Gene Expression Profiling

Last Review Date: August 12, 2022
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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.

(Skip cross referencing and go directly to Guideline Section)

Related Medical Guidelines
- Analysis of KRAS Status
- BRAF Mutation Analysis
- Carrier Screening for Parents or Prospective Parents
- Gene Expression Profiling and Biomarker Testing for Breast Cancer

Related MCG Criteria (list not all-inclusive)
- Alzheimer’s disease — MCG #: A-0590 (early onset), A-0809 (late onset)
- Amyotrophic Lateral Sclerosis (ALS) — A-0591
- Autism Spectrum Disorders/Developmental Delay/Intellectual Disability (See MCG #s below for chromosomal microarray analysis and whole genome/exome sequencing)
- BCR-ABL1 Genetic Mutation Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia — A-0759, A-0771
- Breast Cancer — PALB2 Gene — A-0989
- Breast Cancer (Hereditary) — Gene Panel — A-0767
- Breast or Ovarian Cancer (Hereditary) — BRCA1 and BRCA2 Genes — A-0499
- Cancer of Unknown Primary — A-0673
- Cancer Multigene Molecular Profiling — A-0789
- Cardiac Ion Channel Genetic Testing — MCG #: A-0594 (Brugada Syndrome), A-0607 (Long QT Syndrome), A-0636 (Catecholaminergic Polymorphic Ventricular Tachycardia), A-0831 (Romano–Ward Syndrome), A-0833 (Andersen-Tawil Syndrome), A-0834 (Timothy Syndrome), A-0918
- Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy (CADASIL) Syndrome — A-0668
- Coronary Artery Disease — A-0656 (KIF6 Gene) —, A-0658 (Genetic Panel)
Cowden Syndrome — A-0585
Cystic Fibrosis — A-0597
Deafness and Hearing Loss — MCG #s: A-0596 (Nonsyndromic - GJB2, MT-RNR1, MT-TS1, POU3F4, PRPS1, and SMPX Genes), A-0823 (Nonsyndromic - Microarray and Multigene Panels), A-0802 (Usher Syndrome)
Diabetes Mellitus — MCG #s: A-0598 (Maturity-Onset Diabetes of the Young), A-0826 (Type 2), A-0824 (Permanent Neonatal), A-0825 (Transient Neonatal)
Epidermal Growth Factor Receptor Mutation Analysis for Patients with Non-Small-Cell Lung Cancer — A-0795
Factor V Leiden Mutation Analysis — A-0600
Familial Hypercholesterolemia — A-0958
Familial Hyperinsulinism — A-0777
Fanconi Anemia — A-0683
Frontotemporal Dementia (FTD) — A-0906
Glycogen Storage Disease, Type I — A-0684
Heart-Transplant Rejection (AlloMap®) — A-0623
Hereditary Cardiomyopathy — MCG #s: A-0627 (Arrhythmogenic Right Ventricular), A-0633 (Nonsyndromic), A-0648 (Dilated)
Hereditary Pancreatitis — MCG #s: A-0646 (CFTR, CPA1, CTRC, PRSS1, and SPINK1 genes), A-0797 (next generation sequencing panel)
Huntington Disease — A-0605
Li-Fraumeni Syndrome - TP53 Gene — A-0584
Melanomas, cutaneous — MCG #s: A-0601 (BAP1, CDK4, and CDKN2A Genes), A-0837 (Gene Expression Profiling)
Multiple Endocrine Neoplasia (MEN) Syndrome — A-0582 (Type 1), A-0842 (Type 2)
Muscular Dystrophies (Duchenne, Becker)— A-0608
Neuroblastoma - MYCN Gene and Gene Expression Profiling — A-0610
Niemann-Pick Disease (Acid Sphingomyelinase Deficiency) — A-0611
Ovarian Cancer (Hereditary) — Gene and Gene Panel Testing — A-0782
Pancreatic Cancer (Hereditary) — Gene Panel — A-0797
Pancreatitis (Hereditary) — A-0646
Parkinson Disease — A-0671
Peripheral Neuropathies — A-0691
Polycystic Kidney Disease — MCG #s: A-0725 (Autosomal Dominant), A-0852 (Autosomal Recessive)
Prostate Cancer - BRCA1 and BRCA2 Genes — A-0612
Prostate Cancer (Hereditary) — Gene Panel — A-0854
RET Proto-Oncogene Germline Mutations — A-0842
Retinal Disorders (Hereditary) – Gene Panels — A-0912
Rett Syndrome — A-0687
Statin-Induced Myopathy — A-0981

