Oncotype DX Prostate Order Form

Tel: 877.ONCOTYPE | oncotypeDX.com

Complete and FAX 650.362.6487

Genomic Health® | oncotype DX® Prostate Cancer Assay

ONCOTYPE DX PROSTATE CANCER ASSAY

REQUIRED: Test results will be customized based on risk assessment indicated below. See reverse for the specific definition of these categories.

Patient's NCCN® Clinical Risk Assessment (Select ONE): ☐ **Very Low** ☐ **Low** ☐ **Intermediate** (See Reverse)

STUDY INFORMATION/CODE

Study Name/Code (If applicable) _____

PATIENT INFORMATION

Patient Name (Last, First, MI)

DOB (mm/dd/yyyy) ☐ Male ☐ Female

Medical Record / Patient # (Optional)

Address

City State ZIP Country

Primary Phone Alternate Phone

CLINICAL INFORMATION (COMPLETE ALL)

Pre-Biopsy PSA _____ ng/mL

Prostate Volume

Stage ☐ T1c ☐ T2a ☐ T2b ☐ T2c

Gleason Score (Primary + Secondary) ☐ 3+3 ☐ 3+4 ☐ 4+3*

Biopsy Cores

a) # of Cores Collected _____ **b**) # of Positive Cores _____

c) Max % tumor involvement in any core ☐ ≤ 50% ☐ > 50% **d**)* # of 4+3 Positive Cores _____

Pre-Oncotype DX GPS management recommendation?

☐ Radical Prostatectomy ☐ External Beam Radiation ☐ Brachytherapy

☐ Active Surveillance ☐ Other _____

BILLING INFORMATION

Submitting Diagnosis ☐ Prostate Cancer Other _____ Select ICD-10 Code ☐ C61 ☐ Other _____

Select Billing Type ☐ Medicare ☐ Private Insurance ☐ Medicaid ☐ Patient ☐ Pathology Account (Restricted to contracted accounts)

Hospital Status (Medicare only) ☐ Non-Hospital Patient ☐ Hospital Outpatient ☐ Hospital Inpatient - Discharge Date _____

Primary Insurance Company Name Member ID # Prior Authorization #

Secondary Insurance Company Name Member ID #

BENEFITS INVESTIGATION

Genomic Health will investigate the patient's insurance benefits, and may contact the patient should the patient's financial responsibility exceed a pre-determined amount. (See reverse for details.)

☐ **Check the box if the patient *IS AWARE OF A DIAGNOSIS OF PROSTATE CANCER* and Genomic Health is authorized to contact the patient.**

SPECIMEN RETRIEVAL

Genomic Health will obtain the specimen on your behalf. Check box if location is listed on attached pathology report, or indicate location of specimen in the fields provided below.

☐ Reference attached pathology report

Location of Specimen Phone Fax Contact Name

ORDERING INFORMATION

Practice Account Name

Ordering Physician Name Fax Email

Contact Name Contact Phone Contact Email

Additional Physician / Recipient Name

Email

Phone Fax

PHYSICIAN SIGNATURE & ATTESTATION

Your signature constitutes a Certification of Medical Necessity and your attestation of the following: 1) Test results will be used with other clinical data to help determine the appropriate treatment plan for the patient; 2) The patient's consent has been obtained for Genomic Health Inc's release of the test results to the patient's third party payer when necessary as part of the reimbursement process; 3) The patient meets the assay criteria OR if the patient does not meet these criteria, the reason(s) have been indicated in the Exception Criteria space provided (see reverse for details); and 4) The proper NCCN Clinical Risk Assessment has been selected above; 5) Attestation covers attested details on the reverse side.

For Medicare Beneficiaries: I further certify that I have completed requisite training and have enrolled in the Genomic Health CTR Program and that the patient meets the Medicare patient eligibility criteria provided on the reverse side of this form.

Ordering Physician Signature **Print Physician Name** **Date** (mm/dd/yyyy)

Exception Criteria

PATHOLOGY INFORMATION | PATHOLOGY TO COMPLETE

SUBMIT SPECIMEN WITHIN 24 HOURS

Pathology Account

Submitting Pathologist Name

Phone Fax

No substitutions for this assay

Specimen ID Specimen Barcode

Date of Collection (mm/dd/yyyy) Date Block Pulled From Archive (Medicare only)

Pathology Comments

GH1007 Rev#22 Feb-2016

Include a pathology report with specimen submission

301 Penobscot Drive | Redwood City | CA | 94063

REQUISITION FORM INSTRUCTIONS

Online ordering is available at online.genomichealth.com. For assistance in setting up a Portal Account for online ordering, please contact Customer Service.

