# Daniel Gottry

August 12, 2004

Humana Inc. FAX: 1-888-717-7887
P.O. Box 14614
Lexington, KY 40512-4614

To: Humana - Grievance and Appeals Analyst

Re: Partial Nonapproval of Services
Employee Name: Daniel Gottry

*I am requesting an Expedited Medical Review. Initial authorization was entered into your system on July 12, 2004 with your response sent to me on August 6, 2004. Because my current prosthetic no longer fits (although I am using 18-20 layers of "socks") I have fallen several times and fear re-injury.*

Thank you for your response to my request for services from Pongratz Orthotics and Prosthetics, Inc., 2530 East Thomas Road, Phoenix, Arizona 85016. According to your letter, you have partially denied the request based on:

1. A physician's review indicating that the request is "beyond the extent of DME [durable medical equipment] needed to return to basic level of function".
2. Limitations and exclusions which specify that no benefits will be provided for treatment, services, supplies or surgery that is not medically necessary.

   *The applicable portions of the definition included in your response are that services and supplies are appropriate in the treatment of the patient's diagnosed sickness or injury. In order to be considered medically necessary, the services or supplies must be:*

   a. *Consistent with the symptom or diagnosis and treatment of the insured person's injury or sickness;*
   b. *Appropriate with regard to standards of good medical practice;*
   c. *Not solely for the convenience of an insured person, physician, hospital or ambulatory care facility; and*
   d. *The most appropriate supply or level of service which can be safely provided to the insured person. When applied to the care of an inpatient, it further means that the insured person's medical symptoms or conditions require that the services cannot be safely provided to the insured person on an outpatient basis.*

There are some inherent difficulties in addressing the basis for denial of services … the most significant being the arbitrary nature of the justifications. My own experience has demonstrated that amputees face issues of this kind in part because of their relatively small number … there is certainly an ineffective "lobby" for services for amputees and minimal information, even from the medical community, relative to services for amputees. In dealing with medical insurance providers, this is complicated by the fact that a great number of amputees are from the military and therefore receiving services from the government rather than from private insurance providers.

With these limits understood, I would like to address, to the extent possible, both of the issues related to your denial of requested services:

1. **A physician's determination that the request is "beyond the extent of DME [durable medical equipment] needed to return to basic level of function", and**

An agreement on the definition of "basic level of function" becomes of critical importance. This statement becomes highly arbitrary, depending on what is deemed to be my basic level of function. The best I've been able to some up is terms like central, essential, necessary, primary … and NOT non-essential, secondary, superfluous.

I contend that an *ability to effectively exercise and maintain my personal health* and an *ability to perform my occupation at an acceptable level* are indeed essential and necessary and certainly NOT superfluous. Throughout the years, my primary mode of exercise has been "biking". There are some options that will allow this activity but it does require a prosthetic knee that is something beyond the simplest componentry.

Within the medical community, I understand that "basic" or "standard" generally refers to "treatment that is established and accepted by the medical community as routine or normal or is a device that has functioning components essential to the device that will return an individual to a functional level."

In fact, the requested knee mechanism is established and accepted by the medical community at large as a standard prosthesis and is a routinely prescribed prosthetic option for individuals meeting criteria for the knee. This device is also recognized by ***Medicare*** and the ***Veterans Administration***. Therefore, the microprocessor knee meets the criteria to be considered as "standard" or "basic" prosthetic care.

Dale Berry, CP has served as chairman of a Forum of Walter Reed Army Medical Center in Washington, DC, concerning microprocessor-controlled prosthetic knees. This forum was initiated to establish clinical protocols and procedures for microprocessor-controlled prosthetic knees in the treatment of transfemoral amputations.

According to Berry, common historical standards would indicate that the use of the C-Leg should be recognized as a routine and standard means of prosthetic treatment." In fact, his conclusion is that the sole reason the C-Leg is not recognized as routine and standard is its cost.

The following are excerpts from his article in BioMecanics, July 2004.

