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Prosthetics • Orthopedic Bracing • Seating & Mobility No. 18

The Crisis in O&P Care Delivery

An extraordinary event transpired May 13, 2013: The American Orthotic and Prosthetic Association (AOPA), primary business confederation of prosthetic limb and orthopedic brace providers in the United States, sued the O&P industry's primary funding source, the Centers for Medicare and Medicaid Services (CMS), in federal district court.

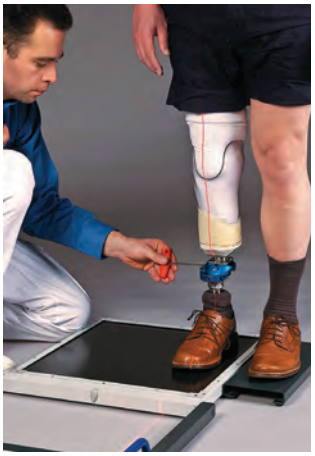
This drastic step came only after 20 months of a non-stop double-barreled assault on the long-accepted business customs and reimbursement policies under which O&P providers have delivered assistive devices to patients covered by Medicare and Medicaid and which threatens to put many dedicated and once-successful practices out of business; in fact, some have already succumbed.

IMPORTANT INFORMATION FOR MEDICARE AMPUTEES AND THEIR DOCTORS!
READ NOW

What has become nothing less than a full-blown crisis for the orthotic and prosthetic specialty was launched with the August 2011 release of a Department of Health and Human Services Office of Inspector General report entitled "Questionable Billing for Lower Limb Prosthetics."

Subsequently, CMS contractors issued a letter to all physicians enrolled in the Medicare program stating that only notations in the physician's record would henceforth be acceptable for establishing the medical necessity, and thus the reimbursement, for prosthetic or orthotic claims. The formerly fully acceptable documentation of the attending prosthetist or orthotist, based on a thorough patient evaluation and accumulated years of specialized training and experience, was suddenly deemed inconsequential. In truth, board-certified prosthetists and orthotists typically possess far more insight as to the appropriate prosthetic or orthotic device for a given patient than does the doctor who refers that patient for O&P care.

But that was just the beginning. CMS then unleashed an army of bounty-hunters known as "recovery audit contractors" (RACs) to reclaim previously approved reimbursements to O&P providers for claims submitted under the then-existing guidelines, ostensibly to combat supposed fraud and abuse but in reality to shore up a suddenly curtailed budget in the run-up to implementation of the Affordable Care Act, which includes a promise to extract $750 billion over 10 years from Medicare providers.



Courtesy Otto Bock Health Care

By arbitrarily overturning claims already reimbursed, the RACs have withheld payments to O&P providers for current approved claims, creating for many a substantial, in some cases fatal, financial blow.

Yes, overturned reimbursements and now-predictable initial denials of new claims can be appealed, but the appeals process is now taking as long as two years. Most O&P practices are small businesses, many of which lack the resources to survive a extended delay in receiving payment for their services.

(Continued on page 2)

Congress, We Have a Problem

Friends, as outlined in this newsletter, changes in Medicare reimbursement are inhibiting our ability to continue providing our patients the absolute best orthotic and prosthetic outcomes we can deliver. Here's how you can help:

If you are a health care provider to patients who require prosthetic or orthotic care, or a Medicare-eligible patient who receives that care, we encourage you to express your concerns to your senators and district representative in Washington, D.C. A sample letter appears on page 2.

Representatives

The Hon. Mark Meadows (North Carolina District 11)
1516 Longworth House Office Bldg. • Washington, DC 20515

The Hon. Patrick McHenry (North Carolina District 10)
2334 Rayburn House Office Bldg. • Washington, D.C. 20515

Senators

The Hon. Richard Burr
217 Russell Senate Office Bldg. • Washington, DC 20510

The Hon. Kay Hagan
521 Dirksen Senate Office Bldg. • Washington, DC 20510

CMS Actions Adversely Affecting O&P Patient Care

(Continued from page 1)

What Does This Mean for Patients?

As challenging as the current state of affairs is for O&P providers, it can be considerably worse for Medicare patients, who now face potentially long delays in receiving a new prosthesis or orthosis while all now-necessary extra documentation is gathered and in many cases will no longer be approved to receive the most appropriate componentry for their condition.

