April 10, 2018

Appeals Department
DenyFirst Insurance Company
666 No-Care Lane
Anywhere USA 66666

Re. Claim #: 123456789

To Whom It May Concern:

The Issues

My name is Tom Toughday and I am appealing DenyFirst's denial of Claim # 123456789 for a vacuum system addition to my above-knee prosthesis on the ground that it is experimental and investigational. DenyFirst is wrong for the following three reasons:

1. **Vacuum Is Not New:** Vacuum systems have been available since the 1990's. Medicare created codes for these devices 15 years ago. Given the length of time that amputees have successfully used vacuum systems, do the facts support DenyFirst's conclusion that they are experimental and investigational?

2. **Vacuum Provides Established Clinical Benefits:** Multiple studies show that vacuum systems help limit volume fluctuations in amputees' residual limbs, minimize pistoning in the prosthetic socket, promote healing of damaged tissue, reduce pain, and score higher on mobility and balance tests than non-vacuum users. Does the published literature support DenyFirst's conclusion that vacuum devices are experimental and investigational?

3. **Other Insurers Disagree:** DenyFirst's coverage position for vacuum systems finds little support from other national private insurance companies. Neither Aetna nor Anthem declare these devices experimental or investigational. Is DenyFirst's designation of vacuum

systems reasonable in light of the fact that other national private insurance company implicitly disagree with DenyFirst?

History

On November 3rd 2012, doctors amputated my right leg above the knee as a result of vascular disease. I was 52 years old.

My wound site took a long time to heal and I was unable to begin the fitting process for a prosthesis until 60 days after the amputation surgery. By the spring of 2013 I was walking outdoors with the support of crutches. At the end of that summer, I could safely walk both inside and outside without any assistive devices.

In September 2013, I was able to return to work as a high school English teacher. The job requires me to walk several hundred yards every day to and from my car to the classroom where I teach. In addition, I stand roughly 50 percent of the time while teaching so that I can write notes on the blackboard for my students.

During the spring, I have also returned to my position as an assistant baseball coach. This requires me to be on my feet for 2 hours every day after school, hitting ground balls to our infielders and throwing pitches for batting practice. The field is roughly 300 yards behind the school.

After work, I return home to my two-story house where I live with my wife, Annabelle, of 25 years. She and I will frequently run errands together, especially on weekends.

Since returning to work full time and resuming my coaching duties, a common problem I experience is compromised fit in my prosthetic socket. Specifically, the longer I am on my feet and walking during the day, the worse my fit gets. The only way I can currently deal with this is by stopping my activity, finding a private location, removing my prosthesis and then re-donning it. Even then, I often experience tissue breakdown and blistering one the end of my residual limb. This limits my ability to walk and perform my coaching responsibilities.

My prosthetist's records document that these issues result from volume changes in my residual limb that naturally occur throughout the course of the day. Despite multiple attempts to address these problems with different prosthetic interventions, none has materially improved the situation.

As a result and in consultation with my prosthetist, on February 1st my physician prescribed me a vacuum system that could be added to my prosthesis.[1] That same day, my prosthetist requested authorization from DenyFirst to proceed with the prescribed solution.

Two weeks later, DenyFirst sent a two-page letter denying the request for authorization.[2] The boilerplate denial stated that DenyFirst considered the prescribed vacuum device experimental and investigational and referred me to DenyFirst Medical Policy DNYU-1. I am appealing that first-level denial with this letter.

Analysis

While DenyFirst claims that the prescribed vacuum system is experimental and investigational, a review of the relevant facts and clinical literature establishes that this conclusion is not supported by the evidence.

1. Vacuum systems are clinically-accepted in the prosthetic profession and have been for well over a decade.

As noted in published clinical research, prosthetists have been using vacuum systems since 1999.[3] In addition, Medicare created reimbursement codes for vacuum systems in 2002 (effective January 1, 2003). Importantly, Medicare does not pay for experimental and investigational treatments.[4]

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[1] See Exhibit A (Physician Prescription).
[2] See Exhibit B (DenyFirst Denial Letter).
[3] See Exhibit C (*Vacuum Suspension and its Effects on the Limb,* Street, G.M., Orthopaedie-Technik (Apr. 2007)).
[4] There are extremely limited exceptions to this rule but none of them apply to prosthetic devices like the prescribed vacuum system.

Taken together, these facts show that physicians have been prescribing and prosthetists have been fitting vacuum devices on amputees to address a range of clinical issues for well over a decade. The evidence therefore undercuts DenyFirst's characterization of this technology as experimental and investigational.

2. Published, peer-reviewed clinical research shows that vacuum devices address a range of problems experienced by amputees.

Specifically, they offer 6 distinct clinical benefits: (1) residual limb volume management; (2) reduction in pistoning in the prosthetic socket; (3) improved healing of ulcers; (4) pain reduction; (5) improved ability to walk; and (6) higher user balance scores. This appeal will address each in turn.

