

## Updates to Stain Coverage Coming in June 2025

Key revisions will be implemented by CMS, effective June 8, 2025 for Local Coverage Determination L35986 pertaining to medical necessity for IHC and special stains in several types of specimen pathologies. Feedback and collaboration with CAP, ASCO and NCCN helped inform these updates.

Notable updates include:

- **GI Pathology - Lynch Syndrome Screening:** Age restriction removed.  
Previously, IHC testing for mismatch repair proteins was covered for colorectal cancer patients up to age 70, and for those over 70 meeting certain Bethesda guidelines, as well as for individuals with endometrial cancer. The June revision removes the age restriction and covers MMR IHC for all individuals with newly diagnosed colorectal or endometrial cancer, per updated NCCN Guidelines.
- **Breast Pathology - Ki-67:** Recognized prognostic value.  
Routine testing of all breast cancers with Ki-67 IHC is not recommended. However, this update does concede that Ki-67 has prognostic value in patients with ER+/HER2- lymph node positive breast cancer to inform therapeutic treatment.
- **Documentation Guidelines:** This LCD update also re-emphasizes the importance of documentation support for medical necessity for each stain by indicating the block(s) tested, rationale, specific markers, and single vs cocktail antibodies. Generic statements such as "IHC confirms diagnosis" may not be covered as reasonable or medically necessary. Report documentation should indicate review of H&E prior to ordering IHC, clinical evidence should support the use of the stain to inform patient management, and the pathologist should avoid over-utilization by refraining from added stains when the diagnosis is already known.

This LCD is being adopted by CGS (KY and OH) and is expected to expand to Noridian according to the College of American Pathologists, who began advocating for this change in 2021.

APS will continue to monitor denials for documentation and will notify clients of any documentation improvement opportunities. Link to full LCD listed below. If you have any questions, please contact your Practice Manager.

[LCD - Special Histochemical Stains and Immunohistochemical Stains \(L35986\)](#)