AOPA In Advance SmartBrief
Breaking News
October 4, 2018

AOPA Headlines:

AOPA Submits Comments on Draft Lower Limb Prosthesis Policy Released by Blue Cross Blue Shield of IL, TX. MT, NM, and OK

On October 1, 2018, AOPA submitted comments on a draft policy governing coverage of lower limb prostheses, including microprocessor-controlled prostheses issued by Health Care Services Corporation (HCSC), which operates Blue Cross Blue Shield of Illinois, Texas, Montana, New Mexico, and Oklahoma. The draft policy, as written will significantly reduce access to advanced prosthetic technology for BCBS subscribers in these five states. AOPA expressed its concern regarding the draft policy in its comments which are summarized below and linked at the end of this article.

AOPA's first concern is that HCSC published the draft policy on September 15, 2018 with comments due no later than October 1, 2018. AOPA commented that 15 days was not sufficient time to perform a complete review of the draft policy and provide informed comments. AOPA suggested a minimum 60-day comment period to allow stakeholders

adequate time to comment on the draft policy. Despite the unrealistic deadline, AOPA submitted comprehensive comments regarding the draft policy and negative impact it will have on BCBS subscribers.

AOPA commented that the draft policy is unnecessarily restrictive and will limit access to advanced technology, especially to BCBS subscribers who may be classified as limited community ambulators (K2) but may benefit more from receiving microprocessor-controlled prosthetic knees. AOPA refenced studies published by the RAND Corporation, the health economics firm Dobson-DaVanzo, and the Mayo Clinic that showed that the use of microprocessor-controlled knees by limited community ambulators reduced the rate of falls and fall related injuries. The draft policy would effectively eliminate BCBS coverage except for patients who were assessed as high functioning community ambulators (top percentage of K3 patients).

AOPA's comments also referenced the recent report of the inter-agency workgroup that was convened to provide a consensus statement on Medicare coverage of lower limb prostheses after the Medicare draft LCD was released several years ago. The inter-agency workgroup recommended the potential creation of a National Coverage Determination that would address Medicare coverage of microprocessor knee in K2 patients. AOPA's comments expressed concern that restricting access to advanced prosthetic technology was not in BCBS' best interest nor the best interest of their subscribers as it was contradictory to the consensus statement of the inter-agency workgroup and the overall health of their subscribers.

AOPA is hopeful that HCSC will seriously consider AOPA's comments before publishing the final version of the policy revision.

AOPA's complete comments may be viewed here.

AOPA 101st National Assembly Highlights

AOPA's 101st National Assembly proved to be another success for AOPA and the O&P community. Exhibitors and attendees came from over twenty countries, making it an insightful global event.

The exhibit hall opened with an original performance from MUSQUEAM – "People of the River Grass." The Musqueam people are the oldest known residents of Vancouver and have lived here for thousands of years.

The morning opening session featured key note speaker, Tobie Hatfield, senior director of athlete innovation for Nike. Following Hatfield's world class insights, were the Award Winning Thranhardt Lecture series.

The educational line-up included *Outcomes and Evidence-Based Practice in P&O: How are you Documenting Value in your Clinic and Using it to Improve Reimbursement?* Presenters of this panel included James Campbell, PhD, CO, FAAOP, Brian Hafner, PhD, Andreas Hahn, PhD, PE, Russell Lundstrom, MS, Brittany Pousett, CP(c), MSc, and Scott Sabolich, CP.

Friday morning's AOPA Annual Membership Business Meeting presented the Lifetime Achievement Award to C. Michael Schuch, CPO, FAAOP, FISPO (deceased). Barbara Schuch accepted the award on behalf of her husband. The Ralph R. "Ronney" Snell, CPO, FAAOP, Legislative Advocacy Award was presented to both Denise Hoffmann and Pam Lupo, CO. The Edwin and Kathryn Arbogast Award for best prosthetic abstract was presented to Katherine Ching from the University of Pittsburgh for *An Analysis of Internal Consistency within OPUS in Upper Extremity*. The Otto and Lucille Becker Award for best orthotic abstract was presented to Peter Zenger from the University of Pittsburgh for *Self-Efficacy Related to Education Level in O&P*.