Chromosomal Microarray Analysis (CMA) — MCG #s: A-0588 (Autism Spectrum Disorders), A-0810 (Developmental Delay), A-0812 (Prenatal Testing), A-0917 (Congenital Anomalies), A-0924 (Intellectual Disability)
Noninvasive Prenatal Testing (NIPT) — MCG#s A-0848 (Microdeletion Syndromes), A-0849 (Monogenic Disorders), A-0850 (Sex Chromosome Disorders)
Whole genome/exome sequencing — MCG #s: A-0710 (Cancer), A-0865 (Cardiovascular Disorders), A-0866 (Primary Immunodeficiency Disorders), A-0870 (Autism Spectrum Disorders), A-0871 (Metabolic, Mitochondrial, and Neurologic Disorders), A-0872 (Congenital Anomalies), A-0926 (Developmental Delay and Intellectual Disability)

Guideline
Members are eligible for GEP testing per the related policies above and as applicable below:

I. Advanced cancer, next generation sequencing (NGS), when performed with a diagnostic lab test that has received FDA approval or clearance* when the following criteria are met:
   1. Member has
      i. either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and
      ii. not been previously tested using the same NGS test for the same cancer genetic content; 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

* See List of Cleared or Approved Companion Diagnostic Devices to match the test with the drug under consideration. The member’s Pharmacy benefit should be checked for formulary inclusion. (Note: The FDA’s list of tests approved for use in conjunction with specific drugs may be searched in its entirety by selecting “All” in the “Show entries” drop down menu)

The following tests are not covered for Medicaid members, as proprietary lab analysis (PLA) codes are not reimbursed by NYS Medicaid (list may not be all-inclusive):

- FoundationOne CDx (0037U)
- FoundationOne Liquid CDx (0239U)
- Guardant360 CDx (0242U)
- LeukoStrat CDx FLT3 (0023U)
- myChoice® CDx (0172U)
- Oncomine Dx Target Test (0022U)
- Praxis Extended RAS Panel (0111U)
- therascreen FGFR RGQ RT-PCR Kit (0154U)
- therascreen PIK3CA RGQ PCR Kit (0155U [tumor tissue], 0177U [plasma])

II. Breast cancer, clinical management
   (See EmblemHealth Gene Expression Profiling and Biomarker Testing for Breast Cancer Medical Guideline)

III. Non-small cell lung cancer (NSCLC)
   Guardant360 lab-developed test (LDT) (see Section I for the FDA-approved Guardant360 CDx companion diagnostic test)

1. Medically necessary for Medicare members when LCD criteria, Plasma-Based Genomic Profiling in Solid Tumors, are met

2. Medically necessary for Commercial members for indications outside the scope of a companion diagnostic when:
   i. The member has a diagnosis of metastatic or recurrent NSCLC, AND
   ii. NSCLC diagnosis has been confirmed based on a histopathologic assessment of tumor tissue, AND
   iii. No previous multi-gene panel testing has been performed for NSCLC, AND
   iv. Insufficient tumor tissue is available for broad molecular profiling and member is unable to undergo an additional standard tissue biopsy due to documented medical reasons (i.e., invasive tissue sampling is contraindicated due to the member’s clinical condition)

IV. NSCLC/Metastatic colorectal cancer, tumor tissue evaluation — Medicare members only per Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms LCD (e.g., OncoVantage®)
V. Hematolymphoid diseases, evaluation of blood or bone marrow samples (i.e., acute myelogenous leukemia [AML], myelodysplastic syndromes [MDS], myeloproliferative neoplasms [MPN]) — covered for all lines of business using criteria from **LCD: Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases**

* Note: The clonoSEQ® assay is considered medically necessary for Commercial and Medicare members for initial assessment of dominant clonal sequences and for response assessment after primary treatment for members diagnosed with acute lymphoblastic leukemia, (ALL), chronic lymphocytic leukemia (CLL), or multiple myeloma (MM).

