MOLECULAR TESTING, GENE EXPRESSION PRIOR AUTHORIZATION FORM

This form must be completed by a person with thorough clinical knowledge of the member's current clinical presentation and his/her clinical evaluation history. **Clinical documentation supporting the medical necessity of this request is required (include the AHCP Order for genetic testing).** For more information, please refer to the medical policy document MC/L012 Gene Expression Profiling located at https://www.preferredone.com/medical-policy/.

Please email this form and clinical documentation to Intake@Preferredone.com or fax to (763) 847-4014.

Patient Name	**Member ID #**	**DOB**	
ICD 10 DX	**Ordering Provider Signature**	**Procedure Code(s)**	
Date of Service	**Date of Lab Draw**		
Ordering Provider First & Last Name		**NPI #**	
Address		**City**	
Phone	**Fax**	**State**	**Zip**
Servicing Provider Name (Lab)		**NPI #**	
Clinic/Site of Service		**NPI #**	
Address		**City**	
Phone	**Fax**	**State**	**Zip**

CHARACTERISTICS OF COVERED TESTS	**Check Box**
Each test has been approved for its intended use by the appropriate regulatory/oversight body (implies analytic validity)	☐
Each test has sufficient sensitivity and specificity (clinical validity) for targeting the member's specific clinical condition	☐
The results of each molecular test will directly impact clinical decision-making and clinical care (clinical utility) for the individual	☐

BREAST CANCER		**Check Box**
Is there more than 1 primary tumor? ◯ YES ◯ NO		
No previous gene expression profiling has been performed (does not include reflex testing)		☐
GENE EXPRESSION PROFILING WILL BE PERFORMED USING THE 21-GENE ASSAY (ONCOTYPE DX® BREAST CANCER ASSAY) IN WOMEN OR MEN		☐
Characteristics of the largest or the primary tumor	Hormone-receptor positive (estrogen and progesterone receptors)	☐
	Human epidermal growth factor (HER2) receptor negative	☐
	Pathologic tumor (pT) stage_____(eg, pT1, pT2, pT3, etc.)	
	Pathologic node (pN) stage_____(eg, pN0, pN1mi, pN1, etc.)	
	Tumor size_____cm (must be greater than 0.5cm	
	Oncotype DX® Breast Cancer Assay, EndoPredict®, Prosigna™ (PAM50) Breast Cancer Gene Signature assay, or MammaPrint™ have not been previously performed.	☐

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Patient Name	
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BREAST CANCER (continued)		**Check Box**
GENE EXPRESSION PROFILING WILL BE PERFORMED USING THE 12-GENE ASSAY (ENDOPREDICT®), 50-GENE ASSAY (PROSIGNA™ [PAM50]), 70-GENE ASSAY (MAMMAPRINT [AMSTERDAM SIGNATURE]) IN WOMEN		☐
Characteristics of the largest or the primary tumor	Hormone-receptor positive (estrogen and progesterone receptors)	☐
	Human epidermal growth factor (HER2) receptor negative	☐
	Node-negative (pathologic node [pN] stage pN0)	☐
	1 to 3 positive nodes (pathologic node [pN] stage of pN1, pN2, or pN3)	☐
	Oncotype DX® Breast Cancer Assay, EndoPredict®, Prosigna™ (PAM50) Breast Cancer Gene Signature assay, or MammaPrint™ have not been previously performed.	☐
GENE EXPRESSION PROFILING WILL BE PERFORMED USING THE 6-GENE ASSAY (BREAST CANCER INDEX^{SM}) IN WOMEN		☐
Characteristics of the largest or the primary tumor	Hormone-receptor positive (estrogen and progesterone receptors)	☐
	Human epidermal growth factor (HER2) receptor negative	☐
	Node-negative (pathologic node [pN] stage pN0)	☐
	1 to 3 positive nodes (pathologic node [pN] stage of pN1, pN2, or pN3)	☐
	Breast Cancer Index^{SM} has not been previously performed	☐

