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Laboratory Agrees to $601,000 Settlement for False Claims Act Allegations Related to Special Stain Utilization

On May 2nd, 2017, it was announced that Piedmont Pathology, P.C. in Hickory, N.C. agreed to pay the United States $601,000 to settle allegations that it violated the False Claims Act by submitting false claims to Medicare and Medicaid for procedures that were not medically necessary. These allegations were brought to light from a lawsuit filed by whistleblower, Dr. Kim Geisinger (the Relator), a pathologist who formerly worked for Piedmont Pathology. Under the False Claims Act, private citizens can bring suit on behalf of the government for false claims and share in the recovery. Once the case is filed, the United States may choose to take over the case or allow the Relator to pursue the case. Dr. Geisinger will receive around $120,200 from the recovery announced on May 2nd. The claims settled by this lawsuit are allegations only and there has been no determinations of liability.

The merit behind this filing stems from an LCD implemented in October 2015 by Palmetto GBA (L35922). Palmetto GBA has been at the forefront of aggressive actions taken to reduce what the MAC considers to be waste related to the utilization of Special Stains. Prior to the transition to ICD-10, Medicare MACs relied on LCD's for IHC stains that were driven by diagnosis accompanying the charge to make payment determination. In 2014, Palmetto released on its website an educational article related to use of Special Stains on gastric biopsies. This article contended that the total number of gastric biopsies requiring special stains should be equal to or less than 20%. The College of American Pathologists (CAP) issued a formal complaint with CMS shortly after it was published and the MAC removed the article. From there, the first draft of L35922 was created.

L35922 does not provide "allowed" (payable) diagnosis for Special Stains. Instead, the LCD provides guidelines for general medical necessity for performing additional tests, such as Special Stains, that haven't been requested by the treating practitioner, but the pathologist feels are needed. The LCD also illustrates the common scenarios that may be promoting medically unnecessary over-utilization or incorrect billing for 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

The full LCD can be found here:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35922&ContrId=381&ver=8&ContrVer=1&CntrctrSelected=381*1&Cntrctr=381&name=&DocType=Active&s=34%7c48%7c53%7c58&bc=AggAAAQAAAAAAA%3d%3d&

The specifics as to how the Relator and the United States feel medical necessity were not met by Piedmont Pathology have not been made public. What is clear is that CMS expects a review of the H&E stained slides prior to ordering any additional testing to determine a diagnosis. APS has written multiple White Papers regarding this topic over the past 2 years. For copies of these or additional questions, please contact your Practice Manager.