

MEDICAL POLICY UPDATE



August 2023



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Policy

| Policy Title | Anticipated Issue Date | 30 Day Notification Information |
|--|------------------------|--|
| A-0066 - Gallium Scan | 01/01/2024 | This is a new policy. The policy will publish on January 1, 2024. |
| A-0532 - Breast Cancer Gene Expression Assays | 01/01/2024 | This is a new policy for NY. This policy will publish on January 1, 2024. |
| eviCore Radiation Oncology Guideline | 10/01/2023 | eviCore has issued an update regarding their Radiation Oncology guidelines which will go into effect October 1, 2023. |
| G-44 - Extracorporeal Membrane Oxygenation [ECMO] for Adult Conditions | 10/09/2023 | This policy is scheduled for annual review. The policy will publish on October 9, 2023. |
| G-46 - Inhaled Nitric Oxide | 10/09/2023 | This policy is scheduled for annual review. The policy will publish on October 9, 2023. |
| I-117 - Panitumumab (Vectibix®) | 10/09/2023 | This policy was scheduled for annual review. The denial statement was updated. The policy will publish on October 9, 2023. |
| I-118 - Alemtuzumab (Lemtrada™) | 10/16/2023 | This policy is scheduled for annual review. Policy updates include minor language revisions. Policy will publish October 16, 2023. |
| I-12 - Human Growth Hormone | 09/04/2023 | This policy is being updated with new to market therapy somatrogon-ghla (Ngenla) indicated for |

| Policy Title | Anticipated Issue Date | 30 Day Notification Information |
|--|------------------------|--|
| | | growth hormone deficiency. Policy will publish September 4, 2023. |
| I-123 - Fulvestrant (Faslodex®) | 10/09/2023 | This policy was scheduled for annual review. Denial statement updated to not medically necessary. Policy will publish on October 9, 2023. |
| I-127 - Blinatumomab (Blincyto™) | 10/09/2023 | This policy was scheduled for annual review. Denial statement updated to not medically necessary. Policy will publish on October 9, 2023. |
| I-133 - Ixabepilone (Ixempra®) | 10/09/2023 | This policy was scheduled for annual review. Criteria language was updated. Denial statement updated to not medically necessary. Policy will publish on October 9, 2023. |
| I-136 - Brentuximab Vedotin (Adcetris®) | 10/09/2023 | This policy was scheduled for annual review. Criteria and denial statement was updated. Policy will publish on October 9, 2023. |
| I-150 - Daratumumab (Darzalex™) | 10/09/2023 | This policy was scheduled for annual review. Denial statement and diagnosis codes were updated. Policy will publish on October 9, 2023. |
| I-169 - Yondelis | 10/09/2023 | This policy was scheduled for annual review. Denial statement was updated. Policy will publish on October 9, 2023. |
| I-171 - Ocrelizumab (Ocrevus®) | 09/18/2023 | This policy is scheduled for annual review. There is no indication for change in coverage. Policy updates include minor language changes. Policy will publish October 16, 2023. |
| I-173 - Radicava (edaravone) | 10/23/2023 | This policy is scheduled for annual review. There are no indications for change in coverage. Policy updates include minor language changes. Policy will publish October 23, 2023. |
| I-200 - erenumab (Aimovig) | 10/23/2023 | This policy is scheduled for annual review. This policy is recommended for archival. Policy will publish October 23, 2023. |
| I-213 - Brexanolone (Zulresso) | 10/09/2023 | This policy is up for an annual review. There are no indications for a change in coverage at this time. Denial statement is being updated to not medically necessary. Policy will publish on October 9, 2023. |
| I-220 - Teprotumumab-trbw (Tepezza) | 10/16/2023 | The policy was revised to remove the criteria regarding disease severity due to updated Food and Drug Administration labelling as of July 2023. Denial statement is being updated to not medically necessary. Policy will publish on October 16, 2023. |
| I-224 - Delaware Step Therapy Override Exception | 09/18/2023 | This policy is scheduled for annual review. Minor language updates were made to the policy. Policy will publish September 18, 2023. |
| I-250 - Inclisiran (Leqvio) | 10/23/2023 | This policy is being updated with new indication of primary hyperlipidemia. Policy will publish October 23, 2023. |
| I-259 - Entranacogene dezaparvovec (EntranaDez) | 10/16/2023 | Disease severity and anti-AAV5 antibody criteria were revised. Denial statement updated to not |

