Confirm mdx
for Prostate Cancer

Confirm mdx Test Requisition Form

Ordering Physician

Account Information

Patient Information

Name: First Last

Address:

City: State: Zip:

Date of Birth: Month Day Year Phone:

MRN/Patient ID:

1. Test Ordered

☑ Confirm mdx for Prostate Cancer

2. Clinical Information: (Please provide a copy of pathology report, history & physical, and office/progress notes with test order)

Specimen ID(s): Collection Date: Month Day Year Date retrieved from archive: Month Day Year

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

(Medicare only) If mpMRI performed, PI-RADS Score: / Date: Month Day Year

Last 2 PSA Results: PSA: ng/mL Date: Month Day Year PSA: ng/mL Date: Month Day Year

Other Risk Factor(s):

☐ PSA level increase of greater than 0.35 ng/mL/year if PSA level less than or equal to 10 ng/mL

☐ PSA doubling time of less than 3 years, when initial PSA level greater than or equal to 4 ng/ml and other causes of rising PSA (i.e., infection, inflammation) have been ruled out for individuals whose PSA doubling occurred in less than 2 years

☐ African descent (including African American and Caribbean of African ancestry)

3. Confirm mdx Specimen Request:

☐ I want mdxhealth to request the specimen. Mdxhealth will obtain the patient's prostate biopsy from the Pathology Laboratory. Fax signed requisition, pathology report, and patient's insurance to (949) 788-0014.

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

ICD-10 Codes:

☐ R97.20 Elevated Prostate Specific Antigen [PSA]
☐ D29.1 Benign neoplasm of prostate
☐ D40.0 Neoplasm of uncertain behavior of prostate
☐ N40.2 Nodular prostate without lower urinary tract symptoms
☐ N40.3 Nodular prostate with lower urinary tract symptoms
☐ 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.

5. Authorization and Statement of Medical Necessity:

I hereby authorize testing and confirm that an informed consent has been obtained, if required by state law. I confirm that this is medically necessary and the results will be used in the medical management decisions for the patient. I hereby attest that the person listed in the Ordering Physician space above 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, Inc. 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 you 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.

PLEASE KEEP A COPY AND RETAIN IN PATIENT'S MEDICAL RECORD

Mdxhealth Interal Use Only: Total Pages: Blocks: Slides:

Mdxhealth, Inc. P: 866.259.5644 • F: 949.788.0014 • E: cs@mdxhealth.com • **www.mdxhealth.com**

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Medicare Coverage Indications for Confirm 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 ≤ 75 years of age - Prostate Specific Antigen (PSA) (or adjusted PSA in special populations, i.e., patients taking 5alpha-reductase inhibitors) OR repeat PSA are >3 and <10ng/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 <10ng/mL AND/OR DRE findings are very suspicious for cancer.

  EXCEPTION: a molecular biomarker test may be performed in men with PSA levels >10 ng/mL who are being considered for repeat biopsy IF appropriate according to consensus guidelines AND according to the following: the specific biomarker test has been validated in men with PSA levels>10 ng/mL AND a Multiparametric MRI (mpMRI) is negative, if performed.
- 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 a 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.
- 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.

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