AOPA In Advance SmartBrief
Breaking News
September 4, 2018

AOPA Headlines:

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.

O&P News **Special Announcement**

The American Orthotic and Prosthetic Association (AOPA) continues its stride toward innovation by creating an online presentation and platform for O&P News. With an efficient website and click-ready flip-book, advertisers are more likely to garner viewership and gain exposure in the overall health-care arena. As always, AOPA strives to provide the best resources and value for our members, as we continue to expand the scale of the publication and both the numbers and therapeutic breadth of its readership through this new platform.

As of September 2018, O&P News will no longer produce a print edition. We value our readership and acknowledge the demand of ready and quick access to the latest articles. You will have immediate digital access across all device platforms. Digital subscription is easy, just fill out the postcard with your email information featured in O&P News August 2018 issue. Or subscribe at *bit.ly/OPNSubscribe.* We are excited to expand our reach across all platforms and are thankful for all our readers!

Mission:

Educate and inform health professionals who serve the greater limb-loss community and those living with mobility challenges.

Distribution:

O&P News targets the extended community of health professionals serving individuals living with mobility challenges and is their connection to relevant news from the world of orthotics and prosthetics.

With electronic distribution cresting 20,000 and print subscriptions over 12,000, it is clear that the O&P News audience is interested in receiving the magazine electronically. Therefore, AOPA has decided to begin electronic publication only beginning September 2018. August 2018 will be the last print issue.

Each issue will continue to feature clinical insights from top minds in patient care, research summaries, product news, and more.

Advertisers:

Advertisers continue to express interest in an integrated advertising approach of print and digital ads. This can now be accomplished through the print platform of *O&P Almanac* and the digital platform of *O&P News.*

Advertisers will receive the added benefit of reaching a broader audience through advertisements in the magazine flip book as well as banner ads on the website and in the email distribution of the magazine. Get additional punch for your advertising investment through the greatly expanded breadth of readers and accountability of O&P News. Contact Bob Heiman at 856-673-4000 or *bob.rhmedia@comcast.net* to secure your placement!

Don't miss an issue! Subscribe today by returning the postcard included with this issue of O&P News or visit *bit.ly/OPNSubscribe*.

Spinal Bracing RFP Extended to September 20th

AOPA, under the auspices of its Orthotics 2020 program, circulated a request for proposals early in 2018 relating to 5 subject areas for original orthotic papers, with the original deadline for receipt of applications by April 30, 2018. Proposals have been received in all five of those categories. This notification is to announce a **re–opening of the opportunity to submit grant applications/extension of the deadline for applications as to the two revised RFPs on spinal bracing (available below). Extensions do not apply to any of the other research categories/RFPs which have already advanced into the decision stage.**

AOPA will now be accepting applications for grants as to the two revised spinal bracing RFPs, available below, provided that they are received no later than **September 20, 2018 at 11:59 pm**.

In all other respects, except for this extended deadline date, all terms stated in the original AOPA announcements remain intact and in effect as to these two revised spinal bracing RFPs.

Please review closely the terms of the RFPs. One problem we have noticed with responses is that there were multiple scoliosis applications/research protocols submitted under the RFP for back

bracing. The category of back bracing is neither written nor intended to solicit submissions related to scoliosis. There may come a time when we will be looking for scoliosis papers, but this is NOT that time, so please do not commit your valuable time and energies to submitting scoliosis proposals in response to this back bracing RFP.

Back bracing is a very important and primary category in the orthotics profession. We have intentionally expanded the publication/notification /outreach to a broader audience of potential investigators toward submission of proposals as to these two revised spinal bracing RFPs. We will encourage and will welcome all high-quality submissions which are in accordance with the terms of the two RFPs.

2018 Clinical or Comparative Effectiveness RFP on Back Bracing and Factors on Favorable Patient Outcomes (FINAL 75)

2018 Clinical or Comparative Effectiveness RFP on Back Bracing and Factors on Favorable Patient Outcomes (S S-150)

Please contact AOPA staff at ymazur@AOPAnet.org with any questions.