| Policy Title | Anticipated Issue Date | 30 Day Notification Information |
|--|------------------------|---|
| | | medically necessary. Policy will publish on October 16, 2023. |
| I-272 - Rozanolixizumab-noli (Rystiggo) | 09/04/2023 | Coverage criteria was established for the recently Food and Drug administration approved medication Rozanolixizumab-noli (Rystiggo) for treatment of generalized Mysathenia Gravis. Policy will publish on September 4, 2023. |
| I-274- Glofitamab-gxbm (Columvi) | 09/04/2023 | This is a new policy that establishes criteria for new to market therapy glofitamab-gxbm (Columvi) indicated for relapsed or refractory diffuse large B-cell lymphoma. Policy will publish September 4, 2023. |
| I-28 - Infliximab and Infliximab Biosimilars | 10/09/2023 | This policy is up for annual review. There are no indications for a change in coverage at this time. Denial statement is being updated to not medically necessary. Policy will publish on October 9, 2023. |
| I-37 - Ustekinumab (Stelara®) | 10/09/2023 | This policy is up for annual review. There are no indications for a change in coverage at this time. Denial statement is being updated to not medically necessary. Policy will publish on October 9, 2023. |
| I-53 - Omalizumab (Xolair®) | 10/09/2023 | This policy is up for annual review. Minor administrative changes were made to the policy. Denial statement was updated to not medically necessary. Policy will publish on October 9, 2023. |
| I-78 - Intravitreal Implants | 10/16/2023 | This policy is up for annual review. There are no indications for a change in coverage at this time. Denial statements are being updated to not medically necessary. Policy will publish on October 16, 2023. |
| M-70 - Ambulatory Blood Pressure Monitoring (ABPM) | 10/09/2023 | This policy is scheduled for annual review. Policy criteria and coding updates have been made. This policy will publish on October 9, 2023. |
| M-84 - Rhinomanometry | 09/11/2023 | This policy is scheduled for annual review. Due to low spend, minimal supportive literature and lack of coverage by other insurers, it is recommended to archive the policy. The policy will be archived on October 16, 2023. |
| R-101 - Hepatobiliary System Imaging | 10/16/2023 | This policy is being archived. This policy will archive effective October 16, 2023. |
| S-194 - Subtalar Arthroereisis | 10/09/2023 | This policy is scheduled for annual review. No change to coverage criteria. This policy will publish on October 9, 2023. |
| S-197 - Manipulation Under Anesthesia (MUA) | 10/10/2023 | This policy is scheduled for annual review. Current coverage criteria will be maintained. This policy is scheduled to publish on October 9, 2023. |
| S-282 - Surgery for Groin Pain in Athletes | 10/09/2023 | This is a new policy scheduled to be published on October 09, 2023. |

| Policy Title | Anticipated Issue Date | 30 Day Notification Information |
|--------------------------------|------------------------|---|
| S-89 - Bone Growth Stimulation | 10/09/2023 | This policy is scheduled for annual review. Administrative changes made. This policy will publish on October 9, 2023. |



Policy

Coverage Criteria Established for (Somatrogon-ghla) Ngenla



Highmark Blue Cross Blue Shield of Western New York has established new criteria for I-12 Human Growth Hormone. This policy is updated with coverage criteria for new to market therapy (somatrogon-ghla) Ngenla, a human growth hormone indicated for pediatric individuals ages 3 years or older with growth hormone deficiency.

This Medical Policy will apply to professional providers and facility claims. The effective date is September 4, 2023.

Place of Service: Outpatient

Please refer to Medical Policy I-12, Human Growth Hormone, for additional information.

