

# MEDICAL POLICY UPDATE



October 2022



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## Policy

| Policy Title   | Anticipated Issue Date | 30 Day Notification Information  |
|--|------------------------|--|
| eviCore Lab Management Clinical Guideline                | 01/01/2023             | Accept the updated eviCore Laboratory Management Guideline. There will be an MPU published in the October 2022 newsletter. The eviCore Laboratory Management Guideline update will be in effect January 1, 2023. |
| I -159 - Oncologic Indications for Histone Deacetylase ( | 12/05/2022             | This policy is scheduled for annual review. Policy criteria is being updated with NCCN recommendation statement. Policy will publish December 5, 2022.   |
| I-229 Belantamab mafodotin (Blenrep)                     | 12/05/2022             | This policy is scheduled for annual review. Policy criteria is being updated with NCCN recommendation statement. Policy will publish December 5, 2022.   |
| I-236 Casimersen (Amondys-45)                            | 12/05/2022             | This policy is up for annual review. There are no indications for a change in coverage at this time. Policy will remain  |

| Policy Title   | Anticipated Issue Date | 30 Day Notification Information   |
|--|------------------------|---|
|  |                        | experimental/investigational. Policy will publish on December 5, 2022.  |
| I-237 Pepaxto  | 12/05/2022             | Product was voluntarily removed from the market on October 22, 2021. Policy will archive on December 5, 2022.   |
| I-238 Evinacumab-dgnb (Evkeeza)  | 12/05/2022             | This policy is up for annual review. There are no indications for a change in coverage at this time. Minor revisions were made to the policy include removal of a reference to an archived policy. Policy will publish on December 5, 2022. |
| I-254 Spesolimab (Spevigo)   | 10/31/2022             | This is a new policy for new to market Spevigo. Policy will publish on October 31, 2022.  |
| I-255 Tenecteplase (TNKase)  | 12/05/2022             | This policy establishes coverage criteria for Tenecteplase for acute ischemic stroke. Policy will publish on December 5, 2022.  |
| I-258 Elivaldogene autotemcel (Skysona)                                | 11/07/2022             | This policy is being created to establish criteria for new to market gene therapy Skysona (elivaldogene autotemcel). Policy will publish November 7, 2022.  |
| I-58 Enzyme Replacement Therapies                                      | 11/07/2022             | Policy is being updated to include new to market enzyme replacement therapy olipudase alfa-rpcp (Xenpozyme). Policy will publish November 7, 2022.  |
| L-264 - Serum Biomarker Panel Testing for Systemic Lupus Erythematosus | 12/05/2022             | This policy is being updated. Policy position and CPT coding updated. This policy is scheduled to publish December 5, 2022.   |
| O-19 Ostomy Supplies   | 12/05/2022             | This is an annual review. Maintain current coverage criteria. This policy will publish on December 5, 2022.   |
| O-5 Powered Exoskeletal Robotic Systems                                | 12/05/2022             | This is an annual review. Maintain current coverage criteria. This policy will publish on December 5, 2022.   |
| S-116 Corneal transplantation  | 12/05/2022             | This policy is scheduled for annual review. Coding and administrative updates have been completed. Denial statements were updated. This policy is due to publish on December 5, 2022.   |
| S-118 Small Bowel, Small Bowel/Liver and Multivisceral Transplant      | 12/05/2022             | This policy is scheduled for annual review. Coding updates were done. Administrative updates were done. This policy is scheduled to publish on December 5, 2022.  |

