ASSOCIATION FOR MOLECULAR PATHOLOGY
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James J. Corcoran, MD, MPH
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Re: Draft Local Coverage Determination Noncovered Services (DL33777) HHV-6

Dear Dr. Corcoran:

Thank you for the opportunity to comment on this draft local coverage determination policy. The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

Coverage for Herpes Virus Type 6 (HHV-6)

AMP requests that First Coast provide coverage for HHV-6 testing. In particular, HHV-6 re-activation occurs in 30 to 70 percent of cancer patients undergoing allogeneic hematopoietic stem cell transplantation, with subsequent encephalitis (and significant morbidity and mortality) in a minority of these patients. HHV-6 reactivation usually manifests as HHV-6 viremia, and typically occurs between two and four weeks after transplantation. Strategies to prevent, detect, and manage these infectious complications improve transplant outcomes. In particular, detection of HHV-6 viremia (or in in the cerebrospinal fluid) in an immunocompromised host would necessitate treatment with anti-viral agents, which have been shown to improve outcome (NCCN Prevention and Treatment of Cancer-Related infections Guidelines). According to NCCN Guidelines, the "preventive measures for infection management in patients with cancer include routine surveillance to monitor for early laboratory indications of infection (especially in the context of viral reactivations) and the appropriate use of prophylaxis and/or preemptive therapy with antimicrobial agents in high-risk patient groups." (NCCN Prevention and Treatment of Cancer-Related infections Guidelines). Because virtually every adult has been infected with HHV-6 in childhood, serologic methods for assessing viral exposure in the context of acute viral re-activation are of no clinical utility. The preferred laboratory method for directly detecting HHV-6 reactivation is qualitative or quantitative detection of HHV-6 DNA by PCR-based methods (Ogata, 2013).

We request that the following CPT codes be removed from the list of noncovered services on the basis that the HHV-6 PCR assays associated with these CPT codes are medically necessary for the diagnosis and therapeutic decision making in immunocompromised patients.

- 87532 INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); HERPES VIRUS-6, AMPLIFIED PROBE TECHNIQUE
- 87533 INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); HERPES VIRUS-6, QUANTIFICATION

We respectfully ask that you consider these comments which were prepared by members of AMP who provide services to Medicare beneficiaries covered by First Coast. We are happy to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this draft LCD. Please direct your correspondence to Tara Burke, AMP Senior Policy Analyst, at tburke@amp.org.

Sincerely,

Federico Monzon, MD
President, AMP

References

Arbuckle, Jesse H.; Medveczky, Peter G. (2011). "The molecular biology of human herpesvirus-6 latency and telomere integration". Microbes and Infection. 13 (8–9): 731–41. doi:10.1016/j.micinf.2011.03.006. PMC 3130849Freely accessible. PMID 21458587.

FDA Approval for Belinostat. National Cancer Institute. https://www.cancer.gov/about-cancer/treatment/drugs/fda-belinostat. Published July 8, 2014. Accessed November 13, 2016.

FDA approves Farydak for treatment of multiple myeloma. (2015, February 23). Retrieved November 13, 2016, from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm435296.htm

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Prevention and Treatment of Cancer-Related Infections, Version 2. 2016. NCCN.org

Ogata et al. Human herpesvirus 6 (HHV-6) reactivation and HHV-6 encephalitis after allogeneic hematopoietic cell transplantation: a multicenter, prospective study. Clinical infectious diseases, 2013, 57(5):671-681.

Scheurer ME1, Pritchett JC, Amirian ES, Zemke NR, Lusso P, Ljungman P. HHV-6 encephalitis in umbilical cord blood transplantation: a systematic review and meta-analysis. Bone Marrow Transplant. 2013 Apr; 48(4):574-80. doi: 10.1038/bmt.2012.180. Epub 2012 Sep 24.