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CMS Local Coverage Determination (LCD) L35986 – Ohio and Kentucky MoIDX: Special Histochemical Stains and Immunohistochemical Stains

CGS, Medicare's Administrative Contractor (MAC) for Ohio and Kentucky, recently released LCD L35986 that details coverage indications, limitations and medical necessity policy for special stains and immunohistochemical stains that became effective October 1, 2015.

Citing Medicare's Benefit Policy Manual (Chapter 15) this policy identifies general medical necessity criteria for performing additional tests, such as special stains, that haven't been requested by the treating practitioner, but the pathologist feels are needed. These can be performed by the pathologist under the following circumstances.

- Services are medically necessary for a complete and accurate diagnosis to be rendered and reported to the treating practitioner;
- Results of the test are communicated to, and used by, the treating practitioner in the treatment of the patient; and
- The pathologist documents in the surgical pathology report why the additional testing was done

Much scrutiny has been directed to the use and billing of special stains and especially IHC stains over the past few years. For example, Medicare's Comparative Billing Report (CBR201407) in the summer of 2014 focused on these services specifically performed on gastric and combined gastric/colon biopsies provided to Medicare Part B beneficiaries in 2013. The study was based on statistical debriefing developed to define the national and state averages derived from national claims data analysis. At that time, five thousand pathologists across the country received a report reflecting the frequency of their individual billing or referral patterns for IHC and special stains that were deemed to deviate from the calculated standards.

This LCD released by CMS does not designate specific special stains and/or IHC stains and how they should be used clinically, but rather, illustrates the common scenarios that may be promoting medically unnecessary over-utilization or incorrect billing of these services such as:

- Reflex templates or pre-orders for special stains and/or IHC stains prior to review of the routine H&E stain by the pathologist
- Use of special stains and/or IHC stains without clinical evidence that the stain is actionable or provides the treating physician with information that changes patient management
- Use of added stains when the diagnosis is already known based on morphologic evaluation of the primary stain



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Coverage policies, rationale and guidance are defined in the link indicated below for clinical conditions including pathologies of the:

- Breast
- Prostate
- Lung
- GI
- Cervical
- GYN
- Bladder
- Kidney
- Skin/Cutaneous/Soft Tissue
- Peripheral Nervous System
- Bone Marrow
- Chemosensitivity and Resistance Tumor Profiling

For the full text of this Medicare policy, visit the below website:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35986&ContrId=238&ver=3&ContrVer=2&CtrctrSelected=238*2&Ctrctr=238&s=All&DocType=Active%7cFuture&bc=AggAAAIAAAAAAA%3d%3d&