| Policy Title  | Anticipated Issue Date | 30 Day Notification Information   |
|---|------------------------|---|
| S-121 Liver Transplant  | 12/05/2022             | This policy is scheduled for annual review. Coding updates and administrative updates were completed. This policy is scheduled to publish on December 5, 2022.  |
| S-186 Magnetic Resonance Imaging (MRI)-Guided Focused Ultrasound Surgery (MRgFUS) | 12/12/2022             | This policy is scheduled for annual review. There is no change in coverage criteria. The policy will publish on December 12, 2022.  |
| S-275 Prostate disease: Diagnosis, staging, and treatment                         | 12/05/2022             | An inquiry was received regarding the prostatic urethral lift (PUL) procedure. Policy language clarification regarding infection provided surrounding PUL procedure. Policy will publish on December 5, 2022. |
| Y-23 Chronic Pain Management  | 12/12/2022             | This policy is up for annual review. It is a West Virginia only policy. There will be no changes in coverage criteria. The policy will publish on December 12, 2022.  |
| Z-14 Acupuncture  | 12/12/2022             | This policy is scheduled for annual review. There are no changes to the coverage criteria. Some diagnosis codes are being removed. The policy will publish on December 12, 2022.                              |
| Z-27 Eligible Providers   | 12/05/2022             | This is an annual review. Maintain current coverage criteria. This policy will publish on December 5, 2022.   |
| Z-32 Standby Services   | 12/05/2022             | This policy is an annual review and will be archived with a publish date of December 5, 2022.   |



## Reminder: Laboratory Management Coverage Guideline Update



Highmark Blue Cross Blue Shield is providing a reminder to all providers.

The Laboratory Management coverage guideline will be updated and take effect January 01, 2023. This applies to both professional provider and facility claims.

The changes to the Laboratory Guidelines are as follows:

### New: Three (3) guidelines

| Guideline Name                         | Guideline #  | Procedure Codes Addressed by Guideline | Summary of change (to be reviewed in conjunction with actual GL)   |
|--|--------------|--|--|
| Parathyroid Hormone Testing            | MOL.CS.390.X | 83970                                  | New Test Specific Guideline for non-molecular clients  |
| Iron Status Testing                    | MOL.CS.389.X | 82728, 84466, 83540, 83550, 84238      | New Test Specific Guideline for non-molecular clients  |
| Laboratory Procedure Code Requirements | MOL.AD.391.X | all                                    | New administrative guideline addressing correct CPT coding requirements for laboratory assays. This guideline will replace, and expand on, Molecular Pathology Tier 2 Molecular CPT Codes (MOL.AD.102) |

### Retired: Two (2) Guidelines

| Guideline Name                                 | Guideline #  | Procedure Codes Addressed by Guideline | Summary of change (to be reviewed in conjunction with actual GL)   |
|--|--------------|--|--|
| Molecular Pathology Tier 2 Molecular CPT Codes | MOL.AD.102.A | 81400 - 81408                          | Retired guideline, replaced by new Laboratory Procedure Code Requirements (MOL.AD.391)                                       |
| ProMark Proteomic Prognostic Test              | MOL.TS.296.A | 81479                                  | Retired test specific guideline; Requests will now be managed by the Investigational and Experimental guideline (MOL.CU.117) |

### Criteria Changed with Impacts: Fifteen (15) guidelines

| Guideline Name | Guideline # | Procedure Code Impacted by Update, if applicable | Summary of change (to be reviewed in conjunction with actual GL) |
|----------------|-------------|--|--|
|----------------|-------------|--|--|

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|---|--------------|--|--|
| Breast Cancer Index for Breast Cancer Prognosis | MOL.TS.248.A |  | <p>Criteria: Per ASCO guideline recommendation, updated to allow for coverage in individuals with 0-3 positive lymph nodes to determine benefit of extended endocrine therapy</p> <p>Background: admin edits</p> <p>Guidelines and Evidence, References: updated</p>   |
| Lynch Syndrome Genetic Testing                  | MOL.TS.197.A |  | <p>Criteria: Per NCCN recommendation, added colorectal cancer diagnosed under 50 as a criterion (without the need for tumor testing first); clarified CRC at any age with abnormal tumor testing meets criteria; clarified footnote +++: only MLH1 hypermethylation testing (not BRAF) is indicated in endometrial cancers.</p> <p>Added "Other Considerations" section with cross-reference to Hereditary Cancer Syndrome Multigene Panels guideline.</p> <p>Background, References; Guidelines and Evidence and Test Information: admin edits, updated.</p>  |
| BRCA Analysis                                   | MOL.TS.238.A |  | <p>Criteria: updated to allow for testing in patients with triple negative breast cancer diagnosed at any age (previously at 60 years or younger); added "At least two close blood relatives (on the same side of the family) with either breast cancer or a confirmed diagnosis of prostate cancer at any age".</p> <p>Additional clarification of intent criteria edits: In personal history of prostate cancer section, amended "close relative with breast cancer at &lt;50 years" to "50 years or younger."; updated language from "two breast primary tumors" to "multiple primary tumors."</p> <p>Replaced Scope section with an "Other Considerations"</p> |

