Harmony® Vacuum System
Guide to Appeal Reimbursement Denials





Receiving an insurance denial can be discouraging, but your options do not stop here. The following is designed to explore common Ottobock Harmony® denial reasons and assist you in structuring arguments if your reimbursement request is denied. Your appeal should explicitly target the one reason for your reimbursement denial.

Denials: Request the Necessary Information
When you receive a denial, you have the right to request all documentation that the payor used to make the determination (e.g. review notes, coverage policies, and definitions). The instructions for making this request are usually stated in the body of the denial letter or on the back of the letter. If no instructions are given, call, fax, or mail in a request. When you call the insurance company, sometimes customer service may be able to read the reviewer's notes to you over the phone. Specifically, ask why the claim was denied. Request the definition for the denial reason. For example, if the denial states that the product is experimental or investigational, request the insurance company's definition of experimental devices. If the insurance company states it is not medically necessary, ask for their definition of medically necessary and request the coverage policy. Finally, ask what documentation you will need to send with the appeal to receive a favorable decision.

Experimental/Investigational Denials
Cigna and Aetna both have policies stating that Harmony® is experimental/ investigational. However, not all of their plans follow these policies. For example, both companies have Federal plans which may only make coverage decisions based on medical necessity. They also administer employer plans and Medicare Advantage plans that may have different rules for coverage of Harmony®. Therefore, we recommend to always check patient's benefits and the specific plan's policy for coverage of Harmony®.

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Private insurers often have different definitions for experimental and investigational. In fact some payors only accept randomized, controlled, peer-reviewed clinical studies with statistically significant outcomes over alternatives. The studies we currently have for Harmony® may not meet every insurance company's criteria.

If you find that the patient's policy states that it does not cover the Harmony® system, it can be tough fighting the determination. Be prepared to appeal at least 2 - 3 times. We have found cases with strong patient involvement (calling, writing letters, and advocacy by other interested parties) have higher success rates. If the patient has a self-insured employer plan, his/her human resource department might be willing to contact the insurance company to advocate for the need of this prosthetic device. Ultimately, the human resource department is the insurance company's customer and not the patient. See the document titled *Getting the Insurance Coverage You Need* for encouraging patient involvement. This can be accessed on www.ottobockus.com or requested by calling Ottobock Customer Service at 800 328 4058.

One option you have is to ask for an exception to your case. Only the medical director has the ability to make this decision so your claim will go through individual consideration. You have better chances for an exception if there is documentation of other products failing and/or there is a unique medical need (e.g. the product is needed to go back to work or to perform activities of daily living). This will also mean that ALL of your documentation will be reviewed so it needs to follow requirements.

Not Medically Necessary Denials

After you've checked that the Harmony® is a covered item, check the documentation requirements in the payor's supplier manual. Documentation should be as patient specific as possible. Medicare documentation requirements are the most stringent. Fulfilling these requirements should also strengthen your claim for reimbursement with other carriers. General medical necessity for the prosthesis needs to be documented by a physician (treatment plans, history and physical, progress/consultation notes, etc.) and available upon request. Medical necessity for each add-on code needs to be documented in the patient's medical record.

You can reference the clinical studies located at www.ottobockus.com to review the results which may justify the benefits of vacuum as they relate specifically to your patients' situation (e.g. volume fluctuation and socket/skin issues that could benefit from the Harmony®'s Volume Management System).

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Deluxe Denials
Again after you check that the code and item are a covered product, ask these questions:

- Does the medical necessity justify the level of service?
  - Can a standard product be justified with the medical necessity documented?
- Have you ruled out other choices?
  - Have other options been tried and failed?
  - Does the patient have any history on alternative systems?
- What Activities of Daily Living can the patient not complete without this product?

CMS Coverage [Utilization]
The Harmony® Vacuum System was first introduced in 2001 by TEC Interface Systems. According to CMS, Medicare Part B [DME MAC] has allowed payment for nearly 13,000 vacuum units since the codes were established in 2003. Note that this does not include usage for patients NOT on Medicare.

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

Medicare Part B Utilization[1]

	L5781	L5782
2003	446	6
2004	836	66
2005	913	146
2006	699	150
2007	898	199
2008	1,421	336
2009	1,557	360
2010	2,099	296
2011	2,170	341

The use of this information may not have an effect on private payor coverage.

[1] Centers for Medicare and Medicaid Services. Part B National Summary Data File (Previously known as BESS). Accessed on 01/30/2012 from http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PartBNationalSummaryDataFile.html

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Preparing Your Appeal

- Request copies of the medical records (physicians, therapists, rehabilitation facility, hospital, home health, etc.) to support your case.
- Write a cover letter.
  - Restate the reason why the claim was denied.
  - Quote their policy and why you disagree (if applicable).
  - Include a bulleted list detailing the attached documentation.
  - Lead them down the path to find proof of why you think the claim should be paid.
- Follow the instructions provided with the Explanation Of Benefits (EOB).

Conclusion

We hope that this helps you in obtaining the best possible reimbursement outcome for the Harmony® System. For additional reimbursement information for the Harmony® please contact Ottobock Customer Service at 800.328.4058 and ask to speak with a Reimbursement Specialist.