

Ottobock Vacuum Solutions.

Guide to Appealing Reimbursement Denials. Appeal Letter Template.

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



If you find that the patient's policy states that it does not cover the vacuum, it can be tough fighting that 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.

Contact the Payer and Request the Necessary Information.

When you first receive a denial, you have the right to request all documentation that the payer used to make the determination (e.g. review notes, coverage policies, and definitions). The instructions for making this request are usually located in the body of the denial letter, or on the back of the letter. If no instructions are given, call, fax, or mail 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 the item 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.

Most private payers post their commercial plan policies on their websites. A few still have commercial plan policies that list vacuum as investigational. However, not all their plans follow commercial policies. For example, Federal plans make coverage decisions based on medical necessity. Employers' self-funded plans may have their own coverage policies. Medicare Advantage plans follow Medicare guidelines. Therefore, we always recommend verifying the patient's benefits and reviewing the specific plan's policy for coverage of vacuum.

Private payers often have different definitions for experimental and investigational. Some only accept randomized, controlled, peer-reviewed clinical studies with statistically significant outcomes over alternatives, while others only require that the device be FDA cleared. The studies we currently have may not meet every insurance company's criterion.

Avoiding Not Medically Necessary Denials.

After you have checked that vacuum is a covered item, check the documentation requirements in the payer's supplier manual to be sure that your patient meets all of their criteria for coverage and that each requirement is documented. Documentation should be as patient specific as possible. General medical necessity for the prosthesis should be documented by a physician (treatment plans, history and physical, progress/consultation notes, etc.). Medical necessity should also be documented for each add-on code used.

Avoiding Deluxe Denials.

After you check that the code and item are a covered product, ask these questions:

- Does the patient's 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?

Requesting an Exception.

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

CMS Coverage [Utilization].

The Harmony Vacuum System was first introduced in 1995 by TEC Interface Systems and Medicare coding was established January 1, 2003. According to Medicare utilization statistics, during the time between 2003 when the codes were established and 2023 (the most current utilization), Medicare Part B DME MAC allowed payment for over 40,000 vacuum units.

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.

¹ Medicare DME MAC Utilization – Number of Units Allowed Per Year

Year	L5781	L5782	Year	L5781	L5782
2003	446	6	2014	2,117	147
2004	836	66	2015	2,405	115
2005	913	146	2016	2,572	120
2006	699	150	2017	2,814	127
2007	898	199	2018	2,314	153
2008	1,421	336	2019	2318	141
2009	1,557	360	2020	2075	114
2010	2,099	296	2021	2014	76
2011	2,170	341	2022	2055	86
2012	2,355	198	2023	2022	68
2013	2,314	153			

¹Centers for Medicare and Medicaid Services. Part B National Summary Data File. Accessed from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-National-Summary-Data-File/Overview.html>

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).
 - Ask for an exception to their policy (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).

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Vacuum Sample Appeal Letter.

Subscriber:

Subscriber ID:

Member's Name:

Member's Date
of Birth:

Reference Number:

Group Name:

Group Number:

Facility:

Provider:

To whom it may concern:

This letter is written in appeal of (name of insurance company)'s decision to deny a request for the (Ottobock, model #, name of pump) described by HCPCS code(s) _____. The denial, dated _____, denied the (pump) as investigational based on (Policy Name and Number). We are requesting that (insurance company) make an exception to the policy and cover the (pump) for (patient name). (State reason why patient needs it). Medical history and treatment pathways are as follows:

A. BACKGROUND

_____ is a _____ year old (male/female). Patient is married with _____ children ages _____. Patient had left/right leg amputated on _____ due to _____.

- Explain what happened to cause the amputation.
- Describe the level of amputation.
- Describe missing joints and bones.
- Describe other medical conditions the patient is experiencing as a result of the amputation.

B. DAILY ACTIVITIES BEFORE AND AFTER AMPUTATION

Patient would like to safely perform daily activities for self-care (i.e. feeding, bathing, dressing, grooming), return to work, home and property maintenance, exercise, and grocery and other shopping (not all inclusive).” Include descriptions of the situation or terrain that might require transferring, navigating stairs, curbs, ramps, uneven terrain, etc.

