

CAPITOL STREET

August 10, 2023

Novitas & First Coast Oncology Genetic Testing LCD

Public Meetings This Week: Outlook, Next Steps

Relevant Companies



On July 27, 2023, Novitas & First Coast (Medicare contractors, or MACs) extended the comment period on a local coverage determination (LCD) "Genetic Testing for Oncology" that reflected a final, restrictive policy for about 13 cancer tests. The LCD restricts coverage in the Medicare population for oncology related DNA and RNA genetic testing. The two Medicare Administrative Contractors have made clear that many of these new innovations in MedTech, though promising, are at present misused, inappropriate, and overly complicated. As a result, beneficiaries are accessing high-priced tests that illustrate little clinical or financial benefit. Report is [here](#).

»» Our Take & Next Up

Novitas/First Coast are holding open meetings on the oncology testing LCD August 10 & August 11 (First Coast [here](#) and Novitas [here](#)). We expect this final policy may be implemented largely as proposed sometime after the comment period deadline (9/9/2023). LCDs can take up to a year after the comment period before enactment, however, this may be <6 months for finalization. As a reminder, the original LCD for Genetic Testing for Oncology -- set to start July 17, 2023 -- surprisingly denied coverage (last-minute) for 13 tests (MAAAs) and now the two Medicare contractors, Novitas & First Coast, have opened a new LCD that follows the final decision which we view as negative for test makers, including Castle.

»» Key Points

The final LCD [released](#) June 2023 denied coverage for all current molecular biomarker tests that risk-stratify people with cutaneous squamous cell carcinoma, including the DecisionDx-SCC & DecisionDx-Melanoma tests (Castle). The decision was due to lack of clarity on how results impact and change patient management. Castle was not alone, it was among thirteen genetic tests deemed "not medically reasonable and necessary." They include Cxbladder Detect (PEB NZ), Enhanced

Cxbladder Detect (PEB NZ), Cxbladder Monitor (PEB NZ), Cxbladder Triage (PEB NZ), Enhanced Cxbladder Triage (PEB NZ), Cxbladder Resolve (PEB NZ), ThyroSeq CRC (SKHHY), PancraGEN (IDXG), DecisionDX-Melanoma (CSTL), DecisionDX-SCC (CSTL), UroVysion FISH (ABT), Colvera (CSRIO), PancreaSeq Genomic Classifier (Univ of Pittsburgh Med Center). NOTE: many of these are MAAAs (multi-analyte assays with algorithmic analysis) ...

Contact us to keep reading and learn more.

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