OPKO Health

4Kscore®

A DIAGNOSTIC BLOOD TEST FOR DETECTING THE RISK OF

AGGRESSIVE PROSTATE CANCER

The 4Kscore Test requisition form has been modified to support updated coverage criteria from Medicare, while minimizing your workflow disruption.

A copy of the test requisition should be retained in the patient's medical record, as part of Medicare's requirement for documentation of Shared Decision Making prior to ordering the 4Kscore Test.

1 Documentation of shared decision making, including a detailed discussion about management options and patient preferences, is required prior to processing the test. **BOTH provider and patient signatures**, **legible names, and dates are required.**

SHARED DECISION MAKING

Patient Acknowledgment: [Requisition statement for patient acknowledging shared decision making and consent for the 4Kscore Test]

Print Patient Name: _____ Patient Signature: _____ Date: _____

Statement of Shared Decision Making: [Requisition statement for authorized provider acknowledging shared decision making and medical necessity of 4Kscore Test]

Print Provider Name: _____ Provider Signature: _____ Date: _____

PLEASE RETAIN THE COPY OF THIS DOCUMENT WITHIN THE PATIENT'S RECORDS.
PATIENT AND PROVIDER SIGNATURES WITH PRINTED NAMES AND DATES, AND ALL QUESTIONS, MUST BE COMPLETED.

2 **ALL QUESTIONS** in the Prostate Cancer Risk Evaluation section **MUST BE COMPLETED**

- Questions 1-3 capture information related to Medicare criteria for coverage:
  - PSA and age range
  - Very high risk clinical factors
  - Factors to be considered prior to ordering 4Kscore Test

- Questions 4 and 5 capture clinical factors included in the test algorithm:
  - A biopsy history is mandatory for all 4Kscore Test orders
  - A DRE is mandatory to meet Medicare coverage criteria

- The 4Kscore Test can be ordered directly or reflexing from a PSA result ≥ 3.0 ng/mL.

Please note: at least two prior abnormal PSA results must already be present (see Question #1) to meet Medicare coverage criteria.

PROSTATE CANCER RISK EVALUATION

1. Patient confirmed PSA (two or more results several weeks apart):

❑ 45-75 years and PSA 3-10 ng/mL

❑ > 75 years and PSA 4-10 ng/mL

❑ Other _____

2. Is the 4Kscore Test medically reasonable and necessary for the prostate biopsy decision, or does the patient have factors that indicate a biopsy should occur no matter what the 4Kscore result is?

❑ **Yes,** the 4Kscore Test is medically reasonable and necessary for the biopsy decision. The patient DOES NOT have factors that already indicate a biopsy should occur.

❑ **No,** the 4Kscore Test will not assist with the biopsy decision. The patient DOES have factors indicating that a prostate biopsy should occur, no matter what the 4Kscore result is.

3. Below factors have been taken into consideration in making the decision to order the 4Kscore Test:

- Some ethnicities are known to have a higher risk for prostate cancer
- The patient should have at least a 10-year life expectancy
- The patient has been worked up for benign disease.

❑ Yes ❑ No (Review factors prior to ordering the 4Kscore Test)

4. Biopsy History: Has the patient had a previous biopsy?

❑ No prior biopsy ❑ Yes, Negative ❑ Yes, Positive

(The 4Kscore Test will not be performed with a Positive biopsy result)

5. DRE Results

❑ Nodule ❑ No Nodule

4Kscore® Test

J148-8 ❑ 4Kscore Test (S)

J264-3 ❑ PSA Total w/ Reflex to 4Kscore Test ≥ 3.0 ng/mL (S)

K135-4 ❑ PSA Total + % Free w/Reflex to 4Kscore Test ≥ 3.0 ng/mL (S)

EVALUATION AND EARLY DETECTION OF AGGRESSIVE PROSTATE CANCER

Screening:

Screening for prostate cancer is an individual decision for you to discuss with your health care provider.

Prostate cancer is the second leading cause of cancer death in men, estimated at 31,500 deaths in 2019.

Many men who have prostate cancer will not need any therapy.

2 out of 100 men with prostate cancer will die from it within 5 years of diagnosis.

Aggressive prostate cancer should be diagnosed early to prevent it from spreading to distant areas of the body, after which 70 out of 100 men will die from it within 5 years of diagnosis.

