Gene Expression Profiling

Last Review Date: July 14, 2021  Number: MG.MM.LA.13u

Medical Guideline Disclaimer

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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 and MCG Criteria (list not all-inclusive)

AlloMap® Molecular Expression Testing for Post-Heart-Transplant Rejection — MCG #ACG: A-0623 (AC)
Analysis of KRAS Status
BCR-ABL1 Genetic Mutation Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia — MCG #s: ACG: A-0759 (AC), ACG: A-0771 (AC)
BRAF Mutation Analysis
BRCA 1 and 2 Genetic Testing (Sequence Analysis/Rearrangement)
Cancer of Unknown Primary - Gene Expression Profiling — ACG: A-0673 (AC)
Cancer Multimomic Molecular Profiling — ACG: A-0789 (AC)
Carrier Screening for Parents or Prospective Parents
Epidermal Growth Factor Receptor Mutation Analysis for Patients with Non-Small-Cell Lung Cancer (MCG Criteria #ACG: A-0795 ([AC])
Factor V Leiden Mutation Analysis — MCG #ACG: A-0600 (AC)
Gene Expression Profiling and Biomarker Testing for Breast Cancer
Gene Expression Testing for Multiple Myeloma
Genetic Analysis of PIK3CA Status in Tumor Cells

Genetic Counseling and Testing

Genetic Testing for Alzheimer’s disease — MCG #s: ACG: A-0590 (AC) for early onset disease (considered medically necessary); ACG: A-0809 (AC) for late onset disease (considered not medically necessary)

Genetic Testing for Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy (CADASIL) Syndrome — MCG #ACG: A-0668 (AC)

Genetic Testing for Colorectal Cancer/Lynch Syndrome
Genetic Testing for Cystic Fibrosis — MCG #ACG: A-0597 (AC)

Genetic Testing for Frontotemporal Dementia (FTD)
Genetic Testing for Hereditary Pancreatitis — MCG #s: ACG: A-0646 (AC) for CFTR, CPA1, CTRC, PRSS1, and SPINK1 genes; ACG: A-0797 (AC) for next generation sequencing panel
Genetic Testing for Peripheral Neuropathies — MCG #ACG: A-0691 (AC)

Genetic Testing for PTEN Hamartoma Tumor Syndrome

Genetic Testing for RET Proto-Oncogene Germline Mutations — MCG # ACG: A-0842 (AC)
Genetic Testing for Statin-Induced Myopathy — MCG #ACG: A-0981 (AC)

MYvantage® Hereditary Comprehensive Cancer Panel
Noninvasive Prenatal Testing (NIPT) for Fetal Aneuploidy — hybrid EmblemHealth–MCG policy

Guideline

Members are eligible for GEP testing per the policies above and as follows, as applicable:

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.

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)
Gene Expression Profiling

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

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: Decipher® Prostate Cancer Classifier Assay
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]


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)

