MEDICAL POLICY UPDATE

July 2022

HIGHMARK. WEST VIRGINIA

IN THIS ISSUE

Policy

Policy Title	Anticipated Issue Date	30 Day Notification Information
G-44 - Extracorporeal Membrane Oxygenation [ECMO] for Adult Conditions	9/5/2022	This policy is scheduled for annual review. Criteria regarding cardiogenic shock has been added to the pediatric section. Information about the oxygen saturation index was added to the section on neonates. Policy will publish on September 5, 2022.
I-151 Site of Care	10/1/2022	This policy is being updated to add Saphnelo (J0491), Nexviazyme (J0219) and Vyvgart (J9332) to our site of care program. Policy will publish October 1, 2022.
I-152 - Exondys 51 (Eteplirsen)	8/1/2022	This policy was scheduled for annual review. There is no change in coverage. This policy will publish on August 1, 2022.

Policy Title	Anticipated Issue Date	30 Day Notification Information
I-198 - Burosumab (Crysvita)	8/29/2022	This policy was scheduled for annual review. Age for XLH updated to 6 months and up per FDA. This policy will publish on August 29, 2022.
I-201 Treatment of Hereditary Amyloidosis	8/1/2022	Crtieria was established for vutrisiran (Amvuttra), a new FDA approved injection for TTR amyloidosis. Policy will publish on August 1, 2022.
I-233 - Lumasiran (Oxlumo)	9/5/2022	This policy is up for annual review. There are no indications for a change in coverage at this time. Minor language revisions were made to the policy. Policy will publish on September 5, 2022.
I-247 Efgartigmod alfa-fcab (Vyvgart)	10/1/2022	This policy is being updated to change the place of service to Outpatient-Infusion. Policy will publish on October 1, 2022.
I-252 - West Virginia Telemedicine Exception	8/29/2022	This is a new policy established for the WV telehealth mandate. The policy will publish on August 29, 2022.
I-27 - Certolizumab (Cimzia®)	8/29/2022	This policy is up for annual review. Formatting changes and minor language revisions were made to the policy. Policy will publish on August 29, 2022.
I-33 - Belimumab (Benlysta®)	10/24/2022	This policy is up for annual review. Initial authorization period and reauthorization criteria were established for belimumab. Policy language was also revised. Policy will publish on October 24, 2022.
I-90 - Abatacept (Orencia®) IV and SC	10/24/2022	This policy is up for annual review. New indications for graft-versus-host disease acute prophylaxis and chronic treatment and immune checkpoint toxicity were added. Reauthorization criteria was also established for this policy. Policy will publish on October 24, 2022.
I-92 - Naltrexone Extended Release Injection (Vivitrol®	8/29/2022	This policy is up for annual review. There are no indications for a change in coverage at this time. Policy will publish on August 29, 2022.
L-225 - GI Effects Comprehensive Stool Profile	8/29/2022	This policy is scheduled for annual review. Minor administrative changes made. This policy will publish August 29, 2022.
L-263 - Biochemical Markers of Bone Remodeling	8/29/2022	This policy is scheduled for annual review. Minor administrative changes made. This policy will publish August 29, 2022.
L-4 - Intraepidermal Nerve Fiber Density Testing	10/24/2022	This policy is scheduled for annual review. Verbiage and coding changes made. This policy is scheduled to publish October 24, 2022.
L-42 - Rapid Platelet Function Assay - ASA	8/29/2022	This policy is scheduled for annual review. Minor administrative changes made. This policy will publish August 29, 2022.
S-184 - Gender Reassignment Surgery	9/5/2022	This policy is scheduled for annual review. There is no change in the coverage criteria. Policy will publish on September 5, 2022.
S-51 - Responsive Neurostimulation for the Treatment of	10/24/2022	This is the annual review of medical policy S-51. Language and denial statement have been updated. Policy will publish on October 24, 2022.
V-45 - Medication Assistance for Methadone Treatment	8/29/2022	This is the annual review with updates to diagnosis codes for policy. This will publish August 29, 2022.
Y-22 - Opioid Dependence Therapy	8/29/2022	This is the annual review, no recommended changes, policy replacement. This will publish August 29, 2022.

