Gene Expression Profiling

Last Review Date: November 12, 2023	Number: MG.MM.LA.13xv2

Medical Guideline Disclaimer

 The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. 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. 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 Services Company LLC, ("EmblemHealth") has adopted the herein 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 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 (those ending in "u") 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 (those ending in "u") 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. Autosomal Dominant 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
19. Bridge Urinary Tract Infection Detection and Resistance Test
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. Genome PACT
71. GeneTrails® Solid Tumor Panel
72. Genomic Unity® AR Analysis
73. Genomic Unity® CACNA1A Analysis (covered for Commercial and Medicare)
74. Genomic Unity® CSTB Analysis (covered for Commercial and Medicare)
75. Genomic Unity® FXN Analysis (covered for Commercial and Medicare)
76. Genomic Unity® SMN1/2 Analysis (covered for Commercial and Medicare)
77. Genomind Professional PGx Express CORE Anxiety & Depression
78. GPS Cancer
79. Guardant360® LDT (covered for Commercial and Medicare; see Section III)
80. Guardant360 CDx (covered for Commercial and Medicare; see Section I)
81. Guardant Reveal™

82. Healthy Weight DNA Insight
83. Healthy Woman DNA Insight
84. HCMNext
85. H/I Gene Expression Ratio
86. Hemophagocytic Lymphohistiocytosis Panel by next generation sequencing (NGS)
87. Hereditary Spherocytosis/Elliptocytosis NextGen Sequencing Panel
88. HERmark (Covered for Medicare, see Gene Expression Profiling and Biomarker Testing for Breast Cancer)
89. HLA-DQB1*06:02 typing for the diagnosis or management of narcolepsy
90. HOX13:IL17BR
91. Hypokalemic and Hyperkalemic Periodic Paralysis Disorders NGS Sequencing Panel
92. Insight® DX Breast Cancer Profile
93. Intellectual Disability (IDNEXT) Panel
94. Insight TNBCtype
95. 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
96. Leukoencephalopathy NGS Panel
97. Lipodystrophy NGS Panel
98. LungLB
99. LUNGSEQ® Panel
100. Lymph3Cx Lymphoma Molecular
101. Subtyping Assay
102. Macula Risk PGx
103. Macular Degeneration Mutation Analysis
104. Mammastatin
105. miReview®
106. Mammostrat
107. Melaris®
108. Molecular Intelligence
109. My5-FU™ (previously OnDose™)
110. myChoice® CDx (Covered for Commercial and Medicare; see Section I)
111. Myeloid Molecular Profile
112. myPath® Melanoma (covered Medicare)
113. MyPRS® Myeloma Prognostic Risk Signature
114. Myriad Foresight® Carrier Screen (previously Counsyl Foresight Carrier Screen)
115. myRisk™
116. MSK-IMPACT (covered for Medicare; see Section I)
117. Neurotransmitter Metabolism Deficiency NextGen DNA Screening Panel
118. Next Gen RASopathy Panel
119. Next Generation Sequencing Panel for ASXL1, RECQL4, RNU4ATAC, SOX2
120. NextStepDx PLUS®

121. NGS Epilepsy/Seizure Panel
122. NGS RASopathy Panel
123. OmniSeq Comprehensive
124. Oncomine Dx Target (Covered for Commercial and Medicare members; see Section I)
125. 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)
126. Oncotype MAP™ PanCancer Tissue Test (covered for Medicare)
127. Oncofocus®
128. OncoVantage®(covered for Medicare)
129. OnkoMatch™
130. OnkoSight™ next generation sequencing for hematologic malignancies
131. Oncovue
132. OnoCEE
133. OPA 1 gene sequencing for autosomal dominant optic atrophy and/or optic neuropathy
134. Osteogenesis Imperfecta NGS Panel-Recessive
135. OvaNext™ (covered for Medicare)
136. Overa (aka OVA1 Next Generation or second-generation Multivariate Index Assay [MIA2G] test)
137. PAM50 Breast Cancer Intrinsic Classifier™
138. PancNext™
139. PancraGEN (previously Pathfinder TG®) (covered for Medicare)
140. PancreaSeq Genomic Classifier
141. Panexia®
142. PanGIA Prostate
143. Paradigm Cancer Diagnostics [PCDx] Test
144. Pediatric Neurology Region of Interest Trio
145. Percepta Bronchial Genomic Classifier (covered for Medicare)
146. Pervenio™ Lung NGS (covered for Medicare)
147. PIGMENTED LESION Assay (covered for Medicare)
148. Pontocerebellar Hypoplasia Panel
149. Post-Op Px™ (formerly the Prostate Px Plus)
150. Praxis Extended RAS Panel (covered for Commercial and Medicare members; see Section I)
151. PredictSure IBD
152. PreludeDx™ DCISionRT®
153. Preparent Global Panel
154. Previstage™
155. Progenity CFnxt
156. Progenity® Pan-Ethnic Carrier Screening Panel
157. Prolaris (covered for Medicare, see Section VI)
158. PROGENSA® PCA3 (Covered for Commercial and Medicare members; see Section VI)
159. ProOnc TumorSource DX
160. Proove profile panels (e.g., Opioid Risk Panel)
161. Prometheus® IBD sgi Diagnostic™
162. ProstateNext
163. ProstateNow
164. RadTox cfDNA

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

Revision History

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

References

AHRQ. Technology Assessment on Genetic Testing or Molecular Pathology Testing of Cancers with Unknown Primary Site to Determine Origin. February 2013. http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id90TA.pdf. Accessed September 8, 2022.

Centers for Medicare & Medicaid Services. Local Coverage Determinations. https://www.cms.gov/medicare-coverage-database/indexes/lcd-alphabetical-index.aspx?DocType=1. Accessed September 8, 2022.

Centers for Medicare & Medicaid Services. National Coverage Determination for Next Generation Sequencing (NGS). Version 2. January 2020. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=372&ncdver=2&KeyWord=next%20generation%20sequencing&KeyWordLookUp=Title&KeyWordSearchType=Exact&bc=CAAAAAAAAAAA. Accessed September 8, 2022.

National Cancer Care Network (NCCN). Clinical Practice Guidelines in Oncology. Colon Cancer. Version 1.2022. http://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed September 8, 2022.

National Cancer Care Network (NCCN). Clinical Practice Guidelines in Oncology. Cutaneous Melanoma. Version 3.2022. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed July 13, 2021.

National Cancer Care Network (NCCN). Clinical Practice Guidelines in Oncology. Multiple Myeloma. Version 5.2022. http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed July 13, 2021.

National Cancer Care Network (NCCN). Clinical Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 1.2023. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. July 13, 2021.

National Cancer Care Network (NCCN). Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer Version 4.2022. http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed July 13, 2021.

National Cancer Care Network (NCCN). Clinical Practice Guidelines in Oncology. Occult Primary (Cancer of Unknown Primary [CUP]). Version 1.2023. http://www.nccn.org/professionals/physician_gls/pdf/occult.pdf. Accessed July 13, 2021.

National Cancer Care Network (NCCN). Clinical Practice Guidelines in Oncology. Prostate Cancer Version 4.2022. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 13, 2021.

National Cancer Care Network (NCCN). Clinical Practice Guidelines in Oncology. Prostate Cancer Early Detection Version 1.2022. https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf. Accessed September 8, 2022.

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.