Local Coverage Determination (LCD):
MolDX: ConfirmMDx Epigenetic Molecular Assay (L36329)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

**Contractor Information**

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
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<td>Noridian Healthcare Solutions, LLC</td>
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**LCD Information**

**Document Information**

- **Original Effective Date**: For services performed on or after 10/01/2015
- **Revision Effective Date**: For services performed on or after 05/21/2018
- **Revision Ending Date**: N/A
- **Retirement Date**: N/A
- **Notice Period Start Date**: N/A
- **Notice Period End Date**: N/A
Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Indications and Limitations of Coverage

Noridian will provide limited coverage for the ConfirmMDx epigenetic assay for prostate cancer (MDxHealth, Irvine, CA) to reduce unnecessary repeat prostate biopsies. The MolDX Contractor recognizes that evidence for clinical utility for ConfirmMDx in males with previous negative prostate biopsy who are being considered for repeat biopsy is promising with evidence of some clinical utility at the current time. The MolDX Contractor believes the clinical studies planned will generate sufficient additional data to demonstrate the utility of ConfirmMDx in males with previous negative prostate biopsy who are being considered for repeat biopsy. Continued coverage of ConfirmMDx for males with previous negative prostate biopsy who are being considered for repeat biopsy will be dependent on semi-annual review of interim data, and/or peer-reviewed publications and/or presentations of clinical utility data demonstrating ConfirmMDx for males with previous negative prostate biopsy directs patient management as measured using clinical endpoints in one or more studies.
ConfirmMDx is covered under the following conditions:

1. Males aged 40 to 85 years old that have undergone a previous cancer-negative prostate biopsy within 24 months and are being considered for a repeat biopsy due to persistent or elevated cancer-risk factors, and
2. The previous negative prostate biopsy must have collected a minimum of 8 tissue cores (but not have received a saturation biopsy of > 24 tissue cores) and remaining FFPE tissue from all cores is available for testing, and
3. Minimum tissue volume criteria of 20 microns of prostate biopsy core tissue is available (40 microns preferable), and
4. Previous biopsy histology does not include a prior diagnosis of prostate cancer or cellular atypia suspicious for cancer (but may include the presence of high-grade prostatic intraepithelial neoplasia (HGPIN), proliferative inflammatory atrophy (PIA), or glandular inflammation), and

5. Patient is not being managed by active surveillance for low stage prostate cancer, and

6. Tissue was extracted using standard patterned biopsy core extraction (and not transurethral resection of the prostate (TURP), and

7. Patient has not been previously tested by ConfirmMDx from the same biopsy samples or similar molecular test.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:

ONCOLOGY (PROSTATE), PROMOTER METHYLATION PROFILING BY REAL-TIME PCR OF 3 GENES (GSTP1, 81551 APC, RASSF1), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A LIKELIHOOD OF PROSTATE CANCER DETECTION ON REPEAT BIOPSY

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes  Description
D29.1  Benign neoplasm of prostate
N40.0  Benign prostatic hyperplasia without lower urinary tract symptoms
N40.1  Benign prostatic hyperplasia with lower urinary tract symptoms
N40.2  Nodular prostate without lower urinary tract symptoms
N40.3  Nodular prostate with lower urinary tract symptoms
N41.0  Acute prostatitis
N41.1  Chronic prostatitis
N41.9  Inflammatory disease of prostate, unspecified
**ICD-10 Codes**

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<th>Code</th>
<th>Description</th>
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<tr>
<td>N42.81</td>
<td>Prostatodynia syndrome</td>
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<tr>
<td>N42.82</td>
<td>Prostatosis syndrome</td>
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<tr>
<td>N42.83</td>
<td>Cyst of prostate</td>
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<tr>
<td>N42.89</td>
<td>Other specified disorders of prostate</td>
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<tr>
<td>N42.9</td>
<td>Disorder of prostate, unspecified</td>
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<tr>
<td>R97.20</td>
<td>Elevated prostate specific antigen [PSA]</td>
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</table>

ICD-10 Codes that DO NOT Support Medical Necessity N/A

ICD-10 Additional Information [Back to Top]

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**General Information**

**Associated Information**

N/A

**Sources of Information**

N/A

**Bibliography**

**References:**

15. Wojno KJ et al. Reduced rate of repeated prostate biopsies observed in ConfirmMDx clinical utility field study. Am Health Drug Benefit, 2014; May; 7(3):129-34.

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Revision History Information

<table>
<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
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<tr>
<td>05/21/2018 R4</td>
<td></td>
<td>LCD is updated to remove CDD from the title and remove the Pascual trial requirement, delete #8 under the conditions in which Confirm MDx is covered, revise indications and limitations, update for 21st Century Cures Act required fields and add sources 17. Partin and 18. Van Neste.</td>
<td>• Creation of Uniform LCDs With Other MAC Jurisdiction • Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes</td>
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<tr>
<td>01/01/2018 R3</td>
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<td>2018 Annual CPT/HCPCS Updates: Replaced 81479 with 81551.</td>
<td>• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes</td>
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<td>10/01/2016 R2</td>
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<td>The following ICD-10 codes are added/deleted effective 10/1/16: Added code: R97.20. Deleted code: R97.2</td>
<td>• Revisions Due To ICD-10-CM Code Changes</td>
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<td>10/01/2015 R1</td>
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<td>N40.0 descriptor was changed in Group 1 from Enlarged prostate without lower urinary tract symptoms to Benign prostatic hyperplasia without lower urinary symptoms. The Part A LCD (L36328) is retired and Part A contract numbers are added to the Part B LCD.</td>
<td>• Creation of Uniform LCDs With Other MAC Jurisdiction</td>
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The Part B LCD is updated to add "CDD" (Coverage with Data Development) to the title identifying LCDs which are coverage requiring data development.

Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A54227 - (MCD Archive Site)

Related National Coverage Documents N/A

Public Version(s) Updated on 05/22/2018 with effective dates 05/21/2018 - N/A Updated on 02/06/2018 with effective dates 01/01/2018 - 05/20/2018 Updated on 09/28/2016 with effective dates 10/01/2016 - 12/31/2017

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. Back to Top

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Keywords

- MDxHealth
- Epigenetic
- MoIDX
- 81479
- prostate

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