of Tennessee

Policy

Reimbursement Policy

Prostate Biopsy Specimen Analysis

I. Policy Description

Prostate cancer is characterized by a malignancy of the small walnut-shaped gland that produces seminal fluid. This malignancy can present with a wide clinical range, from only being a microscopic, well-differentiated tumor that may never be clinically significant all the way to being an aggressive, high-grade cancer (Taplin & Smith, 2024).

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) In the initial diagnosis of prostate cancer as a follow up to abnormal PSA results, presence of a palpable nodule on digital rectal examination, **or** suspicious radiologic findings, pathological examination of tissue obtained from a prostate biopsy involving 12 core extended sampling (see Note 1 below) **MEETS COVERAGE CRITERIA**.
2) When the clinical suspicion of prostate cancer remains in an individual for whom an initial biopsy was negative for prostate cancer, pathological examination of tissue from a follow-up prostate biopsy (excluding prostate saturation biopsy) **MEETS COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

3) Pathological examination of tissue obtained from a prostate saturation biopsy **DOES NOT MEET COVERAGE CRITERIA** for the diagnosis, staging, or management of prostate cancer.

NOTES:

Note 1: One vial per sextant, with no more than two core samples per vial.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

The FDA has cleared numerous devices including needles, reagents, instrumentation, and imaging systems for use in prostate biopsy. Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
88305	Level IV – Surgical pathology, gross and microscopic examination
G0416	Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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