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|  |              |                     | <p>section and added cross-guideline references.</p> <p>Background, Guidelines and Evidence, and References: updated.</p>   |
| Multiple Endocrine Neoplasia Type 1 (MEN1)                     | MOL.TS.285.A |                     | <p>Criteria: expanded diagnostic testing--added "Individual with recurrent hyperparathyroidism, multigland parathyroid disease, gastrinoma, or multiple neuroendocrine tumors (NETs) at any age"; and added parathyroid adenomas to list of tumors ("i.e., Individual under the age of 30 years with parathyroid adenomas, PHPT, pancreatic precursor lesions, or pancreatic islet tumor regardless of family history")</p> <p>Added "Other Considerations" section with cross-reference to Hereditary Cancer Syndrome Multigene Panels guideline.</p> <p>Background; updated and reorganized.</p> <p>Guidelines and Evidence, References: updated.</p> |
| In-vitro testing for cardiovascular disease (CVD) and CVD risk | MOL.CS.316.X | 84572, 0308U, 0309U | <p>Criteria: removed CPT code tables, language admin updates. Added CPT 84512 for qualitative troponin. Added criteria for Myoglobin. Added ischemia modified albumin, ADMA, and SDMA under "Tests for ASCVD with No Coverable Indications". Added PLA codes 0308U and 0309U.</p> <p>Background: updated.</p> <p>Test Information: admin updates, differentiated quantitative troponin from qualitative troponin; added information about myoglobin, ischemia-modified albumin, asymmetric dimethylarginine (ADMA) and symmetric</p>  |

|                                     |              |  |   |
|-------------------------------------|--------------|--|---|
|                                     |              |  | <p>dimethylarginine (SDMA).</p> <p>Guidelines and Evidence: admin edits; updated; removed CPT tables; added information about myoglobin, ischemia modified albumin, asymmetric dimethylarginine (ADMA), symmetric dimethylarginine (SDMA), HART CADhs®, and HART CVE, hsCRP and homocysteine testing; differentiated quantitative troponin from qualitative troponin.</p> <p>References: updated.</p>   |
| Thyroid Disorder Laboratory Testing | MOL.CS.320.X |  | <p>Criteria: language admin updates; added the following for testing of Tg - "Help stage and risk stratify differentiated thyroid cancers"; clarified type of thyroid cancer from invasive or metastatic to "differentiated" (given that most thyroid cancers are differentiated and not metastatic and thyroglobulin is most useful in these cancers); added ICD table for ICD Indications for Free T3 or Total T3 Testing.</p> <p>Background, Guidelines and Evidence, References: updated.</p> |
| Vitamin D Testing                   | MOL.CS.331.X |  | <p>Criteria: language admin updates; updated ICD tables; added new "Table: Additional Vitamin D, 25 Hydroxy Testing (CPT 82306 or 0038U) Indications for Individuals Less Than 18 years of Age"; added additional criteria for individuals younger than 18 years;</p> <p>Background, References: updated</p> <p>Guidelines and Evidence: admin edits, added information related to vitamin D, 25 hydroxy screening and monitoring.</p>  |

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|--|--------------|--------------------------------------|--|
| Somatic Mutation Testing-Solid Tumors    | MOL.TS.230.A | Added 0334U (Guardant360 TissueNext) | <p>Criteria: Per NCCN recommendations, added the following cancers in "tumor marker panels" section for diagnosis-based coverage (previously covered under minimum biomarker criterion): locally advanced or metastatic ampullary adenocarcinoma; recurrent, unresectable, or metastatic salivary gland tumors; anaplastic gliomas/glioblastoma. Also, grading/terminology clarification: updated "infiltrative glioma" to adult low-grade (WHO grade 1 or 2) glioma.</p> <p>Added "Other Considerations" section with cross-referenced guidelines, updated table of "common cancer types and associated tumors markers".</p> <p>Background: admin edits.<br/>Test Info: updated and reorganized<br/>Updated Guidelines and Evidence, References</p> <p>Added 0334U (Guardant360 TissueNext) to the CPT code table</p> |
| SARS-CoV-2 (COVID-19) Laboratory Testing | MOL.CS.353.X |                                      | <p>Criteria: updated/clarified criteria, billing and reimbursement for Nucleic Acid Testing. Added medical necessity, billing and reimbursement requirements for antigen testing. Clarified time between symptom onset and test for antibody testing.</p> <p>Added an "Other Tests" section to address SARS-CoV-2 genotyping - 87913 as not medically necessary; CPT Code Table: new code 87913 added.</p> <p>Background, Test Info, Guidelines and Evidence, References: updated.</p>   |