> *"While specific recommendations for protocols and procedures were addressed, the forum also touched on deeper underlying questions concerning industry standards for testing and outcome studies, as well as insurance companies' requests that the prosthetics industry prove and document that micro-processor-controlled knees can provide superior fitting solutions and outcomes compared to other knees."*

*“Why are we being asked to do this? As chair of the forum, I opened the meeting by suggesting that the fundamental reason for establishing protocols and procedures for prescribing the microprocessor-controlled knee is the price of this technology.* ***If the cost of microprocessor-controlled knees was comparable to that of nonmicroprocessor-controlled knees … payers and insurance companies would accept the technology as valid and appropriate and would approve it without question.”***

*“… Commonly, insurance companies deny reimbursement for new technology by citing contract language that excludes "deluxe services."* [NOT BASIC] *Although this appears to be a frequently utilized term in the insurance industry, it is difficult to find clear medical guidelines, industry standards, or clinical benchmarks that define what "deluxe services" entail. More important, few if any insurance companies maintain listings of Medicare-approved products or services that meet their definitions of "deluxe," so the question of what is or is not deluxe often ends up being addressed on a case-by-case basis by individual case managers and insurance company medical directors. “*

*“To complicate matters further, contract language will often juxtapose the denial of coverage for "deluxe services" with the approval of coverage for "standard services"-yet another term without specific, published criteria or clinical guidelines to define it.”*

*“If one defines "standard" treatment as that which has been established and accepted by the medical community as routine and normal, the fact that the microprocessor knee unit is approved by the Food and Drug Administration, the Centers for Medicare and Medicaid Services, Veterans Affairs, and the U.S. Army offers compelling evidence that this technology should be considered "standard" care.”*

*“With Medicare approval of the C-Leg and subsequent establishment of L-codes L5847 and L5989 on Jan. 1, 2002, and L5848 on Jan. 1, 2003 (Table 1); FDA approval; and VA fitting guidelines and criteria,* ***the microprocessor knee mechanism has been identified and accepted by physicians, governmental agencies, and the rehabilitation community nationally and internationally as a routine and standard means of prosthetic treatment.”***

*In pursuit of this goal, Hanger Prosthetics and Orthotics followed the model of the universally accepted Short Form (SF-36) Health Survey scoring methodology to create an ongoing evaluation process that they began using in March 2001. A 50-question survey is included in the patient evaluation protocol and asks the patient to rate his or her present prosthesis on a scale of 1 to 5, with questions related to such categories as stability, comfort, function, confidence, and ability to perform activities of daily living. Once the evaluation is completed, the responses are entered into a master database.*

*In addition to the patient survey, a uniform patient evaluation process and protocol were established to clearly document each patient's specific functional, physical, and prosthetic needs. A 14-page evaluation form filled out by the practitioner is utilized to ensure a standardized evaluation process, which facilitates consistency in both patient care and patient assessment. Standardizing the evaluation, training, fitting, and follow-up process in the 600 Hanger P&O practices provides a strong foundation for a quality product analysis and patient outcomes study.*

*Foreseeing the challenges of introducing to the healthcare community the new microprocessor-controlled knee technology found in the Otto Bock C-Leg, Hanger began using this standardized evaluation and patient justification process in March 2003 specifically for C-Leg applications. Hanger practitioners not only attended Otto Bock Healthcare certification training, required by Otto Bock for fitting the C-Leg, but also received Hanger C-Leg evaluator certification and administrative protocol training. The Hanger protocol requires that all C-Leg candidates undergo*

*a uniform and detailed evaluation process, with the evaluation data passed on to Hanger Clinical Operations for review and internal authorization. This process is designed to ensure 100% compliance in the application of the C-Leg to appropriate patients as well as 100% administrative compliance.*

*Nine to 12 months after a patient has been fitted with the C-Leg, he or she is sent a follow-up survey containing the original 50 questions as well as five additional questions regarding the new prosthesis. Follow-up survey answers are then compared to the original survey answers in the database. As of March 2004, initial survey responses had been tabulated for more than 2000 patients; 850 follow-up surveys had been distributed, with 480 of those returned and entered into the database.* ***With only part of the comparison completed, results showed a pattern of improved stability and function, as well as an increased ability to walk on uneven surfaces, ramps, and stairs.***

Dale Berry, CP, CP(c), FAAOP, LP, is vice president of clinical operations for Hanger Prosthetics and Orthotics.

---

Table 1. Relevant L-codes

Code: Definition: Effective date

L5847: Addition, endoskeletal knee-shin system, microprocessor control feature, stance phase: 1/1/2002

L5848: Addition to endoskeletal, knee-shin system, hydraulic stance extension, dampening feature, with or without adjustability: 1/1/2003

L5989: Addition to lower extremity prosthesis, endoskeletal system, pylon with integrated electronic force sensors: 1/1/2002

In my case, the question of provision of "basic" care should be considered in a context of what would be a normal functional level. ***In reality, it is impossible for Humana to provide any care or devices which will provide me with a normal functional level.***

As an AK amputee, 53 year-old survivor of cancer in excellent health with no circulation issues or complications of diabetes, "normal functioning" should include activities which will, without question, be impossible, regardless of the equipment provided. I believe it is incumbent on Humana, however, to provide equipment providing *as normal a functioning level as is possible*.

