

## 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 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 Multiomic Molecular Profiling — ACG: A-0789 (AC)

Cardiac Ion Channel Genetic Testing — MCG #s: ACG: A-0594 (AC), ACG: A-0607 (AC), ACG: A-0636 (AC), ACG: A-0831 (AC), ACG: A-0833 (AC), ACG: A-0834 (AC), ACG: A-0918 (AC)

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

Chromosomal Microarray Analysis (CMA) — MCG #s: ACG: A-0588 (AC), ACG: A-0810 (AC), § ACG: A-0811 (AC), ACG: A-0812 (AC), ACG: A-0823 (AC), ACG: A-0917 (AC), ACG: A-0924 (AC)

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 Profiling of Melanomas — MCG #s: ACG: A-0601 (AC), ACG: A-0670 (AC), ACG: A-0836 (AC), ACG: A-0837 (AC)

[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 Deafness and Hearing Loss/Usher Syndrome — MCG #s: ACG: A-0596 (AC), ACG: A-0823 (AC), ACG: A-0802 (AC)

[Genetic Testing for Frontotemporal Dementia \(FTD\)](#)

Genetic Testing for Hereditary Cardiomyopathy — MCG #s ACG: A-0627 (AC), ACG: A-0633 (AC), ACG: A-0648 (AC)

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)

- myChoice® CDx (0172U)
- Oncomine Dx Target Test (0022U)
- Praxis Extended RAS Panel (0111U)
- theascreen FGFR RGQ RT-PCR Kit (0154U)
- theascreen 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](#)

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](#)
6. Prolaris® Prostate Cancer — covered for Commercial and Medicare using criteria from [LCD: Prolaris™ Prostate Cancer Genomic Assay](#) for Men with Favorable Intermediate Risk Disease
7. PCA3 (e.g., Progenesa) — 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<sup>®</sup> 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<sup>®</sup> Alzheimer's Evaluation
  5. AlloSure<sup>®</sup> 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<sup>®</sup> CTD
    - ii. Avise<sup>®</sup> MTX (aka Avise PG) (Covered for [Medicare](#) members)
    - iii. Avise<sup>®</sup> Lupus
  11. bioTheranostics Cancer TYPE ID (Covered for [Medicare](#) members)
  12. BRCAPlus
  13. BluePrint<sup>®</sup>
  14. BreastNext<sup>™</sup>
  15. BreastOncPx<sup>™</sup>
  16. BreastPRS
  17. BREVAGen/BREVAGenplus
  18. CancerIntercept
  19. CancerNext, CancerNext-Expanded<sup>™</sup>
  20. CancerTYPE ID<sup>®</sup> (Covered for [Medicare](#) members)
  21. Carbohydrate Metabolism Deficiency NextGen DNA Screening Panel
  22. Cardiac DNA Insight
  23. Cardiovascular Health Panel
  24. CellSearch System<sup>®</sup>
  25. CGD Universal Test Panel
  26. Ciliopathies: Sequencing Panel
  27. Ciliopathy NextGen Sequencing (NGS) Panel
  28. Clonoseq<sup>®</sup> (Covered for [Medicare](#) members only)
  29. ColoNext<sup>™</sup>
  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  
Comprehensive Muscular Dystrophy/Myopathy Next Generation DNA Sequencing Panel
37. Comprehensive Molecular Genetic 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<sup>®</sup> CAD (Coverage rescinded for Medicare members eff. Dec. 12, 2018 based on [noncoverage Local Coverage Determination: MolDX: Corus<sup>®</sup> CAD Assay](#))
43. Craniostylosis 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<sup>™</sup>-cancer-DLBCL
50. Envisia Genomic Classifier (Covered for [Medicare](#) members)
51. Epi proColon
52. ExoDx<sup>®</sup> Prostate IntelliScore (EPI) (aka ExosomeDx<sup>®</sup>) (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<sup>®</sup> Heme
59. FoundationOne Liquid CDx (covered for Commercial and Medicare; see [Section I](#))
60. GeneAware
61. GeneFx<sup>®</sup> Colon
62. GeneFx<sup>®</sup> Lung
63. GeneKey
64. GeneStrat<sup>™</sup>
65. GeneSight (Covered for [Medicare](#) members)
66. GeneTrails<sup>®</sup> Solid Tumor Panel
67. Genomind Professional PGx Express CORE Anxiety & Depression
68. GPS Cancer
69. Guardant360<sup>®</sup> 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:IL17BR
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. Mammostrat
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. Preparent 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. Provee profile panels (e.g., Opioid Risk Panel)
146. Prometheus® IBD sgi 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. theascreen FGFR RGQ RT-PCR Kit (Covered for Commercial and Medicare members; see [Section I](#))
167. theascreen 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

July 14, 2021	<p>Added Commercial coverage for 4Kscore and ConfirmMDx (eff. 1/20/2021)</p> <p>Added Commercial coverage for FoundationOne Liquid CDx and Guardant360 LDT</p> <p>Added Medicare coverage for ExoDx® Prostate IntelliScore (EPI)</p> <p>Added noncoverage note communicating that Proprietary lab analysis (PLA) codes are not covered for Medicaid members, as they are not reimbursed by NYS Medicaid</p> <p>Added noncoverage note communicating that CPT codes which are not on the Medicaid Lab Fee Schedule are not covered</p> <p>Updated list of lab tests regarded as investigational</p>
Jul. 8, 2020	<p>Added MSK-IMPACT for Medicare members</p> <p>Removed FoundationOne CDx from Limitations/Exclusions</p>
Feb. 14, 2020	<p>Added Plasma-Based Genomic Profiling in Solid Tumors LCD specific to Guardant360® for Medicare members</p>
Apr. 12, 2019	<p>Added genomic sequence analysis panels (e.g., OncoVantage®) for Medicare members</p>
Mar. 8, 2019	<p>Added Oncotype DCIS, Oncotype DX AR-V7 Nucleus and Xpresys Lung tests for Medicare members</p>
Feb. 8, 2018	<p>Added Clonoseq® for Medicare members</p> <p>Added link to MYvantage® Hereditary Comprehensive Cancer Panel Medical Guideline and removed MYvantage from Limitations/Exclusions</p>
Oct. 12, 2018	<p>Removed Corus® CAD Medicare coverage effective Dec. 12. 2018</p>
Aug. 8, 2018	<p>Added Medicare coverage of Guardant360® Pervenio™ Lung NGS</p>
May 5, 2018	<p>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</p>
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>

	Added language clarifying that whole exome and whole genome sequencing is considered investigational Updated list of lab tests regarded as investigational
Apr. 14, 2017	Added ThyraMIR Thyroid miRNA classifier to list of eligible tests for thyroid lesions with indeterminate cytology Added Melaris to investigational list
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	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
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

## References

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