

Gene Expression Profiling

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Definitions

Gene expression profiling (GEP) is a technology for identifying the genes that are active in a given sample of cells or tissue. This technique enables profiling of genes that are differentially expressed in disease states; thereby providing diagnostic and prognostic information.

Note: This guideline includes gene expression analysis, gene sequencing, and other techniques.

Related Medical Guidelines

[AlloMap® Molecular Expression Testing for Post-Heart-Transplant Rejection](#)

[Analysis of KRAS Status](#)

[Epidermal Growth Factor Receptor Mutation Analysis for Patients with Non-Small-Cell Lung Cancer](#)

[BCR-ABL1 Genetic Mutation Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia](#)

[BRAF Mutation Analysis](#)

[BRCA 1 and 2 Genetic Testing \(Sequence Analysis/Rearrangement\)](#)

[Cardiac Ion Channel Genetic Testing](#)

[Carrier Screening for Parents or Prospective Parents](#)

[Chromosomal Microarray Analysis \(CMA\)](#)

[Gene Expression Profiling and Biomarker Testing for Breast Cancer](#)

[Gene Expression Profiling of Melanomas](#)

[Gene Expression Testing for Multiple Myeloma](#)

[Genetic Analysis of PIK3CA Status in Tumor Cells](#)

[Genetic Counseling and Testing](#)

[Genetic Testing for Alzheimer's disease](#)

[Genetic Testing for Cancer Susceptibility](#)

[Genetic Testing for Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and](#)

[Leukoencephalopathy \(CADASIL\) Syndrome](#)

[Genetic Testing for Colorectal Cancer/Lynch Syndrome](#)

[Genetic Testing for Cystic Fibrosis](#)

[Genetic Testing for Factor V Leiden Mutation Analysis](#)

[Genetic Testing for Frontotemporal Dementia \(FTD\)](#)
[Genetic Testing for Hereditary Cardiomyopathy](#)
[Genetic Testing for Hereditary Hemochromatosis](#)
[Genetic Testing for Hereditary Pancreatitis](#)
[Genetic Testing for Inherited Peripheral Neuropathies](#)
[Genetic Testing for PTEN Hamartoma Tumor Syndrome](#)
[Genetic Testing for RET Proto-Oncogene Germline Mutations](#)
[Genetic Testing for Statin-Induced Myopathy](#)
[Genetic Testing for TP53 Mutations \(Li-Fraumeni Syndrome\)](#)
[Janus Kinase 2 \(JAK2\) V617F Gene Mutation Assay](#)

Guideline

Members are eligible for GEP testing as follows:

- I. Advanced cancer; next generation sequencing (NGS), when performed with a diagnostic lab test that has received FDA approval or clearance (e.g., Foundation One CDx)
Covered for [Medicare](#) members only when the following criteria are met:
 1. Member has
 - i. either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and
 - ii. either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and
 - iii. decided to seek further cancer treatment (e.g., therapeutic chemotherapy)
 2. The diagnostic laboratory test using NGS must have:
 - i. FDA approval or clearance as a companion in vitro diagnostic; and
 - ii. an FDA approved or cleared indication for use in that patient's cancer; and
 - iii. results provided to the treating physician for management of the patient using a report template to specify treatment options
- II. Breast cancer; one of the following
(See EmblemHealth [Gene Expression Profiling and Biomarker Testing for Breast Cancer](#) Medical Guideline)
 1. Breast Cancer Index®
 2. EndoPredict®
 3. HerMark® (Covered for [Medicare](#) members only)
 4. MammaPrint®
 5. Oncotype DX®
 6. Prosigna® Breast Cancer Prognostic Gene Signature Assay
- III. Non-small cell lung cancer (NSCLC) — limited [Medicare](#) coverage of Guardant360® (Guardant Health, Redwood City, CA), a plasma-based comprehensive somatic genomic profiling test (hereafter called CGP) for members with Stage IIIB/IV NSCLC when either of the following criteria are met:
 1. **At diagnosis** — untreated member
 - i. When results for EGFR single nucleotide variants (SNVs) and (insertions and deletions (indels); rearrangements in ALK and ROS1; and SNVs for BRAF are not

available **AND** when tissue-based CGP is infeasible (i.e., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated)

2. **At progression** — treated member
 - i. For members progressing on or after chemotherapy or immunotherapy who have never been tested for EGFR SNVs and indels; rearrangements in ALK and ROS1; and SNVs for BRAFs, and for whom tissue-based CGP is infeasible (i.e., quantity not sufficient for tissue-based CGP from original biopsy); OR
 - ii. For patients progressing on any tyrosine kinase inhibitors (TKIs).