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. 4Kscore® Test (Covered for Commercial and Medicare members; see Section VI)
   2. 23-Gene NGS Pyruvate Metabolism and Related Disorders Panel
   3. 23andMe Health + Ancestry Service
   4. ADmark® Alzheimer’s Evaluation
   5. AlloSure® Kidney (Covered for Medicare members)
   6. Albinism Panel
   7. AmHPR Helicobacter Pylori Antibiotic Resistance NGS Panel
   8. ARISk Autism Risk Assessment Test
   9. Autosomal Dominant and Recessive Polycystic Kidney Disease Nextgen Sequencing (NGS) Panel
   10. Avise tests
       i. Avise® CTD
       ii. Avise® MTX (aka Avise PG) (Covered for Medicare members)
       iii. Avise® Lupus
   11. bioTheranostics Cancer TYPE ID (Covered for Medicare members)
   12. BRCAPlus
   13. BluePrint®
   14. BreastNext™
   15. BreastOncPx™
   16. BreastPRS
   17. BREVAGen/BREVAGenplus
   18. CancerIntercept
   19. CancerNext, CancerNext-Expanded™
   20. CancerTYPE ID® (Covered for Medicare members)
   21. Carbohydrate Metabolism Deficiency NextGen DNA Screening Panel
   22. Cardiac DNA Insight
   23. Cardiovascular Health Panel
   24. CellSearch System®
   25. CGD Universal Test Panel
   26. Ciliopathies: Sequencing Panel
   27. Ciliopathy NextGen Sequencing (NGS) Panel
   28. Clonoseq® (Covered for Medicare members only)
   29. ColoNext™
   30. ColoVantage
   31. Complete Hereditary Spastic Paraplegia Evaluation Panel
   32. Complete Lung
33. Comprehensive Brain Malformations Next Generation Sequencing Panel
34. Comprehensive Dystonia NextGen DNA Screening Panel
35. Comprehensive Inherited Retinal Dystrophies Sequencing Panel
36. Comprehensive Molecular Genetic Panel
37. Comprehensive Muscular Dystrophy/Myopathy Next Generation DNA Sequencing Panel
38. ConfirmMDx (Covered for Commercial and Medicare members; see Section VI)
39. Congenital Myopathy NextGen Sequencing (NGS) Panel
40. Congenital Stationary Night Blindness panel
41. Connective Tissue NGS Panel
42. Corus® CAD (Coverage rescinded for Medicare members eff. Dec. 12, 2018 based on noncoverage Local Coverage Determination: MolDX: Corus® CAD Assay)
43. Craniosynostosis next generation sequencing (NGS) panel
44. DecisionDx tests
   i. Glioblastoma
   ii. Uveal melanoma (Covered for Medicare members only)
45. Decipher (Covered for Commercial and Medicare members; see Section VI)
46. DecodEX Microbial Genetic Identification
47. Distal Hereditary Motor Neuropathy NextGen Sequencing (NGS) Panel
48. Ehlers-Danlos Syndrome NGS Panel Dominant and Recessive
49. ENGAUGE™-cancer-DLBCL
50. Envisia Genomic Classifier (Covered for Medicare members)
51. Epi proColon
52. ExoDx®Prostate IntelliScore (EPI) (aka ExosomeDx®) (covered for Medicare members)
53. ExomeNext
54. ExomeNext-Rapid
55. Expanded Pan-Ethnic Panel
56. Familial Hemiplegic Migraine NextGen Sequencing (NGS) Panel Fetal Akinesia Deformation Sequence/Lethal Multiple Pterygium Syndrome NextGen Sequencing (NGS) Panel
57. FoundationOne CDx (covered for Commercial and Medicare; see Section I)
58. FoundationOne® Heme
59. FoundationOne Liquid CDx (covered for Commercial and Medicare; see Section I)
60. GeneAware
61. GeneFx® Colon
62. GeneFx® Lung
63. GeneKey
64. GeneStrat™
65. GeneSight (Covered for Medicare members)
66. GeneTrails® Solid Tumor Panel
67. Genomind Professional PGx Express CORE Anxiety & Depression
68. GPS Cancer
69. Guardant360® LDT (Covered for Commercial and Medicare members; see Section III)
70. Guardant360 CDX (Covered for Commercial and Medicare members; see Section I)
71. Healthy Weight DNA Insight
72. Healthy Woman DNA Insight
73. HCMNext
74. H/I Gene Expression Ratio
75. Hemophagocytic Lymphohistiocytosis Panel by next generation sequencing (NGS)
76. Hereditary Spherocytosis/Elliptocytosis NextGen Sequencing Panel
77. HERmark (Covered for Medicare members, see Gene Expression Profiling and Biomarker Testing for Breast Cancer)
78. HLA-DQB1*06:02 typing for the diagnosis or management of narcolepsy
79. HOX13:LI7BR
80. Hypokalemic and Hyperkalemic Periodic Paralysis Disorders NGS Sequencing Panel
81. Insight® DX Breast Cancer Profile
82. Intellectual Disability (IDNEXT) Panel
83. Insight TNBCtype
84. Invitae
   i. Autoinflammatory Syndromes Panel
   ii. Primary Immunodeficiency Panel
85. Leukoencephalopathy NGS Panel
86. Lipodystrophy NGS Panel
87. LUNGSEQ® Panel
