Saturation Biopsy for Diagnosis and Staging of Prostate Cancer

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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary saturation biopsy for diagnosis and staging of prostate cancer.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

PROCEDURES

Prior authorization is required.

Designed to retrieve more tissue samples from a prostate than a standard biopsy, a saturation biopsy, either initial or repeat, for a high-risk individual provides pathologists with an extensive selection of cells to test and can be used to help diagnose and stage prostate cancer when previous conventional prostate biopsies have been negative.

Saturation biopsy of the prostate (taking 20 or more core tissue samples at one time) may be considered medically necessary for ANY ONE of the following indications in individuals with two (2) prior extended transrectal prostate biopsies (up to 12 core tissue samples) negative for invasive cancer:

- Individuals with an elevated prostate specific antigen (PSA) that is persistently rising; or
- Individuals with histologic evidence of atypia on prior prostate biopsy; or
- Individuals with histologic findings of high-grade prostatic intraepithelial neoplasia (PIN) on prior biopsy.

Saturation needle biopsy of the prostate not meeting the criteria as indicated in this policy is considered experimental/investigational and, therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: OUTPATIENT

Experimental/investigational (E/I) services are not covered regardless of place of service.

Saturation biopsy of the prostate is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT codes	Description
55700	Biopsy, prostate; needle or punch, single or multiple, any approach.
55705	Biopsy, prostate, incisional, any approach.
55706	Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance.

DIAGNOSIS CODES FOR PROCEDURE CODES 55700, 55705, AND 55706

Code	Description
C61	Malignant neoplasm of prostate.
D07.5	Carcinoma in situ of prostate.
D40.0	Neoplasm of uncertain behavior of prostate.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

POLICY SOURCES

National Comprehensive Cancer Network Guidelines – 2019/2020

The National Comprehensive Cancer Network guidelines (v.2.2019) on early detection of prostate cancer state that routine use of advanced biopsy techniques, including saturation biopsy, is not recommended for initial biopsy. However, based on emerging evidence the guidelines state that saturation biopsy can be considered for "very high-risk" men with previous negative biopsies. The guidelines do not specify a definition of "very high-risk," but state that men with persistently elevated or rising PSA after 1 or more negative TRUS biopsies are considered at "high risk." The guidelines also note that alternative strategies using MRI or biomarkers may avoid the use of biopsy altogether.

NCCN guidelines on prostate cancer (v.2.2020) states for [individuals] who choose active surveillance, an appropriate active surveillance schedule includes PSA measurement no more often than every six (6) months unless clinically indicated and repeat prostate biopsy no more often than every 12 months unless clinically indicated. A repeat prostate biopsy within six (6) months of diagnosis is indicated if the initial biopsy was less than 10 cores or if assessment results show discordance. Repeat biopsies are not indicated when life expectancy is [greater than] 10 years or when men are on observation.

References

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POLICY UPDATE HISTORY

10/08/2021	Approved in Medical Policy Committee
07/27/2022	Annual review, approved in medical policy committee
0/21/2022	Approved in QI/UM