Molecular pathology CPT codes; payment and coverage

During the public meeting for the new Clinical Laboratory Fee Schedule (CLFS) services on July 14, AMP was represented by Aaron Bosslar and Roger Klein who commented regarding pricing for the new Gene Sequencing (GSP) CPT Codes. Our concern is focused in the Proteging Access to Medicare Act (PAMA) bill, respectively. The new CPT book will be released in September.

Representatives from the AMP EAC met with Tamara Synek-Jensen, Director, CMS Coverage and Analysis of Clinical Coverage (AC2) to discuss Medicare coverage of in vitro diagnostic testing and AMP’s concerns with the expansion of the Palmetto MdRx program, PAIM implementation, and retroactive payments for CPT Tier 1 and 2 codes.

AMP responded to several new LCDs issued by NGS, CDS, and First Coast and expects to respond to ones from Capataza and Noridian as well. In addition to commenting on LCDs and engaging with the AC2, several AMP members are monitoring CMS documentation, especially with regards to Medicare and coverage of PGx and rare disease tests.

AMP submitted comments on the proposed 2015 Physician Fee Schedule. Those comments can be accessed here: http://bit.ly/1fii0tI.

On July 24, A Call to Action was sent to AMP members requesting participation in an important AMP project: Micro-costing and Health Economic Value Analysis of Genomic Sequencing Procedures (GSPs). Thank you to those that responded! Boston Healthcare Associates is collaborating with the AMP to collect information about laboratory workflow and professional interpretation to support documentation of the full cost of performing GSP assays (specifically Whole Exome, targeted solid organ neoplasms, and panels such as X-linked intellectual disability or Hearing Loss). Information will also be collected to demonstrate the value of next generation sequencing assays, which will be critical to establishing a favorable reimbursement and market access environment. If you would like to participate or have questions, please contact the AMP NGS Pricing Project Katherine Tyrnan (Katherine.tyrnan@timandco.com).

NGS CPT Code Proposal

AMP will be submitting CPT code change proposals in November for 2016 publication.

 Oversight of LDTs and Companion Diagnostics

In early July, five Senators sent a letter to the Office of Management and Budget (OMB) in the White House pressuring them to publish the draft guidance documents establishing a framework to regulate LDTs. AMP has underscored the need for those offices to discuss this policy issue. Specifically, AMP met with Senators Durbin (D-IL), Brown (D-OH), Warren (D-MA), and Markey (D-MA). In the meeting, AMP confirmed that they do not have a position on the FDA regulation of LDTs, but rather, they are concerned about the delay in the OMB finalizing rules and cited the LDT guidance documents as an example. AMP will continue to engage Congress on this important issue.

On July 31, 2014, the FDA notified Congress that in at least 60 days they intend to publish a draft guidance document entitled Framework/Regulatory Oversight of Laboratory Developed Tests (LDTs) (Framework Guidance) and an accompanying draft guidance document entitled FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs) (The Notice). The FDA is analyzing the proposed policy and intends to continue meeting with Hill offices and also the FDA to express its concerns.

The AMP Professional Relations Committee will host a webinar titled: "Laboratory Developed Test (LDT) Oversight and the Potential Impact on Clinical Practice" presented by Roger Klein and Jennifer Leib on Tuesday, September 16 at 1:00pm (Eastern). Register online now at: https://www2.gotomeeting.com/register/84454610

White Papers

Separate whitepapers addressing threats to the field of molecular pathology and clinical utility, respectively, are in process.

Capitol Hill

Frank Corkerill participated in the 21st Century Cures Roundtable on Personalized Medicine on July 23, in which he noted AMP’s name, the current need for appropriate payment, and indicated that PHOs should be recognized as Qualified Healthcare Professionals.

Over 70 AMP members are expected to participate in AMP Advocacy Day on November 12, 2014! We aim to educate Congressional offices on the following themes:

1. The value of molecular testing and the critical role of the molecular professional to positively impact patient care.
2. The potential impact of the FDA draft guidance on oversight of LDTs.

AMP at Work for You

There’s still time to volunteer to serve as a member of AMP’s Membership Affairs Committee. Applications are due by September 15, 2014 at 11:59 PM EST. Notification of appointments will be made in early October. All members are encouraged to apply, particularly those with an interest in infectious diseases or informatics. Apply online at http://bit.ly/1Dhp4Dk.

Applications are being accepted for free registration for the AMP Online Molecular Genetic Pathology Review. This opportunity is for members outside the U.S. Preference will be given to those in low income countries per the World Bank Classifications. Eligible members may apply online at: http://bit.ly/1dlyfD9. The deadline to apply is September 10.

The Membership Affairs Committee and the International Affairs Working Group look forward to hosting a number of special events during this year’s Annual Meeting. All of these events take place on Thursday, November 12:

• "Caffeinate Your Career" Early Bird Session, hosted by the MAC
• New Members & First Time Attendees Luncheon, hosted by the MAC
• Global Molecular Pathology Network Luncheon, hosted by the IAWG

Details about these and other special events to be held during the AMP 2014 Annual Meeting are online at: http://www.amp.org/meetings/2014/specialevents.cfm.

AMP at Work for You

Members of the AMP Clinical Practice Guidelines Development Group for the Evaluation of Molecular Markers for Colorectal Cancer will be presenting the status of their work at the AMP 2014 Annual Meeting on Saturday, November 15 from 10:45am – 12:15pm. The representatives for AMP are Antonia Sepulveda (Co-Chair), Federico Moronzo, Noralane Lindor, and William Furnhouse.
The AMP Publications and Communications Committee continues to invite case report articles for possible submission to CAP TODAY. View prior articles, take the self tests, and read about submitting a report online at:

http://www.amp.org/publications_resources/AMPCaseReviews.cfm

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