

Ordering Physician

Patient Information

[Blank space for Ordering Physician signature]

Name:
First Last

Address:

City: State: Zip:

Date of Birth: Phone:
Month Day Year

MRN/Patient ID:

Account Information

[Blank space for Account Information]

1. Test Ordered

Select mdx for Prostate Cancer

2. Clinical Information:

Collection Date: Specimen ID:
Month Day Year

Last DRE Result: Very Suspicious for Prostate Cancer Not Very Suspicious for Prostate Cancer

Last PSA Results: PSA: ng/mL Date: Prostate volume: (only if obtained by MRI or ultrasound)
Month Day Year

3. Required Billing Information: (ICD-10 and copy of insurance card required)

ICD-10 Codes:

R97.20 Elevated Prostate Specific Antigen [PSA] N40.2 Nodular prostate without lower urinary tract symptoms

D29.1 Benign neoplasm of prostate N40.3 Nodular prostate with lower urinary tract symptoms

D40.0 Neoplasm of uncertain behavior of prostate Other:

Payment Type: Private Insurance Medicare Medicaid Patient Self-Pay Client (contract required)

Name of insurance: Member ID:

(Medicare only) Was procedure performed in hospital? If yes: hospital outpatient hospital inpatient - discharge date:
Month Day Year

Include copies of both sides of insurance card(s). If two cards are submitted, indicate which is primary.

4. Authorization and Statement of Medical Necessity:

I hereby authorize testing and attest that the person listed in the Physician Signature space below is authorized by law in the relevant jurisdiction to order the test requested herein. I confirm that I have on file the patient's assignment of benefits authorizing insurance benefits to be paid to ancillary healthcare service providers, such as mdxhealth. I further instruct mdxhealth to retain this completed test requisition as part of the patient medical record. I authorize mdxhealth to release the information on this form, and other information provided by me or on my behalf, necessary to process a claim for this service.

For Medicare and Medicare Advantage Beneficiaries: Prior to ordering, I certify that the patient meets the Medicare eligibility criteria provided on the back side of this form.

/ /
 Ordering Physician Signature (No stamped signatures) Date

Submitting this form constitutes a Certification of Medical Necessity and a certification that I have obtained consent for Mdxhealth Inc. to release the test results and relevant medical information to the patient's insurance carrier as part of the coverage and reimbursement process.

Place Patient Label Here

Place Provided Barcode Here

Mdxhealth Internal Use Only: Total Pages: Tubes:

Medicare Coverage Indications for Select mdx

- The patient must not have an established diagnosis of prostate cancer.
- The beneficiary is a candidate for prostate biopsy or repeat prostate biopsy, according to a consensus guideline [i.e., National Comprehensive Cancer Network® (NCCN), American Society of Clinical Oncology® (ASCO), American Urological Association (AUA)].
 - For men \leq 75 years of age - Prostate Specific Antigen (PSA) (or adjusted PSA in special populations, i.e., patients taking 5 alpha-reductase inhibitors) OR repeat PSA are >3 and <10 ng/mL AND/OR Digital Rectal Exam (DRE) findings are very suspicious for cancer
 - For men $>$ 75 years of age - PSA (or adjusted PSA in special populations, i.e., patients taking 5-alpha-reductase inhibitors) OR repeat PSA are ≥ 4 and <10 ng/mL AND/OR DRE findings are very suspicious for cancer.
- The beneficiary has not had a prostate biopsy OR has had a previous negative or nonmalignant but abnormal histopathology finding (i.e., atypical small acinar proliferation (ASAP) or high-grade prostatic intraepithelial neoplasia (HGPIN) on prostate biopsy).
 - Patients under consideration for a repeat biopsy have first undergone repeat PSA and/or DRE testing as recommended by consensus guidelines
- The beneficiary would benefit from treatment of prostate cancer and patient management will be impacted by use of a biomarker in manner already demonstrated in the peer-reviewed published literature to improve patient outcomes.
- The medical record supports the medical necessity for the biomarker test.
- Testing is performed according to the intended use of the test in the intended patient population for which the test was developed and validated.
 - Select mdx testing has not been validated for patients being administered 5a-reductase inhibitors finasteride or dutasteride (5-ARIs)
- For a given clinical indication (pre-OR post-biopsy), only one molecular biomarker may be performed UNLESS a second test, meeting all the criteria established herein, is reasonable and necessary as an adjunct to the first test, according to criteria established in this policy.
- The test is ordered by a physician specialist in the management of prostate cancer, such as a urologist or oncologist. An exception may be made in geographic locations where the specialist(s) cannot be reasonably reached by the beneficiary and the ordering provider is located closer to the beneficiary's place of residence than the nearest specialist. We would generally expect that beneficiaries for whom the test is ordered under this exception to be living in rural locations, islands, or some other location where access to care is limited.

NOTE: If the patient is considered higher risk (due to relevant family or personal cancer history, relevant high-risk genetic mutations, African ancestry, or other clinical parameters highly suspicious for cancer including a persistent and significant increase in PSA), a biopsy may still be warranted. These relative indications for biopsy should be taken into consideration as part of a shared decision making process regarding whether to proceed with biopsy.

The Select mdx for Prostate Cancer test was developed and its performance characteristics determined by mdxhealth. The test is intended for use as aid to clinicians for patient management decisions about the need for a prostate biopsy on men with clinical risk factors suggesting an increased risk for prostate cancer. Use outside of this indication has not been validated by mdxhealth. Test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician and relevant guidelines on the decision for biopsy.