Popular education sessions included, *Technology for Geriatrics, WHO Standards for Prosthetics and Orthotics (Policy, Products, Personnel, & Provision), Multi-disciplinary Panel on Rehabilitation of the Paretic Arm,* and *Business Management for Today's O&P Facility*, to name a few.

Saturday featured a key note by Mike Schultz, two-time Paralympic medalist, followed by a summation of Orthotics 2020 – Defending the Future of Orthotic Care, presented by Tom Fise, JD, and Nicholas LeCursi, CO, which discussed the establishment of the Medical Advisory Board (MAB) who are working cooperatively to advance non-branded studies and data to assess outcomes across identified categories of treatment. Five workgroups have been established to focus on the areas of stroke, osteoarthritis, cranial orthoses, scoliosis and spinal bracing.

Attendees enjoyed the various Special Events happening in the Exhibit Hall, such as the Slap Shot Hockey Game, sponsored by ALPS, with prizes up to $100 and the annual Technical Fabrication Contest with twelve winners totaling prizes of $4200. The Party with a Purpose fundraiser for AOPA's government relations efforts brought in over $30,000, at an exclusive party featuring a 1970's theme.

A special and resounding THANK YOU to the sponsors of the 2018 AOPA National Assembly! AOPA could not create such a successful event without our incredible sponsors.

See all the photos on Flickr and search #AOPA2018 on Twitter.

NIH and DOD Seek to Develop Limb Loss and National Preservation Registry

A new database supported by the National Institutes of Health and the Department of Defense aims to establish the number of people in the United States living with limb loss and to provide insight on their challenges and needs. The Limb Loss and Preservation Registry, expected to be operational in 2020 will be the first national registry of people who have lost limbs and promises to collect data that will improve prevention, treatment and rehabilitation efforts for this population.

"The Limb Loss and Preservation Registry addresses a significant public health knowledge gap," said Dr. Alison Cernich, director of the National Center for Medical Rehabilitation Research (NCMRR) within NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development. "The information housed in this database will be vital to preventing limb loss, improving amputation surgeries, refining rehabilitation approaches and guiding the development of devices for people with limb loss."

NCMRR leads NIH efforts to study recovery and rehabilitation after limb loss. NICHD has awarded a five-year contract, capped at $5 million, to the Mayo Clinic to develop and launch the registry. Registry data will include electronic health records of U.S. adults and children. Researchers studying diseases and conditions that can contribute to limb loss, such as vascular disease and diabetes, will have access to the registry, Dr. Cernich said.

Limb loss also can be caused by a traumatic injury, surgical procedure or through congenital amputation. The registry aims to represent the U.S. population, demographically and geographically. Researchers will be able to sort the data by age, gender and type of limb loss.

NIH is partnering with DoD on developing the registry in an effort to improve the quality of care for active military personnel, veterans and civilian members of the population. According to Dr. Cernich, there aren't enough amputations within DoD alone to provide a

sufficiently large sample from which to draw statistically valid conclusions. In addition, data available from DoD and the Department of Veterans Affairs do not include service members who leave the military and seek care in the private sector.

The Limb Loss and Preservation Registry highlights the ongoing coordination and collaboration among federal partners in rehabilitation research.

"The joint effort between federal agencies allows us to collect data that will inform research and improve the lives of all citizens coping with limb loss," Cernich said.

About the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD): NICHD conducts and supports research in the United States and throughout the world on fetal, infant and child development; maternal, child and family health; reproductive biology and population issues; and medical rehabilitation. For more information, click here.

