4KSCORE TEST MEDICAL NECESSITY AND SHARED DECISION MAKING FORM

PATIENT NAME: _____ COLLECTION DATE: _____

PATIENT DOB: MM/DD/YYYY _____ COLLECTION TIME: _____ ☐ AM ☐ PM ACCT #: _____

INSTRUCTIONS

- This form, or the 4Kscore Test requisition, is required when an EMR order is placed for the 4Kscore Test, as part of Medicare required documentation of medical necessity and Shared Decision Making between the provider and patient.
- The 4Kscore Test order, patient demographics, and insurance information must accompany this form on an EMR printout or other form.
- Patient Name and DOB must be completed on this form.
- Collection date and time must be completed on this form.
- All questions are required for the 4Kscore Test. Patient and provider legible names, signatures and date signed are required.
- Medicare requires documentation of Shared Decision Making in the patient's medical records. Please retain a copy of this completed form and Shared Decision Aid in your records as part of this documenation.

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

SHARED DECISION MAKING

Patient Acknowledgment: By signing this form I acknowledge as the patient that I have had a detailed discussion with my health care provider on the risks and benefits of the 4Kscore Test, and reviewed the Shared Decision Aid on the back of this form. This included a discussion of why the 4Kscore Test was being ordered, my other options including prostate biopsy, and potential risks of getting the 4Kscore Test. After this review and discussion, I understand and agree with the need to order the 4Kscore Test.

Print Patient Name: _____ Patient Signature: _____ Date: MM/DD/YYYY

Statement of Shared Decision Making: By submission of this test requisition and accompanying sample(s), I certify that shared decision making occurred with the patient on the risks and benefits of the 4Kscore Test. This included a discussion of the medical necessity of the 4Kscore Test order, other management options including directly undergoing a prostate biopsy, and potential risks for this management plan. After this discussion, and prior to ordering the test, the patient has agreed that the 4Kscore Test is the best option for him.

I authorize and direct you to perform the testing indicated and; (i) I am authorized by state law to order the test(s) requested herein; (ii) any custom panel and/or ordered test(s) requested on this test requisition form are reasonable and medically necessary for the diagnosis and/or treatment of a disease, illness, impairment, symptom, syndrome or disorder; (iii) the test results will determine my patient's medical management and treatment decisions of this patient's condition on this date of service; and (iv) the full and appropriate diagnosis code(s) are indicated to the highest level of specificity.

Print Provider Name: _____ Provider Signature: _____ Date: MM/DD/YYYY

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4Kscore®

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.

References:

1. American Cancer Society; https://www.cancer.org/cancer/prostate-cancer.html
2. NCCN Clinical Practice Guidelines; https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf

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