


| | |
|---|---|
| MEDICAL POLICY | Genetic Testing: Gene Expression Profile Testing for Breast Cancer (Medicare Only) |
| Effective Date: 1/1/2022 | Medical Policy Number: 48 |
|  1/1/2022 | Medical Policy Committee Approved Date: 6/17; 12/17; 1/18; 8/18; 12/18; 12/19; 05/2021; 9/2021; 11/2021 |
| Medical Officer | Date |

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

| Service | Code(s) | Medicare Guidelines |
|--|-----------|---|
| <i>BluePrint (Agendia®)</i> | CPT 81479 | Local Coverage Articles (LCA): A55116 MoIDX: BluePrint® Coding and Billing Guidelines |
| <i>Breast Cancer Index (BCI) (bioTheranostics, Inc.)</i> | CPT 81518 | Local Coverage Determination (LCD): L37913 , MoIDX: Breast Cancer Index SM Genetic Assay |
| <i>EndoPredict (Myriad®)</i> | CPT 81522 | LCD: L37311 MoIDX: EndoPredict® Breast Cancer Gene Expression Test |
| <i>MammaPrint (Agendia®)</i> | CPT 81521 | LCA: A54447 MoIDX: MammaPrint Coding and Billing Guidelines |
| <i>Oncotype DX Breast (Genomic Health Inc.)</i> | CPT 81519 | LCA: A54482 MoIDX: Oncotype DX® Breast Cancer Assay Billing and Coding Guidelines |

| | |
|-----------------------|---|
| MEDICAL POLICY | Genetic Testing: Gene Expression Profile Testing for Breast Cancer (Medicare Only) |
|-----------------------|---|

| | | |
|--|-----------|--|
| <i>Oncotype DCIS (Genomic Health Inc.)</i> | CPT 0045U | LCD: L36947 MolDX - Oncotype DX® Breast Cancer for DCIS (Genomic Health™) |
| <i>Prosigna (PAM50) (NanoString Technologies Inc.)</i> | CPT 81520 | <ul style="list-style-type: none"> LCD: L36386 MolDX: Breast Cancer Assay: Prosigna |
| <i>DCISionRT® (Prelude Corp., California)</i> | CPT 0295U | For testing performed in services areas which have adopted MolDX guidelines, the MolDX Program requires laboratories to submit a technology assessment (TA) to establish analytical and clinical validity (AV/CV), and clinical utility (CU). (<i>Noridian LCA A54552</i>) The outcome of MolDX TA reviews is maintained in the DEX™ Diagnostics Exchange registry catalog . If a test does not have a coverage determination, clinical validity or utility has not been established via the TA review process and the test not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX or Noridian. The DCISionRT® is a test which has not yet undergone the required TA review to establish clinical utility. |

*In the absence of a Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.), Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5) Therefore, the commercial medical policy, Genetic Testing: **Gene Expression Profile Testing for Breast Cancer** (All Lines of Business Except Medicare) applies to the following services:*

- BreastOncPx™ (LabCorp)
- BreastPRS™ (Signal Genetics)
- Mammostrat® (Clariant Diagnostic Services)
- Molecular Grade Index (AviaraDx, Inc.)
- TargetPrint® (Agendia®)
- Theralink® Reverse Phase Protein Array (RPPA) (Theralink® Technologies, Inc.)

BILLING GUIDELINES

See associated local coverage articles (LCAs) for additional coding and billing guidance:

- LCA for Coding Article for MolDX: Breast Cancer Index™ (BCI) Gene Expression Test ([A56335](#))

| | |
|-----------------------|---|
| MEDICAL POLICY | Genetic Testing: Gene Expression Profile Testing for Breast Cancer (Medicare Only) |
|-----------------------|---|

- LCA for Billing and Coding: MolDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™) ([A57620](#))
- LCA for Billing and Coding: MolDX: Breast Cancer Assay: Prosigna ([A57364](#))
- LCA for Billing and Coding: MolDX: EndoPredict® Breast Cancer Gene Expression Test ([A57608](#))

CPT/HCPCS CODES

| Medicare Only | |
|---|--|
| Prior Authorization Required | |
| 0249U | Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report |
| No Prior Authorization Required | |
| The following codes do not require routine review for medical necessity, but they may be subject to audit. If there is uncertainty regarding the medical necessity and reasonableness of a test, an advance benefit determination request may be submitted. | |
| 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 |
| 81518 | Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy |
| 81519 | Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score |
| 81520 | Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score |
| 81521 | Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis |
| 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 |
| 81523 | Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis |
| Not Covered | |
| 0295U | Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, SIAH2), with 4 |

| | |
|-----------------------|---|
| MEDICAL POLICY | Genetic Testing: Gene Expression Profile Testing for Breast Cancer (Medicare Only) |
|-----------------------|---|

| | |
|--|--|
| | clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a recurrence risk score |
| Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required. | |
| 81479 | Unlisted molecular pathology procedure |
| 81599 | Unlisted multi-analyte with algorithmic analysis |
| 84999 | Unlisted chemistry procedure |

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.