VI. Prostate cancer

1. 4Kscore — covered for Commercial and Medicare using criteria from **LCD: Biomarker Testing (Prior to Initial Biopsy) for Prostate Cancer Diagnosis**

2. ConfirmMDx™ — covered for Commercial and Medicare using criteria from **LCD: ConfirmMDx Epigenetic Molecular Assay**

3. Decipher® Prostate — covered for Commercial and Medicare using criteria from **LCD: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease**

4. ExoDx® Prostate IntelliScore (EPI) (aka ExosomeDx®) — covered for Medicare using criteria from **LCD: Biomarker Testing (Prior to Initial Biopsy) for Prostate Cancer Diagnosis**

5. Oncotype DX® — covered for Commercial and Medicare using criteria from **LCD: Oncotype DX® Prostate Cancer Assay**

   *Commercial coverage to be discontinued eff. Feb. 1, 2023.*

6. Prolaris® Prostate Cancer — covered for Medicare using criteria from **LCD: Prolaris™ Prostate Cancer Genomic Assay for Men with Favorable Intermediate Risk Disease**

   *Commercial coverage to be discontinued eff. Feb. 1, 2023.*

7. PCA3 (e.g., Progensa) — covered for Commercial (eff. 5/3/2021) and Medicare when all biopsies in previous encounter(s) are negative for prostatic cancer, the subsequent prostate specific antigen (PSA) is rising, and when the member or physician wants to avoid repeat biopsy (“watchful waiting”)

8. ProMark® Protemomic Prognostic Test — covered for all lines of business using criteria from **LCD: ProMark Risk Score**

The following tests are not covered for Medicaid members, as proprietary lab analysis (PLA) codes are not reimbursed by NYS Medicaid:

- ExoDx Prostate IntelliScore (EPI) (0005U)
- Oncotype DX (0047U)

The following tests are not covered for Medicaid members, as they are not on the Medicaid Lab Fee Schedule:

- 4Kscore (81539)
- ConfirmMDx (81551)
- Decipher (81542)
- Prolaris (81541)

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

1. Afirma Thyroid FNA Analysis®

2. ThyGeNEXT® (formerly ThyGenX and miRInform®)

3. ThyraMIR Thyroid miRNA classifier

4. ThyroSeq next generation sequencing
The following tests are not covered for Medicaid members, as proprietary lab analysis (PLA) codes are not reimbursed by NYS Medicaid:

- ThyGeNEXT (0245U)
- ThyraMIR (0018U)
- ThyroSeq (0026U)

VIII. Uveal melanoma, primary and localized (DecisionDx covered for Medicare members)

IX. Whole exome/genome sequencing — MCG medically-necessary criteria sets (see Limitations/Exclusions for investigational indications):

1. A-0866 — Whole Genome/Exome Sequencing - Primary Immunodeficiency Disorders
2. A-0871 — Whole Genome/Exome Sequencing - Metabolic, Mitochondrial, and Neurologic Disorders
3. A-0872 — Whole Genome/Exome Sequencing - Congenital Anomalies
4. A-0926 — Whole Genome/Exome Sequencing - Developmental Delay and Intellectual Disability

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/genome sequencing are not considered medically necessary due to insufficient evidence of therapeutic value the following indications (see section IX for medically necessary indications):

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

See also the following MCG criteria:

1. A-0710 — Whole Genome/Exome Sequencing - Cancer
2. A-0865 — Whole Genome/Exome Sequencing - Cardiovascular Disorders
3. A-0870 — Whole Genome/Exome Sequencing - Autism Spectrum Disorders

