HIGHMARK

September 2024

MEDICAL POLICY UPDATE

IN THIS ISSUE

Policy

Policy Titles	Anticipated Issue Date	30 Day Notification Information
A-0184 - Rhinoplasty	09/30/2024	This is a new guideline for NY, guideline will be published on September 30, 2024.
A-0623 - CG Heart Transplant Rejection Gene Expression Profiling (eg AlloMap) and Donor derived cell free DNA (eg AlloSure)	10/28/2024	This policy is being archived and replaced with L-306-001 Transplant Rejection Testing will archive on October 28, 2024.
A-0910 - Ehlers-Danlos Syndrome (Vascular) - COL3A1 Gene	12/02/2024	This is a new guideline for NY, this guideline will be published on December 2, 2024.

Evicore Lab Management Clinical Guidelines	01/01/2025	EviCore update, an MPU will be issued September 2024. Policy will publish January 1, 2025.
E-8 - Patient Lifts	10/28/2024	This is an annual review. The policy language was updated. There were no changes to the policy criteria. The policy will publish on October 28, 2024.
G-49 - Beremagene geperpavec-svdt (Vyjuvek)	10/28/2024	This policy is up for annual review. There are no indications for a change in coverage at this time. Policy will publish on October 28, 2024.
MA G-55 - Beremagene geperpavec-svdt (Vyjuvek)	10/28/2024	This policy is up for annual review. There are no indications for a change in coverage at this time. Policy will publish on October 28, 2024.
I-14 - Immune Globulin Therapy	09/30/2024	This policy has been revised to include the recent FDA approved intravenous immune globulin product Yimmugo. Policy will publish on September 30, 2024.
I-18 - Pharmacologic Treatment of Pulmonary Arterial Hy	01/01/2025	This policy was updated to add generic treprostinil as a preferred product and Remodulin as non-preferred. A medical policy update (MPU) newsletter is required. Policy will publish on January 1, 2025.
I-94 - Intravitreal Injections	01/01/2025	This policy is being updated with the addition of preferred products for wet AMD. Policy will publish January 1, 2025.
MA I-94 - Intravitreal Injections	01/01/2025	This policy is being updated with the addition of preferred products for wet AMD. Policy will publish January 1, 2025.
I-118 - Alemtuzumab (Lemtrada)	11/04/2024	This policy is scheduled for annual review. There is no indication for change in coverage. Policy will publish November 4, 2024.
I-120 - Programmed Death Receptor (PD-1) Programmed Death-Ligand (PD-L1) Blocking Antibodies	09/30/2024	This policy is being revised to include the new FDA expanded indications for Imfinzi for resectable non-small lung cancer in combination with platinum containing chemotherapy and Jemperli for endometrial cancer. Policy will publish on September 30, 2024.
I-145 - Testosterone Androgens	11/04/2024	This is an annual review. There are no indications for a change in coverage at this time. Policy will publish on November 4, 2024.

MA I-145 - Testosterone Androgens	11/04/2024	This is an annual review. Administrative changes were made to the policy. Policy will publish on November 04, 2024.
MA I-150 - Daratumumab (Darzalex)	11/11/2024	This is an annual review. Administrative changes were made to the policy. Policy will publish on November 11, 2024.
I-150 - Daratumumab (Darzalex)	11/11/2024	This is an annual review. Policy was updated to capture expanded indication for Darzalex Faspro. Policy will publish on November 11, 2024.
I-166 - Empliciti	11/18/2024	This is an annual review. There are no indications for a change in coverage at this time. Policy will publish on November 18, 2024.
MA I-166 - Empliciti	11/18/2024	This is an annual review. Administrative changes were made to the policy. Policy will publish on November 18, 2024.
I-172 - Cerliponase Alfa (Brineura)	10/072024	This policy is scheduled for annual review. Policy updates include language revisions. There is no indication for change in coverage. Policy will publish October 7, 2024.
I-180 - Chimeric Antigen Receptor T-Cell Therapy	10/01/2024	This policy is being revised to establish criteria for the recent FDA approved CAR-T therapy afamitresgene autoleucel (Tecelra) which is indicated for the treatment of synovial sarcoma. Additional coding updates were also made to the policy. Policy will publish on October 1, 2024.
I-241 Amivantamab-vmjw (Rybrevant)	10/07/2024	This policy is being updated with expanded indication for use in combination with lazertinib for exon 19 deletions or exon 21 L858R substitution mutations. Policy will publish October 7, 2024.
I-244 - Aducanumab-avwa (Aduhelm)	11/04/2024	This policy will be archived on November 4, 2024, as medication has been removed from the market.
I-262 - Teclistamab (TECVAYLI)	11/18/2024	This is an annual review. There are no indications for a change in coverage at this time. Policy will publish on November 18, 2024.

