APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

According to the American Cancer Society, prostate cancer is the second most common cancer in American men. The disease is typically a slow-growing tumor affecting older men. The majority of patients are over 65 years of age. The American Urological Association sites both digital rectal exam and PSA, prostate specific antigen, as the current screening procedures for prostate cancer. The American Cancer Society recommends that prostate screenings should begin at 50 years of age or even younger, at 40 to 45 years, in men with a family history or who are at high risk.¹

CMS describes Progensa® PCA3 Assay as an FDA approved test that is an mRNA expression assay used alone or in combination with other molecular tests. They state that PCA3 may help improve the specificity of prostate cancer detection by providing additional information about the risk of prostate cancer over the use of the PSA test alone. The PCA3 assay is a urine test performed on the first urine collected following an attentive digital rectal examination.¹ The PROGENSA® Assay is the first FDA-approved test of its kind. It works by measuring the

Clinical Coverage Guideline
concentration of the prostate cancer gene (PCA3) and prostate specific antigen (PSA) RNA molecules and calculating the ratio of the two. The test is recommended for men 50 years or older who have had negative prostate biopsies but are recommended for repeat biopsy by an urologist based on the current standard of care.\(^3\) CMS requires members to have at least one prior negative prostate biopsy before having a PCA3 assay and that the member and the physician both desire to avoid repeat biopsy or watchful waiting. The physician must also provide documentation and rationale for performing a PCA3 assay.\(^2\)

**POSITION STATEMENT**

**Applicable To:**
- Medicaid - Hawaii
- Medicare – Easy Choice (California) and Hawaii

**Exclusions**

Prostate cancer antigen testing (PCA3) is **not considered medically necessary** when all of the following apply:

1. When the physician plans to biopsy the prostate, the CMS MolDX contractor will consider a PCA3 test as investigational and thus, not a covered Medicare benefit.
2. The CMS MolDX contractor considers all other indications for PCA3 not reasonable and necessary.

**Coverage**

Prostate cancer antigen testing (PCA3) is **considered medically necessary** when all of the following apply:

1. All biopsies in previous encounter(s) are negative; **AND**,  
2. Member or physician want to avoid repeat biopsy (watchful waiting); **AND**,  
3. Medical record documentation indicates the rationale to perform a PCA3 assay.

**CODING**

**Covered CPT® Codes**

- 81313 PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (eg, prostate cancer)
- 88299 Unlisted cytogenetic study, when billed for deCODE Prostate Cancer Test.

**Non-Covered ICD-10-CM Diagnosis Codes**

- C61 Malignant neoplasm of prostate
- R97.20 Elevated prostate specific antigen [PSA]
- R97.21 Rising PSA following treatment for malignant neoplasm of prostate
- Z12.5 Encounter for screening for malignant neoplasm of prostate

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

**REFERENCES**


**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/1/2018</td>
<td></td>
</tr>
<tr>
<td>4/6/2017</td>
<td></td>
</tr>
<tr>
<td>1/7/2016</td>
<td></td>
</tr>
<tr>
<td>12/1/2011</td>
<td></td>
</tr>
</tbody>
</table>

Clinical Coverage Guideline page 2