


MEDICAL POLICY	Genetic Testing: Gene Expression Profile Testing for Breast Cancer (Medicare Only)
Effective Date: 6/1/2021  <div style="text-align: right;">6/1/2021</div>	Medical Policy Number: 48
	Medical Policy Committee Approved Date: 6/17; 12/17; 1/18; 8/18; 12/18; 12/19; 05/2021
Medical Officer	Date

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

SCOPE:

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

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA		
<p>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.</p>		
Service	Code(s)	Medicare Guidelines
Molecular diagnostic tests	See LCD	Local Coverage Determination (LCD): L36256 MoIDX: Molecular Diagnostic Tests (MDT) ¹
<i>BluePrint (Agendia®)</i>	CPT 81479	Local Coverage Articles (LCA): A55116 MoIDX: BluePrint® Coding and Billing Guidelines ²
<i>Breast Cancer Index (BCI) (bioTheranostics, Inc.)</i>	CPT 81518 (Note: 81479 prior to 4/15/2019)	<ul style="list-style-type: none"> • LCD: L37913, MoIDX: Breast Cancer IndexSM Genetic Assay³ • LCA: A56335, Coding Article for MoIDX: Breast Cancer IndexTM (BCI) Gene Expression Test LCD L37913⁴
<i>EndoPredict (Myriad®)</i>	CPT 81522 (Note: 81599 prior to 1/1/2020)	<ul style="list-style-type: none"> • LCD: L37311 MoIDX: EndoPredict® Breast Cancer Gene Expression Test⁵ • LCA: L57608 Billing and Coding: MoIDX: EndoPredict® Breast Cancer Gene Expression Test⁶
<i>MammaPrint (Agendia®)</i>	CPT 81521 (Note: 81479,	LCA: A54447 MoIDX: MammaPrint Coding and Billing Guidelines ⁷

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	84999 prior to 1/1/2018)	
<i>Oncotype DX Breast (Genomic Health Inc.)</i>	CPT 81519	LCA: A54482 MoIDX: Oncotype DX® Breast Cancer Assay Billing and Coding Guidelines ⁸
<i>Oncotype DCIS (Genomic Health Inc.)</i>	CPT 0045U (Note: 81479, 84999 prior to 1/1/2018)	<ul style="list-style-type: none"> LCD: L36947 MoIDX - Oncotype DX® Breast Cancer for DCIS (Genomic Health™)⁹ LCA A57620, Billing and Coding: MoIDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™)¹⁰
<i>Prosigna (PAM50) (NanoString Technologies Inc.)</i>	CPTs 81520 (Note: 0008M termed 12/31/2017)	<ul style="list-style-type: none"> LCD: L36386 MoIDX: Breast Cancer Assay: Prosigna¹¹ LCA: A57364, Billing and Coding: MoIDX: Breast Cancer Assay: Prosigna¹²

Per the [Medicare Policy Manual](#) commercial medical policies may be applied to Medicare coverage determinations in the absence of an appropriate NCD, LCD, LCA, or CMS Coverage Manual.

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®)

CPT CODES

Medicare Only	
No Prior Authorization Required	
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

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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
<p>Unlisted Codes</p> <p>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.</p>	
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.

REFERENCES

1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): L36256. LCD Title: MoIDX: Molecular Diagnostic Tests (MDT). For services performed on or after 11/01/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36256>. Accessed 04/02/2021.
2. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA) A55116. LCA Title: MoIDX: BluePrint® Billing and Coding. Effective: 12/01/2019. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55116>. Accessed 04/02/2021.
3. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37913. LCD Title: MoIDX: Breast Cancer IndexSM Genetic Assay. Original Effective Date: For services performed on or after 05/02/2021. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37913>. Accessed 04/02/2021.
4. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA) A56335. LCA Title: Coding Article for MoIDX: Breast Cancer IndexTM (BCI) Gene Expression Test LCD L37913. Original Effective Date: 04/15/2019. Revision Effective Date: 05/02/2021. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56335>. Accessed 04/02/2021.
5. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37311. LCD Title: MoIDX: EndoPredict® Breast Cancer Gene Expression Test. Revision Effective Date: For services performed on or after 11/01/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37311>. Accessed 04/02/2021.
6. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA) A57608. LCA Title: Billing and Coding: MoIDX: EndoPredict® Breast Cancer Gene Expression Test. Original Effective Date: 11/01/2019. Revision Effective Date: 01/01/2020. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57608>. Accessed 04/02/2021.
7. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA) A54447. LCA Title: MoIDX: MammaPrint Billing and Coding Guidelines. Effective: 01/01/2018. Revision Effective Date: 11/01/2019. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=54447>. Accessed 04/02/2021.
8. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA) A54482. LCA Title: MoIDX: Oncotype DX® Breast Cancer Assay Billing and Coding Guidelines. Revision Effective Date: 11/01/2019. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=54482>. Accessed 04/02/2021.
9. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L36947. LCD Title: MoIDX - Oncotype DX® Breast Cancer for DCIS (Genomic HealthTM). Revision Effective Date: For services performed on or after 12/01/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36947>. Accessed 04/02/2021.
10. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA) A57620. LCA Title: Billing and Coding: MoIDX: Oncotype DX® Breast Cancer for DCIS (Genomic HealthTM). Original Effective Date: 12/01/2019. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57620>. Accessed 04/02/2021.
11. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L36386. LCD Title: MoIDX: Breast Cancer Assay: Revision Effective Date: For services performed on or after

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11/01/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36386>. Accessed 04/02/2021.

- 12. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA) A57364. LCA Title: Billing and Coding: MolDX: Prosigna. Original Effective Date: 11/01/2019. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57364>. Accessed 04/02/2021.