Gene Expression Profiling

Last Review Date: February 14, 2025	Number: MG.MM.LA.13yv2

Medical Guideline Disclaimer

The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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
Medical Necessity Guidelines: Experimental, Investigational or Unproven Services

Related MCG Criteria (list not all-inclusive)

Alzheimer's disease — MCG #s: 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 Multiomic Molecular Profiling — A-0789

Cardiac Ion Channel Genetic Testing — MCG #s: 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-0 683

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 (those ending in "u") 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 the 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, ConfirmMDx™, and ExoDx®Prostate IntelliScore (EPI) (aka ExosomeDx®) — covered for Commercial and Medicare using criteria from Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis
2. Genomic Prostate Score (formerly Oncotype DX®) — covered for Medicare using criteria from Billing and Coding: MolDX: Oncotype DX® Genomic Prostate Score*
   *Commercial coverage discontinued eff. Feb. 1, 2023.
3. Prolaris® Prostate Cancer* and Decipher® Prostate — covered for Commercial and Medicare members with very-low risk, low-risk, favorable/unfavorable intermediate-risk, or high-risk localized or biochemically recurrent prostate cancer as a guide to management (i.e., active surveillance or definitive therapy) when life expectancy is ≥ 10 years.
   *Commercial coverage discontinued eff. Feb. 1, 2023, reinstated eff. Jan. 1, 2025
4. 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")
5. 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 (those ending in "u") are not reimbursed by NYS Medicaid:

- ExoDx Prostate IntelliScore (EPI) (0005U)
- Genomic Prostate Score® (GPS) Test (previously 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 (those ending in "u") are not reimbursed by NYS Medicaid:

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

VIII. Uveal melanoma (UM), primary and localized (DecisionDx) is covered for Commercial and Medicare members when the following criteria are met:

1. Member has primary, localized uveal melanoma
2. No evidence of metastatic disease
3. No previous DecisionDx-UM testing performed after current diagnosis when a result was successfully obtained

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. 23-Gene NGS Pyruvate Metabolism and Related Disorders Panel
2. 23andMe Health + Ancestry Service
3. Accelerate PhenoTest® BC kit
4. ADmark® Alzheimer's Evaluation
5. AlloSure® Heart (as a standalone or combination with the AlloMap [aka HeartCare Comprehensive Solution]. (The AlloMap remains a covered standalone test for all members)
6. AlloSure® Kidney (covered for Medicare)
7. Albinism Panel
8. AmHPR Helicobacter Pylori Antibiotic Resistance NGS Panel
9. ARISk Autism Risk Assessment Test
10. Autosomal Dominant and Recessive Polycystic Kidney Disease Nextgen Sequencing (NGS) Panel
11. Avise tests
    i. CTD
    ii. MTX (aka Avise PG) (covered for Medicare)
    iii. Lupus
12. BRCAPlus
13. BluePrint®
14. BreastNext® (covered for Medicare per Medicare Fee Schedule)
15. BreastOncPx™
16. BreastPRS
17. BREVAGen/BREVAGenplus
18. Bridge Urinary Tract Infection Detection and Resistance Test
19. CancerIntercept
20. CancerNext® (covered for Medicare per Medicare Fee Schedule), CancerNext-Expanded™
21. CancerTYPE ID® (covered for Medicare)
22. Carbohydrate Metabolism Deficiency NextGen DNA Screening Panel
23. Cardiac DNA Insight
24. Cardiovascular Health Panel
25. CellSearch System®
26. CGD Universal Test Panel
27. Ciliopathies: Sequencing Panel
28. Ciliopathy NextGen Sequencing (NGS) Panel
29. Clarava
30. ClonoSEQ® (covered for Medicare and Commercial; see Section V)
31. ColoNext® (covered for Medicare per Medicare Fee Schedule)
32. ColoVantage
33. Complete Hereditary Spastic Paraplegia Evaluation Panel
34. Complete Lung
35. Comprehensive Brain Malformations Next Generation Sequencing Panel
36. Comprehensive Dystonia NextGen DNA Screening Panel
37. Comprehensive Inherited Retinal Dystrophies Sequencing Panel

