
4K Score Testing

Policy

VCHCP covers 4K Score Testing except in the limited circumstances outline below.

Background

The 4K score tests are immunoassays that employ distinct monoclonal antibodies. The score combines measures of four (4) prostate-specific kallikrein with an algorithm including patient age, digital rectal exam (DRE) (nodules or no nodules) and a prior negative prostate biopsy. OPKO Diagnostics is the only laboratory that performs 4k testing.

Indications:

- The intended use of the test is to aid in the decision whether to proceed with a prostate biopsy or MRI in men with elevated PSA levels and/or suspicious DRE.

Contraindications:

- The test is not intended for patients with a previous diagnosis of prostate cancer or who have had a DRE in the previous four days or who have received a 5a reductase inhibitor therapy in the previous 6 months or who have undergone invasive treatment for symptomatic benign prostate hypertrophy in previous six (6) months.
- This test is rarely indicated in patients with less than 10 years life expectancy.

A. Attachments: None

B. History:

Created by: Howard Taekman, MD

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VCHCP Medical Policy 001: 4K Score Testing

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2/20/25	Yes	Howard Taekman, MD and Robert Sterling, MD	Moved “OPKO Diagnostics is the only laboratory that performs 4k testing” in background section and modified indication section by adding “in men with elevated PSA levels and/or suspicious DRE”
2/12/26	No	Robert Sterling, MD	Annual Review