Assay results will be delivered to the Ordering Physician and additional recipients via the secure online portal and/or by fax based on the physicians' report delivery preferences on file at Genomic Health, Inc. (GHI). To establish or change report delivery preferences, please contact Customer Service 877.662.6897.

The result report is based upon GHI's analysis of the submitted specimen and information provided on the Requisition Form. Additional materials or information that may have been submitted with the specimen are not considered in analyzing the specimen or preparing the report.

ASSAY

A. Select the appropriate NCCN® Risk Assessment (NCCN v.3.2012).
NCCN clinical risk assessment is required to determine the extent of the clinical experience information to be included in the report for the patient. If the NCCN clinical risk assessment is not provided, a report with clinical experience for all three risk categories (Very Low Risk, Low Risk & Modified Intermediate Risk) will be sent.

NCCN Very Low Risk (Must meet **ALL** of the following criteria):
- Gleason Score ≤ 6
- PSA < 10 ng/mL
- Clinical stage T1c
- Fewer than 3 positive biopsy cores, ≤ 50% involvement in any core
- PSA density < 0.15 ng/mL/g

NCCN Low Risk (Must meet **ALL** of the following criteria):
- Gleason Score ≤ 6
- PSA < 10 ng/mL
- Clinical stage T1-T2a

NCCN Intermediate Risk (Must meet ONE of the following):
- Gleason Score ≤ 6, AND
  Clinical stage T2b-T2c, OR
  PSA 10-20 ng/mL
- Gleason Score 3+4, AND all of the following:
  Clinical stage T1-T2c
  PSA ≤ 20 ng/mL
- Gleason Score 4+3, AND all of the following:
  Clinical stage T1-T2c
  PSA ≤ 20 ng/mL
  Only 1 positive core of 4+3 disease

BILLING INFORMATION

A. Indicate the party responsible for payment.

B. Billing Type:
- All Medicare patients will have an eligibility check and may be contacted during the process. If Patient is selected, a representative will contact the ordering physician's office to collect payment information.
- If the patient's insurance is Medicare, enter the hospitalization status. If Inpatient, enter the date of discharge from the hospital.
- Before selecting Bill Pathology Account, verify with GHI that you have a contracted account on file.

C. Complete the Primary and Secondary Insurance Information fields.

D. Include a copy of the front and back of both the primary and secondary insurance cards.

CLINICAL CRITERIA (MEDICARE)

The Oncotype DX Prostate Cancer Assay is covered only when the following clinical conditions are met:
- Needle biopsy with localized adenocarcinoma of the prostate (no clinical evidence of metastasis or lymph node involvement), and
- Biopsy consistent with the 1.2015 NCCN Prostate Cancer Early Detection guidelines
- Patient stage as defined by one of the following:
  - Very Low Risk Disease (T1c AND Gleason Score ≤ 6 AND PSA < 10 ng/mL AND < 3 prostate biopsy cores positive AND ≤ 50% cancer in any core AND PSA density of < 0.15 ng/mL/g) OR
  - Low Risk Disease (T1-T2a AND Gleason Score ≤ 6 AND PSA < 10 ng/mL).
- Patient's life expectancy is > 10 years based on the Social Security Actuarial tables, and
- Patient is a candidate for, and is considering conservative therapy 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 biospy, and
- Test is ordered by a physician certified in the Genomic Health Oncotype DX Prostate Cancer Assay Certification and Training Registry (Oncotype DX CTR), and
- 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 specific cancer mortality in patients not treated definitively who were deemed NCCN Very-Low and Low risk by the assay.

BENEFITS INVESTIGATION - PATIENT CONTACT

A. A patient insurance benefit investigation will be performed to determine whether the cost of the assay could be covered by the patient's third party payer(s).

B. Select the box if the patient is aware of his prostate cancer diagnosis and the Ordering Physician is authorizing Genomic Health to contact the patient directly regarding his financial responsibility. Patients will only be contacted should their financial responsibility exceed the pre-specified limit (see Prostate.OncotypeDX.com/benefits-investigation for details). If the box is unchecked, Genomic Health will contact the Ordering Physician if the patient's financial responsibility exceeds the pre-specified limit.