I-266 - Lecanemab-irmb (Leqembi) DE	10/28/2024	This policy is up for annual review. The policy criteria were revised to remove the criteria related to oral Alzheimer's Disease medications. Additional coding updates were also made. Policy will publish on October 28, 2024.
MA I-272 - Teclistamab (TECVAYLI)	11/18/2024	This is an annual review. Administrative changes were made to the policy. Policy will publish on November 18, 2024.
I-272 - Rozanolixizumab-noli (Rystiggo)	01/01/2025	This policy was updated to add Rystiggo as a non-preferred product. A medical policy update (MPU) newsletter is required. Policy will publish on January 1, 2025.
I-275 - Talquetamab-tgvs (Talvey)	11/04/2024	This policy is scheduled for annual review. There is no indication for change in coverage. Policy will publish November 4, 2024.
MA I-284 - Talquetamab-tgvs (Talvey)	11/04/2024	This policy is scheduled for annual review. There is no indication for change in coverage. Policy will publish November 4, 2024.
MA I-303 Axatilimab-csfr (Niktimvo)	09/30/2024	This is a new policy for the recent FDA approved medication axatilimab-csfr (Niktimvo) for adult and pediatric individuals who are diagnosed with chronic graft-versus-host disease. Policy will publish on September 30, 2024.
MA I-304 - Denileukin diftitox-cxdl (Lymphir)	10/07/2024	This is a new policy establishing coverage criteria for new to market therapy Lymphir indicated for adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL). Policy will publish October 7, 2024.
L-306 - Transplant Rejection Testing	10/28/2024	This is a new Highmark policy created to replace policy A-0623-001 CG. This policy addresses medical necessity for Gene Expression Profiling (eg AlloMap) and Donor derived cell free DNA (eg AlloSure) testing in heart and kidney transplant recipients. The policy is expected to publish on 10/28/2024.
M-23 - Esophageal pH Monitoring	10/28/2024	This policy is scheduled for annual review. The literature and research review supports our criteria. There is no change in coverage and no change to operational guidelines. The policy will publish on October 28, 2024.

MCG M-52 - Percutaneous Coronary Intervention	09/30/2024	This is a new guideline scheduled to publish on September 30, 2024.
M-72 - Retinal Telescreening for Diabetic Retinopathy	10/28/2024	This is an annual review. Administrative changes were made. The policy will publish on October 28, 2024.
M-333 Left Atrial Appendage Closure, Percutaneous	09/30/2024	This is a new guideline scheduled to publish on September 30, 2024.
O-13 - Cranial Orthosis for Plagiocephaly	11/04/2024	This policy is scheduled for annual review. There is no change in the policy criteria. The policy is scheduled for November 4, 2024.
S-28 - Cosmetic Surgery vs. Reconstructive Surgery	09/30/2024	This policy is scheduled for annual review. Criteria regarding rhinoplasty was removed. Criteria regarding umbilectomy was added. The policy will publish on September 30, 2024.
S-140 Aortic Aneurysm, Thoracic, Repair with Graft	09/30/2024	This is a new guideline scheduled to publish on September 30, 2024.
S-245 - Percutaneous Left Atrial Appendage Closure Devi	09/30/2024	This policy is being archived with an effective date of September 30, 2024.
S-289 - Bone Graft Substitutes	10/28/2024	This policy will be archived effective October 28, 2024.
MCG S-300 - Carotid Endaterectomy	09/30/2024	This is a new guideline scheduled to publish on September 30, 2024.
MCG S-1310 - Percutaneous Revascularization, Lower extremity	09/30/2024	This is a new guideline scheduled to publish on September 30, 2024.
V-2 - Concurrent Care	11/04/2024	This is an annual review. There are no recommended revisions. This policy will publish on November 4, 2024.
V-3 - Billing of Observation Services	11/04/2024	This policy will be archived as of November 4, 2024.
V-37 - Autism Spectrum Disorders	10/28/2024	This policy was scheduled for annual review. Updates to coding and policy criteria have been made. The policy will publish October 28, 2024.
Y-5 - Vision Therapy (Orthoptics and Pleoptics)	11/04/2024	This policy is scheduled for annual review. there are no changed to the policy criteria. The policy will publish on November 4, 2024.

Y-21 - Cognitive Rehabilitation	11/04/2024	This policy is scheduled for annual review. There are no changes to policy criteria. The policy will publish on November 4, 2024.
Z-4 - Transcranial Magnetic Stimulation (TMS)	10/28/2024	This is an annual review. The minimum age for transcranial magnetic stimulation for the treatment of major depressive disorder was reduced from 18 to 15. The requirement of four failed psychopharmacologic trials was reduced to two. The policy position was reorganized. The policy will publish on October 28, 2024.
Z-26 - Allergy Skin Testing	12/23/2024	This is an annual review. SET is being revised too experimental/investigational. This policy will publish on December 23, 2024.