Coverage Criteria Established for Epcoritamab-bysp (Epkinly)



Highmark Blue Cross Blue Shield of Western New York has established new criteria for I-270 epcoritamab-bysp (Epkinly). This a new policy creating coverage criteria for epcoritamab-bysp (Epkinly) which is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

This new Medical Policy will apply to professional providers and facility claims. The effective date is August 7, 2023.

Place of Service: Outpatient

Please refer to Medical Policy I-270, Epcoritamab-bysp (Epkinly), for additional information.

Coverage Criteria Established for Glofitamab-gxbm (Columvi)



Highmark Blue Cross Blue Shield of Western New York has established new criteria for I-270 Glofitamab-gxbm (Columvi). This a new policy creating coverage criteria for glofitamab-gxbm (Columvi) which is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

This new Medical Policy will apply to professional providers and facility claims. The effective date is September 4, 2023.

Place of Service: Outpatient

Please refer to Medical Policy I-274, Glofitamab-gxbm (Columvi), for additional information.

Reminder: Radiation Oncology Coverage Guideline Update



Highmark Blue Cross Blue Shield of Western New York is providing a reminder to all providers.

The Radiation Oncology coverage guidelines will be updated and take effect October 1, 2023. This applies to both professional provider and facility claims.

The updates are as follows:

| Section Name | Version/Release Number | Section Number/Policy Number | Summary of change |
|---|------------------------|------------------------------|---|
| Preface to the Radiation Oncology Guidelines | v1.0.2023 | RO.AD.100.A | Minor editorial updates |
| Abbreviations for Radiation Oncology Guidelines | v1.0.2023 | RO.AD.101.A | Added abbreviation and definition for RFS (relapse-free survival) |
| Brachytherapy of the Coronary Arteries | v1.0.2023 | RO.RST.102.A | Discussion and References updated |
| Hyperthermia | v1.0.2023 | RO.RST.103.A | Discussion and references updated |
| Image-Guided Radiation Therapy (IGRT) | v1.0.2023 | RO.RST.104.A | Minor editorial change in Policy section |
| Image-Guided Radiation Therapy (IGRT) | v1.0.2023 | RO.RST.104.A | Discussion and references updated |
| Neutron Beam Therapy | v1.0.2023 | RO.RST.105.A | Discussion and references updated |
| Proton Beam Therapy | v1.0.2023 | RO.RST.106.A | Added indication for proton beam coverage for head and |

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| | | | neck cancer invading orbit, skull base, or cavernous sinus |
| Proton Beam Therapy | v1.0.2023 | RO.RST.106.A | Added "curative" in front of CSI for clarity- no change in policy as it was already at the header |
| Proton Beam Therapy | v1.0.2023 | RO.RST.106.A | Changed "and" to "or" for clarity in Policy: Group 1: I. and V. and Group 2: V. and X. |
| Proton Beam Therapy | v1.0.2023 | RO.RST.106.A | Discussion and References updated |
| Proton Beam Therapy | v1.0.2023 | RO.RST.106.A | Added 1 reference |
| Proton Beam Therapy | v1.0.2023 | RO.RST.106.A | Removed 1 reference |
| Adrenocortical Carcinoma | v1.0.2023 | RO.TXS.107.A | Discussion section and NCCN reference updated |
| Anal Canal Cancer | v1.0.2023 | RO.TXS.108.A | References updated |
| Bladder Cancer | v1.0.2023 | RO.TXS.109.A | Discussion and References updated |
| Brain Metastases | v1.0.2023 | RO.TXS.111.A | Allow HA-IMRT for individuals with SCLC with brain metastases |
| Brain Metastases | v1.0.2023 | RO.TXS.111.A | Reduced number of fractions allowed for whole brain radiation therapy from 15 to 10 |
| Brain Metastases | v1.0.2023 | RO.TXS.111.A | Discussion and References updated |
| Brain Metastases | v1.0.2023 | RO.TXS.111.A | Added 1 reference |
| Bone Metastases | v1.0.2023 | RO.TXS.110.A | Added hepatocellular carcinoma as indication for SBRT |
| Bone Metastases | v1.0.2023 | RO.TXS.110.A | Discussion and References updated |
| Bone Metastases | v1.0.2023 | RO.TXS.110.A | Added 3 references |
| Breast Cancer | v1.0.2023 | RO.TXS.112.A | Provided indications for when IMRT would be approved for breast cancer |
| Breast Cancer | v1.0.2023 | RO.TXS.112.A | Discussion and References updated |
| Breast Cancer | v1.0.2023 | RO.TXS.112.A | Added 1 reference |
| Cervical Cancer | v1.0.2023 | RO.TXS.113.A | References updated |