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| Special Circumstances Influencing Coverage Determinations      | MOL.AD.364.K  |   | Applicable laws section added to address legislation in AZ, CA, IL, LA and WA; clarifying edit in Introduction (changed 'override' to 'override or supplement').<br><br>References: updated.   |
| Micronutrient testing  | MOL.CS.372.X  | Added 82542 (Coenzyme Q10), 83786 (Iodine)  | Criteria: admin language edits, modified DOS limits for the following: CPT 82180- vitamin C, CPT 82379- carnitine (total and free), CPT 82607- vitamin B12, CPT 84207- vitamin B6, CPT 84252- vitamin B2, CPT 84425- vitamin B1, CPT 84446- vitamin E, CPT 84590- vitamin A, CPT 84597- vitamin K, CPT 84591- vitamin B3. Added for CPT 83789- iodine and CPT 82542- coenzyme Q10; ICD tables: updated<br><br>Background, References: updated.<br><br>Test Information, Guidelines and Evidence: updated, admin edits.   |
| Investigational and Experimental Laboratory Testing (Highmark) | MOL.CU.117.XK | added 0303U; 0304U; 82541, 82542, 91065, 95012, 83987; 0337U; 0338U; 81382, 81376, 81479, 86364, 86258, 86671, 82784; 83520, 88230, 86352; 0332U; 84378; 0333U; 0342U; 0335U; 0336U; 0351U; 0058U; 0059U; 0343U; 0344U; 0346U; 0341U; 83516, 83518; 0301U; 0302U; deleted 0056U, 0014U, 0013U | <b>New tests added to the I/E list:</b><br>Adhesion Biochip Normoxic / Hypoxic (0303U; 0304U)<br>Aerodiagnostics Breath Tests (82541, 82542, 91065, 95012, 83987)<br>CELLSEARCH Circulating Multiple Myeloma Cell (CMMC) Test (0337U)<br>CELLSEARCH HER2 Circulating Tumor Cell (CTC-HER2) Test (0338U)<br>CICA Test (81382, 81376, 81479, 86364, 86258, 86671, 82784)<br>Cunningham panel (83520, 88230, 86352)<br>EpiSwitch CiRT (0332U)<br>Glycomark (84378)<br>FM/a fibromyalgia (81599)<br>HelioLiver Test (0333U)<br>IMMray PanCan-d (0342U)<br>IriSight Prenatal Analysis – Proband (0335U); IriSight Prenatal Analysis – |

|                        |              |  |  |
|------------------------|--------------|--|--|
|                        |              |  | <p>Comparator (0336U)<br/> MeMed BV® (0351U)<br/> Merkel SmT Oncoprotein Antibody Titer (0058U);<br/> Merkel VP1 Capsid Antibody (0059U)<br/> miR Sentinel Prostate Cancer Test (0343U)<br/> OWLiver (0344U)<br/> QUEST AD-Detect, Beta-Amyloid 42/40 Ratio (0346U)<br/> Single Cell Prenatal Diagnosis (SCPD) Test (0341U)<br/> Synvasure Alpha Defensin Lateral Flow Test (83516, 83518)<br/> ProMark Proteomic Prognostic Test (81479)<br/> PrismRA (81479 or 81599)<br/> Bartonella ddPCR and Digital ePCR (0301U, 0302U)<br/> TruGraf Kidney (81479)</p> <p><b>Deleted</b> MatePair tests (0056U, 0014U, 0013U) – PLA codes retired</p> <p><b>Updated:</b> Mi-Prostate Score (changed name to MyProstateScore and added CPT code 81599); Molecular Microscope MMDx—Heart (0087U) – description; Vectra (81490) – test name and lab; Percepta Genomic Sequencing Classifier (81479) – test name; Signatera (0340U) – PLA code and test description</p> |
| Celiac Disease Testing | MOL.CS.319.X |  | <p>Criteria:<br/> Tissue Transglutaminase IgA – test frequency updated from 6 to 4 based on guideline recommendations, added clarifying billing statement “When testing is medically necessary, no more than 1 unit of CPT 86364 may be billed for the same date of service”, and clarified that medical necessity criteria did not pertain to tissue transglutaminase IgG;</p> <p>Deamidated Gliadin Peptide IgA, IgG - test frequency updated from 6 to 4 based on guideline recommendations, added clarifying billing statement “ICD Code table:</p>  |