Policy

Preferred Product Established for Treprostinil

Highmark Blue Cross Blue Shield has revised criteria for I-18 Pharmacologic Treatment of Pulmonary Arterial Hypertension. Treprostinil (generic) is the preferred product for continuous subcutaneous (SQ) or intravenous (IV) infusion that is required for all individuals and indications.

Remodulin (Brand name Treprostinil) is a non-preferred product unless the individual had an adequate therapeutic trial and experienced a documented drug therapy failure or intolerance to the preferred product, or the preferred product is contraindicated.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is January 1, 2025.

Place of Service: Inpatient/Outpatient

Please refer to Medical Policy I-18, Pharmacologic Treatment of Pulmonary Arterial Hypertension, for additional information.

Biosimilar Preferred Products Established for Avastin

Highmark Blue Cross Blue Shield has updated the preferred products for I-94, Intravitreal Injections. The following are the preferred anti-vascular endothelial growth factor (anti-VEGF) for members initiating new therapy for neovascular (wet) age-related macular degeneration (AMD).

- Bevacizumab (Avastin)
- Bevacizumab-awwb (Mvasi)
- Bevacizumab-bvzr (Zirabev

This revised Medical Policy will apply to professional providers and facility claims. The effective date is January 1, 2025.

Place of Service: Outpatient

Please refer to Medical Policy I-94, Intravitreal Injections, for additional information.

Coverage Criteria Established for Crovalimab-akkz (Piasky)

Highmark Blue Cross Blue Shield has established new criteria for I-130, Complement Inhibitors (Soliris, Ultomiris, Empaveli). This policy is updated with coverage criteria for new to market Piasky, a complement C5 inhibitor indicated for the treatment of adult and
pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is September 2, 2024.

Place of Service: Outpatient

Please refer to Medical Policy I-130, Complement Inhibitors (Soliris, Ultomiris, Empaveli) for additional information.

Preferred Products Established for Interluekin-5 Antagonists

Highmark Blue Cross Blue Shield has revised criteria for the interleukin-5 antagonists. Benralizumab (Fasenra) and mepolizumab (Nucala) are now the preferred interleukin-5 antagonist products for all individuals for asthma indications. Preferred product requirements are only applicable to interleukin-5 antagonists and do not apply to other treatment options for severe asthma.

Reslizumab (Cinqair) will now be considered a non-preferred product and will require the individual to have an adequate therapeutic trial and experienced a documented drug therapy failure or intolerance to both of the preferred products.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is January 1, 2025.

Place of Service: Outpatient

Please refer to Medical Policy I-146, Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions, for additional information.

Coverage Guidelines Developed for Afamitresgene autoleucel (Tecelra)

Highmark Blue Cross Blue Shield has established new criteria for the recently FDA approved cellular therapy afamitresgene autoleucel (Tecelra) which is indicated for adult individuals with unresectable or metastatic synovial sarcoma.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is October 1, 2024.

Place of Service: Inpatient/Outpatient

Please refer to Medical PolicyI-180, Chimeric Antigen Receptor T-Cell Therapy, for additional information.

Preferred Products Established for Treatment of Anti-Acetylcholine Receptor (AChR) Antibody Positive, Generalized Myasthenia Gravis

Highmark Blue Cross Blue Shield has established preferred products for Treatment of Anti-Acetylcholine Receptor (AChR) Antibody Positive, Generalized Myasthenia Gravis. The preferred products include:

- Efgartigmod alfa-fcab (Vyvgart)
- Efgartigmod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)
- Eculizumab (Soliris)
- Ravulizumab-cwvz (Ultomiris)

The non-preferred product will be Rozanolixizumab-noli (Rystiggo).

This revised Medical Policy will apply to professional providers and facility claims. The effective date is January 1, 2025.

Place of Service: Outpatient

Please refer to Medical Policy I-272, Rozanolixizumab-noli (Rystiggo), for additional information.

Coverage Criteria Established for Axatilimab-csfr (Niktimvo)

Highmark Blue Cross Blue Shield has established new guidelines for the recently FDA approved medication Axatilimab-csfr (Niktimvo) which is indicated for the treatment of adult and pediatric individuals with chronic graft-versus host disease that have had treatment failure of at least two (2) lines of systemic therapy.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is September 30, 2024.

Place of Service: Outpatient

Please refer to Medical Policy I-292, Axatilimab-csfr (Niktimvo), for additional information.

Coverage Criteria Established for Denileukin diftitox-cxdl (Lymphir)

Highmark Blue Cross Blue Shield has established new criteria for I-293, Denileukin diftitox-cxdl (Lymphir). This is a new policy creating criteria for Lymphir, a new to market therapy indicated for adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL).

This new Medical Policy will apply to professional providers and facility claims. The effective date is October 7, 2024.

Place of Service: Outpatient

Please refer to Medical Policy for I-293, Denileukin diftitox-cxdl (Lymphir), for additional information.

Allergy Skin Testing Criteria Revised

Highmark Blue Cross Blue Shield has revised criteria for Z-26, Allergy Skin Testing.