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

1. 4Kscore® Test (covered for Commercial and Medicare; see Section VI)
2. 23-Gene NGS Pyruvate Metabolism and Related Disorders Panel
3. 23andMe Health + Ancestry Service
4. Accelerate PhenoTest® BC kit
5. ADmark® Alzheimer’s Evaluation
6. AlloSure® Heart (as a standalone or combination with the AlloMap [aka HeartCare Comprehensive Solution]. (The AlloMap remains a covered standalone test for all members)
7. AlloSure® Kidney (covered for Medicare)
8. Albinism Panel
9. AmHPR Helicobacter Pylori Antibiotic Resistance NGS Panel
10. ARISk Autism Risk Assessment Test
11. AutosomalDominant and Recessive Polycystic Kidney Disease Nextgen Sequencing (NGS) Panel
12. Avise tests
   i. Avise® CTD
   ii. Avise® MTX (aka Avise PG) (covered for Medicare)
   iii. Avise® Lupus
13. BRCAPlus
14. BluePrint®
15. BreastNext® (covered for Medicare per Medicare Fee Schedule)
16. BreastOncPx™
17. BreastPRS
18. BREVAGen/BREVAGenplus
20. CancerIntercept
21. CancerNext® (covered for Medicare per Medicare Fee Schedule), CancerNext-Expanded™
22. CancerTYPE ID® (covered for Medicare)
23. Carbohydrate Metabolism Deficiency NextGen DNA Screening Panel
24. Cardiac DNA Insight
25. Cardiovascular Health Panel
26. CellSearch System®
27. CGD Universal Test Panel
28. Ciliopathies: Sequencing Panel
29. Ciliopathy NextGen Sequencing (NGS) Panel
30. Clarava
31. ClonoSEQ® (covered for Medicare and Commercial; see Section V)
32. ColoNext® (covered for Medicare per Medicare Fee Schedule)
33. ColoVantage
34. Complete Hereditary Spastic Paraplegia Evaluation Panel
35. Complete Lung
36. Comprehensive Brain Malformations Next Generation Sequencing Panel
37. Comprehensive Dystonia NextGen DNA Screening Panel
38. Comprehensive Inherited Retinal Dystrophies Sequencing Panel
39. Comprehensive Molecular Genetic Panel
   Comprehensive Muscular Dystrophy/Myopathy Next Generation DNA Sequencing Panel
40. Comprehensive Molecular Genetic Panel
41. ConfirmMDx (Covered for Commercial and Medicare members; see Section VI)
42. Congenital Myopathy NextGen Sequencing (NGS) Panel
43. Congenital Stationary Night Blindness panel
44. Connective Tissue NGS Panel
45. Corus® CAD (Coverage rescinded for Medicare members eff. Dec. 12, 2018 based on noncoverage Local Coverage Determination: MolDX: Corus® CAD Assay)
46. Craniosynostosis next generation sequencing (NGS) panel
47. DecisionDx tests
   i. DiffDx - Melanoma
   ii. Glioblastoma
   iii. SCC
   iv. Uveal melanoma (covered for Medicare)
48. Decipher (covered for Commercial and Medicare members; see Section VI)
49. DecodEX Microbial Genetic Identification
50. Distal Hereditary Motor Neuropathy NextGen Sequencing (NGS) Panel
51. Ehlers-Danlos Syndrome NGS Panel Dominant and Recessive
52. ENGAUGE™-cancer-DLBCL (covered for Medicare)
53. Envisia Genomic Classifier (covered for Medicare)
54. Epi proColon
55. EpiSign Complete
56. ExoDx®Prostate IntelliScore (EPI) (aka ExosomeDx®) (covered for Medicare)
57. ExomeNext
58. ExomeNext-Rapid
59. Expanded Pan-Ethnic Panel
60. Familial Hemiplegic Migraine NextGen Sequencing (NGS) Panel Fetal Akinesia Deformation Sequence/Lethal Multiple Pterygium Syndrome NextGen Sequencing (NGS) Panel
61. FoundationOne CDx (covered for Commercial and Medicare; see Section I)
62. FoundationOne® Heme
63. FoundationOne Liquid CDx (covered for Commercial and Medicare; see Section I)
64. GeneAware
65. GeneFx® Colon
66. GeneFx® Lung
67. GeneKey
68. GeneStrat™
69. GeneSight (For Medicare members, see Pharmacogenetics Testing LCD [replaced Retired GeneSight® Assay for Refractory Depression LCD)
70. GeneTrails® Solid Tumor Panel
71. Genomic Unity® AR Analysis
72. Genomic Unity® CACNA1A Analysis (covered for Commercial and Medicare)
73. Genomic Unity® CSTB Analysis (covered for Commercial and Medicare)
74. Genomic Unity® FXN Analysis (covered for Commercial and Medicare)
75. Genomic Unity® SMN1/2 Analysis (covered for Commercial and Medicare)
76. Genomind Professional PGx Express CORE Anxiety & Depression
77. GPS Cancer
78. Guardant360® LDT (covered for Commercial and Medicare; see Section III)
79. Guardant360 CDx (covered for Commercial and Medicare; see Section I)
80. Guardant Reveal™
81. Healthy Weight DNA Insight
82. Healthy Woman DNA Insight
83. HCMNext
84. H/I Gene Expression Ratio
85. Hemophagocytic Lymphohistiocytosis Panel by next generation sequencing (NGS)
86. Hereditary Spherocytosis/Elliptocytosis NextGen Sequencing Panel
87. HERmark (Covered for Medicare, see Gene Expression Profiling and Biomarker Testing for Breast Cancer)
88. HLA-DQB1*06:02 typing for the diagnosis or management of narcolepsy
89. HOX13:IL17BR
90. Hypokalemic and Hyperkalemic Periodic Paralysis Disorders NGS Sequencing Panel