Whereas O&P practices formerly could rely on CMS reimbursement for most prosthetic limbs or braces they provided, no such assurance exists today. When a claim is disapproved, either the patient assumes responsibility or the O&P provider must bear the cost; neither option is satisfactory.

Sample Letter to Congress

Dear _____:

As a Medicare patient with a physical disability, I am writing to express concern over recent changes by the Centers for Medicare and Services (CMS) to coverage for prosthetic limbs and orthopedic braces. These revisions are preventing reputable prosthetic/orthotic suppliers from providing appropriate care allowing beneficiaries like me to maintain a reasonable quality of life.

Although for decades physicians have relied on a qualified prosthetist or orthotist to evaluate patients and determine the most appropriate limb or brace for their condition, CMS now accepts only extensive documentation in the physician's record for establishing medical necessity for these devices. Unfortunately, frustration over these uncompensated administrative requirements is leading many physicians to refuse to comply, but it is we patients who are then denied treatment.

Moreover, over-aggressive audits by Medicare contractors are depriving physically challenged beneficiaries of the appropriate level of prosthetic/orthotic care to which they are entitled while robbing suppliers (typically small businesses) of the cash flow they need to survive, further restricting patients' access to care.

While I support efforts to ensure that only appropriate claims are paid and to fully investigate all instances of actual fraud and abuse, I believe CMS and its contractors are unfairly targeting prosthetic/orthotic suppliers and the patients who rely on them for their care and personal mobility.

As my legislative representative in Washington, I request you and your congressional colleagues take action requiring CMS to revise its policies and procedures without delay so as to no longer prevent Medicare beneficiaries from receiving these vital services.

Sincerely,

Signature

Moreover, because CMS auditors are regularly disallowing claims for advanced components that can help patients achieve their maximum potential, many providers have concluded they have no choice but to select less-expensive, basic alternatives with resulting diminished benefit to the patient.

For instance, in some parts of the country claims for limbs tailored to the capabilities of CMS Functional Level 3 amputees ("community ambulator"—ability or potential to walk with a variable cadence and traverse most environmental barriers) are almost automatically rejected, even with perfect documentation. As a result, these amputees now must make do with less-expensive Functional Level 2 ("limited community ambulator") componentry, including low-performance prosthetic feet, basic knee units for above-knee amputees, and less-innovative socket designs.

Initially, CMS took aim at lower-limb prosthetics. Now the focus has expanded to spinal orthoses (see page 3 article), and claims for AFOs (ankle-foot orthoses) and KAFOs (knee-ankle-foot orthoses) are soon to receive similar treatment.

What Can We Do? What Can You Do?

As long-time providers of O&P services, our company and our practitioners are as dedicated as anyone to curbing fraud and abuse in our specialty and not wasting government funds. But, as the AOPA lawsuit charges, the HHS OIG report alleging widespread fraud and abuse is seriously flawed and based on numerous erroneous conclusions regarding how O&P care is prescribed and administered. In short, it vastly overstates the "fraud" and "abuse" in our field.

For example, the OIG report's authors misunderstood that it is not unusual that most Medicare amputees may not see the "referring physician" who first prescribed their prosthetic care because that physician is commonly the surgeon who amputated their limb and has no other participation in their case. Why such a fundamental misconception made it into the final report raises troubling questions.

We are hopeful the AOPA lawsuit will be successful and in time a corrective judgment will help alleviate the prevailing crisis in O&P care delivery. Another potential resolution is action in Congress. O&P practitioners and practice owners are visiting and contacting their elected officials to apprise them of the CMS actions and the need for relief. We also encourage our readers and patients to contact their senators and representatives about this highly important issue.

A sample patient letter appears on page 2. Names and addresses of members of Congress can be found at www.house.gov/representatives/ and www.senate.gov.

Note to Our Readers

Mention of specific products in our newsletter neither constitutes endorsement nor implies that we will recommend selection of those particular products for use with any particular patient or application. We offer this information to enhance professional and individual understanding of the orthotic and prosthetic disciplines and the experience and capabilities of our practice.

We gratefully acknowledge the assistance of Otto Bock Health Care and Tillges Technologies in compiling this issue.

CMS Now Requires 'Doc'-umentation For TLSOs as Well

First lower-limb prostheses, now spinal braces.