Skin Endpoint Titration (SET) criteria is being removed and will now be considered Experimental/Investigational

This revised Medical Policy will apply to professional providers and facility claims. The effective date is December 23, 2024.

Place of Service:

Please refer to Medical Policy Z-26, Allergy Skin Testing, for additional information.

REMINDER: Laboratory Management Coverage Guidelines

Highmark Blue Shield is providing a reminder to all providers.

The Laboratory Management coverage guideline will be updated and take effect January 01, 2025. This applies to both professional provider and facility claims.

The changes to the Laboratory Guidelines are as follows:

- 7 New clinical guidelines include:

Guideline Name	Guideline #	Procedure Code(s) Impacted	Summary of change
Laboratory Billing and Reimbursement	MOL.AD.412.X	All	New guideline replacing Laboratory Claim Reimbursement and Laboratory Procedure Code Requirements
ColoSense for Colorectal Cancer	MOL.TS.413.A	81599	New guideline managing ColoSense colorectal cancer screening test (standard non-coverage version)
Vitamin B12 Deficiency Testing	MOL.CS.415.X	82607, 83921, 83090	New guideline managing Vitamin B12 Deficiency testing - previously managed under the Micronutrients guideline (MOL.CS.372.X)

Vitamin Testing	MOL.CS.416.X	82180, 84591, 84207, 84252, 84425, 84446, 84590, 84597, 84591	New guideline managing Vitamin testing - previously managed under the Micronutrients guideline (MOL.CS.372.X)
Mineral Testing	MOL.CS.417.X	82310, 82495, 82525, 83789, 83735, 83785, 84255, 84630, 84999	New guideline managing Mineral testing - previously managed under the Micronutrients guideline (MOL.CS.372.X)
Metabolic Testing	MOL.CS.418.X	82016, 82017, 82136, 82128, 82127, 82379, 82542, 82725, 82542, 82978, 83919, 83921, 83918, 82726	New guideline managing Metabolic testing - previously managed under the Micronutrients guideline (MOL.CS.372.X)
Inflammatory Bowel Disease Biomarker Testing	MOL.TS.359.A	86255, 81479, 82397, 86140, 88346, 88350,0203U	New guideline to manage molecular Inflammatory Bowel Disease testing

- **10 clinical guidelines that are being retired include:**

Guideline Name	Guideline #	Summary of change (to be reviewed in conjunction with actual GL)	Reason for Change
Bloom Syndrome Genetic Testing	MOL.TS.132.A	Retired test-specific guideline. Criteria and test information incorporated into BRCA Analysis (MOL.TS.238); No change in coverage	Retired guideline
Canavan Disease Genetic Testing	MOL.TS.145.A	Retired due to infrequent use	Retired guideline
Gaucher Disease Genetic Testing	MOL.TS.173.A	Retired due to infrequent use	Retired guideline
Niemann-Pick Disease Types A and B Genetic Testing	MOL.TS.207.A	Retired due to infrequent use	Retired guideline

Niemann-Pick Disease Type C Genetic Testing	MOL.TS.208.A	Retired due to infrequent use	Retired guideline
Tay-Sachs Disease Genetic Testing	MOL.TS.226.A	Retired due to infrequent use	Retired guideline
Micronutrient testing	MOL.CS.372.X	Broken into 4 smaller, more focused guidelines	Retired guideline
Laboratory Claim Reimbursement	MOL.CS.105.X	Replaced by Laboratory Billing and Reimbursement	Retired guideline
Genetic Presymptomatic and Predictive Testing for Adult-Onset Conditions in Minors	MOL.CU.298.A	Information and criteria within were added to guideline Genetic Testing to Predict Disease Risk MOL.CU.115.A	Retired guideline
Laboratory Procedure Code Requirements	MOL.AD.391.X	Replaced by new Laboratory Billing and Reimbursement guideline	Retired guideline

- **26 clinical guideline updates for content criteria revisions with impacts including:**

Guideline Name	Guideline #	Procedure Code Impacted by Update, if applicable	Summary of change (to be reviewed in conjunction with guideline)
Flow Cytometry	MOL.CS.103.A	88182, 88184, 88185, 88187, 88188, 88189	Criteria: Added criterion that flow cytometry is not medically necessary when performed in peripheral blood in cases of isolated anemia or thrombocytopenia (per ASCP Choosing Wisely), changed criterion regarding IHC and flow cytometry performed on same DOS - previously was considered always not medically necessary and now will be considered on a case by case basis such as for lymphoma (per NCCN guideline for B-cell lymphoma which supports doing both IHC and flow), admin updates and clarification of intent edits throughout, addition of approvable ICD codes in Billing & Reimbursement (addressed by existing coverage criteria; no change in decision making); Background: Added benefit/harm statement per CMS final