C. In each example below, discuss Activities that patient did prior to amputation and would like to get back to. Explain any difficulties doing these activities with current socket and how elevated vacuum will help.

Return to Work (if applicable):

Patient, currently works as a _____ and hopes to return to the

- Work force (in the same position) or transition to a different position (i.e. office environment).
- Describe what it will take to get to work (e.g. getting ready in morning, transportation, getting into building, etc.).
- Describe work environment and activities the patient will perform at work.
- Describe equipment that will be operated.

Family:

Patient is anxious to participate in functions with his/her family. As Patient has _____ children, he/she wants to be able to keep up with their activities. Reported activities are _____.

Exercise Activities:

Patient would like to return to reasonable exercise activities. Reported interests are _____.

Home Maintenance, Housekeeping, Yardwork:

Describe activities that patient wants to get back to, keeping in mind the patient's potential functional level.

D. PROSTHETIC PRESCRIPTION

Patient's prosthesis will be fabricated and assembled as follows:

- Positive model of patient
- Trial prosthesis (describe if applicable)
- Definitive [external powered] below knee prosthesis
- Socket
- Foot
- Pump
- Etc.

E. EVIDENCE-BASED MEDICAL NECESSITY FOR VACUUM (use any that apply)

Suspension problems due to shear forces or volume loss:

[State problems patient is experiencing due to shear forces of volume loss.] For his/her lifestyle and activities, [patient] requires excellent proprioception and control of the prosthesis.

Vacuum-assisted socket systems are known to provide excellent suspension and prosthesis control by eliminating relative movements and shear forces between the residual limb and the socket (1-4), and to prevent volume fluctuations of the residual limb that may result in loose socket fit (2,4-7) that needs to be compensated for by putting on several pairs of socks in the course of the day.

Elevated vacuum suspension systems manage limb volume fluctuation, a problem that people with limb loss are challenged with. Over time and on a daily basis, these volume changes can affect how the socket fits. When the limb volume increases, the socket becomes tighter, exerting pressure, restricting blood flow, and allowing for accumulated cell waste. When limb volume decreases, the socket is loose-fitting often causing pressure to bony prominences, which may result in pain and/or injury to the limb (6).

1. Beil TL, Street GM: Comparison of interface pressure with pin and suction suspension systems. *J Rehabil Res Dev.* 2004; 41(6A): 821-828.
2. Goswami J, Lynn R, Street GM, Harlander M: Walking in a vacuum-assisted socket shifts stump fluid balance. *Prosthet Orthot Int.* 2003; 23: 107-113.
3. Beil TL, Street GM, Covey SJ: Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. *J Rehabil Res Dev.* 2002; 39(6): 693-700.
4. Board WJ, Street GM, Caspers C: A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthet Orthot Int.* 2001; 25: 202-209.
5. Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: A systematic review. *Technol Innov.* 2014; 15(4), 333-341.
6. Sanders JE, Harrison DS, Myers TR, Allyn KJ. Effects of elevated vacuum on in-socket residual limb fluid volume: case study results using bioimpedance analysis. *J Rehabil Res Dev.* 2011; 48(10): 1231-1248.
7. Street GM. Vacuum Suspension and its Effects on the Limb. *Orthopädie-Technik.* 2007; 04.

Current suspension is suction:

(State problems that the patient experiences due to volume changes, pistoning, shear forces, step length symmetry, etc.) Board (2001) conducted a randomized trial comparing “suction suspension” to “vacuum-assisted suspension” evaluating changes in volume, tibia and liner pistoning, and stance phase and step length symmetry. Volume: Residual limb volume (n=10) measurements were taken before and after patients walked 30-minutes on a treadmill. Results demonstrated a significant volume increase of 3.7% or 30 ml (p=0.007) when using vacuum as compared to a significant volume decrease of 6.5% or 52 ml when using suction. Pistoning: Pistoning of the tibia and liner (n=11) were measured using X-ray and extraction force and a

significant decrease ($p=0.000$) in both tibia and liner pistoning was found in favor of the vacuum system. Symmetry: Gait symmetry ($n=10$) was assessed with video and found significant improvements in both stance phase symmetry ($p=0.037$) and step length symmetry ($p=0.000$). Conclusion: The authors concluded that while suction suspension fits well, it also causes volume loss due to the pressure that it exerts, which in turn worsens the fit, subjecting the skin to higher stresses and “shear forces” with potential for ulcers. Vacuum suspension, such as the (pump), retains correct fit, averts volume loss, and lessens pistoning in the socket, maintaining skin integrity, symmetry, and comfort (1).