As stated in *Pongratz Orthotics & Prosthetics'* letter to Humana, I am a very active adult. As they stated, *"given the functional level of Mr. Gottry the following componentry (C-Leg, microprocessor feature) has been selected to maximize his capability and provide the security and safety his active lifestyle requires."*

I further believe that my safety in the performance of my occupation is certainly "basic". I serve in a key position in a non-profit agency which provides shelter for homeless families. My occupation requires my ability to provide tours and monitor many activities on a 7 ½ acre shelter campus. In order to do this, I must be able use stairs and safely navigate on terrains which include asphalt, concrete, grass, dirt, gravel, and cobblestones.

The features of the C-Leg are particularly beneficial in these applications. Its microprocessor provides the user the ability to:

- Walk down stairs step over step
- Walk at variable cadence
- Walk down ramps
- Walk on uneven ground (gravel, grass, cobblestones)
- Achieve stability and security while in a flexed position
- Achieve a smooth and natural transition during gait from heel strike to mid-stance by allowing the knee to be in a flexed position at heel strike
- Engage stumble recovery feature in the event of tripping/slipping on uneven/slick surfaces

While this is certainly not true in every situation, in my case, the C-Leg is certainly not "beyond the extent of DME needed to return to basic level of function."

**2. Limitations and exclusions which specify that no benefits will be provided for treatment, services, supplies or surgery that is not medically necessary.**

***a. Consistent with the symptom or diagnosis and treatment of the insured person's injury or sickness;***

There would appear to be no question that I am a cancer surviving AK amputee in excellent health with no circulation issues or complications of diabetes. I believe this definition is not in conflict with the request for approval.

***b. Appropriate with regard to standards of good medical practice;***

This is obviously a valid (although arbitrary) question. It would appear, however, that the C-Leg is appropriate with regard to standards of good medical practice. Prosthetists, the FDA, CMS/Medicare, AAOP, the VA, and over 150 insurance companies nationwide have recognized and accepted microprocessor-controlled knees as a *standard level* of prosthetic treatment. Further indication of acceptance of microprocessor-controlled knees is Medicare's subsequent assignment of L-Codes L5847 and L5989 in January 2002, the code L5848 in January 2003, and the code L5846 in January 1996. These codes are mostly, if not exclusively, associated with microprocessor-controlled knees. Other indications of acceptance include FDA clearance and the VA fitting guidelines and criteria. The C-Leg has been in use since 1997 in Europe and Canada and since 1999 in the United States. The C-Leg is currently being used by thousands of AK amputees in more than 20 countries.

***c. Not solely for the convenience of an insured person, physician, hospital or ambulatory care facility;***

I know it is understood that amputation can certainly not be considered a "convenience". The reasons for this choice relate to its ability to provide both function and safety, appropriate to my medical condition.

***d. The most appropriate supply or level of service which can be safely provided to the insured person. When applied to the care of an inpatient, it further means that the insured person's medical symptoms or conditions require that the services cannot be safely provided to the insured person on an outpatient basis.***

Again, this is a valid (although arbitrary) question. According to Brad Kennedy, the C-Leg has made a tremendous difference. (From "MEMS PROSTETIC HELPED SAVE AMPUTEE ON SEPT 11", an article in "Small Times: Big News in Small Tech" 1/25/02).

> *One person with that knowledge and interest is Brad Kennedy, a prosthetist at Methodist Rehabilitation Center in Jackson, Miss. Kennedy, who has fitted 20 of the devices, also has used a C-Leg for two of the eight years since he lost a leg in a car accident.*
>
> *"Initially, when they told me about the C-Leg, I thought it was a lot of hype. There's no way a knee can do what they say it can do," he said.*
>
> *"It's a very expensive component … but in my personal opinion, it's definitely worth every penny."*
>
> *While most of his patients' insurance plans cover the C-Leg, the approval process still can be tedious. He said insurers require quite of bit of documentation, including letters of medical necessity and detailed explanations of how a patient's ability will be boosted by the device.*
>
> *"It's maybe an option once they (get assistance) to cover the cost," he said. "I would definitely look into all these avenues. The C-Leg has made that much of a difference to me."*

