4K Score Testing

Policy

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

Indications

- The intended use of the test is to aid in the decision whether to proceed with a prostate biopsy or MRI.
- 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 six months or who have undergone treatment for symptomatic benign prostate hypertrrophy other than alpha blockers in previous six (6) months. This test is rarely indicated in patients with less than 10-year life expectancy.
- OPKO Diagnostics is the only laboratory that performs 4k testing.

A. Attachments: None
B. History:

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Committee Review: UM: November 14, 2019; QAC: November 26, 2019
Reviewed/No Updates by: Howard Taekman, MD & Robert Sterling, MD

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