			rule, other updates; References: updated.
Immunohistochemistry (IHC)	MOL.CS.104.A	88341, 88342, 8844	Criteria: removed unit limit rules, clarified language when IHC is performed on histological lesions, clarified coverage for H. pylori infections with chronic gastritis, clarified language around performance of IHC and Flow together (per NCCN); Billing and Reimbursement: Removed corresponding B&R rules to align with criteria changes. Guideline and Evidence: Admin edits
Sexually Transmitted and Other Reproductive Tract Infection Testing	MOL.CS.106.A	81513, 81514, 0352U, 87510, 87511, 0068U, 87490, 87590, 87529, 87660, 87661; Added 0505U	Criteria: added coverage criteria for 3 select BV assays previously considered E/I/U (CPT codes: 81513, 81514, & 0352U) per IDSA/ASM 2024 guide, changed Gardnerella vaginalis detection testing (87510, 87511) from covered with criteria to not medically necessary (per IDSA/ASM 2024 guide), added new PLA code to BV section (E/I/U) - 0505U (Vaginal Infection Testing from NxGen MDx), changed Candida subtyping test 0068U from E/I/U to NMN to align with new eviCore standard definitions since exceptions can be considered (no change in decision making), clarified symptoms associated with Candida in Criteria section, specified that repeat testing for test-of-cure is not medically necessary for Candida and BV (per IDSA/ASM 2024 and ACOG 2020 guideline for Vaginitis, added additional symptoms to existing list in criteria for Chlamydia and N. Gonorrhoeae per CDC and WHO, reduced frequency limits for direct probe studies from 3 units to1 unit per DOS for Chlamydia (87490) and N. gonorrhoeae (87590) (supported by CDC 2021 guideline, which only mentions amplified techniques for

			extragenital specimens), clarification of intent edit - specifying that T. vaginalis testing is medically necessary in individuals with an affected partner even if individual is asymptomatic (already included in Billing & Reimbursement section), increased frequency limit for amplified probe for HSV (87529) from 1 per DOS to 2 per DOS (per CDC STI guidelines, extragenital sites may also need to be tested), reduced frequency limit for T. vaginalis (CPT 87660 & 87661) from 3 units per DOS to 1 unit per DOS (CDC STI guideline does not mention the need to test multiple specimens or extragenital sites), removed ICD code table for NOS Testing for Genitourinary Conditions (currently not in use), admin and clarification of intent edits throughout; CPT code table: added 0505U; Guidelines and Evidence: Added benefit/harm statement per CMS final rule, updated; Background: added to guideline; Test Information: updated, added RCL for NAT/NAAT; References: updated
Experimental, Investigational, or Unproven Laboratory Testing	MOL.CU.117.XK	ADDED new PLA Codes: 0507U, 0490U, 0491U, 0492U, 0496U, 0506U, 0486U, 0497U, 0498U, 0511U, 0482U, 0493U, 0510U, 0501U, 0495U, 0512U, 0513U, 0508U, 0509U; DELETED: 0396U	Criteria: Added Guardant Reveal and BarreGEN, removed the following tests that are now addressed in Inflammatory Bowel Disease Biomarker Testing guideline (still E/I/U) Crohn's Prognostic, IBD sgi Diagnostic, PredictSURE IBD, removed PrecivityAD blood tests (addressed by Cognitive Impairment Biomarkers guideline); CPT Code Table: Added Guardant Reveal and BarreGEN, removed Crohn's Prognostic, IBD sgi Diagnostic, PredictSURE IBD, Precivity AD; Corrected PLA code for EarlyTect to 0452U; ADDED new PLA Codes: Avantect Ovarian Cancer Test (0507U), CELLSEARCH Circulating Melanoma Cell (CMC) Test (0490U), CELLSEARCH ER Circulating Tumor Cell (CTC-ER) (0491U), CELLSEARCH PD-L1 Circulating Tumor Cell (CTC-PD-L1) (0492U), ColoScape PLUS (0496U), EndoSign Barrett's Esophagus Test (0506U), Northstar Response (0486U), OncoAssure Prostate (0497U, new code and updated description), OptiSeq Colorectal Cancer NGS Panel (0498U), PARIS (0511U), Preeclampsia sFlt-1/PlGF Ratio (PERA) (0482U), Prospera (0493U),

