

Medicare's Palmetto GBA and WPS Finalize their Updated Policies for Special Stains and IHC Stains

For reimbursement of provider services, Medicare's Rule Number One is that the services must be reasonable and necessary. Two Medicare Administrative Contractors (MACs), Palmetto GBA and WPS, recently finalized their Local Coverage Determinations (LCD) outlining updated medical necessity guidelines for special stains and IHC stains. Pathology and lab providers in those jurisdictions will want to familiarize themselves with the updates that become effective July 14, 2024, to ensure that their ordering practices and documentation of medical necessity for stains meet the new policy criteria for payment.

Palmetto GBA – <u>L35922</u> – covers Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia

WPS – <u>L36805</u> – covers Indiana, Iowa, Kansas, Michigan, Missouri, and Nebraska

The policies identify medical necessity for the use of special stains and IHC stains and both state that Medicare will only cover the stains ordered by pathologists when all of the following conditions have been met:

- they are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician;
- results of the stains are communicated to and are used by the treating physician in the treatment of the patient; and
- the pathologist documents in the pathology report why the additional stains were performed

Also addressed are scenarios that Medicare has found on claims review can drive medically unnecessary over-utilization or incorrect billing such as:

- Reflex templates or pre-orders for special stains and/or IHC stains prior to review of the routine hematoxylin and eosin (H&E) stain by the pathologist; or
- 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; or
- Use of added stains when the diagnosis is already known based on morphologic evaluation of the primary stain

The LCDs further describe that reflex templates or pre-orders for special stains and/or IHC stains prior to the review of the routine H&E stain by the pathologist are not reasonable and necessary, with limited exceptions such as "...renal, liver, and neuromuscular biopsies, and for the suspicion of an infectious disease, particularly in an immune compromised patient. In certain clearly defined circumstances, it may be reasonable to perform some IHC on sentinel lymph nodes when the frozen sections show they are free of tumor."

Both LCDs state that results of the stains must be documented in the pathology report, and specify that a statement alone to the effect of "IHC confirms the diagnosis" will not be covered as reasonable and necessary.



Providers are encouraged to review the specimen-specific portions of the LCDs where applicable to their clinical practices as these sections have been revised as well.

With these updated LCDs, providers should prepare for more scrutiny of their documentation for special stains and IHC stains. It is important to note that, while these particular LCDs apply to the Palmetto GBA and WPS jurisdictions, it would not be surprising to see other Medicare MACs and/or commercial insurers adopt the same, or similar, guidelines.

Should you have any questions, please contact your Practice Manager.