Genetic Testing for Oncology (DL39365): C21 Recommendations on Proposed LCD

Public Open Meeting

August 11, 2023

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Coalition for 21st Century Medicine

The Coalition represents the world's most innovative diagnostic technology companies, clinical laboratories, researchers, physicians, and venture capitalists—all linked by a common mission: to develop and commercialize state-of-the-art diagnostics that improve patient health.

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Summary of Key Points

- **C21 appreciates Novitas' review of genetic diagnostic tests and efforts to develop transparent coverage policy**
- **C21 respectfully requests that Novitas convene a CAC to discuss clinical utility for the 13 tests for which Novitas is proposing to eliminate existing coverage**
  - **Many of these tests have been covered for numerous years, and the proposed LCD represents a substantial disruption in beneficiary care**
- **Recommend the following changes to Proposed LCD DL39365 due to substantive concerns with reliance on external compendia**
  - Revise the Proposed LCD so coverage for multi-analyte tests is not determined solely based on inclusion in a single external compendium
  - NCCN and other databases are important indications of test utility, but Novitas lacks authority to exclusively delegate coverage determinations to third party compendia

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Novitas' Review of Molecular Diagnostic Tests

- **C21 supports Novitas' longstanding "Biomarkers in Oncology" LCD (L35396)**
  - LCD has been in effect for nearly a decade and covers a number of C21 member tests based on individualized evidentiary reviews
- **Novitas has historically adjudicated coverage for new technologies prior to establishing an LCD**
  - Case-by-case claims adjudication required by 21st Century Cures Act in the absence of an evidentiary basis for non-coverage
  - Appreciate Novitas' willingness to engage with labs on clinical evidence in support of coverage (and to begin covering tests without requiring explicit modification of the existing LCD)
- **However, Novitas proposes to make inclusion in one of the following databases a requirement for coverage**
  - NCCN, NIH ClinGen, and Memorial Sloan Kettering OncoKB
  - Novitas does not recognize recognize alternative, evidence-based guidelines like professional society recommendations

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Cannot Rely Exclusively on Inclusion in Third Party Compendia for Coverage

- Novitas can make coverage decisions based in part on inclusion in NCCN or other guidelines or compendia as part of specific evidentiary review
- **However, Novitas cannot make coverage or non-coverage decisions based exclusively on inclusion in third-party guidelines**
  - Section 1862(l)(5)(D)(iv) of the Social Security Act specifically requires "evidence…considered by the contractor" in support of an LCD
  - Section 13.2.3 of the Medicare Manual states MACs may use external guidelines or compendia to "supplement" its own review, but a MAC may not use these sources as a substitute for its own review
- **Proposed LCD's exclusive reliance on inclusion in compendia creates a de facto non-coverage policy for all new tests**
  - Contravenes Section 1862(l) of the Act's requirement of test-specific review prior to a non-coverage determination (no guarantee that compendia will have reviewed any particular test at all, particularly for novel assays)

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Novitas Cannot Delegate Coverage Review

- Congress delegated to HHS Secretary the authority to "enter into contracts with any eligible entity to serve as a [MAC]"
- **Congress did not, however, grant the Secretary or the MACs the authority to delegate these powers to other private parties**
- Cannot subdelegate a material part of the HHS' LCD authority to external compendia organizations
- NCCN, ClinGen, and MSK do not provide laboratories and stakeholders notice and comment protections for coverage determinations as required for MACs

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Reconsideration Process Insufficient to Support Reliance on External Databases

- Proposed LCD would preempt non-covered tests and force labs to seek reconsideration
- Proposed framework would not permit opportunity for comment or public meeting prior to non-coverage determination based on compendia
- **Thus, reconsideration does not satisfy requirement that MACs may not impose a policy restricting coverage of an item or service absent an evidentiary review**
  - Non-coverage would take effect before MAC (or compendia) conducts evidentiary review
- **Novitas must review evidence, consider public comment, and hold a public meeting *before* a non-coverage determination is made based on a compendia decision**

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External Compendia Not Representative for Multi-Analyte Tests

