

## Clinical Policy: Gene Expression Profile Testing of Cancer Tissue

Reference Number: WA.CP.MP.511

Date of Last Revision: 08/21

Effective Date: 09/01/21

[Coding Implications](#)

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### Description

This policy describes the medical necessity guidelines for gene expression profile testing of cancer tissue to aid treatment decision-making.

### Policy/Criteria

- I. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Health Technology Assessment, that gene expression profile testing of *breast and prostate* cancer tissue is considered **medically necessary** when test results will impact treatment decisions.
- II. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Health Technology Assessment, that the following **additional criteria** will be applied to specific gene expression profile tests:
  - A. Breast Cancer:
    1. Oncotype DX, EndoPredict, Prosigna, and MammaPrint tests area covered for Stage 1 or 2 disease when
      - Estrogen receptor positive and human epidermal grow factor receptor 2 (Her2-NEU) negative, and
      - Lymph node negative or 1-3 lymph node(s) positive
    2. Mammostrat and Breast Cancer Index (BCI) are covered only for women with stage 1 or 2 cancer deciding about hormone therapy.
  - B. Prostate Cancer:
    1. Oncotype DX and Prolaris are covered only for low risk or favorable intermediate risk disease.
    2. Decipher is covered for men deciding between active surveillance and adjuvant radiotherapy after radical prostatectomy.
- III. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Health Technology Assessment, that when medically necessary, gene expression profile tests will be **covered** at a rate of one test per twelve months per index cancer.
- IV. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Health Technology Assessment, that gene expression profile testing of cancer tissue is **not medically necessary** for *multiple myeloma or colon cancer*.

### Background

This policy is based entirely on Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) and Health Care Authority Billing Guidelines.

**Coding Implications**

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<b>CPT® Codes</b>	<b>Description</b>
81479	Unlisted molecular pathology procedure (used for Decipher prostate cancer classifier assay)
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (used for Breast Cancer Index)
81519	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes (used for Oncotype DX)
81520	Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (used for Prosigna)
81521	Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes (used for MammaPrint)
81522	Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score
81525	Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes
81540	Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes
81541	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (used for Prolaris)
81542	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score
81552	Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspiration or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
81599	Unlisted multianalyte assay with algorithmic analysis (used for Mammostrat and Endopredict)
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes
0045U	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score
0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (used for Oncotype DX prostate cancer assay)

CPT® Codes	Description
0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)
0090U	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical results (i.e., benign, indeterminate, malignant)
0153U	Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement
S3854	Gene expression profiling panel for use in the management of breast cancer treatment

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	08/19	08/19
Annual review. References updated. Added benefit limit.	08/20	09/20
Annual review. Expanded Description. References updated. Replaced “members” with “members/enrollees”. Added codes 81522, 81542, 81552, 0045U, 0089U, 0090U, 0153U. Multiple myeloma and colon cancer testing changed from not covered to not medically necessary.	08/21	09/21

**References**

1. King, V., Mosbaek, C., Carson, S., Lazur, B, Leof, A., Liu, R., Harrod, C. Center for Evidence-based Policy, Oregon Health & Science University. Gene Expression Profile Testing of Cancer Tissue. Washington Health Technology Assessment. February 16, 2018.
2. Washington State Health Care Authority. Physician-related Services/Health Care Billing Guide. <https://www.hca.wa.gov/assets/billers-and-providers/Physician-related-serv-bg-20210701.pdf> Revision effective July 1, 2021.

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note: For Medicaid members/enrollees**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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