O&P PAC Corner

The O&P PAC Corner provides information on the activities of the O&P PAC, including the names of individuals who have made recent donations to the O&P PAC and the names of candidates the O&P PAC has recently supported. We would like to thank the following AOPA member(s) for their recent contributions to the O&P PAC:

- Vinit Asar
- Devon Bernard
- Dale Berry, CP
- Jeffrey Brandt, CPO
- Jim Campbell, PhD.,CO, FAAOP
- Rick Fleetwood, MPA
- Brian Franklin
- Elizabeth Ginzel, CPO, LPO
- Denise Hoffman
- Eileen Levis
- Sam Liang
- Jeff Lutz, CPO
- Ann Mantelmacher
- Stuart Marquette, CO
- Brian Mayle
- Michael Oros, CPO, FAAOP
- Paul Prusakowski, CPO
- Scott Ranson
- John Roberts, CPO
- Cathy Rubel
- Scott Schneider
- Chris Snell, BOCP
- Clint Snell, CPO
- Ted Snell, P
- Wanda Stephans
- Sarah Stilley
- Terry Supan, CPO, FAAOP
- James Weber, MBA
- Chris Wilson
- Jon Wilson, CP
- Lilly Woodard
- Shane Wurdeman, CP, FAAOP, PhD, MSPO

The purpose of the O&P PAC is to advocate for legislative or political interests at the federal level, which have an impact on the orthotic and prosthetic community. The O&P PAC achieves this goal by working closely with members of the House, Senate and other officials running for office to

educate them about the issues, and help elect those individuals who support the orthotic and prosthetic community
To participate in, support, and receive additional information about the O&P PAC, please sign an O&P PAC Authorization card today.

Any questions please contact Devon Bernard at dbernard@AOPAnet.org.

RAC Audits for Custom Fabricated Knee Orthoses Announced

Performant Recovery, the national Home Health, Hospice, and DMEPOS RAC contractor, has announced that it will be initiating a post-payment complex medical review for custom fabricated knee orthoses (KO) described by HCPCS codes L1844 and L1846. Performant Recovery added the review to its list of approved issues on September 14, 2018. Providers whose claims are selected for review will receive a letter from Performant Recovery requesting relevant documentation to support medical necessity for the orthoses that was provided.

If you receive an additional documentation request (ADR) from Performant Recovery, it is very important to respond - failure to do so will result in automatic claim denial and recovery of any payments previously made. As with all RAC reviews, specific rules are in place that limit the number of ADRs that O&P providers may receive to a maximum of 10 ADRs per Tax ID every 45 days, and the lookback period for reviews is three years.

The RAC audit for custom KOs is the third O&P specific approved issue since the award of the new RAC contract to Performant Recovery. The RAC announcement on the audit of custom KOs may be found by **clicking here** and searching for issue 0107.

Questions regarding this issue may be directed to Joe McTernan at jmcternan@AOPAnet.org or Devon Bernard at dbernard@AOPAnet.org.

AOPA Submits Comments Regarding Improving the Medicare Gap Filling Process

On September 10, 2018, AOPA submitted formal comments to CMS regarding suggestions on how to improve the "gap filling" process that is currently used to establish Medicare fee schedule amount for new HCPCS codes. The opportunity to provide comments was the result of the annual proposed rule regarding Medicare coverage of End Stage Renal Disease (ESRD) and DMEPOS competitive bidding. The proposed rule requested suggestions from interested parties on how to improve the gap filling process.

Gap filling is used to establish Medicare fee schedules for new HCPCS codes. Current statutory requirements mandate that when a new code is issued, CMS establishes a base price for the device, deflates the price to 1986-1987 rates by applying the annual consumer pricing index for urban areas (CPI-U) and then re-inflates it by applying the annual update to the Medicare O&P fee schedule. Since the O&P update has not always equaled the CPI-U, gap filling results in a slightly lower price than the base price that was established for the device.

The gap filling process has never been transparent and represents an archaic and outdated process that does not consider important factors such as professional service and clinical expertise when calculating Medicare fee schedules. AOPA welcomed the opportunity to provide comments and made several suggestions it believes will greatly improve the current system.

AOPA's comments may be viewed here.

New Medicare ID Card Update

The new Medicare ID cards with a Medicare Beneficiary Identifier (MBI), instead of the Health Insurance Claim Number (HICN), are now being mailed to beneficiaries living in Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Texas, Utah, Washington and Wyoming.

Once beneficiaries receive their new MBI cards, they may start using them right away. You may continue to use either the HCIN or MBI through December 31, 2019.

Department of Veterans Affairs Office of Inspector General Issues a Report on VA Payments for Prosthetics

As many AOPA Members may already be aware, earlier this week, the Department of Veterans Affairs Office of Inspector General (VA OIG) issued a report regarding VA overpayments for prosthetic devices described by not otherwise classified (NOC) procedure codes. The full report may be accessed here.