- **The external compendium requirement is particularly inappropriate for multi-analyte tests because multi-analyte tests are not reviewed for ClinGen or OncoKB**
- Under the Proposed LCD, coverage of multi-analyte and algorithmic tests would be entirely dependent on NCCN
- **Reliance on NCCN guidelines is not an appropriate substitute for evidentiary review of individual tests**
  - Guidelines are consensus-based and only represent certain specialties
  - Updates are irregular and review varies by disease state
  - Guidelines are challenging for providers (and the MACs) to operationalize into a coverage policy
- **Novitas also proposes to non-cover tests with a majority recommendation from NCCN**
  - Category 2B tests have between 50 and 85% NCCN consensus that "intervention is appropriate" based on lower-level evidence
  - Novitas' proposed blanket non-coverage of tests with Category 2B evidence is inconsistent with its proposal to rely on NCCN

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NCCN Compendia Difficult to Operationalize as Coverage Policy

- NCCN presented at the Novitas' Open Meeting in 2022 and stated it has 84 guidelines for oncology consisting of 218 algorithms
- **NCCN does not follow uniform standards of evidence requirements or transparency**
- **Standards for inclusion vary significantly** between different cancers, e.g., breast, bladder, prostate, cutaneous melanoma and uveal melanoma
- For example, 2018 and 2019 Uveal Melanoma guidelines include 'PRAME mutation' with category 2A support
  - However, there is no PRAME mutation test

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Proposed LCD Defines Screening Inconsistent with Longstanding CMS Policy

- Genetic and genomic tests have been demonstrated to have clinical utility in the Medicare population
- Proposed LCD requires patients to have "***established a diagnosis of cancer or found significant evidence to create suspicion for cancer*** in their patient via a clinical evaluation and abnormal results (cancer or suspicious for cancer) from histologic and/or cytologic examination"
- Response to Comments article associated with earlier, withdrawn Final LCD takes position that oncologic tests performed prior to a confirmed diagnosis of cancer are "screening" tests
- **Novitas' position is inaccurate and inconsistent with longstanding CMS definition of a screening test, which requires an absence of "signs or symptoms" of a condition (e.g., Hematuria)**
- Signs or symptoms of cancer may exist even without "significant evidence to create suspicion for cancer in their patient via a clinical evaluation and abnormal results…from histologic and/or cytologic examination"

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Proposed LCD Would Eliminate Coverage of Tests Used in Clinical Practice

- Existing Biomarkers for Oncology coverage policy (L35396) has provided longstanding coverage for numerous tests based on clinical validity and utility evidence
- Laboratories should be able to submit interpretation of the evidence in the Proposed LCD and additional information including published literature or case studies
- CMS and MACs should not remove longstanding coverage of tests used by physicians unless there is new published evidence demonstrating clinical utility

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Proposed LCD Would Eliminate Longstanding Medicare Coverage

Test	Medicare Coverage Effective Date
DecisionDx-Melanoma	December 2018 (Palmetto)
DecisionDx-SCC	April 2022
Cxbladder Detect	July 2020
Cxbladder Monitor	July 2020
Cxbladder Triage	January 2023
PancraGEN	November 2010
UroVysion	July 2014
Colvera	January 2021

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Recommendations for Evidentiary Review of 13 Specifically-Referenced Tests

- **Novitas must consider and substantively respond to stakeholder comments on its test-specific evidentiary review of the 13 tests**, including comments regarding:
  - Overarching framework for review of evidence (e.g., overall approach, level of evidence required);
  - Interpretation of published literature cited in proposed LCD;
  - Published literature not cited in proposed LCD;
  - Other clinical guidelines and consensus statements not referenced in the proposed LCD; and
  - Clinician experience with such tests (even if unpublished).
- **Novitas must apply a consistent standard of review to all tests within the scope of the proposed LCD.**
  - Novitas assumes analytical validity of compendia-supported tests solely because they are run in CLIA-certified laboratories – but does *not* afford some presumption to tests that are explicitly reviewed, even though they are also run in CLIA-certified laboratories.
  - Same presumption should be afforded to tests specifically under review.

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Recommend Modification or Withdrawal of Proposed LCD

- **C21 respectfully recommends modifying DL39365 in the Final LCD to remove non-coverage if a test is not included in external databases**
  - **Novitas can use inclusion in database as evidence of coverage**
  - **In order to non-cover a test, Novitas must perform its own independent assessment of the literature and evidence**
- **Alternatively, Novitas could withdraw DL39365 at the end of the comment period**
  - Using stakeholder comments and CAC meeting to assist in the development of a new Proposed LCD may allow for improvements to the LCD framework
  - CAC meeting and multi-stakeholder dialogue can address key questions in advance of a new Proposed LCD
  - Critical to convene CAC given breadth and impact of the Proposed LCD, as Novitas is proposing to revise its coverage approach for every molecular cancer test

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