88. Lymph3Cx Lymphoma Molecular
89. Subtyping Assay
90. Macula Risk PGx
91. Macular Degeneration Mutation Analysis
92. Mammastatin
93. miReview®
94. Mammastrat
95. Melaris®
96. Molecular Intelligence
97. My5-FU™ (previously OnDose™)
98. myChoice® CDx (Covered for Commercial and Medicare members; see Section I)
99. Myeloid Molecular Profile
100. myPath®
101. MyPRS® Myeloma Prognostic Risk Signature
102. Myriad Foresight® Carrier Screen (previously Counsyl Foresight Carrier Screen)
103. myRisk™
104. MSK-IMPACT (covered for Medicare members; see Section I)
105. Neurotransmitter Metabolism Deficiency NextGen DNA Screening Panel
106. Next Gen RASopathy Panel
107. Next Generation Sequencing Panel for ASXL1, RECQL4, RNU4ATAC, SOX2
108. NextStepDx PLUS®
109. NGS Epilepsy/Seizure Panel
110. NGS RASopathy Panel
111. OmniSeq Comprehensive
112. Oncomine Dx Target (Covered for Commercial and Medicare members; see Section I)
113. Oncotype DX® tests
   i. AR-V7 Nucleus (Covered for Medicare members)
   ii. Breast DCIS (Covered for Medicare members)
   iii. Colon cancer (Covered for Medicare members)
   iv. Prostate (Covered for Commercial and Medicare members; see Section VI)
114. Oncotype MAP™ PanCancer Tissue Test
115. Oncofocus®
116. OncoVantage® (Covered for Medicare members)
117. OnkoMatch™
118. OnkoSight™ next generation sequencing for hematologic malignancies
119. Oncovue
120. OnoCEE  
121. OPA 1 gene sequencing for autosomal dominant optic atrophy and/or optic neuropathy  
122. Osteogenesis Imperfecta NGS Panel-Recessive  
123. OvaNext™  
124. Overa (aka OVA1 Next Generation or second-generation Multivariate Index Assay [MIA2G] test)  
125. PAM50 Breast Cancer Intrinsic Classifier™  
126. PancNext™  
127. PancraGEN (previously Pathfinder TG®) (Covered for Medicare members)  
128. Panexia®  
129. PanGIA Prostate  
130. Paradigm Cancer Diagnostics [PCDx] Test  
131. Pediatric Neurology Region of Interest Trio  
132. Percepta Bronchial Genomic Classifier (Covered for Medicare members)  
133. Pervenio™ Lung NGS (Covered for Medicare members)  
134. PIGMENTED LESION Assay (Covered for Medicare members)  
135. Pontocerebellar Hypoplasia Panel  
136. Post-Op Px™ (formerly the Prostate Px Plus)  
137. Praxis Extended RAS Panel (Covered for Commercial and Medicare members; see Section I)  
138. Prepnear Global Panel  
139. Previstage™  
140. Progenity CFnxt  
141. Progenity® Pan-Ethnic Carrier Screening Panel  
142. Prolaris (Covered for Commercial and Medicare members; see Section VI)  
143. PROGENSA® PCA3 (Covered for Commercial and Medicare members; see Section VI)  
144. ProOnc TumorSource DX  
145. Proove profile panels (e.g., Opioid Risk Panel)  
146. Prometheus® IBD sg Diagnostic™  
147. ProstateNext  
148. RenalNext™  
149. ResponseDX Tissue Origin Test Rotterdam/Veridex (Covered for Medicare members)  
150. RetnaGene AMD  
151. Rotterdam Signature  
152. Saethre-Chotzen Syndrome (TWIST) Sequencing and MLPA (Greenwood Genetic Center)  
153. ScolioScore™ AIS Prognostic Test  
154. SelectMDx for prostate cancer  
155. Sema4 Signal Hereditary Cancer High Prevalence Panel  
156. Signatera™  
157. Spastic Paraplegia Next Generation Sequencing Panel  
158. Stickler Syndrome NGS Panel  
159. SymGene68™ Next Generation Sequencing Cancer Panel  
160. SYMPHONY™ Genomic Breast Cancer Profile (combines BluePrint, MammaPrint and TargetPrint tests)  
161. Skeletal Dysplasia Ciliopathy NGS Panel  
162. SYMPHONY™ Personalized Breast Cancer Genomic Profile  
163. TAADNext  
164. Target Now™ molecular profiling test (aka MI Profile, MI Profile X)  
165. TargetPrint®
166. therascreen FGFR RGQ RT-PCR Kit (Covered for Commercial and Medicare members; see Section I)
167. therascreen PIK3CA RGQ PCR Kit (Covered for Commercial and Medicare members; see Section I)
168. TheraPrint®
169. theraseek Sequence Analysis for Functional Disorders
170. Thrombocytopenia NextGen Sequencing (NGS) Panel
171. TruGenome Undiagnosed Disease Test
172. TruGenome Technical Sequence Data (whole exome sequencing test for labs and physicians who will make their own clinical interpretations make their own clinical interpretations)
173. Universal Carrier Panel
174. Vectra DA (Covered for Medicare members only)
175. Vita Risk™
176. Vitreoretinopathy NGS Panel
177. BDX-XL2 (formerly Xpresys Lung) (Covered for Medicare members only)