Jurisdiction D Releases Quarterly TPE Results: Diabetic Shoes

Noridian, the Durable Medical Equipment Administrative Contractor (DME MAC) for Jurisdiction D, recently published the quarterly results of their Target, Probe & Educate (TPE) audits for Therapeutic Shoes for Persons with Diabetes. The audit results are based on claims for code A5500 reviewed during April 2018-June 2018 and they show an overall claim potential improper payment rate is **33%.**

The top denial reasons for the TPE results are:

- Documentation does not support basic coverage criteria
- Detailed Written Order (DWO) was not received
- Documentation was not received in response to the Additional Documentation Request (ADR) letter
- Medical record documentation was not received

View the complete results and a full list of denial reasons here.

Two New Issues Proposed for RAC Audits

On August 7, 2018, the Centers for Medicare and Medicaid Services published two new proposed issues for review by Performant Recovery, the Recovery Audit Contractor (RAC) for DMEPOS, Home Health, and Hospice claims nationwide. The two issues that have been proposed for RAC review are custom fabricated knee orthoses described by L1844 and L1846 and DMEPOS services delivered to a Medicare beneficiary during a Hospice benefit period.
The proposed RAC review for custom fabricated knee orthoses is a complex review meaning that claims will be reviewed to ensure that the knee orthoses delivered were medically necessary and meet the coverage guidelines outlined in the Medicare local coverage decision (LCD) and Policy Article for knee orthoses.

The second issue that has been proposed for RAC review is an automated review for DMEPOS services that were provided during a Medicare covered hospice benefit period. As hospice is considered a Medicare Part A benefit, claims submitted to Part B contractors, including DME MACs, are typically not covered as Part B services unless they are unrelated to the patient's terminal disease. When this is the case, providers are required to submit the claim with a "GW" modifier.

AOPA will continue to monitor both the CMS and RAC websites to confirm if and when these two issues are approved for RAC review.

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

Thank you to our Supplier Plus Members

Jurisdiction D Releases Quarterly TPE Results

Noridian, the Durable Medical Equipment Administrative Contractor (DME MAC) for Jurisdiction D, recently published the quarterly results of their Target, Probe & Educate (TPE) audits. The audits are based on claims audited/reviewed during April 2018-June 2018 and the results are as follows:

- Ankle Foot Orthoses/Knee Ankle Foot Orthoses (L4360, L4361, L4386 and L4387) had an overall claim potential improper payment rate is 34%. This is an increase over last quarter's overall claim potential improper payment rate of 19%.
- Knee Orthoses (L1810, L1812, L1830, L1832, L1833, L1843, L1845 and L1852) had an overall claim potential improper payment rate is 57%. This is a decrease from last quarter's overall claim potential improper payment rate of 77%.
- Spinal Orthoses (L0625, L0626, L0627, L0630, L0631, L0637, L0641, L0642, L0643, L0648 and L0650) had an overall claim potential improper payment rate is 51%. This is an increase over last quarter's overall claim potential improper payment rate of34%.

The top and common denial reasons for all TPE results (in no order) are as follows:

- Documentation does not support basic coverage criteria.
- Detailed Written Order (DWO) is incomplete or missing elements.
- Documentation was not received in response to the Additional Documentation Request (ADR) letter.
- Claim is the same or similar to another claim on file.
- Documentation does not include verification that the equipment was lost, stolen or irreparably damaged in a specific incident.

View the complete results and a full list of denial reasons here.

Questions? Contact Joe McTernan at jmcternan@AOPAnet.org or Devon Bernard at dbernard@AOPAnet.org

VA Roundtable Airs Broad Challenges to VA Proposed Rule That Would Limit Amputee Veterans' Choice between Private Sector and VA Care, Medical Necessity and Other Issues

On July 25, AOPA was among several entities represented at a Congressional Roundtable discussion conducted by the House Veteran's Affairs Health Subcommittee. The Roundtable was presided over by the Subcommittee Chair Rep. Neal Dunn, M.D. (R-FL) and Representative Julia Brownley (D-CA), with Rep. Annie Custer (D-NH) also attending a portion of the session. The list of participants is attached. Such roundtables are informal discussions with no sworn testimony and no recording of statements, to encourage a free exchange. The primary topic for the session was VA prosthetic care, with a distinct focus of the VA's proposed rule of October 16, 2017, including controversial provisions that would make VA the sole determinant of where a Veteran could receive O&P care (private sector vs. VA clinic)—thus it would limit the long-standing choice of provider afforded to many, if not all Veterans—and a tightening of the definition of medical necessity, along with brief discussion of other matters.

