Local Coverage Determination (LCD):
MolDX: Prostate Cancer Genetic Assay (ZBE44) (DL35368)

[PROPOSED/DRAFT]

Please note: This is a Proposed/Draft policy.
Proposed/Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review.
Proposed/Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Contractor Information

<table>
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<tr>
<th>Contractor Name</th>
<th>Contract Number</th>
<th>Contract Type</th>
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<tbody>
<tr>
<td>Palmetto GBA</td>
<td>11202</td>
<td>MAC - Part B</td>
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</table>

Proposed/Draft LCD Information

Document Information

[PROPOSED/DRAFT]

Source LCD ID
N/A

Proposed LCD ID
DL35368

Proposed LCD Title
MolDX: Prostate Cancer Genetic Assay (ZBE44)

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Jurisdiction
South Carolina

CMS National Coverage Policy
ConfirmMDx is covered under the following conditions:

1. Males aged 40 to 75 years old that have undergone a previous cancer-negative prostate biopsy within 15 months and are being considered for a repeat biopsy due to persistent or elevated cancer-risk factors

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

3. Minimum tissue volume criteria of 20 microns of prostate biopsy core tissue is available (40 microns preferable)

4. Previous biopsy histology does not include a prior diagnosis of prostate cancer or cellular atypia suspicious for cancer but 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 or similar molecular test
and
8. Testing has been ordered by a physician who is certified in the MolDx approved ConfirmMDx Certification and Training Registry (CTR) program

Palmetto GBA expects MDxHealth to accrual patients in the PASCUAL trial and expects that roughly 50% will be for Medicare patients that are enrolled in the PASCUAL trial. Palmetto GBA expects that preliminary interim analysis of the PASCUAL trial results will become available 2 years from the beginning of the trial. If the interim analysis demonstrates a substantially lower re-biopsy rate without adverse events, physician participation in the ConfirmMDx CTR program will be expanded, effectively increasing the number of patients tested and covered. If the interim analysis demonstrates poor patient accrual, suggesting limited merit of this assay in clinical practice, or fails to demonstrate a substantially decreased re-biopsy rate, limited coverage will continue until either 1200 patients have been tested or 3 years from the date of this LCD, which ever if first. Regardless of the final outcomes, when trial accrual is complete, Palmetto GBA expects peer-reviewed presentation and publication of the PASCUAL trial results. The trial results will be reviewed by Palmetto GBA in the context of a LCD reconsideration. Full coverage and removal of the CTR requirement are expected with favorable trial findings, or non-coverage for unfavorable findings.

Certification and Training Registry (CTR) Program

Because of the complicated nature of management decisions utilizing the ConfirmMDx assay and the potential for missing early prostate cancer, testing is furnished only by physicians who are enrolled in the MolDx approved CTR program. The MDxHealth CTR program serves as a control to assure the appropriate selection of patients, compliance with management decisions and stringent follow up to ensure the benefits of the test outweigh its risks. As part of this requirement MDxHealth will provide to Palmetto GBA regular reports every 6 months.

The goals of the ConfirmMDx Certification and Training Program are as follows:

- To avoid missing clinically relevant early prostate cancers with associated increased morbidity and mortality,
- To inform prescribers and patients on the safe-use conditions for ConfirmMDx,
- To collect longer term outcomes.

Palmetto GBA is aware that MDxHealth has initiated a confirmatory prospective trial (PASCUAL Clinical Trial) addressing the clinical utility and safety of ConfirmMDx. To assure safe use, MDxHealth will ensure that healthcare providers who order ConfirmMDx are registered and certified in the ConfirmMDx CTR program. ConfirmMDx testing is available only through these providers. The following criteria must be met in order for a healthcare provider to become certified:

- Must have been trained and certified as being a registered investigator as part of the Confirm Mdx PASCUAL trial,
- Must follow patients in a similar fashion to those enrolled in the PASCUAL trial,
- Must provide and document patient counseling as to the benefits and risks of ConfirmMDx testing, highlighting the possibility of missing a clinically significant early prostate cancer,
- Must collect and provide, on request to MDxHealth, a limited number of clinical data elements in patients where the test is ordered but the patient is not a participant in a registry or trial where similar outcome data is being collected separately.