91. Insight DX Breast Cancer Profile
92. Intellectual Disability (IDNEXT) Panel
93. Insight TNBCType
94. Invitae
   i. Autoinflammatory Syndromes Panel
   ii. Dystonia Comprehensive Panel
   iii. Hereditary Spastic Paraplegia Panel
   iv. Overgrowth Syndromes Panel
   v. PCM MRD Monitoring
   vi. PCM Tissue Profiling and MRD Baseline Assay
   vii. Primary Immunodeficiency Panel
95. Leukoencephalopathy NGS Panel
96. Lipodystrophy NGS Panel
97. LungLB
98. LUNGSEQ® Panel
99. Lymph3Cx Lymphoma Molecular
100. Subtyping Assay
101. Macula Risk PGx
102. Macular Degeneration Mutation Analysis
103. Mammastatin
104. miReview®
105. Mammostrat
106. Melaris®
107. Molecular Intelligence
108. My5-FU™ (previously OnDose™)
109. myChoice® CDx (Covered for Commercial and Medicare; see Section I)
110. Myeloid Molecular Profile
111. myPath® Melanoma (covered Medicare)
112. MyPRS® Myeloma Prognostic Risk Signature
113. Myriad Foresight® Carrier Screen (previously Counsyl Foresight Carrier Screen)
114. myRisk™
115. MSK-IMPACT (covered for Medicare; see Section I)
116. Neurotransmitter Metabolism Deficiency NextGen DNA Screening Panel
117. Next Gen RASopathy Panel
118. Next Generation Sequencing Panel for ASXL1, RECQL4, RNU4ATAC, SOX2
119. NextStepDx PLUS®
120. NGS Epilepsy/Seizure Panel
121. NGS RASopathy Panel
122. OmniSeq Comprehensive
123. Oncomine Dx Target (Covered for Commercial and Medicare members; see Section I)
124. Oncotype DX® tests
   i. AR-V7 Nucleus (covered for Medicare)
   ii. Breast DCIS (covered for Medicare)
   iii. Colon cancer (covered for Medicare)
   iv. Prostate (Covered for Medicare, see Section VI)
125. Oncotype MAP™ PanCancer Tissue Test (covered for Medicare)
126. Oncofocus®
127. OncoVantage® (covered for Medicare)
128. OnkoMatch™
129. OnkoSight™ next generation sequencing for hematologic malignancies
130. Oncovue
131. OnoCEE
132. OPA 1 gene sequencing for autosomal dominant optic atrophy and/or optic neuropathy
133. Osteogenesis Imperfecta NGS Panel-Recessive
134. OvaNext™ (covered for Medicare)
135. Overa (aka OVA1 Next Generation or second-generation Multivariate Index Assay [MIA2G] test)
136. PAM50 Breast Cancer Intrinsic Classifier™
137. PancNext™
138. PanraGEN (previously Pathfinder TG®) (covered for Medicare)
139. PancreaSeq Genomic Classifier
140. Panexia®
141. PanGIA Prostate
142. Paradigm Cancer Diagnostics [PCDx] Test
143. Pediatric Neurology Region of Interest Trio
144. Percepta Bronchial Genomic Classifier (covered for Medicare)
145. Pervenio™ Lung NGS (covered for Medicare)
146. PIGMENTED LESION Assay (covered for Medicare)
147. Pontocerebellar Hypoplasia Panel
148. Post-Op Px™ (formerly the Prostate Px Plus)
149. Praxis Extended RAS Panel (covered for Commercial and Medicare members; see Section I)
150. PredictSure IBD
151. PreludeDx™ DCISionRT®
152. Preparent Global Panel
153. Previstage™
154. Progenity CFnxt
155. Progenity® Pan-Ethnic Carrier Screening Panel
156. Prolaris (covered for Medicare, see Section VI)
157. PROGENSA® PCA3 (Covered for Commercial and Medicare members; see Section VI)
158. ProOnc TumorSource DX
159. Proove profile panels (e.g., Opioid Risk Panel)
160. Prometheus® IBD sgi Diagnostic™
161. ProstateNext
162. RadTox cfDNA
163. RenalNext™
164. ResponseDX Tissue Origin Test Rotterdam/Veridex (covered for Medicare)
165. RetnaGene AMD
166. Rotterdam Signature
167. Saethre-Chotzen Syndrome (TWIST) Sequencing and MLPA (Greenwood Genetic Center)
168. ScolioScore™ AIS Prognostic Test
169. SelectMDx for prostate cancer
170. Sema4 Signal Hereditary Cancer High Prevalence Panel
171. Signatera™
172. Spastic Paraplegia Next Generation Sequencing Panel
173. Stickler Syndrome NGS Panel
174. SymGene68™ Next Generation Sequencing Cancer Panel
175. SYMPHONY™ Genomic Breast Cancer Profile (combines BluePrint, MammaPrint and TargetPrint tests)
176. Skeletal Dysplasia Ciliopathy NGS Panel
177. SYMPHONY™ Personalized Breast Cancer Genomic Profile
178. TAADNext
179. Target Now™ molecular profiling test (aka MI Profile, MI Profile X)
180. TargetPrint®
181. therascreen FGFR RGQ RT-PCR Kit (Covered for Commercial and Medicare members; see Section I)
182. therascreen PIK3CA RGQ PCR Kit (Covered for Commercial and Medicare members; see Section I)
183. TheraPrint®
184. theraSEEK Sequence Analysis for Functional Disorders
185. Thrombocytopenia NextGen Sequencing (NGS) Panel
186. TruGenome Undiagnosed Disease Test
187. TruGene Technical Sequence Data (whole exome sequencing test for labs and physicians who will make their own clinical interpretations make their own clinical interpretations)
188. Tuteva
189. Universal Carrier Panel
190. Vectra DA (covered for Medicare)
191. Vita Risk™
192. Vitreoretinopathy NGS Panel
193. BDX-XL2 (formerly Xpresys Lung) (covered for Medicare)

