lack of randomization, lack of objective outcome measures, retrospective design, methodology or procedures not clearly reported, and baseline differences in disease severity between groups. Therefore, based on paucity of data there is currently insufficient evidence to support the use of the Intrepid Dynamic Exoskeletal Orthosis (IDEO) brace for lower extremity injuries. A summary of the relevant studies are outlined below.

A systematic literature review (Highsmith et al., 2016) evaluated the available evidence and formulate empirical evidence statements (EESs), regarding outcomes associated with IDEO utilization. Twelve studies were identified and rated. Subjects (n = 487, 6 females, mean age 29.4 year) were studied following limb trauma and salvage. All included studies had high external validity, whereas internal validity was mixed because of reporting issues. Moderate evidence supported development of four EESs 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 use improved agility, power and speed, compared with no-brace or conventional bracing alternatives.  

A retrospective review (Hill et al., 2016) described 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 category that received an IDEO prescription was injuries at or surrounding the ankle joint (25.0%), followed by tibia injuries (17.5%) and nerve injuries below the knee (16.4%). Over 80% of the sample avoided amputation within a one year time period using this treatment modality. Future studies should longitudinally track IDEO users for a longer term to
determine the long term viability of the device. The authors stated “There is a paucity of research detailing the demographics, injury patterns and amputation outcomes of patients who have been prescribed an IDEO”. 6

Another review (Bedigrew et al., 2014) prospectively evaluated 84 service members (53 less than and 31 > 2 years after injury) who enrolled in the 8-week integrated orthotic and rehabilitation initiative. Fifty-eight sustained fractures, 53 sustained nerve injuries with weakness, and six had arthritis (there was some overlap in the patients with fractures and nerve injuries, which resulted in a total of > 84). They completed 4 weeks of physical therapy 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 pertaining to whether patients were considering an amputation. By 8 weeks, patients improved in all physical performance measures and all relevant patient-reported outcomes. Patients less than and greater than 2 years after injury improved similarly. Forty-one of 50 patients initially considering amputation favored limb salvage at the end of 8 weeks. Efforts are underway to determine whether the Return to Run clinical pathway with the Intrepid Dynamic Exoskeletal Orthosis (IDEO) can be successfully implemented at additional military centers in patients > 2 years from injury while sustaining similar improvements in patient outcomes. The authors stated “The ability to translate this integrated orthotic and rehabilitation program into the civilian setting is unknown and warrants further investigation.” 3

The PRIORITI-MTF study (ClinicalTrials.gov Identifier: NCT02158884) is a multicenter before-after program evaluation where participants at least 1 year out from a traumatic lower extremity injury serve as their own controls. Participants are evaluated before receiving the IDEO, immediately after 4 weeks of physical therapy with the IDEO and at 6 and 12 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 (SMFA) and the Veterans Health Survey (VR-12). Secondary outcomes include pain, depression, posttraumatic stress, and satisfaction with the IDEO. Results of this study are not currently published. 7-8

**Professional Society Guidelines**

At the current time, there are no guidelines by any professional society that include the Intrepid Dynamic Exoskeletal Orthosis (IDEO) brace for lower extremity injuries.

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<tr>
<th>*HCPCS</th>
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<tr>
<td>L1945</td>
<td>Ankle foot orthosis, plastic, rigid anterior tibial section (floor reaction), custom fabricated</td>
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<tr>
<td>L2755</td>
<td>Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only</td>
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*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. 2

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**REFERENCES**

**Government Agency**


**Peer Reviewed Publications**


Other References


Review/Revision History:

2019: New Policy