|  |              |             |  |
|--|--------------|-------------|--|
|  |              |             | <p>Updated R74.0 to R74.X; CPT 86258 is not reimbursable when billed with CPT 86364 on the same date of service,” and “When testing is medically necessary, no more than 1 unit of CPT 86258 may be billed for the same date of service.”</p> <p>CPT code table: Removed 86255.</p> <p>Background, Guidelines and Evidence, References: updated.</p> |
| Lyme Disease Testing                                 | MOL.CS.332.X | Added 0316U | <p>Criteria: added section for "Borreliosis, OspA protein biomarker by Nanotrap capture with antigen detection by Western Blot" 0316U; admin updates.</p> <p>CPT Code Table: Added 0316U.</p> <p>Background, Guidelines and Evidence, References: updated.</p>   |
| Human Platelet and Red Blood Cell Antigen Genotyping | MOL.TS.361.A |             | <p>Criteria: clarified by adding detail on platelet refractoriness indications</p> <p>Guidelines and Evidence: admin edit, updated</p> <p>References: updated</p>  |

There are an additional 55 coverage guidelines that criteria were changed with no impacts including administrative updates, content edits, and background updates.

As of January 1, 2023, 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

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## Coverage Guidelines Established for Pegfilgrastim-pbbk (Fylnetra®)



Highmark Blue Cross Blue Shield has established new guidelines for I-88 Granulocyte Colony-Stimulating Factors. This policy now includes criteria for pegfilgrastim-pbbk (Fylnetra).

This revised Medical Policy will apply to Professional providers and Facility claims. The effective date is November 1, 2022.

**Place of Service: Outpatient**

Please refer to Medical Policy for I-88, Granulocyte Colony-Stimulating Factors, for additional information.

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## Coverage Criteria Established for ranibizumab-eqrn (Cimerli)



Highmark Blue Cross Blue Shield has established new criteria for Medical Policy I-94 Intravitreal Injections. This policy now includes coverage criteria for the new to market therapy ranibizumab-eqrn (Cimerli).

This revised Medical Policy will apply to professional providers and facility claims. The effective date is October 17, 2022.

**Place of Service: Outpatient**

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

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## Coverage Guidelines Established for Betibeglogene autotemcel (Zynteglo)



Highmark Blue Cross Blue Shield has established criteria for I-253 Betibeglogene autotemcel (Zynteglo). This new policy includes criteria for the recently FDA approved gene cell therapy Betibeglogene autotemcel (Zynteglo).

This revised Medical Policy will apply to Professional providers and Facility claims. The effective date is October 10, 2022.

**Place of Service: Outpatient**

Please refer to Medical Policy for I-253, Betibeglogene autotemcel (Zynteglo), for additional information.

## Injectable Drug Added to Site of Care



Highmark Blue Cross Blue Shield has added the following injectable drug to site of care criteria:

- Sutimlimab-jome (Enjaymo)

This revised Medical Policy will apply to both professional providers and facility claims. The effective date will be February 1, 2023.

**Place of Service: Outpatient-Infusion**

Please refer to Medical Policy I-251, Sutimlimab-jome (Enjaymo) , 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.

Write to us at [medicalpolicy@highmark.com](mailto:medicalpolicy@highmark.com)



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