UM-CDG-045 Early Prostate Cancer Detection	Approved By: Director, Health Services	Effective Date: 10/22/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address early prostate cancer detection. In early stages, prostate cancer often has no identifiable symptoms and therefore, early detection is key in finding prostate cancer while in a potentially curative stage. Prostate specific antigen (PSA) is a protein generated by the prostate gland and circulates throughout the body. This is a marker for prostate cancer and can be detected with a blood test. Testing may aid in differentiating between prostate cancer and noncancerous conditions associated with an elevation in PSA.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

Digital Rectal Examination (DRE): recommended complementary test done as part of prostate screening along with PSA testing.
Fluorescent in situ Hybridization (FISH): technique where a probe targets specific genetic sequence and is labeled/tagged with fluorescent dye.
Core Needle Biopsy/Fine Needle Aspiration: techniques to remove a small core of tissue.

POLICY

SECUR Health Plan will follow Medicare guidance for DRE and PSA blood tests but referring to NCD 190.31 and NCD 210.1. If criteria in these NCDs does not sufficiently provide guidance, SECUR Health Plan will follow the below guidance.

The following DRE and PSA tests will be considered medically necessary for the early detection of prostate cancer when the following is met:

1. Covered at a frequency of once every twelve (12) months and at least eleven (11) months have passed following the month in which the last covered screening was performed, and
2. Member is at least 45 years of age and at an average risk for prostate cancer or member is at least 40 years of age and at a high risk for prostate cancer as demonstrated by one or more of the following:
   - African American ethnicity, or
   - Breast cancer diagnosed at age 45 or younger in a first, second, or third-degree relative assigned female at birth, or
   - Breast or ovarian cancer diagnosed in a first, second, or third-degree relative assigned male at birth, or

- Metastatic prostate cancer diagnosed in a first or second-degree relative, or
- Personal history of colorectal or endometrial cancer at age 50 or younger, or
- Personal history of pancreatic cancer, or
- Personal history of pathogenic or likely pathogenic variant in a gene associated with a high risk for prostate cancer

SECUR Health Plan considers the following as not medically necessary:

1. Tests considered screening in the absence of clinical signs or symptoms of disease that are not specifically identified by law, or
2. Tests that confirm a diagnosis or known information, or
3. Tests to determine the risk of developing a disease or condition, or
4. Tests performed to measure the quality of a process, or
5. Tests without diagnosis specific indications, or
6. Tests identified as investigational by available literature and/or the literature supplied by the developer and are not part of a clinical trial.

The above fall within Medicare's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of an illness or injury. (§1862(a)(1) of the Act).

For those with no specific Medicare guidance about a specific MDT or LDT, the test is not considered medically necessary unless analytical validity, clinical validity, or clinical utility have been established by one or more of the following:

- MoIDX Program approved technical assessment
- FDA approval/clearance performed within FDA labeling indications and approved by the MoIDX Program

Insufficient evidence to determine that FNA for the diagnosis of prostate cancer and FISH testing of prostate tissue speciments for TMPRSS2::ERG rearrangement exists and therefore these services are considered not medically necessary.

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