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Prolaris®

Biopsy Test Request Form (TRF)

PATIENT INFORMATION			ORDERING PHYSICIAN		
PATIENT NAME (LAST, FIRST, INITIAL)			NAME (LAST, FIRST, DEGREE)		NPI #
PATIENT ID # (OPTIONAL)	<input type="radio"/> FEMALE <input type="radio"/> MALE	BIRTH DATE (MM/DD/YYYY)	MYRIAD ACCOUNT NO: (If new customer or account number is unknown, please complete the address info or call (800)469-7423)		
STREET ADDRESS			ADDRESS		
CITY	STATE	ZIP	CITY	STATE	ZIP
DAYTIME PHONE NUMBER	ALTERNATE PHONE NUMBER		OFFICE CONTACT	PHONE	FAX
			EMAIL		

CLINICAL INFORMATION	
Pre-Biopsy PSA: _____ ng/mL	Highest Gleason Score on Current Biopsy: <i>Primary Grade + Secondary Grade = Gleason Score</i>
Clinical Stage (Based on DRE): <input type="radio"/> T1a <input type="radio"/> T1b <input type="radio"/> T1c <input type="radio"/> T2a <input type="radio"/> T2b <input type="radio"/> T2c <input type="radio"/> T3a <input type="radio"/> T3b <input type="radio"/> T4	_____ + _____ = <input type="text"/>
Biopsy Cores: Total number of cores taken: _____ Total number of positive cores: _____	
Date of Biopsy: _____	
Planned Treatment before Prolaris Score™ (Check most probable): <input type="radio"/> Radical Prostatectomy <input type="radio"/> Radiation <input type="radio"/> ADT <input type="radio"/> Watchful Waiting <input type="radio"/> Active Surveillance <input type="radio"/> Other: (specify) _____	
Prostate Volume _____ cc OR Prostate Length _____ cm, Width _____ cm, Height _____ cm	
<input type="radio"/> Patient has received pelvic radiation and/or androgen deprivation prior to their biopsy	
<i>For Medicare Patients Only:</i>	
At the time of biopsy: <input type="radio"/> Hospital Inpatient (>24 hour stay) Discharge Date: _____ <input type="radio"/> Hospital Outpatient <input type="radio"/> Non-Hospital Patient	

ANCESTRY			
Select all that apply:	<input type="radio"/> Ashkenazi Jewish	<input type="radio"/> Black/African	<input type="radio"/> Middle Eastern
	<input type="radio"/> Asian	<input type="radio"/> Hispanic/Latino	<input type="radio"/> Pacific Islander
		<input type="radio"/> Native American	<input type="radio"/> White/Non-Hispanic

TEST OFFERING
Prolaris Biopsy Test

SPECIMEN INFORMATION
<input type="radio"/> I want Myriad Genetic Laboratories, Inc. to request the specimen. (COMPLETE the information below.)
LOCATION OF SPECIMEN _____ PHONE _____ FAX _____ CONTACT NAME _____
<input type="radio"/> I have a specimen to send Myriad Genetic Laboratories. (FOLLOW mailing instructions in the test kit) Specify: <input type="radio"/> Blocks and/or <input type="radio"/> Slides

HEREDITARY RISK ASSESSMENT
Does patient have a close blood relative with breast cancer, ovarian cancer, pancreatic cancer, or prostate cancer? <input type="radio"/> Yes <input type="radio"/> No

AUTHORIZED SIGNATURE
I hereby authorize testing and confirm that informed consent has been obtained, if required by state law. I confirm that this is medically necessary and the results will be used in the medical management and treatment decisions for the patient. I confirm that the patient has an estimated life expectancy ≥ 10 years. I certify that I will discuss with the patient their test results and how their results helped inform treatment recommendations. I hereby attest that the person listed in the Ordering Physician space above is authorized by law in the relevant jurisdiction to order the test(s) requested herein. I confirm that I have on file the patient's assignment of benefits authorizing insurance benefits to be paid to ancillary healthcare service providers, such as Myriad Genetics Laboratories, Inc. (MGL). I authorize MGL to release the information on this form, and other information provided by me, necessary to process a claim for this service.
For Medicare Beneficiaries: I further certify that I have completed requisite training and have enrolled in the Prolaris CTR Program. The Medicare patient eligibility criteria are provided on the backside of this form.
_____ Healthcare Provider's Signature _____ Date _____