NOTE: Third-party reimbursement is affected by many factors. Genomic Health Inc. makes no representation or guarantee that full or partial insurance reimbursement or any other payment will be available. While Genomic Health tries to provide correct information, we make no representations or warranties, expressed or implied, as to the accuracy of the information. These support services have no independent value to providers and are included within the cost of the Onco*type* DX® testing services.

SPECIMEN RETRIEVAL

If indicated, GHI will request the retrieval of the appropriate specimen for the ordered assay on your behalf.

NOTE: If the specimen retrieval section is not completed and the specimen is not submitted with the Requisition Form, GHI assumes you will initiate the retrieval of the specimen.

ORDERING INFORMATION

Additional physician/recipient information is optional. If another physician is responsible for the care of this patient and has requested a copy of the result, enter the applicable information in the spaces provided under this section.

PHYSICIAN SIGNATURE & ATTESTATION

A. Sign and date the Requisition Form and print your name. The signature must be of an Ordering Physician (treating physician or pathologist) or his/her representative.

NOTE: *Stamped signatures are NOT acceptable.*

B. ATTESTATION: The signature constitutes a certification of the following: (1) with respect to tests reimbursed by Medicare, Medicaid or other third party payers, the test is medically necessary and the results will be used in the management of the patient; (2) If the Ordering Physician is not the treating physician (or his/her authorized representative), the Ordering Physician confirms that the treating physician has ordered the assay for this purpose; (3) the treating physician has obtained the patient's consent for GHI to send the patient's test results to the patient's third party payer in connection with an appeal of a reimbursement denial or other reimbursement matter, if GHI has made prior attempts to obtain reimbursement without the release of such tests results; (4) the patient meets the criteria defined in both the Assay and Clinical Criteria (Medicare) sections unless otherwise indicated in the Exception Criteria field.

Onco*type* DX Prostate Cancer Specimen Criteria

A. If the Requisition Form attestation has been signed and no exception criteria have been entered, you attest that the specimen is from a newly diagnosed and biopsied (≤ 6 months) prostate cancer patient meeting the NCCN Very Low risk, NCCN Low risk, or Modified NCCN Intermediate risk criteria specificed in the Assay Section on this page.

If GHI determines that the specimen does not fit the criteria stated above, the patient's test report will indicate, where appropriate, that the clinical interpretation of the assay result is unknown or adjusted. In all cases, it is the treating physician's responsibility to determine whether and how the assay result should be used in determining a treatment plan for that patient.

B. In some cases additional assessment methods may be used to verify that the specimen meets the criteria for the Onco*type* DX assay.

PATHOLOGY INFORMATION

A. Enter the identification number for the most representative specimen (i.e. the longest linear length of the highest grade tumor) on the appropriate line.

B. While the GHI laboratory can accept tumor blocks and unstained slides, blocks are preferred.

C. Include a copy of the pathology report with the Specimen Kit submission box. The pathology report may be used for reimbursement and/or administrative purposes.

SUBMIT REQUISITION FORM TO GENOMIC HEALTH

A. Fax the completed, signed Requisition Form to the fax number indicated on the reverse side.

B. If submitting a specimen, include the Requisition Form with the specimen collection kit. See specimen preparation and shipment instructions.

SPECIMEN INSTRUCTIONS

SPECIMEN PREPARATION INSTRUCTIONS

A. For specimen criteria and specimen preparation instructions, visit oncotypeDX.com.

B. Please send either:
1. One fixed paraffin embedded tumor block.
2. Eight 5 µm serial unstained slides.

IMPORTANT: Hand number the serially sectioned slides to indicate the order in which they were cut. Unnumbered slides will be rejected.

C. Neutral buffered formalin is the preferred fixative. Alternative fixatives are not recommended.

D. Label all specimens with S-Barcode labels from the Specimen Collection and Transportation Kit.

E. Affix a coinciding S-Barcode in the designated area on the Requisition Form.

NOTE: Discard any remaining S-Barcode labels and do not use for future submissions.

F. If you have any questions, please contact customer service at the phone number listed on the front side of this form.

DOMESTIC SHIPPING INSTRUCTIONS

A. Before shipping, make a copy of the Requisition Form and retain it for your records.

B. Place the Onco*type* DX Specimen Kit into the FedEx® Clinical Pak.

C. Complete the FedEx® US Airbill. The airbill is pre-printed with Genomic Health shipping information.

D. Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.

E. Place the package in the designated FedEx® pickup location at your site.

F. If your site does not have standard FedEx® pickup, call 800-GO FEDEX (800-463-3339) to arrange for pick up.

NOTE:
- To order additional kits, email Customer Service at customerservice@genomichealth.com.