Policy Title	Anticipated Issue Date	30 Day Notification Information
Z-100 - Deep Brain Stimulation	10/24/2022	This is the annual review of Z-100. Policy criteria, language, and denial statements have been updated. The policy will publish on October 24, 2022.
Z-29 Hypnosis	8/29/2022	This is the annual review. There are no recommended changes, and the policy will publish August 29, 2022.
Z-46 - Blood and Bone Marrow Storage	8/29/2022	This policy is scheduled for annual review. Minor administrative changes made. This policy will publish August 29, 2022.
Z-7 - Electrical Nerve Stimulation	10/24/2022	This is the annual review of policy Z-7. Language, coding, and criteria have been updated. The policy will publish on October 24, 2022.

Policy

Coverage Guidelines Revised for Belimumab (Benlysta)

NEWS FOR ALL PROVIDER TYPES

Highmark West Virginia has revised criteria for belimumab (Benlysta) to add reauthorization criteria along with the initial and reauthorization period of 12 months. The reauthorization criteria include that the individual meets all initial authorization criteria and has demonstrated disease stability or a beneficial response to therapy.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is October 24, 2022.

Place of Service: Outpatient-Infusion

Please refer to Medical Policy I-33, Belimumab (Benlysta), for additional information.

Coverage Guidelines Revised for Abatacept (Orencia)

NEWS FOR ALL PROVIDER TYPES

Highmark West Virginia has revised criteria for abatacept (Orencia) intravenous injection to add reauthorization criteria along with the initial and reauthorization periods. The reauthorization criteria include that the individual meets all initial authorization criteria and has demonstrated disease stability or a beneficial response to therapy.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is October 24, 2022.

Place of Service: Outpatient-Infusion

Please refer to Medical Policy I-90, Abatacept (Orencia), for additional information.

Criteria Established for Vutrisiran (Amvuttra)

Highmark West Virginia has established new guidelines for Vutrisiran (Amvuttra). Vutrisiran (Amvuttra) may be considered medically necessary for the treatment of individuals 18 years of age and older with a diagnosis of hereditary TTR amyloidosis when **ALL** of the following criteria are met:

- Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of amyloidosis; **and**
- Diagnosis of polyneuropathy associated with hereditary TTR amyloidosis; **and**
- Documented mutation in TTR gene as confirmed by genetic testing; **and**
- A complete neurologic examination has been performed, showing clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, carpel tunnel, etc.)**; and**
- Vutrisiran (Amvuttra) is not being used for sensorimotor or autonomic neuropathy unrelated to hATTR amyloidosis; **and**
- Documentation of baseline functional ambulation performance (FAP) stage of 1 or 2; **and**
- Has documentation of **ANY** of the following:
    - Peripheral neuropathy impairment score (NIS) of five (5) or greater; **or**
    - Polyneuropathy disability (PND) score of IIIb or lower; **and**
- Has not had a prior liver transplant or scheduled liver transplant; **and**
- Individual has normal liver function tests; **and**
- Individual is not simultaneously utilizing other gene targeted therapy for polyneuropathy of hATTR; **and**
- Initial authorization will be for a 12-month period.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is August 1, 2022.

Place of Service: Outpatient

Please refer to Medical Policy I-201, Treatment of Hereditary Amyloidosis, for additional information.

Policy Established for West Virginia Telehealth Exception

Highmark West Virginia has established new guidelines for West Virginia Telehealth Exception. The policy will be as follows:

West Virginia Mandate

Effective April 7, 2017, pursuant to WV code §30-3-13A, a physician or health care provider may not prescribe any drug with the intent of causing an abortion via telemedicine. The term "abortion" has the same meaning ascribed to it in §16-2F-2 of this code, which is listed below.

§16-2F-2 (1)

"Abortion" means the use of any instrument, medicine, drug, or any other substance or device with intent to terminate the pregnancy of a female known to be pregnant and with intent to cause the expulsion of a fetus other than by live birth. This article does not prevent the prescription, sale, or transfer of intrauterine contraceptive devices, other contraceptive devices, or other generally medically accepted contraceptive devices, instruments, medicines or drugs for a female who is not known to be pregnant and for whom the contraceptive devices, instruments, medicines or drugs were prescribed by a physician solely for contraceptive purposes and not for the purpose of inducing or causing the termination of a known pregnancy.

