DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
BACKGROUND

VASS (Otto Bock Harmony Vacuum-Assisted Socket System, Otto Bock HealthCare; Minneapolis, MN) is a newer technology that manufacturers claim helps control volume fluctuation in the residual limbs of lower-extremity amputees, reduces forces to the limbs, and improves both suspension and proprioception without restricting vascular flow. Maintaining limb volume can help preserve the fit of the socket. A polyurethane liner sits directly against the skin, and a suspension sleeve creates a seal between the prosthesis and the residual limb. A Harmony® vacuum pump sits below the socket and evacuates air with each step, ultimately creating a vacuum between the liner and the socket wall. The vacuum facilitates perspiration evaporation within the socket and minimizes friction during movement, thus providing greater control of the prosthesis and reducing shearing forces to the skin and tissue. Due to the paucity of evidence regarding the system’s efficacy, the VASS™ is considered experimental and investigational.

POSITION STATEMENT

The Vacuum Assisted Socket System (VASS™; Otto Bock Harmony® System) is considered experimental and investigational.

CODING

CPT® Codes - No applicable codes

ICD-9-CM Procedure Codes - No applicable codes

Non-Covered HCPCS Level II © Codes - This list may not be all inclusive.

- **L5685** Addition to lower extremity prosthesis, below knee, suspension/sealing sleeve, with or without valve, any material, each
- **L5781** Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system
- **L5782** Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system, heavy duty
- **L5984** All endoskeletal lower extremity prosthesis, axial rotation unit, with or without adjustability
- **L5987** All lower extremity prosthesis, shank foot system with vertical loading pylon
- **L5988** Addition to lower limb prosthesis, vertical shock reducing pylon feature
- **L7368** Lithium ion battery charger, replacement only

HCPCS Level II © Modifiers

- **EY** No physician or other licensed health care provider order for this item or service.
- **K0** Lower limb extremity prosthesis functional Level 0
  - Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
- **K1** Lower extremity prosthesis functional Level 1
  - Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
- **K2** Lower extremity prosthesis functional Level 2
  - Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
- **K3** Lower extremity prosthesis functional Level 3

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Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

K4  Lower extremity prosthesis functional Level 4
Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

LT  Left side
RT  Right side

Non-Covered ICD-9-CM Diagnosis Code

V49.71  Lower limb amputation status; great toe
V49.72  Lower limb amputation status; other toe
V49.73  Lower limb amputation status; foot
V49.74  Lower limb amputation status; ankle
V49.75  Lower limb amputation status; below knee
V49.76  Lower limb amputation status; above knee
V49.77  Lower limb amputation status; hip


REFERENCES

Peer Reviewed


Government Agencies, Professional and Medical Organizations


Other

### HISTORY AND REVISIONS

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