Beil (2002) also compared vacuum suspension to suction suspension (using total surface weight-bearing sockets) by measuring impulse and peak pressures during ambulation ($n=9$). Results: Findings were favorable for vacuum, both during stance phase (impulse $p=0.00$, peak $p=0.003$) and during swing phase (impulse $p=0.000$, average $p=0.000$, and peak 0.001). It is believed that elevated vacuum prevents loss of volume due to less fluid being pushed out in stance phase more fluid being pushed into the residual limb during swing phase (2).

1. Board WJ, Street GM, Caspers C A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthet Orthot Int* 2001; 25:202-209
2. Beil TL, Street GM, Covey SJ. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. *J Rehabil Res Dev*. 2002;39(6):693-700

Current suspension is PIN suspension:

Ferraro (2011) conducted an outcomes study ($n=13$) comparing pin suspension to electronic vacuum suspension. All subjects used each suspension system for at least 30 days (1). A validated measurement tool called the Activity-specific Balance Confidence (ABC) scale was used to evaluate the subject’s confidence when performing certain activities ($n=16$) regarding balance. Subjects taking the survey rated their confidence in performing each activity on a scale from 0 (no confidence) to 100 (completely confident) (2). A score below 67 indicates a risk of falling (3).

Results: Four surveys were excluded from the final analysis; (survey not complete, subject did not use both suspension systems, vacuum system was not electronic, and incorrect amputation level). The ABC scores for the remaining 9 surveys were: Vacuum Suspension (80 ± 10) and Pin Suspension (65 ± 20), resulting in a confidence level of 95% ($p=0.0359$) in favor of vacuum. Subjects ($n=13$) were also surveyed on a variety of related problems experienced with suspension systems. Results for pistoning, blisters, volume change, difficulty knee bending, redness, falls, and walking time, all favored vacuum suspension over pin suspension; however, the results were not significant, possibly due to small sample size (4).

An earlier study by Beil (2004) compared pin suspension to suction suspension ($n=9$) by measuring impulse and peak pressures in the socket during ambulation. Results: During stance phase there was no difference between the two suspension methods

($p=0.076$); however, during swing phase, differences were significant (positive pressure impulses $p=0.008$, average positive pressure $p=0.004$, distal negative impulse $p=0.053$ and peak pressure $p=0.026$) demonstrating that pin suspension exerts an occlusive pressure on the proximal tissues of the residual limb, while at the same time generating considerable suction at the distal end of the socket, and that these pressures are likely causing both the persistent and the day-to-day skin issues witnessed with pin suspension users (5).

1. Ferraro C. Outcomes study of transtibial amputees using elevated vacuum suspension in comparison with pin suspension. *Journal of Prosthetics and Orthotics*. 2011;23(2):78-81.
2. Powell LE, Myers AM. The activities-specific balance confidence (ABC) scale. *J Gerontol Med Sci* 1995;50A:M28-M34.
3. Lajoie, Y. and Gallagher, S. P. (2004). Predicting falls within the elderly community: comparison of postural sway, reaction time, the Berg balance scale and the Activities-specific Balance Confidence (ABC) scale for comparing fallers and non-fallers. *Archives of Gerontology and Geriatrics* 38(1):11-26.
4. Sanders JE, Harrison DS, Myers TR, Allyn KJ. Effects of elevated vacuum on in-socket residual limb fluid volume: Case study results using bioimpedance analysis. *JRRD*. 2011;48(10):1231-1248
5. Beil TL, Street GM. Comparison of interface pressures with pin and suction suspension systems. *JRRD*. 2004;41(6A): 821-828.

History of unhealed wounds and/or distal pain:

Describe patient's history of residual limb wounds and/or distal pain. Until recently, standard practice was to delay the prosthetic fitting until the residual limb was in good condition and could withstand the forces generated by the prosthesis. In his research, VanVelzen (2005) found that ideally, the surgical wound from the amputation must be healed, the stump matured and conically shaped, and there should be no remaining edema when the prosthesis is fit (1,2,3).