The use of misoprostol (Cytotec) and mifepristone (Korlym, Mifeprex) prescribed via telemedicine for the intent of causing an abortion is considered not medically necessary and therefore non-covered.

This new Medical Policy will apply to professional providers and/or facility claims. The effective date is August 29, 2022.

Place of Service: Telehealth

Please refer to Medical Policy I-252, West Virginia Telehealth Exception, for additional information.

Criteria Revised for Intraepidermal Nerve Fiber Density Testing

Highmark West Virginia has revised criteria for L-4, Intraepidermal Nerve Fiber Density Testing. Measurement of sweat gland nerve fiber density language has been added to the policy and will be considered investigational/experimental.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is 10/24/2022.

Place of Service: Inpatient/Outpatient

Please refer to Medical Policy L-4, Intraepidermal Nerve Fiber Density Testing for additional information.

Criteria Revision for Electrical Nerve Stimulation

Highmark West Virginia has revised criteria for Z-7, Electrical Nerve Stimulation.

The implantation of a vagus (vagal) nerve stimulator for seizure control may be considered medically necessary only when used as a last resort for individuals with epilepsy (aged four (4) years and older) with partial onset seizures who have not undergone a bilateral or left cervical vagotomy.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is October 24, 2022.

Place of Service: Inpatient/Outpatient

Please refer to Medical Policy Z-7, Electrical Nerve Stimulation, for additional information.

Criteria Revision for Deep Brain Stimulation

Highmark West Virginia has revised criteria for Z-100, Deep Brain Stimulation.

Bilateral stimulation of the anterior nucleus of the thalamus may be considered medically necessary when the individual has an average of six (6) or more seizures per month, over the three (3) most recent months prior to DBS implantation (with no more than 30 days in between seizures). Note: DBS has not been evaluated in individuals with less frequent seizures.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is October 24, 2022.

Place of Service: Inpatient/Outpatient

Please refer to Medical Policy Z-100, Deep Brain Stimulation, for additional information.

Reminder: Cardiology & Radiology Coverage Guideline Update

NEWS FOR ALL PROVIDER TYPES

Highmark West Virginia is providing a reminder to all providers.

The Cardiology & Radiology coverage guideline will be updated and take effect October 01, 2022. This applies to both professional provider and facility claims.

The significant changes to the Cardiology & Radiology guidelines are indicated below:

Abdomen Imaging Guidelines Key Changes

- AB-16 –Adrenal Cortical Lesions
  - Revamped entire section for clarity and ease of use. Reorganized subsections, with additional subsection created. Updated imaging criteria in all subsections.
- AB-48 –Fistulae
  - New section dedicated to fistulous disease.
- AB-26 –Cirrhosis and Liver Screening for HCC; Ascites and Portal Hypertension
  - Updated criteria for HCC screening, ascites, and monitoring after Fontan procedure based on guidance from the updated guidance from the American Association for the Study of Liver Diseases (AASLD).
- AB-1.0 –General Guidelines
  - Added additional red flag for individuals over 60 years of age with unintentional weight loss
  - Added discussion of preoperative radiologic imaging
  - Added information describing experimental and investigational procedures

Breast Imaging Guidelines Key Changes

- Added indication of Breast US for dense breast in BR-1: Breast Ultrasound
- Added table with imaging for equivocal rupture of breast implants on clinical exam in BR-1: Breast Ultrasound and BR-5: MRI Indications
- Removed indication for MRI Breast for all newly diagnosed breast cancer and added MRI Breast for selective individuals with newly diagnosed breast cancer for consistency with Oncology guidelines in BR-5: MRI Indications
- Removed indication for annual surveillance for individuals with personal history of cancer before age 50 in BR-5: MRI Indications