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| Endometrial Cancer | v1.0.2023 | RO.TXS.114.A | References updated |
| Esophageal Cancer | v1.0.2023 | RO.TXS.115.A | References updated |
| Gastric Cancer | v1.0.2023 | RO.TXS.116.A | Discussion and references updated |
| Head and Neck Cancer | v1.0.2023 | RO.TXS.117.A | Policy language updated to be definitive for clarity |
| Head and Neck Cancer | v1.0.2023 | RO.TXS.117.A | NCCN quote in Policy section updated to reflect current language |
| Head and Neck Cancer | v1.0.2023 | RO.TXS.117.A | References updated |
| Hepatobiliary Cancer | v1.0.2023 | RO.TXS.118.A | References updated |
| Hepatobiliary Cancer | v1.0.2023 | RO.TXS.118.A | Added 2 references due to NCCN changing the Hepatobiliary Cancers guideline into two new guidelines |
| Hodgkin Lymphoma | v1.0.2023 | RO.TXS.119.A | Policy language updated to be definitive for clarity |
| Hodgkin Lymphoma | v1.0.2023 | RO.TXS.119.A | References updated |
| Kidney Cancer | v1.0.2023 | RO.TXS.120.A | References updated |
| Multiple Myeloma and Solitary Plasmacytomas | v1.0.2023 | RO.TXS.121.A | References updated |
| Non-Hodgkin Lymphoma | v1.0.2023 | RO.TXS.122.A | References updated |
| Non-Malignant Disorders | v1.0.2023 | RO.TXS.123.A | Discussion and references updated |
| Non-Small Cell Lung Cancer | v1.0.2023 | RO.TXS.124.A | Provided indications for when IMRT would be approved for NSCLC |
| Non-Small Cell Lung Cancer | v1.0.2023 | RO.TXS.124.A | Discussion and References updated |
| Non-Small Cell Lung Cancer | v1.0.2023 | RO.TXS.124.A | Added 1 reference |
| Oligometastases | v1.0.2023 | RO.TXS.125.A | Added an indication for prostate cancer as histology indicated for oligometastases |
| Oligometastases | v1.0.2023 | RO.TXS.125.A | Discussion and References updated |

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| Oligometastases | v1.0.2023 | RO.TXS.125.A | Updated Discussion formatting in section I. |
| Oligometastases | v1.0.2023 | RO.TXS.125.A | Added 1 reference |
| Pancreatic Cancer | v1.0.2023 | RO.TXS.127.A | Discussion and references updated |
| Primary Craniospinal Tumors and Neurologic Conditions | v1.0.2023 | RO.TXS.128.A | Added meaning of 3DCRT, IMRT, and FSRT at first use in the Policy section |
| Primary Craniospinal Tumors and Neurologic Conditions | v1.0.2023 | RO.TXS.128.A | Minor editorial updates in Policy section |
| Primary Craniospinal Tumors and Neurologic Conditions | v1.0.2023 | RO.TXS.128.A | References updated |
| Prostate Cancer | v1.0.2023 | RO.TXS.129.A | Minor editorial updates to Policy section |
| Prostate Cancer | v1.0.2023 | RO.TXS.129.A | Discussion and references updated |
| Rectal Cancer | v1.0.2023 | RO.TXS.130.A | Minor editorial update to Policy section |
| Rectal Cancer | v1.0.2023 | RO.TXS.130.A | Discussion and NCCN reference updated |
| Skin Cancer - Melanoma | v1.0.2023 | RO.TXS.131.A | Discussion and NCCN references updated |
| Skin Cancer - Non-Melanoma | v1.0.2023 | RO.TXS.132.A | Minor editorial updates to Policy section |
| Skin Cancer - Non-Melanoma | v1.0.2023 | RO.TXS.132.A | Discussion and references updated |
| Small Cell Lung Cancer | v1.0.2023 | RO.TXS.133.A | Added indications throughout policy for when IMRT is medically necessary and specified modality in section "II" of the policy |
| Small Cell Lung Cancer | v1.0.2023 | RO.TXS.133.A | Added "3DCRT" abbreviation |
| Small Cell Lung Cancer | v1.0.2023 | RO.TXS.133.A | Reworded and restructured "II" for clarity |
| Small Cell Lung Cancer | v1.0.2023 | RO.TXS.133.A | Restructured "III" for clarity |