The key paragraph in the report addresses purported overpayment by the VA to prosthetic providers of $7.7 million from October 2014 through July 2017. The paragraph reads as follows:

"The VA Office of Inspector General (OIG) substantiated allegations received in January and February 2016 alleging the Veterans Health Administration (VHA) was overpaying for prosthetic items because it incorrectly used Not Otherwise Classified (NOC) codes to classify the items for payment to vendors. Incorrectly using an NOC code can result in an overpayment because the payments are not based on pre-established reimbursement rates. For example, the Touch Bionics I-Limb, when classified with the correct code, costs VHA about $27,000. However, VHA paid vendors as much as $61,702 for the same item when classified using an NOC code. The OIG found that VHA overpaid vendors about $7.7 million from October 2014 through July 2017. The OIG found prosthetists incorrectly used NOC codes to classify prosthetic items when existing codes adequately described the items. Prosthetists incorrectly used NOC codes because they were either unaware of the existing codes or because they allowed vendors to classify the items with NOC codes. The incorrect use of NOC codes to classify some prosthetic items was not detected because the Prosthetic and Sensory Aids Service lacked a process to monitor the use of NOC codes. Because prosthetists incorrectly used NOC codes to classify prosthetic items for reimbursement, VHA paid more for the items. The OIG made five recommendations including determining which codes are appropriate to classify prosthetic items for reimbursement and issuing revised guidance, establishing an oversight and reporting structure that defines the roles and authorities to approve recommendations for the use of codes to classify specific prosthetic components, developing processes to monitor the use of NOC codes, and implementing processes to establish pricing guidance that ensures VA pays a fair price for items classified using an NOC code."

Fundamentally, The OIG's critique is based on the errant assumption that the Medicare code/HCPCS process and PDAC coding verifications are working appropriately. If that were true, the OIG conclusions in the report might be at least partially correct, but the assumption is false, and so the OIG criticism is wrong, missing the point. The situation reflected in the VA OIG report represents a clear, but unfortunate choice—will veteran

amputees receive the high quality of care to which virtually everyone in America says they deserve or will their access to advanced technology be limited due to an outdated and ineffective coding system. If the VA had followed the limitations of the Medicare-based HCPCS coding system and product verification, it is exceedingly unlikely that amputee veterans would have gained access to, and the benefits of these new technologies. Knowing this, key leaders within the VA prosthetics leadership identified a way to make sure amputee veterans could receive these newer devices—by providers using the Not Otherwise Classified—NOC codes.

Below is a summary of why the CMS-based coding system, also generally used by the VA is broken.

Is the Coding Process/System, and the Related Assignment of Pricing for New Prosthetic and Orthotic Products, in Its Obsession to Reduce Costs, Serving as an Impediment to Investment in Innovative Technologies That Could Benefit Medicare Beneficiaries?

Research and development (R&D) for health care—whether in pharmaceuticals or in devices, represents a substantial capital commitment of resources. Companies commit to R&D based on their expectation that the increased benefits and value of new, improved technologies will be recognized via higher, justified pricing and reimbursement. If pricing is locked regardless of increases in value, companies and their investors will refrain from substantial resource commitments that offer no return on the investment. This is a basic business concept and not hard to understand.

The group with proper authority for overseeing new code requests – Medicare's HCPCS Workgroup – presents profound challenges that severely discourage the introduction of new orthotic and prosthetic technology to market, and this disincentive is reinforced by an outdated pricing policy currently under examination. In an era of unparalleled technological innovation, where FDA records demonstrate that 98% of the new medical devices applications it processes are approved as to their safety and effectiveness, the number of applications to the HCPCS Coding Workgroup has *decreased*. Over the last 5 years, O&P manufacturers have submitted only 24 applications for new products, a nearly 50% decline when compared to the preceding 5 years (49 applications).