Cardiac Imaging Guidelines Key Changes

- New content
  - Evaluation of Conditions other than Coronary Artery Disease (CD-7.7) criteria added for left heart catheterization without coronary angiography
  - Updated title and content to include treatment with cardiotoxic agents unrelated to cancer therapeutics. Added section to cover imaging required for treatment with new FDA approved mavacamten for HCM. New section Obstructive Hypertrophic Cardiomyopathy (HCM) (CD-12.3)
  - New section created -Cardiac Sarcoidosis (CD-3.9)
- Formatting changes
  - Updated to new format
  - Sections reorganized for ease of use

Chest Imaging Guidelines Key Changes

- Added imaging for non-cardiac chest pain, other than substernal in CH-4.1: Non-Cardiac Chest Pain –Imaging
- New subsection: CH-7.2: Adult Cystic Fibrosis

- Added indication for imaging after initial diagnosis for symptomatic post-COVID individuals with concern of interstitial lung disease in CH-13.2: Coronavirus Disease 2019 (COVID-19)
- Added indication for CT with suspected Cystic Lung disease in CH-19.1: Pneumothorax/Hemothorax

Head Imaging Guidelines Key Changes

- New subsection: Normal Pressure Hydrocephalus (NPH) (HD-8.4)
- New subsection Headache and Suspected Vascular Dissection (HD-11.1)
- Added imaging post SARS-CoV-2 vaccines in Neuro-COVID-19 and Sars-CoV-2 Vaccines (HD-14.2)
- Added repeat imaging at 6 months after diagnosis in Acoustic Neuroma and Other Cerebellopontine Angle Tumors (HD-33.1)

Musculoskeletal Imaging Guidelines Key Changes

- MS-28 –Nuclear Medicine
    - Added FDG PET/CT as option for imaging of suspected bone infection if MRI or CT cannot be done
- MS-4.1, MS-9.2, MS-19, MS-21, MS-24, MS-25, MS-26
    - Updated contrast options to align with the latest ACR recommendations.

OB Ultrasound Imaging Guidelines Key Changes

- Detailed First-Trimester Obstetric Ultrasound Evaluation
    - New Indication-driven study performed between 12 and 13+6 weeks gestation (OB 9.0)
    - Coded as: CPT®76801 PLUS CPT®76813 (and CPT® 76802 PLUS CPT® 76814 if twins)
- Short Interval Pregnancy –OB 9.11
    - Added new guideline section to address this pregnancy complication
- Pre-gestational Diabetes Mellitus, Not on Medication –OB 9.6.1
    - Deleted this sub-section
        - Once diagnostic criteria is met for ‘pre-gestational diabetes –imaging is the same whether on medication or not

Oncology Imaging Guidelines Key Changes

- ONC-11 –Breast Cancer
    - Updated to state bilateral mammogram and/or ultrasound are indicated for newly diagnosed breast cancer unless additional risk criteria are met
- ONC-19 –Prostate Cancer
    - Added discussion of latest radiotracers (Illucix, Locametz)
    - Added PSMA PET/CT for patients being considered for treatment with Pluvicto
- ONC-6 –Thyroid Cancer
    - Several more permissive updates, including updated PET/CT criteria

Pelvis Imaging Guidelines Key Changes

- Added indication for MRI for adenomyosis in PV-4.1: Adenomyosis
- Added option for MRI Pelvis and updated indications for Ultrasound in PV-7.1: Pelvic Inflammatory Disease
- New subsection: PV-21.3: Pelvic Fistula
- Added imaging for mesh and graft complications in PV-22.3: Pelvic Prolapse

PVD Imaging Guidelines Key Changes

- New content

    - Section created to address pelvic pain when pelvic congestion syndrome is suspected. Pelvic congestion syndrome (PVD-13.4)
    - Title updated and content included to discuss management of non-aortic dissections as well as other pathologies such as penetrating aortic ulcers - Aortic and Arterial Dissection and Other Aortic Conditions (PVD-6.7)
    - Upper Extremity PVD -Imaging (PVD-4.1) Original Section PVD-4.1 -split into arterial and venous imaging guidelines to align with new section order. Added: Arterial duplex is the initial imaging study in individuals with suspected arterial insufficiency
- Formatting changes
    - Updated to new format
    - Sections reorganized for ease of use

