DRAFT Medical Coverage Policy | Prostate Cancer Detection with IsoPSA

EFFECTIVE DATE: 03|01|2023
POLICY LAST UPDATED: 12|07|2022

OVERVIEW

IsoPSA® is a blood-based single parameter, structure-based assay for improved detection of high-grade prostate cancer. The test partitions isoforms of prostate-specific antigen with an aqueous two-phase reagent. The test aims to improve specificity by testing specific changes in PSA that arise specifically in cancer cells and would not be affected by conditions such as prostate hyperplasia, inflammation, or age that reduce the specificity of the standard PSA assays.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

The IsoPSA® test will be considered medically reasonable and necessary when all the following are met:

- Testing of men 50 years of age and older who have a confirmed* moderately elevated PSA (greater than 4 and ≤ 25 ng/mL)

AND

- No other relative contraindication for prostate biopsy including:
    - Less than a 10-year life expectancy

*PSA elevation should be verified after a few weeks under standardized conditions (e.g., no ejaculation, manipulations, and urinary tract infections) in the same laboratory or other CLIA approved laboratory before considering a biopsy.

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

The IsoPSA® test will be considered medically reasonable and necessary when all of the criteria above have been met.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable genetic testing and not medically necessary/not covered benefits/coverage.

BACKGROUND

Screening modalities for prostate cancer (PCA) include digital rectal exam (DRE) and prostate-specific antigen (PSA) test at a frequency of every twelve months for men ages fifty and over in effort to detect increased risk for adenocarcinoma of prostate. PSA is a reliable immunocytochemical marker for adenocarcinoma of the prostate. However, screening and early treatment of prostate cancer have come under scrutiny due to concerns for over diagnosis of low-risk cancers. Guidelines have been updated due to studies to refine the use of PSA, which remains the primary screening test. Investigations into adjunctive testing may provide opportunities to avoid biopsies and reduce overdiagnosis.

IsoPSA® aims to improve the existing standard of care PSA testing for the detection of high-grade prostate cancer. CGS released a non-coverage LCD draft in October 2021. Since that time, clinical utility data has been published and NCCN guidelines have been updated to include IsoPSA®. One of the initial concerns addressed in the draft LCD was while the test offered a 93% sensitivity, resulting in approximately twenty-two missed cancers in 1000 patients based on the mathematical models, there was uncertainty if this would provide confidence to providers to be comfortable not performing a biopsy. In Scovell et al. changes in recommendations were reported in 60.2% for decisions on prostate biopsy resulting in a 55% net reduction in recommendations for prostate biopsy demonstrating confidence in this real-world population to utilize the test in decision making. In addition, this study provides the clinical utility data that was previously lacking. At the time of the open meeting in June 2022 the impact of age, prostate volume, and comorbid conditions as well as use outside of the initial biopsy had not been investigated. Since the June 2022 meeting additional literature has been published that addresses the accuracy of IsoPSA® in men with BPH and on 5-APIs, prior initial biopsies, and a broader range of PSA levels. Based on this latest information, the restriction for benign disease and prior negative biopsies was removed. The range of PSA was expanded to allow baseline PSA levels from 4-25 ng/mL. However, we did not agree with expansion in the baseline PSA range of 26-100 ng/mL due to poor strength of data to support this range and concern for lack of long-term data on outcomes for missed cancers. The NCCN algorithm includes IsoPSA® test for use outside the areas investigated in the IsoPSA®studies, and CGS does not consider the use outside the population studied applicable. The limited coverage criteria align with the population studied in the IsoPSA® literature.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are covered for Medicare Advantage Plans and Commercial Products when medical criteria above are met:

The IsoPSA® test

0359U Oncology (prostate cancer), analysis of all prostate-specific antigen (PSA) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer (New code effective 01/01/2023. For Dates of Service prior to 01/01/2023, CPT code **81599** (Unlisted multianalyte assay with algorithmic analysis) may have been used)

RELATED POLICIES

Genetic Testing Services
Proprietary Laboratory Analyses (PLA)

PUBLISHED

Provider Update, January 2023

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Prostate Cancer Detection with IsoPSA® (L39284)
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article: Billing and Coding: Prostate Cancer Detection with IsoPSA™ (A59066)