*Kennedy credits the technology, specifically the MEMS, for making the difference: No previous prosthetic limb has allowed him to walk down stairs, step over step, while holding a clipboard or his wife's hand.*

*"The technology is benefiting us big time, and they're steadily improving it," he said.*

According to Next Step Orthotics & Prosthetics:

*The stability of the [C-Leg] knee is a vast improvement over traditional knees, so uneven terrain is easier to negotiate. This technology allows the wearer to utilize a step-over-step gait, which is useful particularly when stepping down out of a vehicle, walking down ramps, stepping off curbs, or going down stairs. The C-Leg also helps you to move on flat terrain at different gait speeds - with confidence.*

According to Tim McCarthey, a retired police officer from Bethany, Oklahoma who lost his leg following an accident:

*"My old prosthesis was made up of a suction socket, a hydraulic knee, a torque absorber, a shock absorber, and a PathFinder foot. My current prosthesis is the C-Leg, made by Otto Bock. It is a computerized prosthesis that is programmed to know my walking habits. It is constantly checking my gait and making adjustments up to 50 times per second. This means I can go from a walk to a run and then back to walk without having to make adjustments to the hydraulic setting. The C-Leg has an advanced swing-phase control and stance control, allowing me to walk with less effort and more safely. I can now go down stairs, hills, and ramps step-over-step without holding onto anything and without fear of falling down. I have not fallen down one time since I started using the C-Leg, in comparison to the fact that falling down was a regular occurrence with the old prosthesis. The C-Leg has totally changed my life overnight."*

There is another consideration, beyond the issues outlined in Humana's denial of services … that being the issue of durability. Certainly the requested C-Leg has a greater front-end expense. However, my limited research indicates that this may not be the end of the story.

When attending an activity with an amputee support group, I met a gentleman with a C-Leg. His insurance company's motivation in providing the C-Leg was primarily selfish! This gentleman (in his upper 60's) had gone through three traditional knees in a period of one year … each one destroyed by relatively normal activity. The C-Leg provided durability that the other knees could not provide, thereby reducing his insurance company's overall expense.

This story seems to be less than unique! According to Greg, a patient of Lehneis Prosthetics:

*"My first prosthesis should have been fine - a Flex-Foot with a pylon and a mechanical knee. But my original prosthetist was never able to get it to fit right. It was so painful that I couldn't walk," Greg recalled.*

*"I've been through so many knees and legs - destroyed most of them because I'm so active!" he laughed. "But this C-Leg is absolutely the greatest."*

Because of his suitability for the more durable C-Leg, as an active adult, his practitioner was able to acquire approval of his insurance company.

In Wired Magazine's July 2001 article "Born to Run":

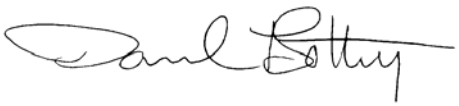
*Geoff Turner's San Francisco apartment is a personal museum of one man's struggle with technology. A dozen broken artificial legs line his walls, a rogue's gallery of fractured prosthetic knees, cracked plastic feet, and shattered hopes. Each now-useless medical device comes with its own story: where it broke, how much it hurt, how many calls to manufacturers and insurance companies Turner had to make to get it replaced.*

Humana has indicated, to an extent, its appreciation of the value of the C-Leg by its

authorization for me to apply any funding received toward the purchase of a C-Leg, provided that I pay the balance of the cost and commit to paying any repair costs. As an employee of a non-profit homeless shelter, this financial commitment is impossible. There have been a number of needs that have required my financial commitment, beyond the $2,500 paid in deductibles and co-payments. These have included the purchase of a vehicle that would accommodate my physical limitations ($16,000+) and the move to a one-story home with much less maintenance ($18,000+ in fees and out-of-pocket costs).

I am hopeful that you will concur that the C-Leg's *unique* features are most appropriate to my *unique* situation.

Sincerely,



Daniel Gottry

P.S. While this request and/or offer may be a bit unusual, I wish to make it anyway. Should Humana understand the benefits of this newer technology in my situation, I would be very interested in being involved with Humana, long-term, in providing regular responses as they relate to the effectiveness and efficiencies of this product. Since, as I indicated, we amputees lack the "lobby" needed to make dramatic improvements, I believe that I should do everything that I can, personally, to educate and inform.