During the same 5-year period, the HCPCS Coding Workgroup has approved only two new O&P codes, one of which – a powered ankle-foot system for lower-extremity amputees – Medicare's contractors later designated as non-covered for all Medicare beneficiaries. This tells the story that only 4% of HCPCS code applications submitted over the last five years have resulted in a new device gaining access to Medicare beneficiaries, and less directly, to VA patients. These numbers suggest that the obstacles to both obtaining a code and maintaining coverage for it are stifling prosthetic and orthotic innovation.

Below are a few examples of significant new technologies where both patient access, and manufacturer return on investment have been severely hampered by regulatory actions that short-changed Medicare's recognition of significant advances because Coding and Pricing authorities were excessively locked into assuring that there be no increase in payment

commensurate in any way with either increased value, or manufacturer R&D investment needed to bring the product to market.

1. Ossur Pro-Flex was introduced as a new, highly dynamic foot design. Yet, it was classified according to predicate products that shared its basic design features even though the performance characteristics of the new product were very different from the predicate products it was classified as being similar to.

2. Bionix, powered ankle/foot—a relatively new product, which was issued a new HCPCS code (L5969) but with an unreasonable reimbursement amount. After 4 months the DME MAC contractors indicated that there was "insufficient information to demonstrate that the item meets the Medicare standard to be considered reasonable and necessary" and that claims for L5969 will be denied as not reasonable and necessary. The Medicare fee schedule for this code was subsequently eliminated. A code without any Medicare allowable is not a viable code that anyone will use. After years of effort by the manufacturer, it appears this inequity may be poised to be addressed and rectified.

3. Genium knee (mentioned specifically in the OIG report)—the manufacturer did not seek a new code, planning to await some research and clinical results with the product. The DME MACs took the initiative to assert that the device was NOT experimental and assigned the new device the identical allowable reimbursement as the preceding "C-leg" device, despite significantly advanced product performance largely attributable to advances in software—CMS has locked into hardware only, ignoring the valuable software advances that deliver better performance.

Turning to another dimension of coding and pricing policy for new orthotic and prosthetic technologies, the standards upon which the PDAC evaluates coding verification applications and the rationales underlying its decisions are not publicly available in any format. To the extent that industry experts can assess the reasoning behind the PDAC's coding decisions, they note that these determinations appear to rest only on the device's appearance not its performance characteristics, that is, what that same device actually *does* for the patients who need them[instead of whether it looks like the original 'predicate product, which may have been on the market for 30 years (does today's automobile *look* exactly like cars built 30 years ago, or *operate exactly the same way*?)]. As a result, prosthetic and orthotic manufacturers almost universally decline to voluntarily submit coding verification requests to the PDAC, a process which itself lacks transparency.

AOPA has tried for the past year to activate discussion, via a Roundtable or Joint Hearing whereby the House VA Health Subcommittee, and the House Ways & Means Health Subcommittee could gain a greater understanding of the many problems with the coding and product verification processes, and the adverse impact these can have on new product development and ultimately the adverse impact this has on both Medicare amputees, as well as amputee Veterans access to technology demonstrated in a recent report by the RAND Corporation to reduce serious falls, and death from falls by 450%.

The HCPCS coding system, and CMS coding verification are at best marginally functional, and at worst dysfunctional. We cannot address whether either the percent of the mark-ups or

reimbursements paid that are mentioned in the VA OIG report were appropriate. What we can say, is that VA personnel, the VA Coding committee, and the private sector contractors who serve the amputee veteran community were faced with the dilemma of how to try to keep the care for amputee veterans current with new technology, and assure that veterans who had sacrificed a limb in the service of their country received timely access to improved mobility, despite the profound problems with the coding and product verification systems used by Medicare. Perhaps they could have done a better job, which may have saved the VHA money, but the steps these parties took did undoubtedly improve Veterans access to quality care, and improved mobility.

AOPA has been working, and will continue to work, with others, including the O&P Alliance and the HCPCS Coding Alliance to rectify these shortcomings. We' will continue to keep AOPA members informed on our progress. The AOPA VA Committee, chaired by Frank Snell, is actively engaged on this report, and will be discussing this further when they meet at the AOPA National Assembly in Vancouver in late September.

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December 12, 2018	*New Codes, Medicare Changes & Updates* AOPA Webinar Learn more and register here