Persons with transtibial limb loss have (4X) greater likelihood of successful prosthetic use than persons with higher-level amputations (3). However, they are also more likely to experience skin complications on the residual limb (4,5). Presence of ulcers or unhealed surgical wounds may delay prosthetic rehabilitation and increase the need for medical treatment (3,6). As a result, it has been suggested that there are benefits to accelerating the initiation of rehabilitation after amputation surgery (7,8).

Both conditions (unhealed wounds and distal pain) are usually caused by relative movements and the resulting shear forces between the residual limb and regular (including suction) below-knee sockets. This problem can be further deteriorated by residual limb volume fluctuations: The volume of the residual limb usually shrinks over the day due to the high pressure acting on it in each and every step, resulting in an increasingly loose fit of the socket that, in turn, aggravates the relative movements and resulting shear forces. The standard treatment of residual limb wounds includes that the patient discontinues the use of the prosthesis to unload the wound from pressure and shear forces to allow for healing.

As a result, the patient then must use a wheelchair or two crutches to walk until substantial wound healing is achieved, which can take weeks or sometimes even months. This is not an option for [patient name]. One randomized prospective clinical trial (4) and two case studies (1,9) have meanwhile shown that a vacuum-assisted socket (Harmony® VASS, Ottobock) allow for using the prosthesis despite residual limb wounds without interfering with wound healing or causing pain or discomfort. In the randomized prospective clinical trial (4), residual limb wounds healed equally fast while continuously using the prosthesis with a vacuum-assisted socket as in the control group that had discontinued prosthesis use. As a result, the intervention group using the vacuum-assisted socket was able to stay active, demonstrated better mobility, and increased prosthesis use over several months after the start of the study/wound treatment. The authors of the clinical trial (4) and the case studies (1,9) assume that the reduction/elimination of relative movements and the resulting shear forces between the residual limb and the socket is the reason why vacuum-assisted socket systems neither interfere with wound healing nor cause considerable pain or discomfort while wearing these sockets in the presence of residual limb wounds. Although not yet studied but supported by our own experience and anecdotal reports from fellow prosthetists, it can therefore also be assumed that the reduction/elimination of these relative movements and shear forces may also contribute to the prevention of residual limb wounds and pain. For the reasons and scientific evidence stated above, we are convinced that the technology of a vacuum-assisted socket is medically necessary to support the active lifestyle and preserve the residual limb health of [patient name].

1. Traballese M, Averna T, Delussu AS, Brunelli S: Trans-tibial prothesization in large area of residual limb wound: Is it possible? A case report. *Disabil Rehabil.* 2009; 4(5): 373-375
2. Van Velzen AD, Nederhand MJ, Emmelot CH, Ijzerman MJ. Early treatment of trans-tibial amputees: Retrospective analysis of early fitting and elastic bandaging. *Prosthet Orthot Int* 2005;29:3 -12.
3. Gauthier-Gagnon C, Grise MC, Potvin D. Predisposing factors related to prosthetic use by people with a transtibial and transfemoral amputation. *JPO.* 1998;10(4):99-109; Waters RL, Mulroy S. The energy expenditure of amputee gait. *Gait and Posture.* 1999;9(3):207-231; Bowker JH, Michael JW (ed): *In: Atlas of limb prosthetics: Surgical, prosthetic and rehabilitation principles.* St. Louis: Mosby Year Book, 1992;381-387.
4. Traballese M, Delussu AS, Fusco A, Iosa M, Averna T, Pellegrini T, Brunelli S: Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. *Eur J Phys Rehabil.* 2012; 48(4): 618-623.
5. Dudek NL, Marks MV, Marshall SC, Chardon JP. Dermatologic conditions associated with use of lower extremity prosthesis. *Arch Phys Med Rehabil.* 2005;86:659-663
6. Meulenbelt HE, Geertzen JH, Jonkman MF, Dijkstra PU. Determinants of skin problems of the stump in lower-limb amputees. *Arch Phys Med Rehabil.* 2009;90:74-81
7. Munin et al. Predictive factors for successful early prosthetic ambulation among lower-limb amputees. *J Rehabil Res Dev.* 2001;38;4
8. White SA, Thompson MM, Zickerman AM, et al. Lower limb amputation and grade of surgeon. *Br J Surg* 1997; 84(4): 509-11.
9. Hoskins RD, Sutton EE, Kinor D, Schaeffer JM, Fatone S: Using vacuum-assisted suspension to manage residual limb wounds in persons with transtibial amputation: A case series. *Prosthet Orthot Int.* 2013; 38(1): 68-74.

