August 10, 2023

Novitas & First Coast Oncology Genetic Testing LCD

Public Meetings This Week: Outlook, Next Steps

Relevant Companies

Interpace Biosciences® CASTLE BIOSCIENCES Abbott SONIC HEALTHCARE

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).

Guideline/database exclusion (versus inclusion) was the basis for Medicare coverage. A new public comment period for the proposed LCD ends September 9, 2023. The original non-coverage was due to not being listed in one of the three major databases: NCCN, NCI/NIH, MSK. Tests were deemed to be not deliberated by a NCCN panel under the NCCN guidelines for clinical evaluation of evidence; NIH database, ClinGen; or the Memorial Sloan Kettering Cancer Center Oncology Knowledge Base, OncoKB. Therefore the tests were deemed "unreasonable and unnecessary," including lack of evidence, little follow-up data, low efficacy, and complicated procedures.

Why discontinue Medicare reimbursement for CSTL's DecisionDx-SCC? DecisionDx-SCC is a GEP test used to identify patients with a high risk of metastasis in cutaneous squamous cell carcinoma (cSCC). Evidence based research, conducted by Novitas, concluded that due to the lack of data, study outcomes, and patient follow ups, this test does not provide any evidence of validity or utility within the Medicare population. CSTL has been reimbursed by the Medicare Administrative Contractor, Novitas, since Q2 2022. CSTL's CEO noted though there are unknowns regarding future coverage, DecisionDX-SCC provides "significant unmet clinical need in the SCC space" illustrated by recent data, and the new Advanced Diagnostic Laboratory Test (ADLT) status granted by CMS, along with recent work in a large multicenter cohort study. This data has not yet been released.

Palmetto MolDX typically establishes coverage for diagnostic tests, so why did the other MACs go rogue? Palmetto's MolDX program was developed to establish coverage and reimbursement determinations for molecular diagnostic tests. MolDX comes to its final decision on a test by studying 3 different criteria: "test registration and ID assignment, application review, and coverage determination and reimbursement". We wonder about Palmetto's place in the coverage world with its comprehensive technical assistance (TA) process, if two other Medicare contractors can provide and pull back coverage for diagnostic testing in whiplash fashion.

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