We have been advised that effective Jan. 1, 2013 the CMS physician documentation standards for justifying medical necessity of lower-extremity prosthetic limbs adopted in 2011 have been extended to thoracic-lumbar-sacral orthoses (TLSOs). That means that to qualify for Medicare reimbursement, all TLSO prescriptions must be supported by detailed notations in the physician's chart establishing need for the device.

Documentation in the beneficiary's physician medical record must show the orthosis was ordered for one of the following indications:

- reduce pain by restricting mobility of the trunk;
- facilitate healing following an injury to the spine or related soft tissues;
- facilitate healing following a surgical procedure on the spine or related soft tissue; or
- otherwise support weak spinal muscles and/or a deformed spine.

As with prosthetic patients, we are ready to partner with our referring physicians to provide whatever clinical and product information is necessary to establish medical necessity in the patient's record for the spinal orthosis ordered.

Please call our office if you have any questions.

PressureGuardian™—Diabetic Foot Wound Care Goes Digital

Digital technology, already revolutionizing health care around the world, is poised to transform diabetic foot wound management as well.

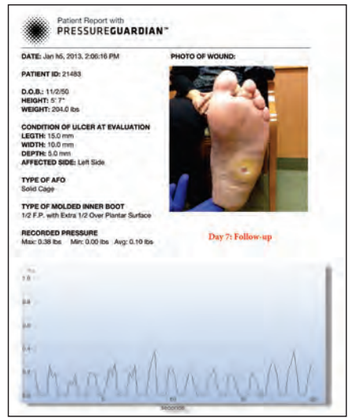
Individuals with diabetes experience a much higher risk of lower-limb amputation than non-diabetics, and a large majority of those amputations are preceded by a non-healing foot ulcer. Once an ulceration develops in an insensate foot, a frequent response is to provide a custom ankle-foot orthosis to offload the wound.

What's New

The effectiveness of the AFO design traditionally has been determined by the experience and intuition of the orthotist, largely due to lack of an effective tool for measuring pressure on and around the ulcer in the AFO environment. Now, a newly introduced product utilizing fundamental digital concepts—WI-FI and an "app"—is making wound care with an AFO decidedly more scientific and therefore effective.

The PressureGuardian™, developed by Tillges Technologies, is a compact portable pressure sensor and WI-FI transmitter that sends pressure data to a data collecting and storing app residing on any Apple iOS device (iPhone, iPad, or iTouch). This capability gives practitioners in the clinical setting accurate static and dynamic force measurements throughout the patient's gait cycle, with which to assess and if necessary adjust reliefs around the wound for maximum benefit, faster healing and prevention of recurrence.

The device is thus an excellent tool for measuring outcomes. Although not currently required, the information it provides may well become a necessary criterion for wound care reimbursement in the future.



Interim patient report shows essential patient information, clinical data, wound photo and pressure readings.

Photos courtesy Tillges Technologies

PressureGuardian load readings, wound photos and detailed patient information can be organized into a comprehensive record, easily emailed to other clinicians and case managers or printed for filing. The non-invasive testing may be repeated many times at short intervals to delineate progress and provide visible biofeedback for patient education, which can increase compliance.

The system is currently designed for use with AFOs that also assist in wound healing, but future plans call for adding capabilities to monitor other orthotic and prosthetic applications, as well as to adapt the data management app for use with Android devices.

A Better Gait for Patients with Knee Instability

Courtesy Otto Bock Health Care

Orthopedic Appliance Company is pleased to offer stance-control technology for patients exhibiting knee instability resulting from isolated quad weakness, polio/post-polio, multiple sclerosis, unilateral paralysis, incomplete spinal cord injury and trauma.

A traditional KAFO (knee-ankle-foot orthosis) provides stability by locking the knee in full extension but also causes patients with a gait deviation that requires more energy and can lead to overuse injuries.

By contrast, a stance control orthosis (SCO) allows the knee to bend during the swing phase of the gait cycle and blocks knee flexion for stability during stance phase. SCOs thus facilitate a more normal gait, which may reduce secondary complications from gait compensations and allow the patient to walk with less effort.

Depending on patient characteristics and needs, OAC can provide either a custom factory SCO, such as the Freewalk model at left, or build stance-control knee joints into a KAFO fabricated in our Asheville laboratory.