Revision History

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<tr>
<th>Date</th>
<th>Revision Details</th>
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| Jul. 14, 2023 | Added ClonoSEQ coverage  
Added the following tests to investigational list: Invitae Dystonia Comprehensive Panel and Hereditary Spastic Paraplegia Panel, PredictSure IBD, RadTox cfDNA  
Updated Medical Policy cross-referencing |
| Oct. 14, 2022 | Communicated discontinuance of Commercial coverage for Oncotype DX Prostate® and Prolaris® eff. Feb. 1, 2023  
Added AlloSure® Heart (as a standalone or combination test with AlloMap [aka HeartCare Comprehensive Solution]) to investigational list  
(The AlloMap remains a covered standalone test for all members) |
| Aug. 12, 2022 | Added whole genome/exome sequencing section citing medically-necessary MCG criteria sets  
Updated Limitations/Exclusions section citing investigational MCG criteria sets  
Updated MCG cross-referencing |
| Jul. 27, 2022 | Added explanatory for searching the FDA’s List of Cleared or Approved Companion Diagnostic Devices web page |
| Apr. 13, 2022 | Added the following tests to investigational list: Accelerate PhenoTest® BC kit, Bridge Urinary Tract Infection Detection and Resistance Test, Clarava, DecisionDx DiffDx – Melanoma, DecisionDx SCC, EpiSign Complete, Invitae PCM MRD Monitoring, Invitae PCM Tissue Profiling and MRD Baseline Assay, LungLB, PancreaSeq Genomic Classifier, PreludeDx™ DCISionRT® and Tuteva |
| Feb. 18, 2022 | Added Invitae Overgrowth Syndromes Panel as investigational |
Positive coverage notations added commensurate with Medical Technologies Database listings and Medicare Fee Schedule:
 ENGAUGE™-cancer-DLBCL (Medicare)
 Genomic Unity® AR Analysis (Medicare)
 Genomic Unity® CACNA1A Analysis (covered Commercial and Medicare)
 Genomic Unity® CSTB Analysis (covered Commercial and Medicare)
 Genomic Unity® FXN Analysis (covered Commercial and Medicare)
 Genomic Unity® SMN1/2 Analysis (covered Commercial and Medicare)
 myPath® Melanoma (Medicare)
 Oncotype MAP™ PanCancer Tissue Test (Medicare)
 OvaNext™ (Medicare)