			PurISTSM (0510U), QuantiDNA Colorectal Cancer Triage Test (0501U), Stockholm3 (0495U), Tempus p-MSI (0512U), Tempus p-Prostate (0513U), VitaGraft Kidney Baseline + 1st Plasma Test (0508U), VitaGraft Kidney Subsequent (0509U); DELETED: 0396U (Spectrum PGT-M); EDITED name or description for 0118U (Eurofins TRAC dd-cfDNA), 0465U (UriFind Urothelial Carcinoma Assay), 0403U (MyProstateScore 2.0), 0248U (3D Predict Glioma); Background: Added benefit/harm statement per CMS final rule
Dentatorubral-Pallidoluysian Atrophy Genetic Testing	MOL.TS.159.A	81177	Criteria: added white matter lesion as a feature for diagnostic testing, admin edit, clarified ethnicity language; Background: updated and added reference; Test Information: added information on ATN1 testing; Guidelines and Evidence: Added benefit/harm statement per CMS final rule, deleted introduction, deleted redundant information present in other parts of the guideline, admin edit; References: deleted introduction, added reference, updated reference.
Expanded Carrier Screening Panels	MOL.TS.165.A	81479, 0400U, 81443, 0449U	Criteria: Removed criteria for individual genes since this guideline now focuses on panels, opened up coverage for carrier screening panels per ACMG recommendation - previously had stricter coverage criteria; Billing and Reimbursement: Updated to align with broader coverage of carrier screening panels; CPT Code Table: removed individual genes; Background: admin edits; Guidelines and Evidence: Added ACOG Hemoglobinopathies and deleted section on concerns for large panels, Added benefit/harm statement per CMS final rule, deleted introduction; References: updated, deleted introduction; TITLE CHANGE: Carrier Screening Panels, Including Targeted, Pan-Ethnic, Universal, and Expanded

Somatic Mutation Testing	MOL.TS.230.A	Various panel codes - see CPT code table in guideline	Criteria: New indications for NGS panel testing in patients with metastatic prostate cancer and unresectable or metastatic biliary tract cancer- based on NCCN guidelines, admin update; Billing and Reimbursement: updated name of referenced guideline on coding; CPT code table: added new PLA codes 0481U (IDH1, IDH2, and TERT Mutation Analysis, Next-Generation Sequencing, Tumor (IDTRT)), 0478U (Lung HDPCR), 0499U (OptiSeq Dual Cancer Panel Kit); Guidelines and Evidence: Added benefit/harm statement per CMS final rule; CPT code table: admin update; Guidelines and Evidence: updated, added Prostate cancer and Biliary Tract cancers NCCN guidelines; References: updated.
Von Hippel-Lindau Disease Genetic Testing	MOL.TS.233.A	81401, 81403, S3842	Criteria: expanded indications for testing of symptomatic individuals to include paraganglioma, endolymphatic sac tumor, pancreatic neuroendocrine tumor, admin edits, removed information on prenatal testing as this is addressed by a clinical use guideline; Intro and CPT code table: admin edits; Background: updated; Guidelines and Evidence: removed intro, added benefit/harm statement per CMS final rule, added a paragraph on clinical diagnostic criteria to support criteria changes; References: removed intro, added references, updated.
BRCA Analysis	MOL.TS.238.A	Various codes - see CPT code table in guideline	Criteria: Based on NCCN HBOC recommendations - added indications 1) full gene sequencing for individuals with cancer and Ashkenazi Jewish ancestry, 2) dx of prostate cancer with close fam member w/ triple neg breast cancer or high risk prostate, admin updates; CPT code table: admin updates; Background: updated; Test information: updated; Guidelines and Evidence: Added benefit/harm statement per CMS final rule, Added ASCO/SSO, AUA/ASTRO & AUA/SUO guidelines, updated; References: updated
Epilepsy Genetic Testing	MOL.TS.257.A	81419	Criteria: added indications for panel testing in drug resistant focal epilepsy and focal epilepsy with a positive family history suggesting of a monogenic cause (per peer reviewed literature and NSGC practice guideline), Billing and Reimbursement: updated name of referenced guideline on coding; CPT code table: admin

			edits; Background: updated; Guidelines and Evidence: updated, Added benefit/harm statement per CMS final rule; References: updated
Gastrointestinal Pathogen Panel (GIPP) Molecular Testing	MOL.CS.277.A	87505, 87506, 87507, 0369U	Criteria - Billing and Reimbursement section - opened coverage for GIPP panels of any size in immunocompromised individuals per ACG guidelines on IBD that recommend ruling out infectious conditions that might mimic IBD inflammation; Guidelines and Evidence: Added benefit/harm statement per CMS final rule, updated; References: updated
Myotonic Dystrophy Type 1 Genetic Testing	MOL.TS.312.A	81234, 81239, S3853	Criteria: added "Posterior subcapsular cataracts with detectable red and green iridescent opacities on slit lamp examination" into criteria for symptomatic individuals, admin edit, Procedures addressed: admin edits; Background: updated with info on cataracts with associated reference and admin edits; Test Information: edited intro, admin edits; Guidelines and Evidence: updated, Added benefit/harm statement per CMS final rule, admin edits; References: admin edit, updated
Cardiovascular Risk and Disease Laboratory Testing	MOL.CS.316.X	83695; 83700	Criteria: Additional criteria for coverage of Lp(a) (per American Heart Association Scientific Statement), admin edits throughout; Background: updated; Guidelines and Evidence: Added benefit/harm statement per CMS final rule, added AHA scientific statement, Australian Atherosclerosis Society position statement, Canadian Cardiovascular Society/Canadian Pediatric Cardiology Association clinical practice update, & AHA/ACC/ACCP/ASPC/NLA/PCNA guideline, and made additional updates; References: updated.
Microsatellite Instability and Immunohistochemistry Testing in Cancer	MOL.TS.356.A	88341, 88342, 81301	Criteria: updated name of referenced guideline, added esophageal and esophagogastric junction cancer as approvable cancer types based on NCCN guideline, updated; CPT code table: admin updates; Background: updated; Test Information: updated; Guidelines and Evidence: Added benefit/harm statement per CMS final rule, added NCCN esophageal