38. Comprehensive Molecular Genetic Panel
    Comprehensive Muscular Dystrophy/Myopathy Next Generation DNA Sequencing Panel
39. Comprehensive Molecular Genetic Panel
40. Congenital Myopathy NextGen Sequencing (NGS) Panel
41. Congenital Stationary Night Blindness panel
42. Connective Tissue NGS Panel
43. Corus® CAD (Coverage rescinded for Medicare members eff. Dec. 12, 2018 based on noncoverage Local Coverage Determination: MolDX: Corus® CAD Assay)
44. Craniosynostosis next generation sequencing (NGS) panel
45. DecisionDx tests
    i. DiffDx - Melanoma
    ii. Glioblastoma
    iii. SCC
    iv. Uveal melanoma (covered for Commercial and Medicare)
46. Decipher (covered for Commercial and Medicare; see Section VI)
47. DecodEX Microbial Genetic Identification
48. Distal Hereditary Motor Neuropathy NextGen Sequencing (NGS) Panel
49. Ehlers-Danlos Syndrome NGS Panel Dominant and Recessive
50. ENGAUGE™-cancer-DLBCL (covered for Medicare)
51. Envisia Genomic Classifier (covered for Medicare)
52. Epi proColon
53. EpiSign Complete
54. ExoDx®Prostate IntelliScore (EPI) (aka ExosomeDx®) (covered for Medicare)
55. ExomeNext
56. ExomeNext-Rapid
57. Expanded Pan-Ethnic Panel
58. Familial Hemiplegic Migraine NextGen Sequencing (NGS) Panel Fetal Akinesia Deformation Sequence/Lethal Multiple Pterygium Syndrome NextGen Sequencing (NGS) Panel
59. FoundationOne CDx (covered for Commercial and Medicare; see Section I)
60. FoundationOne RNA (covered for Medicare)
61. FoundationOne® Heme
62. FoundationOne Liquid CDx (covered for Commercial and Medicare; see Section I)
63. GeneAware
64. GeneFx® Colon
65. GeneFx® Lung
66. GeneKey
67. GeneStrat™
68. GeneSight (For Medicare members, see Pharmacogenetics Testing LCD [replaced Retired GeneSight® Assay for Refractory Depression LCD)
69. Genome PACT
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™ (covered for Medicare)
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. Epilepsy
    iv. Hereditary Spastic Paraplegia Panel
    v. Hypoglycemia panel
    vi. Overgrowth Syndromes Panel
    vii. PCM MRD Monitoring
    viii. PCM Tissue Profiling and MRD Baseline Assay
    ix. Primary Ciliary Dyskinesia Panel
    x. 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 (aka Genomic Prostate Score, 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. PancraGEN® (previously Pathfinder TG®) (covered for Medicare) (Note: Medicare non-covered eff. 02/07/2025)PancreaSeq Genomic Classifier
139. Panexia®
140. PanGIA Prostate
141. Paradigm Cancer Diagnostics [PCDx] Test
142. Pediatric Neurology Region of Interest Trio
143. Percepta Bronchial Genomic Classifier (covered for Medicare)
144. Pervenio™ Lung NGS (covered for Medicare)
145. PIGMENTED LESION Assay (covered for Medicare)
146. Pontocerebellar Hypoplasia Panel
147. Post-Op Px™ (formerly the Prostate Px Plus)
148. Praxis Extended RAS Panel (covered for Commercial and Medicare members; see Section I)
149. PredictSure IBD
150. PreludeDx™ DCISionRT®
151. Preparent Global Panel
152. Previstage™
153. Progenity CFnxt
154. Progenity® Pan-Ethnic Carrier Screening Panel
155. Prolaris (covered for Commercial and Medicare, see Section VI)
156. PROGENSA® PCA3 (Covered for Commercial and Medicare members; see Section VI)
157. ProOnc TumorSource DX
158. Proove profile panels (e.g., Opioid Risk Panel)
159. Prometheus® IBD sgi Diagnostic™
160. Prospera™ (Covered Medicare)