A. Vacuum devices decrease volume fluctuation in users' residual limbs.

Multiple studies confirm this finding. Gerschutz et al. concluded that vacuum limited volume changes to .8% when compared to a non-vacuum system, which produced a 4.9% change in limb volume.[5] Goswami et al. found that vacuum helped prevent volume loss commonly experienced by amputees during the course of a day.[6] Similarly, Board et al. discovered that vacuum prevented volume loss while non-vacuum systems saw amputees experience a decrease in limb volume of 6.5%.[7]

As documented in my prosthetist's clinical notes, my fit worsens over the course of a day due to the loss of volume in my residual limb. This leads to skin breakdown and blisters that limit my ability to walk and perform my daily professional activities. A vacuum system, as shown by the clinical literature, offers the opportunity for me to manage my residual limb volume changes in a way that will

[5] See Exhibit D (*Elevated Vacuum Suspension Influence on Lower Limb Amputee's Residual Limb Volume at Different Vacuum Pressure Settings*, Gerschutz, M. et al., JPO, Vol. 22, No. 4 (2010), 252-256).
[6] See Exhibit E (*Walking in a vacuum-assisted socket shifts the stump fluid balance*, Goswami, J. et al., Prosthet. Orthot. Int. (2003) 27:107).
[7] See Exhibit F (*A comparison of trans-tibial amputee suction and vacuum socket conditions*, Board, et al., P&O Int'l (2001), 25, 202-09).

help prevent these problems and allow me to maintain my mobility. No other device currently available can address these symptoms.

DenyFirst's Medical Policy does not reference any of these studies.

B. Vacuum devices reduce pistoning in the prosthetic socket.

Pistoning refers to up-and-down movement within a prosthetic socket. In a well-fitting socket, the amputee's residual limb is in full contact with the socket wall the entire time, preventing pistoning. However, changes in residual limb volume commonly lead to this unwanted movement, which in turn can cause pain and tissue breakdown.

Ferraro studied pistoning by comparing survey results of patients who wore a traditional prosthesis without a vacuum system to those who utilized a vacuum device. All of the non-vacuum users complained of pistoning while 0% of patients with vacuum did so.[8] In another study, Kahle et al. noted that earlier research revealed that vacuum systems reduced pistoning from an average of 6 mm without the device to 1 mm with it.[9]

As documented in my prosthetist's clinical notes, I regularly experience pistoning in my current prosthesis. This leads to painful pulling at the end of my residual limb that can only be resolved by removing the prosthesis for an extended period of time. A vacuum system, as shown by the clinical literature, offers the possibility of reducing my pistoning, which would permit me to wear my prosthesis longer and improve my mobility. No other device currently available can address these symptoms.

DenyFirst's medical policy contains no reference to either of these studies.

C. Vacuum devices help heal ulcers.

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[8] See Exhibit G (*Outcomes Study of* Transtibial *Amputees Using Elevated Vacuum Suspension in Comparison With Pin Suspension*, Ferraro, C, JPO, Vol. 23 No. 2 (2011) 78-81; see also Exhibit F.
[9] See Exhibit H (*Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure and preference: Ischial containment versus brimless*, Kahle, J. et al., http://dx.doi.org/10.1682/JRRD.2013.01.0003 (Nov. 2013)).

Traballesi et al. compared amputees with unhealed wounds or ulcers who used vacuum to those who did not. The results showed that "the mean wound healing rate, expressed as a percentage of reduction of both wound area and perimeter, was quite faster in the [vacuum group]."[10]

As documented in my physician's and prosthetist's records, I lost my limb to vascular disease. This impairs my ability to heal quickly. Using a system that could help promote healing when I do experience tissue breakdown is important for my long-term health.

While DenyFirst acknowledges the existence of this study, it casually dismisses it as too small, saying that generalization to larger populations cannot be made. Its medical policy does not dispute the validity of the study's findings or the study protocol.

D. Vacuum device users experience less pain when walking with compromised limb tissue than non-vacuum users.

Traballesi et al.'s research further shows that in a population of amputees with unhealed wounds and ulcers, vacuum users walked substantially more with their prosthesis while simultaneously experiencing less pain than non-vacuum users. Specifically, after 60 days, vacuum users wore their prostheses an average of 62 hours a week compared to only 12 hours a week for non-vacuum users.[11]

DenyFirst does not dispute these findings in its medical policy.

[10] See Exhibit I (*Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study*, Traballesi, M. et al., Eur. J. Phys. Rehabil. Med. (2012), 48:613-23).
[11] See Exhibit I.

E. Vacuum device users have higher ambulatory scores than non-vacuum users.

Traballesi et al. measured amputee mobility using the Locomotor Capability Index. After 3 months, vacuum users had a median score on the LCI of 42 out of 42, while non-vacuum users had an average score of only 21.[12]

DenyFirst does not dispute these findings in its medical policy.

F. Vacuum device users have higher balance scores than non-vacuum users.

Ferraro measured amputees' likelihood of falling using the Activity Balance Scale and also monitored their actual fall rates. The ABC scores were "significantly higher" for vacuum device user than non-vacuum system users, a finding that "correlate[s] with a lower incidence of future falls." And in fact, vacuum device users in the study *did* fall less than non-vacuum users.[13]

DenyFirst's medical policy contains no reference to this study.

3. DenyFirst's designation of vacuum systems as experimental and investigational runs counter to the position taken by national insurance companies.

Neither Aetna nor Anthem declare these devices experimental or investigational. Despite DenyFirst's position to the contrary, the private insurance market has therefore recognized the medical necessity of vacuum systems.

Summary

DenyFirst should overturn its original denial for the following three reasons:

1. Vacuum systems are clinically-accepted, long-standing prosthetic interventions and have been recognized as such by Medicare for well over a decade.

[12] See Exhibit I.
[13] See Exhibit G.

2. Published, peer-reviewed clinical literature – most of which DenyFirst's medical policy completely ignores – shows the benefits provided by vacuum devices.

3. Other national insurers cover vacuum devices.

If DenyFirst has any questions about any of the issues outlined in this letter, it should feel free to contact me, my physician, and/or my prosthetist. I look forward to a prompt reply to this appeal.

Regards,

Tom Toughday