Medica Coverage Policy

<table>
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<tr>
<th>Policy Name:</th>
<th>Powered Robotic Lower-Limb Exoskeleton Devices</th>
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<td>Effective Date:</td>
<td>7/15/2019</td>
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Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
Powered exoskeleton orthotics devices, included but not limited to, ReWalk™ Personal and Indego® are investigative and therefore NOT COVERED.

Description
Trauma to the vertebrae surrounding the spinal cord or occlusion or compression of the spinal arteries may result in spinal cord injury. Traumatic injury to the spinal cord causes physiological consequences to parts of the body controlled by nerves at and below the level of the injury, including loss of mobility. In 2015, the National Spinal Cord Injury Statistical Center (NSCISC) reported 12,500 spinal cord injuries occurring every year in the United States, and more than 276,000 Americans are living with spinal cord injuries.

Powered robotic exoskeleton devices, also known as reciprocating gait orthoses or computerized walking systems, are orthotic devices being developed with the intent of assisting individuals with spinal cord injuries and other lower-limb impairments to ambulate. These wearable, computer controlled devices are equipped with joints that correspond to those of the human body. The devices are worn outside of the body and crutches are used to help maintain stability. They are primarily being used in rehabilitation centers in gait training or as an exercise modality, but are emerging for community use to permit wheelchair-bound individuals with paraplegia to stand and walk in the home and/or community setting.

FDA Approval
The FDA has cleared two powered exoskeleton devices for personal/home use. The ReWalk™ (ReWalk Robotics, Inc, Yokneam, Israel) was given a de novo approval in June 2013. The Indego® exoskeleton (Parker Hannifin, Cleveland, OH), received 510(k) clearance in February, 2016. Next generation devices are currently under study.

The FDA previously cleared three exoskeleton devices for institutional and rehab setting: the ReWalk™ Rehabilitation, the REX (Rex Bionics Ltd., Aukland, New Zealand) and the Esko™ GT (Esko Bionics, Richmond, CA).
Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes
97999 – Unlisted physical medicine/rehabilitation service or procedure

HCPCS Codes
E1399 – Durable medical equipment, miscellaneous
L2999 – Lower extremity orthoses, not otherwise specified.

Original Effective Date: 8/1/2016

Re-Review Date(s): 5/15/2019

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