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Follow Up to CMS' Local Coverage Determination (LCD) L35922 (IHC/Special Stains)

This white paper is a follow up to our recent newsletter and white paper articles that we have sent out regarding Medicare's special stain LCD (L35922). As you may recall, this LCD provides guidelines for the charging and billing of IHC/special stains for certain specimen types. This LCD provided guidelines that were acceptable by Medicare for meeting medical necessity when performing additional staining services. According to Medicare, the ordering of special stains up-front or on every specimen type may be promoting medically unnecessary and/or over-utilization and incorrect billing for such services. You may recall that, according to Medicare, the following areas that need to be addressed in ordering special stains:

- Reflex templates or pre-orders for special stains/or IHC stains prior to review of the routine H&E stain by the pathologists
- 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

Following are questions that we've received from our clients regarding this LCD:

Q. As this LCD does not address the issue regarding special stains ordered on the front end by the treating/attending physician, can the pathologists still order H.Pylori stains prior to H&E review if requested by clinicians on the front end? Is this sufficient to justify performing a special stain for H. Pylori prior to reviewing the H&E stain?

A. Per the American Pathology Foundation (APF), the LCD from Medicare for the use of special stains was based on the lack of medical necessity for the stain according to 2 research studies. As noted in one study, "...exceedingly unlikely to find a patient with H. pylori infection who does not have at least moderate plasmacytic infiltration. The policy is set to deter automatic reflex staining of all gastric biopsies prior to the review of the H&E stain. We highly recommend NO routine reflex staining prior to the review of the H&E slide."

Per representatives at APF, the up-front order for a special stain does not establish medical necessity nor does it meet the requirement of having evaluated the specimen with the H&E stain first.

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Q. If gastric biopsies come from the clinician with the request to “R/O H.Pylori” or “R/O HP,” is this sufficient to justify the special stain prior to reviewing the H&E?

A. No. R/O does not fulfill the medical necessity of additional ancillary staining. Also, CMS and other insurers resist paying for procedures that “rule out” a condition.

So, what would you need to document in order to support medical necessity in the pathology report? The pathologist should link what is seen on the H&E slide with the medical indication for the special stain, such as:

- “The H&E stain shows moderate inflammation without evidence of organisms. However, the indicated Giemsa stain shows rare H. pylori bacteria."
- “Chronic gastritis is present. I could not see H.Pylori on routine stains so I performed an immunostain for H.Pylori on block 1A”

It is recommended that you review your process for ordering IHC/special stains and review report documentation to support medical necessity and demonstrate review of the H&E slide.

If there are any other questions you may have, please contact your Practice Manager.