MELANOMA, OCULAR (UVEAL)	**Check Box**
GENE EXPRESSION PROFILING WILL BE PERFORMED USING THE 15-GENE ASSAY (DecisionDX-UM)	☐
The member has localized ocular/uveal melanoma	☐
The request is for risk stratification	☐

PROSTATE CANCER	**Check Box**
Life expectancy is equal to or greater than 10 years	☐
Life expectancy is greater than five years but less than 10 years and the member is symptomatic	☐
POST-BIOPSY	☐
The member has been newly-diagnosed with prostate cancer and the test will be performed to manage treatment	☐
Gene expression profiling will be performed using the 1.4M RNA expression (44,000 genes) whole-transcriptome oligonucleotide microarray (Decipher®)	☐
Gene expression profiling will be performed using the 8-protein multiplex immunofluorescent staining (ProMark®)	☐
Gene expression profiling will be performed using the 31-cell cycle progression (CCP) gene assay (Prolaris™)	☐
Gene expression profiling will be performed using the 17-gene assay (Oncotype DX® Prostate)	☐
The member's disease risk is (see Table 1 below): ☐ Very low ☐ High ☐ Low ☐ Very High ☐ Intermediate, favorable ☐ Intermediate, unfavorable	
POST RADICAL PROSTATECTOMY	☐
Gene expression profiling will be performed using the 1.4M RNA expression (44,000 genes) whole-transcriptome oligonucleotide microarray (Decipher®)	☐

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Table 1. Risk Group for Prostate Cancer

Risk Group	Clinical/Pathologic Features	
Very Low	• Tumor stage or T category T1c; and • Grade Group 1; and • PSA less than 10ng/mL; and • Fewer than 3 prostate biopsy fragments/cores positive, less than or equal to 50% cancer in each fragment/core; and • PSA density less than 0.15ng/mL/g	
Low	• Tumor stage or T category T1-T2a; and • Grade Group 1; and • PSA less than 10ng/mL	
Intermediate	• Has no high- or very high-risk features; and • Has one or more intermediate risk factors (IRF): o Tumor stage or T category T2b-T2c; or o Grade Group 2 or 3; or o PSA 10-20 ng/mL	Favorable Intermediate • 1 IRF; and • Grade Group 1 or 2; and • Less than 50% biopsy cores positive
		Unfavorable Intermediate • 2 or 3 IRFs; or • Grade Group 3; or • Greater than or equal to 50% biopsy cores positive
High	• Tumor stage or T category T3a; or • Grade Group 4 or 5; or • PSA greater than or equal to 20ng/mL	
Very High	• Tumor stage or T category T3b-T4; or • Primary Gleason pattern 5; or • Greater than 4 cores with Grade Group 4 or 5	

Retrieved from National Comprehensive Cancer Network (NCCN) Guidelines. Prostate Cancer. 2.2019, 04/17/19. Page PROS-2. Accessed 07-11-19.

THYROID	**Check Box**
Request is for cytologically indeterminate FNA thyroid neoplasms/nodules, including atypia of undetermined significance/follicular lesion of undetermined significance	☐
Gene expression profiling will be performed using the Afirma Genomic Sequencing BRAF V600E Classifier (a reflex test from the Afirma Genomic Sequencing Classifier)	☐
Gene expression profiling will be performed using the Afirma Genomic Sequencing Classifier	☐
Gene expression profiling will be performed using the Afirma Medullary Thyroid Carcinoma (MTC) Classifier (a reflex test from the Afirma Genomic Sequencing Classifier test)	☐
Gene expression profiling will be performed using the ThyGeNEXT/ThyGenX	☐
Gene expression profiling will be performed using the ThyraMIR (a reflex test from the ThyGeNEXT test)	☐
Gene expression profiling will be performed using the ThyroSeq	☐