Harmony
Reimbursement Reference Guide
Revised September 28, 2017

Harmony
Elevated vacuum suspension has been commercially available in the U.S. since 1999 when Total Environmental Control (TEC) introduced the Vacuum Assisted Socket System (VASS). Today, the VASS is manufactured by Ottobock and marketed as the Harmony.

FDA Status
Under FDA’s regulations, the Harmony is a Class I medical device and exempt from the premarket notification [510(k)] requirements. Given the low risk of Class I medical devices, FDA determined that General Controls are sufficient to provide reasonable assurance of the device's safety and effectiveness; therefore, safety and effectiveness research is not required for this device.

Harmony has met all the General Control requirements which include Establishment Registration (21CFR 807), Medical Device Listing(21 CFR part 807), Quality System Regulation (21CFR part820), Labeling (21CFR part 801), and Medical Device Reporting(21 CFR Part 803). The Harmony is listed under External Limb Prosthetic Component; Listing Number E253231.

Harmony Warranty
Otto Bock HealthCare (Otto Bock) warrants all of its products, to the original purchaser, to be free from defects in materials and workmanship. The Limited Warranty for the Harmony is 24 months. For additional information on the Harmony Warranty, see Harmony Instructions for Use (IFU).

Harmony Certification Training
Ottobock lists Harmony Trained Practitioners on its website. These practitioners have taken a 3.0 CEU on-line course and passed the exam.
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Coding

The Healthcare Common Procedure Coding System (HCPCS) for prosthetics is an add-on code system. Primary codes for vacuum pumps were issued in 2003. Since then, additional features have been added to our pumps. Depending on which model is ordered, functions, such as shock absorption, torsion, or rotation may be provided in addition to vacuum, which are described by add-on codes.

The following HCPCS codes are applicable to Harmony:

**4R144 Harmony P2:** L5781 (vacuum pump) + L5984* (axial rotation) + L5988** (vertical shock pylon)

**4R147 Harmony P3:** L5781 (vacuum pump) + L5984* (axial rotation) + L5988** (vertical shock pylon)

**4R150 Harmony HD (330 lbs):** L5782 (vacuum pump HD) + L5984* (axial rotation) + L5988** (vertical shock pylon)

**4R152 Harmony E2:** L5781 (vacuum pump)

**4R180 Harmony P4:** L5781 (vacuum pump) + L5984* (axial rotation) + L5988** (vertical shock pylon)

**4R181 Harmony P4 HD (330 lbs):** L5782 (vacuum pump HD) + L5984* (axial rotation) + L5988** (vertical shock pylon)

**1C62 Triton Harmony:** L5781 (vacuum pump) + L5986 (multi-axial rotation) + L5987** (shank foot system)

**3R60=VC:** L5781 (vacuum pump) + L5814 (polycentric knee) + L5845 (stance flexion) + L5848** (stance extension damping)

**6S400 EMS Socket:** L5645 (BK flexible inner socket, external frame), OR L5651 (AK flexible inner socket, external frame), OR L5653 (KD expandable wall socket)

* L5984 is not recommended if Harmony pump is used with the Triton foot

** Medicare K-Level 3 only.

Other items that may be coded on a claim related to Harmony (not all inclusive):

- Base Code – L5301, L5312 or L5321
- Replacement socket – L5700 or L5701
- Test Sockets, L5618 – L5628
- UL Material L5940 or L5950
- Acrylic L5629 or L5631
- Cushion Socket – L5646 or L5648
- Flexible Inner Socket-External Frame L5645, L5651
- Expandable Wall Socket L5653
- Supracondylar Suspension - L5670
- Custom Socket Inserts (liners), L5681 or L5683 (initial insert), L5679 (additional insert)
- Prefabricated Socket Inserts (liners) L5679
- Sheaths L8400, L8410
- Sealing Sleeves L5685
- Socks L8420, L8430, L8470, L8480

1 The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier’s contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alphanumeric system changes. 2 K-Level Restrictions may apply to coding.
Harmony
Features and Benefits

Volume Control
Compared to a standard transtibial prosthetic socket, the Harmony’s elevated vacuum pulls more oxygenated fluids into the residual limb during swing phase and pushes less fluids out during weight bearing. The result is less than 1% volume loss during the course of the day.\textsuperscript{1,2} As a result, the socket fit is more consistent and may eliminate the need for the user to remove the prosthesis multiple times/day while attempting to manage volume changes with socks and/or spots.

Reduced Forces
In standard sockets daily volume fluctuations inherently cause an inconsistent fit for many amputees not under vacuum and can lead to pressure points on the limb.\textsuperscript{2,3} Controlling volume under vacuum may reduce these forces and promote better limb health.\textsuperscript{2}

Proprioception
The Harmony’s elevated vacuum leads to heightened proprioception which increases the awareness a user has of her or his leg during walking. As a result, users may experience increased balance, stability and control over the prosthesis.\textsuperscript{2}

Reduced Moisture Build-up
The Harmony pulls air from the sealed socket creating an even pressure total contact environment reducing the likelihood of sweating. The Harmony can also be configured for direct evacuation of moisture from the socket system thus greatly reducing moisture buildup.

Shock Absorber and Torsion Adapter
The Harmony’s mechanical pump has an integrated, adjustable shock absorber and torsion adapter, which work together to increase walking comfort and relieve strain on joints and spine. These features may also contribute to a more natural gait pattern.\textsuperscript{4}

Harmony® System Elements

1. **Liner** ....... Protects your limb

2. **Sheath** ...... Makes it easy to slide into socket and creates an airspace for the vacuum

3. **Socket** ...... Your connection to the prosthesis

4. **Gaiter** ...... Protects the sleeve from the socket edges

5. **Sleeve** ...... Seals the vacuum air space

6. **Tubing** ...... Connects the pump to the socket's air space

7. **Pump** ...... Creates an elevated vacuum in the socket so your limb stays connected
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