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CGS J15 Joint Kentucky & Ohio Open Meeting

Meeting Date and Time:	October 13, 2021 at 3:00 pm CST
Facilitator:	Dr. Meredith Loveless
Location:	Teleconference

Agenda

Draft Local Coverage Determination (LCDs)

1. Revision: Local Coverage Determination (LCD): Colon Capsule Endoscopy (CCE) (L38777)
2. Proposed: Draft Local Coverage Determination (LCD): Prostate Cancer Detection with IsoPSA TM (DL39124)

Local Coverage Determination (LCD): Colon Capsule Endoscopy (CCE) (L38777)

- Blood-based biomarker colorectal cancer screening test
- U.S. Preventive Services Task Force (USPSTF) expanded recommendations to include blood-based biomarker test
- Blood-based biomarker was added to NCD 210.3
- Diagnostic colonoscopy is the standard of care in the event that a colonoscopy cannot be performed, and the provider determines the need for colon endoscopy, coverage criteria has been expanded to allow the CRC screening test.

Proposed: Draft Local Coverage Determination (LCD): Prostate Cancer Detection with IsoPSA TM (DL39124)

- This is a non-coverage policy for prostate cancer detection with IsoPSA TM
- Non-coverage determination is based on the testing considered investigational at this time
- Two published studies presenting clinical validity of the test
- During the evidence of review, there was no peer reviewed published literature on clinical utility
- Medicare does require evidence review for LCD based on the 21st century criteria and that requirement does necessitate that are evidence review for peer reviewed published literature

Concerns according to the published studies:

- Need for published clinical utility data
- Lack of long-term outcome refers to outcomes for missed cancer
- Impact of age, prostate volume, or comorbid conditions such as prostate hypertrophy

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- Not included in National Comprehensive Cancer Network (NCCN biomarker test for men with elevated PSA
- Lack of societal support
- Ability of the test to avoid biopsy in real-world population

Presenters

Bob Rochelle and Dr. Mark Stovsky

IsoPsa's position in the clinical paradigm requires clarification

- ISO PSA is not being positioned as a screening test, but rather as a reflex test to an elevated or rising PSA greater than 4
  - » Statistically to position this test into validated clinical, it's different than it would be if describing a screening application of the test. We believe that we have validated the with the use of the test in a very high powered prospective multi-center study
- Lack of Head-to-Head Data vs. PSA
  - » PSA has been studied and published for decides, and its performance is well-characterized
  - » Validation studies were appropriately designed to allow independent comparative evaluation of the performance of ISO PSA vs total PSA. Importantly, using biopsy as a common independent pathologic comparator, which is essential to prove the validity of a diagnostic test in this space
  - » IsoPSA study design was accepted by the FDA
- Lack of Head-to-Head vs Other Tests
  - » Directly compared IsoPSA to the standards of care
  - » Only comparison required by FDA
  - » It is not within the purview of Cleveland Diagnostics to determine which subset of other marketed tested against which to compare IsoPSA
- Uncertainty that IsoPSA would provide confidence to providers to be comfortable not performing biopsy
  - » No test is perfect-PSA and free PSA lead to both unnecessary biopsies and missed actionable cancers
  - » IsoPSA NPV is robust and superior to PSA
  - » FDA accepted our risk analysis which help to establish the final IsoPsa test cut-off values
  - » The positive predictive value side shows informative statistical value on the positive predictive value side

Dr. Eric Klein

- IsoPSA provides better sensitivity and specificity to assist with over detection and overtreatment of prostate cancer
  - » When someone had a PSA above four and we used IsoPSA as a reflex to decide on biopsy, it reduced the recommendation for biopsy by more than half

Dr. Terry Phillis

- Very helpful with decisions to send patients to biopsy or to await biopsy
- IsoPSA results are easy to interpret for physician, nurse, patients, and other staff
- Allows to test confidently reassure and test less often

Dr. Jason Hafron

- IsoPSA results have shown a 50% reduction in biopsies
  - » Patients who need to be biopsied are appropriately biopsied
- Biopsy is not a benign procedure is associated with it with infection, sepsis, morbidity, the inconvenience, and obviously the cost

Dr. Aaron Berge

- IsoPSA quickly and accurately provides which patients require biopsies or can be observed
- IsoPSA benefits include rapid results, easy for patients to understand, and minimize unnecessary invasive procedures
- Works on a wide range of PSA when compared to other reflex tests

Closing

- Dr. Loveless advised that unpublished papers cannot be used for policy
- Is there any insight as to the timing for NCCN or American Neurological Association on the test?
  - » NCCN is meeting and deliberating next week on October and a decision is expected within a month
- The comment period is opened until October 24, 2021
  - » Send in written comments to supplement your presentation or a summary