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| Small Cell Lung Cancer | v1.0.2023 | RO.TXS.133.A | Discussion and References updated |
| Small Cell Lung Cancer | v1.0.2023 | RO.TXS.133.A | Added 1 reference |
| Soft Tissue Sarcomas | v1.0.2023 | RO.TXS.134.A | References updated |
| Testicular Cancer | v1.0.2023 | RO.TXS.135.A | References updated |
| Thymoma and Thymic Cancer | v1.0.2023 | RO.TXS.136.A | Provided indications for when IMRT would be approved for thymoma and thymic carcinoma |
| Thymoma and Thymic Cancer | v1.0.2023 | RO.TXS.136.A | NCCN reference updated |
| Thymoma and Thymic Cancer | v1.0.2023 | RO.TXS.136.A | Added 1 reference |
| Urethral Cancer and Cancers of the Ureter and Renal Pelvis | v1.0.2023 | RO.TXS.137.A | NCCN reference updated |
| Vulvar Cancer | v1.0.2023 | RO.TXS.138.A | References updated |
| Other Cancers | v1.0.2023 | RO.TXS.126.A | ASTRO reference updated |
| Azedra® (iobenguane I-131) | v1.0.2023 | RO.RX.139.A | NCCN reference updated |
| Azedra® (iobenguane I-131) | v1.0.2023 | RO.RX.139.A | Added URL to reference #2 and removed access date |
| ¹⁷⁷ Lu-dotatate (Lutathera®) | v1.0.2023 | RO.RX.140.A | References updated |
| Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) | v1.0.2023 | RO.RX.144.A | NCCN reference updated |
| Selective Internal Radiation Therapy (SIRT) | v1.0.2023 | RO.RX.141.A | Discussion and references updated |
| Selective Internal Radiation Therapy (SIRT) | v1.0.2023 | RO.RX.141.A | Added 2 references due to NCCN changing the Hepatobiliary Cancers guideline into two new guidelines |
| Xofigo® (Radium-223) | v1.0.2023 | RO.RX.142.A | Discussion and references updated |

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| Zevalin® | v1.0.2023 | RO.RX.143.A | Discussion and references updated |
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At that time, 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 Radiation Oncology 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→Radiation Oncology→*Search Health Plan* by typing in Highmark→Click on Highmark and then click on magnifying glass→Click on FUTURE→ Click on the Radiation Oncology Guideline



Medicare Advantage

Coverage Criteria Established for Epcoritamab-bysp (Epkinly)



Highmark's Medicare Advantage product has established new criteria for I-279 epcoritamab-bysp (Epkinly). This a new policy creating coverage criteria for epcoritamab-bysp (Epkinly) which is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, and high-grade B-cell lymphoma after two or more lines of systemic therapy.



This new Medical Policy will apply to professional providers and facility claims. The effective date is August 7, 2023.

Please refer to Medical Policy I-279, Epcoritamab-bysp (Epkinly), for additional information.

Coverage Criteria Established for Glofitamab-gxbl (Columvi)



Highmark's Medicare Advantage product has established new criteria for I-283 glofitamab-gxbl (Columvi). This a new policy creating coverage criteria for glofitamab-gxbl (Columvi) which is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, and high-grade B-cell lymphoma after two or more lines of systemic therapy.



This new Medical Policy will apply to professional providers and facility claims. The effective date is September 4, 2023.

Please refer to Medical Policy I-283, Glofitamab-gxbl (Columvi), 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



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About this Newsletter

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