

November 2023



Client Communication

Medicare Local Coverage Determination Policy: CGS

Coverage Policy

L36675 - ProMark® Risk Score

CPT: 81479

Revision Effective Date: 12/07/2023

Coverage Indications, Limitations, and/or Medical Necessity

This Contractor will provide limited coverage for the ProMark® (Metamark Genetics) to help determine which patients with early stage, needle biopsy proven prostate cancer can be conservatively managed rather than treated with definitive surgery or radiation therapy.

Criteria for Coverage

The ProMark® assay is covered only when the following clinical conditions are met:

- Needle biopsy with localized adenocarcinoma of prostate (no clinical evidence of metastasis or lymph node involvement), **and**
- Patient Stage as defined by the one of the following:
 - Very Low Risk Disease (T1c AND Gleason Score \leq 6 AND PSA \leq 10 ng/mL AND AND \leq 50% cancer in any core AND PSA density of $<$ 0.15 ng/mL/g) **OR**
 - Low Risk Disease (T1-T2a AND Gleason Score \leq 6 AND PSA \leq 10 ng/mL), **and**
- Patient has an estimated life expectancy of greater than or equal to 10 years, **and**
- Patient is a candidate for and is considering conservative therapy and yet and would be eligible for definitive therapy (radical prostatectomy, radiation therapy or brachytherapy), **and**
- Patient has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, **and**
- Patient has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, **and**
- Test is ordered by a physician certified in the Metamark Genetics Certification and Training Registry (CTR), **and**

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Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with the patient's medical record. Sonic Healthcare does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff.

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- Patient is monitored for disease progression according to active surveillance guidelines as recorded in NCCN guidelines, **and**
- Physician must report the development of metastasis or prostate cancer deaths in patients not treated definitively who were deemed low risk by the assay.

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The ICD10 codes listed below are the top 40 diagnosis codes Sonic most commonly receives from ordering physicians for this limited-coverage test. Medicare supports provider utilization of all the diagnosis codes listed below, except those notated in bold. **If you are providing a diagnosis code that is bolded below, please submit a valid ABN form with the order.** To view the complete policy and the full list of medically supported diagnosis codes, please refer to the CMS website for guidance:

<https://www.cms.gov/medicare-coverage-database/search.aspx>

Code	Description
E03.8	Other specified hypothyroidism
E29.1	Testicular hypofunction
E72.11	Homocystinuria
E78.2	Mixed Hyperlipidemia
R53.83	Other Fatigue
R79.82	Elevated C-reactive protein (CRP)
R94.4	Abnormal results of kidney function studies

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