The session commenced with statements by Chairman Dunn, and Ranking Minority Member Brownley. Both opposed the two key changes, noted above, which the proposed rule would change, posing the question why now? And what is broken that needs fixing? The Chairman also specifically mentioned the need to assure training funds to aid in the education of new prosthetists for future generations of Veterans, specifically citing the NCOPE/AOPA supported work force study which targeted the need for a 60% increase in number of prosthetists to keep pace with retirements and expanding population (AOPA's lead advocate on that issue, Catriona Macdonald, was also present for the session).
AOPA emphasized that VA care needs to be focused in achieving both choice and quality of providers and their care for Veterans. Other topics discussed included brief discussions of the valuable clinical guidelines developed and being implemented by VA and possible expansion of patient outcomes efforts, as well as commentary by the VA OIG reps of purported excessive referral to private sector contractors for diabetic shoes and compression footware in Southern Nevada, and a brief mention of an upcoming OIG report of VA coding practices which intersects well with the final paragraph on the AOPA one-pager, namely ways in which current coding operate as an impediment to innovative technologies. There was also discussion supporting H.R. 2322, the Amputee Veterans Bill of Rights.

In addition to the VA Roundtable, AOPA reps—Executive Director Tom Fise, and Legislative Counsel Colin Roskey (Lincoln Policy Group) along with NAAOP's first Intern Advocate, Nicole ver Kuilen met with Senator Tammy Duckworth (D-IL). The AOPA reps provided a briefing, update

and request for support with topics discussed including: implementation of the prosthetist/orthotist notes provision; latest status of the CMS July 2015 draft LCD and the DME MAC Dear Physician Letter (both now withdrawn though deliberations on LCD-related issues remain active and volatile); S.1191—remaining sections including the section on reinforcing the 'minimal self-adjustment' definition that distinguishes OTS orthotics from custom-fitted and custom-fabricated orthotics; VA matters; and the MEDPAC report on orthotics.

Picture, Seated: Senator Tammy Duckworth (D-IL) and 2018 NAAOP Advocacy Intern Nicole ver Kuilen
Standing AOPA Executive Director, Thomas Fise and AOPA Legislative Counsel Colin Roskey.

Click here to view the one-pager which AOPA distributed to all participants which underscores O&P perspectives on several VA issues.

Attend the Las Vegas Coding & Billing Seminar November 12-13

The Tropicana Las Vegas
3801 S Las Vegas Blvd
Las Vegas, NV 89109

AOPA experts provide the most up-to-date information to help O&P Practitioners and office billing staff learn how to code complex devices, including repairs and adjustments, through interactive discussions with AOPA experts, your colleagues, and much more. Meant for both practitioners and office staff, this advanced two-day event will feature breakout sessions for these two groups, to ensure concentration on material appropriate to each group.
At this seminar you will:

- Receive up-to-date information on Prior Authorization and other Hot Topics
- Ensure your Proof of Delivery meets Medicare Requirements
- Learn how to assess risk areas in your practice
- Learn successful appeal strategies and hints to avoid claim denials
- Practice coding complex devices, including repairs and adjustment
- Attend break-out sessions for practitioners and office staff
- Earn 14 CEs

Register Now

RSVP for the 2018 Party With a Purpose

Mark your calendars and attend the "Party With a Purpose" on Thursday, September 27 during the 2018 AOPA National Assembly in Vancouver. Be there or be square and wear your grooviest threads, as we celebrate and re-live the fabulous 1970's! The night includes dinner, a costume contest, Dr. Disco, a dance off, and much more! This is a special event and certain rules and restrictions may apply. For additional information about the Party with a Purpose or to register, contact Devon Bernard at dbernard@AOPAnet.org.

Upcoming AOPA Events

September 12, 2018	*Medicare as Secondary Payer: Knowing the Rules* AOPA Webinar Learn more and register here
September 26-29, 2018	AOPA National Assembly Vancouver, Canada Learn more and register here
October 10, 2018	*Year End Review: How to Wrap-Up & Get Ready for the New Year* AOPA Webinar Learn more and register here