			guideline, updated; References: updated
Human Platelet and Red Blood Cell Antigen Genotyping	MOL.TS.361.A	81403, Added 0494U, 0488U	Criteria: opened coverage for fetal RhD by NIPS in alloimmunized women with at-risk pregnancies per 2024 ACOG Clinical Practice Update; Guidelines and Evidence: updated, incorporated current EviCore HTA, Added benefit/harm statement per CMS final rule, deleted introduction; References: updated, admin edits, deleted introduction; Added new PLA codes: Rh Test - Natera (0494U), UNITY Fetal Antigen NIPT (0488U)
Pathology Testing with Mohs Micrographic Surgery	MOL.CS.363.A	88342, 88341, 88344	Criteria: updated to change IHC to medically necessary when performed in conjunction with Mohs procedures (per NCCN cutaneous melanoma guideline), admin edit; Billing and Reimbursement: admin edit; Guidelines and Evidence: updated, Added benefit/harm statement per CMS final rule, deleted introduction; References: updated, deleted introduction
Special Circumstances Influencing Coverage Determinations	MOL.AD.364.A	various	Criteria: Added Jurisdiction column to both tables along with description in table notes. Added the following bills to the Broad Biomarker Bills table: Colorado (SB 124), Connecticut (SB 307), Florida (HB 885), Indiana (S 273), Iowa (HF 2668), Minnesota (SF 2995), New York (A 8502). Added information for the following state bills under the “Other Applicable Bills”: Illinois (HB 3202), Illinois (HB 2350), Minnesota (HF 5247), New Jersey (A5235), also added covered lines of business for existing state bills; Background: Added benefit/harm statement per CMS final rule, admin edits throughout; References: Updated
Parathyroid Hormone Testing	MOL.CS.390.X	83970	Criteria: removed restrictions on testing in individuals <18 years of age because hyperparathyroidism is rare in the pediatric population and has a variety of age-specific causes not addressed by this guideline (per peer reviewed literature), adjusted frequency of testing for chronic kidney disease based on KDIGO-MBD guideline, added ICD codes to table in Billing & Reimbursement that align with existing coverage criteria, admin edits throughout; Test Information: Updated; Guidelines and Evidence: Added benefit/harm statement per

			CMS final rule, other updates; References: updated.
Plasma Cell Dyscrasias Laboratory Testing	MOL.CS.397.X	0077U, 0450U, 0451U	Criteria: mass spectrometry for minimal residual disease (MS-MRD, including M-inSight) added to criteria as E/I/U (per review of evidence and NCCN guidelines for multiple myeloma recommending alternative methods of MRD), admin edits and clarification of intent edits throughout; Procedure code table: updated; Billing & Reimbursement: Added statement for MS-MRD testing (PLA codes 0450U/0451U) being not reimbursable, removed remainder of this section since it contained industry standard edits not performed by eviCore for non-mol clients; Background: updated; Test Information: updated; Guidelines & Evidence: updated NCCN guidelines and added guideline from BSH & UKMF; References: updated.
Natriuretic Peptide Laboratory Testing	MOL.CS.399.X	83880	Criteria: increased frequency limitation for BNP or NT-proBNP from 2 DOS per year to 3 DOS per year in order to account for baseline testing and additional evaluations since individuals with symptoms of heart failure may require diagnostic evaluation by multiple specialists (per American College of Cardiology 2023 Expert Consensus Decision Pathway, clarification of intent edits - additions to criteria as well as ICD table in Billing & Reimbursement section with additional signs and symptoms of heart failure not previously specified (per ACC) and clarified that criteria apply only to individuals 18 years of age or older as we are not managing these codes in the pediatric population (per International Society for Heart and Lung Transplantation 2014 Guidelines for the Management of Pediatric Heart Failure, natriuretic peptide can be used as an adjunctive marker for the evaluation and

			monitoring of these patients), admin edits; Background: updated; Test Information: updated; Guidelines and Evidence: updated; References: updated.
Cognitive Impairment Biomarkers	MOL.CS.400.X	Various - see guideline	Criteria: added section for multianalyte assays involving biomarkers included in the guideline with all combinations being considered E/I/U supported by the AAN, NICE, and National Institute on Aging, incorporated PLA codes 0412U, 0445U, and 0459U in this section, admin edits and clarification of intent edits throughout to more clearly indicate that the individual biomarkers are E/I/U regardless of branded test name; Procedure code table: updated; Test Information: updated; Guidelines and Evidence: updated; References: updated. AUGUST: Criteria and CPT code table: Added new PLA codes 0479U (ALZpath pTau217) and 0503U (PrecivityAD2)