161. ProstateNext
162. ProstateNow
163. RadTox cfDNA
164. RenalNext™
165. ResponseDX Tissue Origin Test Rotterdam/Veridex (covered for Medicare)
166. RetnaGene AMD
167. Rotterdam Signature
168. Saethre-Chotzen Syndrome (TWIST) Sequencing and MLPA (Greenwood Genetic Center)
169. ScolioScore™ AIS Prognostic Test
170. SelectMDx for prostate cancer
171. Sema4 Signal Hereditary Cancer High Prevalence Panel
172. Signatera™ (Covered Medicare)
173. Spastic Paraplegia Next Generation Sequencing Panel
174. Stickler Syndrome NGS Panel
175. SymGene68™ Next Generation Sequencing Cancer Panel
176. SYMPHONY™ Genomic Breast Cancer Profile (combines BluePrint, MammaPrint and TargetPrint tests)
177. Skeletal Dysplasia Ciliopathy NGS Panel
178. SYMPHONY™ Personalized Breast Cancer Genomic Profile
179. TAADNext
180. Target Now™ molecular profiling test (aka MI Profile, MI Profile X)
181. TargetPrint®
182. therascreen FGFR RGQ RT-PCR Kit (Covered for Commercial and Medicare members; see Section I)
183. therascreen PIK3CA RGQ PCR Kit (Covered for Commercial and Medicare members; see Section I)
184. TheraPrint®
185. theraSEEK Sequence Analysis for Functional Disorders
186. Thrombocytopenia NextGen Sequencing (NGS) Panel
187. TruGenome Undiagnosed Disease Test
188. TruGenome Technical Sequence Data (whole exome sequencing test for labs and physicians who will make their own clinical interpretations make their own clinical interpretations)
189. TruGraf® Kidney (covered for Medicare)
190. Tuteva
191. Universal Carrier Panel
192. Vectra DA (covered for Medicare)
193. Vita Risk™
194. Vitreoretinopathy NGS Panel
195. BDX-XL2 (formerly Xpresys Lung) (covered for Medicare)

Revision History

Apr. 11, 2025	Added Guardant Reveal Medicare coverage
Feb. 14, 2025	Consolidated 4Kscore, ConfirmMDx™, and ExoDx®Prostate IntelliScore (EPI) sections Reinstated Prolaris Commercial coverage eff. 1/1/2025 Consolidated Decipher and Prolaris sections and updated criteria Added FoundationOne RNA and Prospera as investigational (covered Medicare) Updated Signatera investigational listing to communicate positive Medicare coverage

	Added notation to PancraGen investigational listing to communicate Medicare non-coverage eff. 2/7/2025
Aug. 15, 2024	Added DecisionDx Uveal Melanoma Commercial coverage (previously Medicare only)
Feb. 9, 2024	Added Invitae Epilepsy and Hypoglycemia panels to investigational list
Nov. 10, 2023	Added the following tests to investigational list: Genome PACT Primary Ciliary Dyskinesia Panel ProstateNow TruGraf as investigational (covered Medicare)
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)
Oct. 19, 2021	Added Guardant Reveal™ as investigational Added note in Limitations/Exclusions designating BreastNext, CancerNext, and ColoNext as Medicare-covered per Medicare Fee Schedule
July 14, 2021	Added Commercial coverage for 4Kscore and ConfirmMDx (eff. 1/20/2021) Added Commercial coverage for FoundationOne Liquid CDx and Guardant360 LDT Added Medicare coverage for ExoDx®Prostate IntelliScore (EPI)

	Added noncoverage note communicating that Proprietary lab analysis (PLA) codes are not covered for Medicaid members, as they are not reimbursed by NYS Medicaid Added noncoverage note communicating that CPT codes which are not on the Medicaid Lab Fee Schedule are not covered Updated list of lab tests regarded as investigational
Jul. 8, 2020	Added MSK-IMPACT for Medicare members Removed FoundationOne CDx from Limitations/Exclusions
Feb. 14, 2020	Added Plasma-Based Genomic Profiling in Solid Tumors LCD specific to Guardant360® for Medicare members
Apr. 12, 2019	Added genomic sequence analysis panels (e.g., OncoVantage®) for Medicare members
Mar. 8, 2019	Added Oncotype DCIS, Oncotype DX AR-V7 Nucleus and Xpresys Lung tests for Medicare members
Feb. 8, 2018	Added Clonoseq® for Medicare members Added link to MYvantage® Hereditary Comprehensive Cancer Panel Medical Guideline and removed MYvantage from Limitations/Exclusions
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	Added FoundationOne CDx test coverage for Medicare members 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) Added language communicating noncoverage of testing to confirm results of consumer-based testing 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

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