COLLEGE of AMERICAN PATHOLOGISTS

Medicare Administrative Contractors' Local Coverage Determination (LCD) on Special Histochemical Stains & Immunohistochemical Stains

Background

The LCD on IHC ("The LCD") issued by Medicare Administrative Contractor (MAC) Palmetto GBA for North Carolina, South Carolina, Virginia and West Virginia was effective as of March 16, 2015. Since that time, identical or substantially similar versions of the LCD have been proposed by three additional MACs (Noridian, covering Alaska, Arizona, California, Hawaii, Idaho, Montana, North Dakota, Nevada, Oregon, South Dakota, Utah, Washington, and Wyoming; Cigna Government Services (CGS), covering Kentucky and Ohio; and First Coast, covering Florida, Puerto Rico, and the Virgin Islands). The drafts are not yet effective in those jurisdictions.

Amongst other concerns, the LCD places limits on special stains ordered by pathologists to assist them in making the correct diagnosis for the patient in areas such as breast cancer, gastrointestinal diseases, prostate disease, lung cancer, tumor profiling, cervical/GYN/bladder/kidney tumors, skin/soft tissue and peripheral nervous system lesion and bone marrow samples.

CAP review of the IHC LCD

CAP's comments to Palmetto, Noridian, CGS, and First Coast were developed by over 40 pathologist experts in the areas covered by the LCD. CAP's comments included 28 evidentiary challenges supported by over 53 citations from published scientific literature, including generally accepted guidelines of national organizations.

Palmetto made only three revisions to its final LCD, all of which were adopted in the draft LCDs issued by the other MACs that have proposed that policy. Palmetto's published response to comments on the draft LCD did not address many of the issues CAP raised or was not responsive in many instances.

The LCD used highly selective and partial literature citations, took references out of context, overlooked fine points, misrepresented the opinions of national organizations, and is contrary to generally accepted guidelines. Some examples include:

- The LCD's standards on Lynch Syndrome tumor screening for DNA mismatch repair are not only incorrect, but also inconsistent with current National Comprehensive Cancer Network ("NCCN") guidelines, the recent American Society of Clinical Oncology ("ASCO") clinical practice guideline endorsement, and the Evaluation of Genomic Application in Practice and Prevention ("EGAPP"), a project sponsored by the Office of Public Health Genomics at the Center for Disease Control and Prevention.

- NCCN guidelines also contradict the LCD's rules on the use of special stains on cases with morphologically negative cores.

- The LCD's determination that pathology practices should not exceed ordering of more than 20% of special stains on all gastric biopsies is based on one limited study that is not generalizable to all practices.

Other concerns are:

- Despite the evidence, Palmetto's final LCD is not reviewable. Such review would

require new evidence to be presented.

- The LCD encroaches on pathologists' medical judgment to order the appropriate number of stains based on patient characteristics.
- The LCD's lack of clarity leaves neither providers nor patients able to prospectively determine in what circumstances special stains can be ordered by a pathologist to determine the correct diagnosis.