GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Wearable robotic exoskeletons have been developed to reportedly help individuals ambulate despite partial or complete paraplegia. Although some devices under development are used in the rehabilitation setting there are now devices available for use in the home setting. The devices include fitted braces for the legs and upper body with motorized hip and knee joints, a backpack containing a computer and rechargeable batteries, an array of upper body motion sensors and a computer based wireless control system worn on the individual’s wrist. Generally, the use of these devices requires that individuals are able to stand using an assistive device (eg, standing frame) and their hands and shoulders are able to support crutches or a walker. Typically, these devices are indicated for use by people with paraplegia due to spinal cord injuries at levels T7 to L5 when accompanied by a specially trained caregiver and for individuals with spinal cord injuries at levels T4 to T6 where the device is limited to use in rehabilitation institutions. None of these types of devices are intended for sports or climbing stairs.

Examples of these types of devices include, but may not be limited to, the following:
- ReWalk™ (ReWalk Robotics, Marlborough, MA) consists of an onboard computer, sensor array, and the rechargeable batteries that power the exoskeleton which are contained in a backpack. The complete system weighs about 35 pounds.
- Indego® powered exoskeleton (also known as the Vanderbilt exoskeleton; Parker Hannifin, Macedonia, OH) is used for gait training and is now available for home use. It includes functional electrical stimulation and weighs 26 pounds.
- Ekso™ GT robotic exoskeleton (Ekso Bionics, Richmond, CA) is available for institutional use for rehabilitation. It is undergoing testing for personal use for ambulation in several registered trials.
- X1 Mina Exoskeleton is a joint project of NASA Johnson Space Center and the Florida Institute for Human and Machine Cognition. It is being developed to provide mobility for both abled and disabled users, for rehabilitation, and exercise. It weighs 57 pounds.

At the present time, evaluation of the powered exoskeleton outside of the rehabilitation setting is limited to small studies performed in the laboratory setting. These studies have assessed the user’s ability to perform standard tasks under close supervision. An occasional loss of balance has been noted, raising concerns about the safety of the device under regular use. Further study is needed to determine whether these devices can be successfully used outside of the investigational (laboratory) setting. Long-term outcomes, including quality of life and clinical improvement overall, have not been reported in the medical literature. Currently, evidence in the peer reviewed scientific literature remains insufficient to firmly establish clinical utility and improved long-term health benefits.

POLICY
Powered, robotic lower body exoskeleton devices are non-covered.

HMO, PPO, Individual Marketplace, Elite, Advantage
The use of the robotic lower body exoskeleton device is unproven and therefore non-covered in all settings/levels of care in patients with conditions which impair the ability to ambulate (e.g., spinal cord injury, stroke, Parkinson’s disease, etc) due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature.

Paramount does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and their patient. Paramount administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.
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.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>L2999</td>
<td>Lower extremity orthoses, not otherwise specified</td>
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TAWG REVIEW DATES: 02/22/2018

REVISION HISTORY EXPLANATION
02/22/18: Powered, robotic lower body exoskeleton devices are non-covered. Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.