Amputation is due to dysvascular causes:

State problems patient is experiencing due to dysvascular condition. Focus should be on activities balance, falling, and overall walking.] Dysvascular transtibial amputees, especially those with MFCL-3 mobility grade, benefit from the improved suspension of vacuum-assisted socket systems by reducing their risk of falling, improving their balance and overall walking capabilities. A clinical study by Samitier (2014) has demonstrated that, after 4 weeks of use of a vacuum-assisted socket (Harmony® VASS, Ottobock), dysvascular below-knee amputees with MFCL-3 mobility presented statistically significant improvements in the four square step test (FSST, p=.01) and timed up and go test (TUG, p=.01) as validated indicators of the risk of falling, the Berg Balance scale (BBS, p=.03) as a validated outcome measure of balance, and the 6-minute walk test (6MWT, p=01) and the Locomotor Capabilities Index (LCI-5, p=.04) as validated outcome measures of the overall walking capabilities. The authors conclude that these improvements in safety and function can be explained by the dramatically better suspension between the residual limb and the socket, resulting in improved proprioception and motor control of the prosthesis (1). This technology would therefore help [patient name] maintain or even further improve [patient’s] active professional and private lifestyle.

1. Samitier CB, Guirao L, Costea M, Camos JM, Pleguezuelos E: The benefits of using a vacuum-assisted socket system to improve balance and gait in elderly transtibial amputees. Prosthet Orthot Int. 2014: 1-6. Published online 26 September 2014. DOI: 10.1177/0309364614546927.

F. FUNCTIONAL LIMITATIONS

Describe the nature and extent of any functional limitations (not already addressed) whether from current condition or comorbidities (e.g neuromuscular disease, etc). Describe the impact of the limitations on patient’s daily activities.

G. WHY THE PRESCRIBED COMPONENTS ARE SUITABLE FOR THIS PATIENT

The _____ will allow patient to do daily activities at home and in the community. Patient will be able (list activities that patient wants to get back to from B and then select appropriate information below):

Harmony P3/P4: The Harmony _____ creates a vacuum between liner and socket, making for an unprecedented socket fit. Along with the greatest level of suspension, Harmony _____ also provides the functional benefits of rotation and shock absorption to help reduce stress and strain. Effects of the Harmony _____ includes reduced volume fluctuations, improved suspension, reduced forces within the socket, and improved proprioception.

DVS: The Dynamic Vacuum System (DVS) reduces the movement between the limb and socket associated with limb volume fluctuations. The DVS pump connects to the specific DVS liner magnetically and a knee sleeve is used to seal the system. Elevated vacuum is generated during walking, and this vacuum is maintained in both swing and stance phase. Contrast this to passive systems, such as a one-way valve that only generates suction during swing phase. This gives the user both enhanced control and fit during all phases of ambulation. Effects of vacuum includes reduced volume fluctuations, improved suspension, reduced forces within the socket, and improved proprioception.

Harmony E2: The Harmony E2 is the best vacuum pump for [patient name's] daily activities. It is removable, has intuitive controls, is submersible in water up to 10 feet, and is both quiet and lightweight. Effects of the Harmony E2 includes reduced volume fluctuations, improved suspension, reduced forces within the socket, and improved proprioception.

10. RECOMMENDATION

(Tailor this to your patient.) In summary, a custom fabricated below knee prosthesis with (describe) has been selected for (patient name) as the best componentry that meets his/her needs as a below-knee amputee. Again, we are asking (insurance company) to make an exception for (patient name) who needs this (product name) due to (state the reason identified above). Not only will this prosthesis restore _____ function allowing him/her to get back to daily activities and work, but it may also improve his/her health-related quality of life, body image and balance issues (reducing strain on _____), which in turn should reduce reported _____ pain and any compensatory movements patient has developed during this period of time without _____.

Please contact me if additional information is required or if I can be of further assistance.

Sincerely,

PROSTHETIST NAME, CPO

Date