Nail Disorder Infectious Disease Testing, Including Onychomycosis	MOL.CS.402.X	various - see guideline	Criteria: removed some criteria for gross and microscopic examination so that testing can be approved so long as onychomycosis is suspected (per American Academy of Dermatology and Choosing Wisely, reworded criteria for direct microscopic examination so that requests for PAS stain, and/or GMS stain and/or KOH preparation on the same DOS can be considered on a case-by-case basis rather than always being limited to 1 per DOS (per peer reviewed literature), increased limitation of only 1 unit per DOS for cell culture or direct microscopy to now allowing 4 units per DOS to account for 1 exam per extremity per DOS (infection can affect multiple extremities per peer reviewed literature, updated criterion for special stains 88313 so they are no longer considered not medically necessary for all nail conditions since they may be necessary for differentiating onychomycosis from melanoma (per peer reviewed literature), admin edits and clarification of intent edits throughout; Background: updated; Test Information: updated; Guidelines and Evidence: updated; References: updated
Urinary Tract Infection Molecular Testing	MOL.CS.403.A	various (see guideline); Added 0504U	Criteria: added new PLA code 0504U (Urinary Tract Infection Testing from NexGen MDx) to list of E/I/U UTI panels; added coverage criteria for single-organism tests and multiple-organism panels for select organisms for which nucleic-acid based testing is appropriate for diagnosis and management in UTIs (per 2024 IDSA/ASM and American Society of Transplantation guidelines), admin and clarification of intent edits throughout; CPT code table: added new PLA code 0504U (Urinary Tract Infection Testing from NexGen MDx); Background: updated; Test Information: updated, added Reused content language for NAT/NAAT; Guidelines & Evidence: updated; References: updated
Genetic Testing to Predict Disease Risk	MOL.CU.115.A	N/A	Criteria: incorporated criteria from the Genetic Presymptomatic and Predictive Testing for Adult-Onset Conditions in Minors guideline and restructured to accommodate; Clarification of intent edit - added phrase 'Member is at risk based on the inheritance pattern of the disorder in question.' to the Known Familial

			mutation section; created a single Limitations and Exclusions section to apply to all criteria sections, admin edit in general criteria section; Background: Added benefit/harm statement per CMS final rule, updated with info on testing in minors; References: updated
Whole Genome Sequencing	MOL.TS.306.A	N/A	Criteria: clarification of intent edits- amended provider requirements to make clear that non-genetics providers can order testing, added epilepsy as an example in the list of complex neurodevelopmental disorders, admin update; CPT code table: added introduction, admin update; Background: updated; Test Information: updated; Guidelines and Evidence: Added benefit/harm statement per CMS final rule, updated; References: updated
Exome Sequencing	MOL.TS.235.A	N/A	Criteria: clarification of intent edits - amended provider requirements to make clear that non-genetics providers can order testing, added epilepsy as an example in the list of complex neurodevelopmental disorders; CPT code table: admin edits; Test Information: updated; Guidelines and Evidence: Added benefit/harm statement per CMS final rule, updated; References: updated

There are an additional 71 coverage guidelines that criteria were changed with no impacts including administrative updates, content edits, and background updates.

As of January 1, 2025, coverage guidelines can be accessed utilizing the live link from the medical policy website.

If you wish to see the updates prior to the implementation date, please go to eviCore website under the Future tab for Laboratory Management utilizing the following pathway:

- Provider Resource Center→Medical Policy Search→Medical Policies→EVICORE CLINICAL GUIDELINES (top blue bar)→EVICORE CLINICAL GUIDELINES (body of page)→Access Guidelines→ Laboratory Management →*Search Health Plan* by typing in Highmark→Click on Highmark and then click on magnifying glass→Click on FUTURE→ Click on the Laboratory Management Guideline

Biosimilar Preferred Products Established for Avastin

Highmark's Medicare Advantage product has updated the preferred products for I-94, Intravitreal Injections. The following are the preferred anti-vascular endothelial growth factor (anti-VEGF) for members initiating new therapy for neovascular (wet) age-related macular degeneration (AMD).

- Bevacizumab (Avastin)
- Bevacizumab-awwb (Mvasi)
- Bevacizumab-bvzr (Zirabev)

This revised Medical Policy will apply to professional providers and facility claims. The effective date is January 1, 2025.

Please refer to Medical Policy I-94, Intravitreal Injections, for additional information.

Comments on These Medical Policies?

We want to know what you think about our new medical policy changes. Send us an email with any questions or comments that you may have on the new medical policies in this edition of Medical Policy Update.

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