If no genetic alteration is detected by Guardant360, or if circulating tumor DNA (ctDNA) is insufficient/not detected, tissue-based genotyping should be considered.

IV. Post-heart-transplant rejection; allowable every 1–3 months
(See EmblemHealth [AlloMap](#) Medical Guideline)

V. Prostate cancer

1. Decipher® Prostate is covered for all lines of business using criteria from [LCD: Decipher® Prostate Cancer Classifier Assay](#)
2. Oncotype DX is covered for all lines of business using criteria from [LCD: Oncotype DX® Prostate Cancer Assay](#)
3. Prolaris® Prostate Cancer is covered for all lines of business using criteria from [LCD: Prolaris™ Prostate Cancer Genomic Assay](#) for Men with Favorable Intermediate Risk Disease
4. ProMark® Protomic Prognostic Test is covered for all lines of business using criteria from [LCD: ProMark Risk Score](#)

VI. Thyroid lesions with indeterminate cytology; one-time testing

1. Afirma Thyroid FNA Analysis®
2. ThyGenX (formerly miRInform®)
3. ThyraMIR Thyroid miRNA classifier
4. ThyroSeq next generation sequencing

VII. Uveal melanoma (DecisionDx covered for Medicare members only)

(See EmblemHealth [Gene Expression Profiling of Melanomas](#) Medical Guideline)

Limitations/Exclusions

- I.** Gene expression profiling is not considered medically necessary in the absence of the following:
 1. Analytical/clinical validity
 2. Clinical utility (i.e., result does not impact medical management; e.g., surgery, change in surveillance, chemotherapy, hormonal manipulation, etc.)
- II.** Confirmation of consumer-based testing (including, but not limited to Health + Ancestry [23andMe] has not been shown to be of clinical value and remains experimental/investigational. Testing will be approved only for members who otherwise meet the clinical criteria in these policies
- III.** Whole exome sequencing and whole genome sequencing are not considered medically necessary due to insufficient evidence of therapeutic value for all indications, including but not limited to:

1. Diagnosis in members with suspected genetic disorders
2. Population-based screening
3. Cancer testing to identify targeted therapies
4. Preimplantation genetic diagnosis and screening
5. Invasive prenatal (fetal) testing
6. Products of conception and pregnancy loss
7. Testing for chromosomal rearrangements

IV. The following GEP tests are not considered medically necessary due to insufficient evidence of therapeutic value (list not all-inclusive; note exceptions):

1. 23-Gene NGS Pyruvate Metabolism and Related Disorders Panel
2. 23andMe Health + Ancestry Service
3. ADmark[®] Alzheimer's Evaluation
4. Albinism Panel
5. AmHPR Helicobacter Pylori Antibiotic Resistance NGS Panel
6. Autosomal Dominant and Recessive Polycystic Kidney Disease Nextgen Sequencing (NGS) Panel
7. Avise tests
 - i. Avise[®] CTD
 - ii. Avise[®] MTX (aka Avise PG) (Covered for [Medicare](#) members only)
 - iii. Avise[®] Lupus
8. bioTheranostics Cancer TYPE ID (Covered for [Medicare](#) members only)
9. BRCAPlus
10. BluePrint[®]
11. BreastNext[™]
12. BreastOncPx[™]
13. BreastPRS
14. BREVAGen/BREVAGenplus
15. CancerNext, CancerNext-Expanded[™]
16. CancerTYPE ID[®] (Covered for [Medicare](#) members only)
17. Carbohydrate Metabolism Deficiency NextGen DNA Screening Panel
18. Cardiovascular Health Panel
19. CGD Universal Test Panel
20. Ciliopathies: Sequencing Panel
21. Ciliopathy NextGen Sequencing (NGS) Panel
22. ColoNext[™]
23. ColoVantage
24. Combined Cardiac Panel (Covered for [Medicare](#) members only)
25. Complete Hereditary Spastic Paraplegia Evaluation Panel
26. Complete Lung
27. Comprehensive Dystonia NextGen DNA Screening Panel
28. Comprehensive Inherited Retinal Dystrophies Sequencing Panel
29. Comprehensive Molecular Genetic Panel
Comprehensive Muscular Dystrophy/Myopathy Next Generation DNA Sequencing Panel
30. Comprehensive Molecular Genetic Panel
31. ConfirmMDx[™] (Covered for [Medicare](#) members only)
32. Congenital Myopathy NextGen Sequencing (NGS) Panel
33. Congenital Stationary Night Blindness panel
34. Connective Tissue NGS Panel