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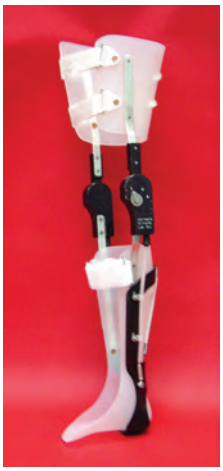


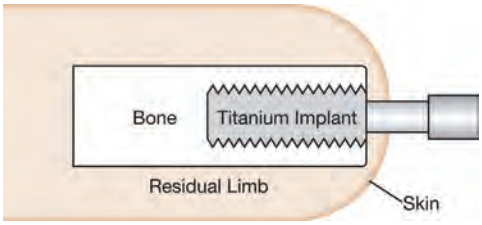
Courtesy Horton Technology Inc.

Limb Attachment Alternative Finally Coming to U.S.

Of the various ingredients that comprise a current-generation prosthetic limb, the point of connection to the human anatomy, the socket, is often considered the most problematic.

Various issues involving the residual limb—skin infections and ulcerations, volume changes, perspiration, skin grafts, scarring, a short limb remnant and abnormal bone formation near the amputation site—present significant challenges to a positive outcome. Continuing innovation in socket design and fabrication has successfully addressed many of these difficulties over the years, however the ultimate solution for some patients may be to eliminate the socket altogether.

In 1990 Swedish physician Rickard Brånemark pioneered *osseointegration* for attaching a prosthetic limb, a technique in which a titanium bolt is surgically implanted into the medullary canal of the residual limb with one end extending percutaneously to provide an attachment point for the prosthesis.



Osseointegration implant cross-section

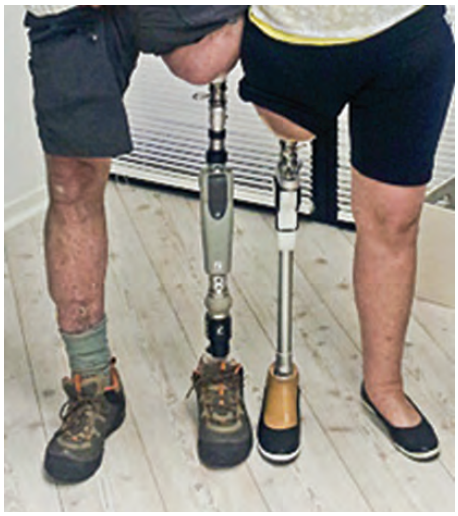
In subsequent years, teams in Europe, Asia, South America and Australia have published clinical studies on their results involving more than 200 patients, mostly transfemoral amputees but also including a significant number of upper-limb and a few transtibial patients.

The results indicate osseointegration can eliminate many problems inherent in prosthetic socket attachment for appropriate patients:

- end weight-bearing is restored;
- prosthesis control is enhanced and energy expenditure substantially reduced;
- risk of sudden prosthesis detachment from the body is minimized;
- common donning and doffing problems are resolved;
- user perception of the limb's place in space (proprioception) is much improved; and
- residual limb pain and skin breakdown caused by constant contact with the socket environment are virtually eliminated.

At the same time, osseointegration carries risk of infection, bone fractures and bone loss.

After more than two decades of development in centers around the world, osseointegra-tion is only now being investigated in this country.



The U.S. Food and Drug Administration recently approved a feasibility trial for an osseointegration implant designed at the University of Utah. The trial, scheduled to begin this summer, initially will involve 10 U.S. military personnel and veterans who have lost a limb, with future plans to expand the study to include up to 300 participants in a few years.

If this trial produces consistent positive results, the future course of prosthetic management in the U.S. could be in for some changes.

Quotable

"Don't listen to anyone who tells you that you can't do this or that. That's nonsense. Make up your mind you'll never use crutches or a stick, then have a go at everything. Go to school, join in all the games you can. Go anywhere you want to. But never, never let them persuade you that things are too difficult or impossible."

—Sir Douglas Bader (1910-1982), a British fighter pilot who lost both legs in a flying accident but still fought in World War II and subsequently was knighted for his work with the disabled. This quote is from his talk to a 14-year-old boy who had lost a leg in a car accident.