Since aggressive cancer may not cause any observable sign in early stages, you may decide to be screened with PSA, which is a prostate-specific protein measured in the blood, and/or a digital rectal examination (DRE), after consultation with your provider.

Guidelines vary on who is appropriate for screening, but generally recommend starting around 45-50 years of age. If you have other risk factors, such as being African-American, having a family history of prostate cancer, or increased genetic risk, your provider may suggest starting earlier.

Benefits of screening are early detection of aggressive prostate cancer before it has spread.

Because your PSA or DRE result may be abnormal in many cases when you don't have cancer, or have a cancer which doesn't need treatment, the downside to getting screened is anxiety, potential invasive procedures such a prostate biopsy, and getting therapy for cancers that would not have harmed you if not treated.

Some options after an abnormal screening result:

Repeat PSA:

PSA may be elevated in many cases without aggressive prostate cancer. Often, a repeat PSA test will show a lower, normal value. Repeating PSAs periodically may also be used to monitor for future abnormal values or persistent and significant elevation (PSA velocity).

The 4Kscore Test:

The 4Kscore Test calculates your risk for aggressive prostate cancer by measuring several proteins in your blood and combining that with clinical findings. It can be used after an abnormal PSA result if you are considering a prostate biopsy, both when you have never had a prior prostate biopsy or after a negative prostate biopsy where your provider is still concerned about your risk for aggressive prostate cancer.

Benefits of the 4Kscore Test are that it is a non-invasive follow up test, and is more specific than PSA and/or DRE for risk of aggressive prostate cancer. Knowing your risk with more certainty may help you decide on whether a prostate biopsy is appropriate for you or not.

The 4Kscore test, like most advanced diagnostic tests, is more expensive than a PSA, and is recommended only in men where the PSA result was abnormal and a prostate biopsy is being considered, where it can help guide your clinical care. It provides you with a risk probability, and does not diagnose or completely rule out prostate cancer. If you have other significant high risk factors, such as a very suspicious DRE, rapidly rising PSA levels, strong family history of prostate cancer, or high risk hereditary prostate cancer gene mutations, you may want to discuss getting a biopsy with your provider instead of further testing.

MRI:

An MRI of the pelvis can show the presence or absence of areas which are suspicious for prostate cancer. The benefits of an MRI is that if a suspicious area is found, it can help guide your provider if a prostate biopsy is done. A MRI is generally an expensive test, and is only recommended in men where there is a suspicion of prostate cancer from other results. MRI result accuracy depends on the skill and experience of the individuals analyzing the image. Not finding a suspicious area does not necessarily mean you do not have aggressive prostate cancer.

Prostate Biopsy:

A prostate biopsy is a surgical procedure where tissue samples ("cores") are taken from the prostate gland, usually through the rectum. Generally during this procedure, a rectal ultrasound probe will be used to visualize the prostate and, in some cases, a MRI image may help guide the needle taking the samples. For standard biopsies, usually 10-12 cores or more are taken.

A prostate biopsy is the method used to diagnose and grade prostate cancer before making a decision on whether you will need treatment or monitoring. The benefits are that if a cancer is found, your provider can then chose the appropriate therapy, or monitor you if therapy is not needed. Because it is only a sampling of the entire prostate gland, a prostate biopsy may miss or under-grade cancer in some cases.

A prostate biopsy is a surgical procedure which may have complications including bleeding, discomfort, and in some cases hospitalization or serious infection. In many cases, a prostate biopsy may not find any cancer, or may find a cancer that does not require treatment, and can be monitored with repeat prostate biopsies and PSA. If a potentially aggressive prostate cancer is found, your provider will decide how to treat it based on the particulars of your case.

Shared Decision

The appropriate management for you depends on your history, clinical findings, and preferences after discussing with your provider. The above information is a guide for screening and evaluation of prostate cancer, and is not all inclusive for risk, benefits, or complications for procedures and tests described. Please review this Decision Aid with your provider to determine the next steps for your care.

Test Performed by BioReference Laboratories, Inc., an OPKO Health, Inc. Company

The ordering and treating clinician should ensure that any and all testing ordered on behalf of his/her patients is reasonable and medically necessary.