<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
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<tbody>
<tr>
<td>Oct. 19, 2021</td>
<td>Added Guardant Reveal™ as investigational&lt;br&gt; Added note in Limitations/Exclusions designating BreastNext, CancerNext, and ColoNext as Medicare-covered per Medicare Fee Schedule</td>
</tr>
<tr>
<td>July 14, 2021</td>
<td>Added Commercial coverage for 4Kscore and ConfirmMDx (eff. 1/20/2021)&lt;br&gt; Added Commercial coverage for FoundationOne Liquid CDx and Guardant360 LDT&lt;br&gt; Added Medicare coverage for ExoDx® Prostate IntelliScore (EPI)&lt;br&gt; Added noncoverage note communicating that Proprietary lab analysis (PLA) codes are not covered for Medicaid members, as they are not reimbursed by NYS Medicaid&lt;br&gt; Added noncoverage note communicating that CPT codes which are not on the Medicaid Lab Fee Schedule are not covered&lt;br&gt; Updated list of lab tests regarded as investigational</td>
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<td>Jul. 8, 2020</td>
<td>Added MSK-IMPACT for Medicare members&lt;br&gt; Removed FoundationOne CDx from Limitations/Exclusions</td>
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<tr>
<td>Feb. 14, 2020</td>
<td>Added Plasma-Based Genomic Profiling in Solid Tumors LCD specific to Guardant360® for Medicare members</td>
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<tr>
<td>Apr. 12, 2019</td>
<td>Added genomic sequence analysis panels (e.g., OncoVantage®) for Medicare members</td>
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<tr>
<td>Mar. 8, 2019</td>
<td>Added Oncotype DCIS, Oncotype DX AR-V7 Nucleus and Xpresys Lung tests for Medicare members</td>
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<tr>
<td>Feb. 8, 2018</td>
<td>Added Clonoseq® for Medicare members&lt;br&gt; Added link to MYvantage® Hereditary Comprehensive Cancer Panel Medical Guideline and removed MYvantage from Limitations/Exclusions</td>
</tr>
<tr>
<td>Oct. 12, 2018</td>
<td>Removed Corus® CAD Medicare coverage effective Dec. 12. 2018</td>
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<tr>
<td>Aug. 8, 2018</td>
<td>Added Medicare coverage of Guardant360® Pervenio™ Lung NGS</td>
</tr>
<tr>
<td>May 5, 2018</td>
<td>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</td>
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<tr>
<td>Apr. 13, 2018</td>
<td>Added FoundationOne CDx test coverage for Medicare members&lt;br&gt; 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)&lt;br&gt; Added language communicating noncoverage of testing to confirm results of consumer-based testing&lt;br&gt; Added language clarifying that whole exome and whole genome sequencing is considered investigational&lt;br&gt; Updated list of lab tests regarded as investigational</td>
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<tr>
<td>Apr. 14, 2017</td>
<td>Added ThyraMIR Thyroid miRNA classifier to list of eligible tests for thyroid lesions with indeterminate cytology</td>
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<tr>
<td>Date</td>
<td>Event Description</td>
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<tr>
<td>Feb. 2, 2017</td>
<td>Added Melaris to investigational list.</td>
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<tr>
<td>Sept. 9, 2016</td>
<td>Added the following tests to investigational list: DecodEX, Oncovue, OvaNext™, Panexia®</td>
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<tr>
<td>Aug. 12, 2016</td>
<td>Added Medicare coverage for CancerTYPE ID®.</td>
</tr>
<tr>
<td>Jul. 8, 2016</td>
<td>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</td>
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<tr>
<td>5/13/2016</td>
<td>Added Medicare coverage for Prosigna™ Breast Cancer Prognostic Gene Signature Assay.</td>
</tr>
<tr>
<td>4/8/2016</td>
<td>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)</td>
</tr>
<tr>
<td>12/21/2015</td>
<td>Amended Limitations/Exclusions Section to reflect positive Medicare coverage for Oncotype Prostate.</td>
</tr>
<tr>
<td>10/9/2015</td>
<td>Amended Limitations/Exclusions Section to reflect positive Medicare coverage for Decipher Prostate Classifier and Prolaris</td>
</tr>
</tbody>
</table>

References


Hayes Inc. Molecular Test Assessment. FoundationOne CDx (Foundation Medicine Inc.) for the Intended Use as a Broad Molecular Profiling Tool. Lansdale, PA: Hayes Inc.; April 2022.

Specialty-matched clinical peer review.