BILLING/PAYMENT INFORMATION
<input type="radio"/> OPTION 1: PLEASE BILL INSURANCE (For Medicare patients: only available if test order date is more than 2 weeks after discharge date)
<input type="radio"/> Include enlarged copies of both sides of insurance card(s). If two cards are submitted, indicate which is primary.
<input type="radio"/> OPTION 2: PATIENT PAYMENT (Please call Customer Service for questions regarding test prices)
<input type="radio"/> Please bill my credit card (all major credit cards accepted) in the amount of \$ _____ Card# _____ Exp. Date: _____ Cardholder Name (please print): _____ Cardholder Signature: _____
<input type="radio"/> Personal check, cashiers check, or money order enclosed, payable to Myriad Genetic Laboratories, Inc.
<input type="radio"/> OPTION 3: OTHER BILLING (To establish an account, submit billing information with this form)
<input type="radio"/> Bill our institutional account #: _____ or established research project code #: _____ or Authorization/Voucher #: _____



IMPORTANT INFORMATION FOR PATIENT*

BILLING TERMS: I represent that I am covered by insurance and authorize Myriad Genetic Laboratories, Inc. (MGL) to give my designated insurance carrier, health plan, or third party administrator (collectively "Plan") the relevant health information necessary for reimbursement. I authorize Plan benefits to be payable to MGL. I understand MGL will contact me if I will be financially responsible for any non-covered service. I agree to assist MGL in resolving insurance claim issues and if I don't assist, I may be responsible for the full test cost. I permit a copy of this authorization to be used in place of the original.

*Translation of Billing Terms are available in Mandarin and Spanish at MyriadPromise.com

Medicare Beneficiaries Eligibility – Indications for Use Under Prolaris LCD IDs L36350 and L37082

THE PROLARIS® ASSAY IS COVERED BY MEDICARE ONLY WHEN THE FOLLOWING CLINICAL CONDITIONS ARE MET:

- Needle biopsy diagnosis of clinically localized adenocarcinoma of the prostate (no clinical evidence of metastasis lymph node involvement or extension beyond the gland), **AND**
- FFPE prostate biopsy specimen with at least 0.5 mm of cancer length, **AND**
- 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 cores with tumor **AND** $\leq 50\%$ 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), **OR**
 - Favorable Intermediate Risk Disease - Predominant Gleason grade 3 (i.e. Gleason score 3+4=7, percentage of positive cores $<50\%$, and no more than 1 NCCN intermediate-risk factor) NCCN intermediate risk factors include T2b-T2c, Gleason score 7, and PSA 10-20 ng/ml, **AND**
- Patient has an estimated life expectancy of greater than or equal to 10 years, **AND**
- Patient is a candidate for and is considering conservative therapy and would be eligible for definitive therapy (including radical prostatectomy, radiation therapy or brachytherapy), **AND**
- Result will be used to determine treatment between definitive therapy and conservative management, **AND**
- Patient has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, **AND**
- Test is ordered by a physician certified in the Myriad Prolaris Certification and Training Registry (CTR), **AND**
- Patient is monitored for disease progression according to established standard of care, **AND**
- Physicians must report the development of metastasis or prostate cancer deaths in patients not treated definitively who were deemed low risk by the assay.

AUA LOW RISK GROUP:

Guideline for the Management of Clinically Localized Prostate Cancer (2007, reviewed and validity confirmed 2011)

- T1c or T2a
- Gleason score ≤ 6
- PSA ≤ 10 ng/mL

NCCN VERY LOW RISK GROUP:

NCCN Guidelines Version 2.2017 Prostate Cancer

- T1c
- Gleason score ≤ 6
- PSA < 10 ng/mL
- Fewer than 3 prostate biopsy cores positive, $\leq 50\%$ cancer in each core
- PSA density < 0.15 ng/mL/g

NCCN LOW RISK GROUP:

NCCN Guidelines Version 2.2017 Prostate Cancer

- T1 - T2c
- Gleason score ≤ 6
- PSA < 10 ng/mL

NCCN FAVORABLE INTERMEDIATE GROUP

NCCN Guidelines Version 2. 2017 Prostate Cancer

"Patients with favorable intermediate-risk prostate cancer (predominant Gleason grade 3 [i.e., Gleason score 3 + 4 = 7], and percentage of positive biopsy cores < 50 percent, and no more than one NCCN intermediate risk factor) can be considered for active surveillance."