**Revision History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Changes and Amendments</th>
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</thead>
<tbody>
<tr>
<td>July 14, 2021</td>
<td>Added Commercial coverage for 4Kscore and ConfirmMDx (eff. 1/20/2021)</td>
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<tr>
<td></td>
<td>Added Commercial coverage for FoundationOne Liquid CDx and Guardant360 LDT</td>
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<td></td>
<td>Added Medicare coverage for ExoDx® Prostate IntelliScore (EPI)</td>
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<tr>
<td></td>
<td>Added noncoverage note communicating that Proprietary lab analysis (PLA) codes are not covered for Medicaid members, as they are not reimbursed by NYS Medicaid</td>
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<tr>
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<td>Added noncoverage note communicating that CPT codes which are not on the Medicaid Lab Fee Schedule are not covered</td>
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<tr>
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<td>Updated list of lab tests regarded as investigational</td>
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<tr>
<td>Jul. 8, 2020</td>
<td>Added MSK-IMPACT for Medicare members</td>
</tr>
<tr>
<td></td>
<td>Removed FoundationOne CDx from Limitations/Exclusions</td>
</tr>
<tr>
<td>Feb. 14, 2020</td>
<td>Added Plasma-Based Genomic Profiling in Solid Tumors LCD specific to Guardant360® for Medicare members</td>
</tr>
<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</td>
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<tr>
<td></td>
<td>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>
</tr>
<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</td>
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<td>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)</td>
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<td>Added language communicating noncoverage of testing to confirm results of consumer-based testing</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 Added Melaris to investigational list</td>
</tr>
<tr>
<td>Feb. 2, 2017</td>
<td>Added the following tests to investigational list: Oncofocus®, Previsstage™</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®. 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</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. 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</td>
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<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>
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<tr>
<td>12/21/2015</td>
<td>Amended Limitations/Exclusions Section to reflect positive Medicare coverage for Oncotype Prostate.</td>
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<tr>
<td>10/9/2015</td>
<td>Amended Limitations/Exclusions Section to reflect positive Medicare coverage for Decipher Prostate Classifier and Prolaris</td>
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**References**