Data Element Collection

- General Elements:
  - Total number of tests submitted to Medicare for payment
  - Number of Medicare patients enrolled in ConfirmMDx clinical trial(s), and
  - Number of Medicare tested patients, not enrolled in ConfirmMDx clinical trials

http://www.cms.gov/medicare-coverage-database/details/lcd-details...B)&DocType=AllProposed&LCntrctr=234*1&bc=AgACAAIAAAAAAA%3d%3d&
Patient Specific Elements:

- At initial testing:
  - PSA and DRE findings
  - Date of previous prostate biopsy(ies), with copies of pathology report preferred
  - ConfirmMDx test results

- Every 6 months:
  - Prostate re-biopsy to include time (weeks/months) for previous negative biopsy, type of biopsy (transrectal vs transperitoneal),
  - Prostate cancer status (Y/N) to include Gleason score, stage, PSA at time of detection and treatment(s), when applicable
  - Deaths

As part of the Certification and Training registry process, MDxHealth will:

- Maintain a secure database of Confirm MDx CTR providers,
- Monitor to ensure that only ConfirmMDx CTR providers are ordering ConfirmMDx testing.
- Monitor use of the test for patients not enrolled in a clinical trial or outcome focused registry,
- Institute corrective action and prevent a certified provider from ordering the test if the provider is found to be non-compliant with the ConfirmMDx CTR program.

MDxHealth will develop policies and procedures to provide Palmetto GBA with the required data elements. MDxHealth will also provide representative samples of educational materials, data collection forms, and reporting forms. The reportable data elements will be submitted to Palmetto GBA every 6 months in a mutually accepted format.

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### Proposed/Draft Process Information

Associated Information
N/A

Sources of Information and Basis for Decision

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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<thead>
<tr>
<th>Date</th>
<th>Meeting Type</th>
<th>Location</th>
<th>Notes</th>
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<td>07/10/2014</td>
<td>Open Meeting</td>
<td>North Carolina</td>
<td>Palmetto GBA J11 A/B Medicare Administrative Contractor (MAC) has scheduled Open Draft Local Coverage Determination (LCD) meetings in the following area in order to allow for the submission of information related to the proposed LCDs. The general public is invited to submit information for Palmetto GBA’s consideration. LCDs are administrative and educational tools that assist providers, physicians and suppliers in submitting correct Medicare claims for coverage.</td>
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<td>Carrier Advisory Committee (CAC) Meeting</td>
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<td>Contractor Advisory Committee(CAC)</td>
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<td>07/15/2014</td>
<td>Open Meeting</td>
<td>West Virginia</td>
<td>Palmetto GBA J11 A/B Medicare Administrative Contractor (MAC) has scheduled Open Draft Local Coverage Determination (LCD) meetings in the following area in order to allow for the submission of information related to the proposed LCDs. The general public is invited to submit information for Palmetto GBA’s consideration. LCDs are administrative and educational tools that assist providers, physicians and suppliers in submitting correct Medicare claims for coverage.</td>
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<td>07/17/2014</td>
<td>Open Meeting</td>
<td>Virginia</td>
<td>Palmetto GBA J11 A/B Medicare Administrative Contractor (MAC) has scheduled Open Draft Local Coverage Determination (LCD) meetings in the following area in order to allow for the submission of information related to the proposed LCDs. The general public is invited to submit information for Palmetto GBA’s consideration.</td>
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**Comment Period Start Date**
07/08/2014

**Comment Period End Date**
08/25/2014

**Released to Final LCD Date**
N/A

**Reason for Proposed LCD**
- New/Updated Technology

**Proposed Contact**
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Columbia, SC 29202  
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Columbia, SC 29202  
J11B.policy@PalmettoGBA.com

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**Coding Information**

**[ PROPOSED/DRAFT ]**

**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

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**ICD-9 Codes that Support Medical Necessity**

**Group 1 Paragraph:**
N/A
## Group 1 Codes:

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ICD-9 Codes that DO NOT Support Medical Necessity
N/A

**Associated Documents**

- **Attachments**
  N/A
- **Related Local Coverage Documents**
  N/A
- **Related National Coverage Documents**
  N/A
Keywords

N/A

Read the LCD Disclaimer