35. Corus[®] CAD (Coverage rescinded for Medicare members effective Dec. 12, 2018 based on [noncoverage Local Coverage Determination: MoldX: Corus[®] CAD Assay](#))
36. Counsyl Foresight Carrier Screen
37. Craniosynostosis next generation sequencing (NGS) panel
38. DecisionDx tests
 - i. Glioblastoma
 - ii. Uveal melanoma (Covered for [Medicare](#) members only)
39. DecodEX Microbial Genetic Identification
40. Distal Hereditary Motor Neuropathy NextGen Sequencing (NGS) Panel
41. Ehlers-Danlos Syndrome NGS Panel Dominant and Recessive
42. ENGAUGE[™]-cancer-DLBCL
43. Epi proColon
44. ExomeNext
45. ExomeNext-Rapid
46. Expanded Pan-Ethnic Panel
47. Familial Hemiplegic Migraine NextGen Sequencing (NGS) Panel Fetal Akinesia Deformation Sequence/Lethal Multiple Pterygium Syndrome NextGen Sequencing (NGS) Panel
48. FoundationOne CDx (Covered for [Medicare](#) members only)
49. GeneAware
50. GeneFx[®] Colon
51. GeneFx[®] Lung
52. GeneKey
53. GeneStrat[™]
54. GeneSight (Covered for [Medicare](#) members only)
55. GeneTrails[®] Solid Tumor Panel
56. GPS Cancer
57. Guardant 360[®] Panel (Covered for [Medicare](#) members only)
58. Healthy Weight DNA Insight
59. Healthy Woman DNA Insight
60. HCMNext
61. H/I Gene Expression Ratio
62. Hemophagocytic Lymphohistiocytosis Panel by next generation sequencing (NGS)
63. Hereditary Spherocytosis/Elliptocytosis NextGen Sequencing Panel
64. HERmark (Covered for [Medicare](#) members only)
65. HLA-DQB1*06:02 typing for the diagnosis or management of narcolepsy
66. HOX13:IL17BR
67. Hypokalemic and Hyperkalemic Periodic Paralysis Disorders NGS Sequencing Panel
68. Insight[®] DX Breast Cancer Profile
69. Intellectual Disability (IDNEXT) Panel
70. Leukoencephalopathy NGS Panel
71. Lipodystrophy NGS Panel
72. LUNGSEQ[®] Panel
73. Macula Risk PGx
74. Macular Degeneration Mutation Analysis
75. Mammastatin
76. miReview[®]
77. Mammostrat
78. Melaris[®]
79. Molecular Intelligence

80. My5-FU™ (previously OnDose™)
81. Myeloid Molecular Profile
82. myPath®
83. MyPRS® Myeloma Prognostic Risk Signature
84. myRisk™
85. MYvantage® Hereditary Comprehensive Cancer Panel
86. Neurotransmitter Metabolism Deficiency NextGen DNA Screening Panel
87. Next Gen RASopathy Panel
88. Next Generation Sequencing Panel for ASXL1, RECQL4, RNU4ATAC, SOX2
89. NextStepDx PLUS®
90. NGS Epilepsy/Seizure Panel
91. NGS RASopathy Panel
92. OmniSeq Comprehensive
93. Oncotype DX® tests
 - i. Breast DCIS
 - ii. Colon cancer (Covered for [Medicare](#) members only)
94. Oncofocus®
95. OnkoMatch™
96. OncoVantage™
97. Oncovue
98. OPA 1 gene sequencing for autosomal dominant optic atrophy and/or optic neuropathy
99. Osteogenesis Imperfecta NGS Panel-Recessive
100. OvaNext™
101. Overa (aka OVA1 Next Generation or second-generation Multivariate Index Assay [MIA2G] test)
102. PAM50 Breast Cancer Intrinsic Classifier™
103. PancNext™
104. PancaGEN (previously Pathfinder TG®) ([Medicare](#) only)
105. Panexia®
106. Paradigm Cancer Diagnostics [PCDx] Test
107. Pediatric Neurology Region of Interest Trio
108. Percepta Bronchial Genomic Classifier (Covered for [Medicare](#) members only)
109. Pervenio™ Lung NGS (Covered for [Medicare](#) members only)
110. Pontocerebellar Hypoplasia Panel
111. Post-Op Px™ (formerly the Prostate Px Plus)
112. Preparent Global Panel
113. Previstage™
114. Progenity CFnxt
115. Progenity® Pan-Ethnic Carrier Screening Panel
116. PROGENSA® PCA3 (Covered for [Medicare](#) members only)
117. ProOnc TumorSource DX
118. Proove profile panels (e.g., Opioid Risk Panel)
119. ProstateNext
120. RenalNext™
121. ResponseDX Tissue Origin Test Rotterdam/Veridex ([Medicare](#) only)
122. RetnaGene AMD
123. Rotterdam Signature
124. Saethre-Chotzen Syndrome (TWIST) Sequencing and MLPA ([Greenwood Genetic Center](#))
125. ScolioScore™ AIS Prognostic Test
126. SelectMDx for prostate cancer

127. Spastic Paraplegia Next Generation Sequencing Panel
128. Stickler Syndrome NGS Panel
129. SymGene68™ Next Generation Sequencing Cancer Panel
130. SYMPHONY™ Genomic Breast Cancer Profile (combines Blueprint, MammaPrint and TargetPrint tests)
131. Skeletal Dysplasia Ciliopathy NGS Panel
132. SYMPHONY™ Personalized Breast Cancer Genomic Profile
133. TAADNext
134. Target Now™ molecular profiling test (aka MI Profile, MI Profile X)
135. TargetPrint®
136. TheraPrint®
137. theraSEEK Sequence Analysis for Functional Disorders
138. Thrombocytopenia NextGen Sequencing (NGS) Panel
139. TruGenome Undiagnosed Disease Test
140. TruGenome Technical Sequence Data (whole exome sequencing test for labs and physicians who will make their own clinical interpretations make their own clinical interpretations)
141. Universal Carrier Panel
142. Vectra DA (Covered for [Medicare](#) members only)
143. Vitreoretinopathy NGS Panel

Revision History

Oct. 12, 2018	Removed Corus® CAD Medicare coverage effective Dec. 12, 2018
Aug. 8, 2018	Added Medicare coverage of Guardant360® Pervenio™ Lung NGS
May 5, 2018	Added Commercial and Medicaid coverage of the Decipher, Oncotype, Prolaris and ProMark gene/biomarker expression profiling tests for prostate cancer to pre-existing Medicare coverage
Apr. 13, 2018	<p>Added FoundationOne CDx test coverage for Medicare members</p> <p>Removed the following test, Thyroid, FNA Cytomorphology with Molecular tests (Quest), from the list of covered tests for thyroid lesions with indeterminate cytology (no longer available from Quest)</p> <p>Added language communicating noncoverage of testing to confirm results of consumer-based testing</p> <p>Added language clarifying that whole exome and whole genome sequencing is considered investigational</p> <p>Updated list of lab tests regarded as investigational</p>
Apr. 14, 2017	<p>Added ThyraMIR Thyroid miRNA classifier to list of eligible tests for thyroid lesions with indeterminate cytology</p> <p>Added Melaris to investigational list</p>
Feb. 2, 2017	Added the following tests to investigational list: Oncofocus®, Previstage™
Sept. 9, 2016	Added the following tests to investigational list: DecodEX, Oncovue, OvaNext™, Panexia®
Aug. 12, 2016	<p>Added Medicare coverage for CancerTYPE ID®.</p> <p>Added the following tests to investigational list: Brevagen/Brevagenplus, My5-FU™ (previously OnDose™), OncoVantage™, OPA 1 gene sequencing for autosomal dominant optic atrophy and/or optic neuropathy, Proove Opioid Risk Test</p>
Jul. 8, 2016	Added the following tests to investigational list: Combined Cardiac Panel, Counsyl preconception carrier genetic screening, miReview®, Myeloid Molecular Profile, Paradigm Cancer Diagnostics [PCDx] Test, Pediatric Neurology Region of Interest Trio, Progenity® Pan-Ethnic Carrier Screening Panel, Rotterdam Signature, Saethre-Chotzen Syndrome (TWIST) Sequencing and MLPA, SelectMDx for prostate cancer

5/13/2016	Added Medicare coverage for Prosigna™ Breast Cancer Prognostic Gene Signature Assay. Added GeneStrat and Molecular Intelligence to list of investigational tests. Reinstated coverage of the following tests for Medicare members: Corus® CAD, ConfirmMDx™, Decipher® Prostate Classifier, Oncotype DX® Colon, Oncotype DX® prostate, Prolaris® and ResponseDX Tissue Origin Test
4/8/2016	Tests no longer covered for Medicare members (NGS Medicare Molecular Pathology LCD effective 4/1/2016) — Corus® CAD, ConfirmMDx™, Decipher® Prostate Classifier, Oncotype DX® colon, Oncotype DX® prostate, Prolaris® and ResponseDX Tissue Origin Test. Non-covered tests added to investigational list — GeneFx® Colon, myPath® (NGS Medicare Molecular Pathology LCD effective 4/1/2016)
12/21/2015	Amended Limitations/Exclusions Section to reflect positive Medicare coverage for Oncotype Prostate.
10/9/2015	Amended Limitations/Exclusions Section to reflect positive Medicare coverage for Decipher Prostate Classifier and Prolaris

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