Pediatric Abdomen Guidelines Key Changes

- PEDAB-5.1 –Upper Urinary Tract
    - Added DSMA scintigraphy for individuals with atypical or recurrent febrile acute urinary tract infections and known vesicoureteral reflux

Pediatric Head Guidelines Key Changes

- Added criteria
    - Metabolic PET Brain/MRI in PEDHD-2.3: PET Brain Imaging (CPT®78608), and PEDHD-6.3: Special Imaging Studies in Evaluation for Epilepsy Surgery
    - Metabolic Brain PET in PEDHD-29: CNS Infection
- Added option for MRA or CTA follow-up of known cerebral artery stenosis in PEDHD-12.3: Pediatric Stroke Subsequent Imaging
- Added indication for imaging related to COVID-19 infection in PEDHD-29: CNS Infection

Pediatric Musculoskeletal Imaging Guidelines Key Changes

- PEDMS-7 –Suspected Physical Child Abuse
    - Added CT Head for individuals less than 1 year of age, even without symptoms

Pediatric Oncology Imaging Guidelines Key Changes

- PEDONC-5 –Pediatric Lymphomas
    - Updates in several subsections, including updated surveillance for Hodgkin lymphoma, PET/CT for Deauville 3 disease, and expansion of PET/CT to include whole body PET/CT (CPT® 78816).
- PEDONC-19.3 –Second Malignant Neoplasms (SMN)
    - Updated criteria to align with general breast imaging guidelines; criteria applies to individuals who received radiation while under 30 years of age.
- PEDONC-2.17 –Other Renal Cell Predisposition Syndromes
    - Added additional syndromes to the list of other renal cell predisposition syndrome

If you wish to see the updates prior to the implementation date, please go to eviCore website under the Future tab for Cardiology & Radiology 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→ Select appropriate Cardiology & Radiology→ *Search Health Plan* by typing in Highmark→Click on Highmark and then click on magnifying glass→ Click on FUTURE→ Select appropriate guideline.

Reminder: Radiation Oncology Coverage Guideline Update

Highmark West Virginia is providing a reminder to all providers.

The Radiation Oncology coverage guideline will be updated and take effect October 15, 2022. This applies to both professional provider and facility claims.

The significant changes to the Radiation Oncology guidelines are indicated below:

Section Name	Section Number	Summary of Change
Brachytherapy of the Coronary Arteries (RO.RST.102.A)	POLICY: I. B.	Indication changed from "For recurrent drug eluting stent in-stent restenosis" to "For recurrent ISR who are not candidates for repeat drug-eluting stents (DES) or bypass surgery".
Proton Beam Therapy (RO.RST.106.A)	POLICY: Group 1: III. Discussion updated accordingly.	Added indication for maxillary sinus or paranasal/ethmoid sinus tumors
Proton Beam Therapy (RO.RST.106.A)	POLICY: Group 1: IV. Discussion updated accordingly.	Added more specific criteria for HCC and intrahepatic cholangiocarcinoma, stating, "IV. Select cases of localized unresectable hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma when ANY of the following criteria are met: A. When a single lesion is present, the lesion must be 15 cm or greater in greatest dimension. B. When 2 lesions are present, 1 lesion is greater than 10 cm in greatest dimension. C. When 3 lesions are present, 1 lesion is greater than 6 cm in greatest dimension".
Bladder Cancer (RO.TXS.109.A)	POLICY: II. C.	Changed from "…up to 33 fractions…" to "…25 to 33 fractions…"
Brain Metastases (RO.TXS.111.A)	Policy: III. B. 1. a.	Put limit of total number of brain metastases is 10 for initial treatment with SRS.
Brain Metastases (RO.TXS.111.A)	Policy: III. B. 2. a.	For an individual who has received prior SRS, one of the criteria for retreatment with SRS was changed to "total number of

		brain metastases treated in the last 12 months is less than or equal to 15".
Brain Metastases (RO.TXS.111.A)	Policy: III. B. 2. b.	Removed requirement of not being treated with more than two episodes of SRS in the past 9 months.
Brain Metastases (RO.TXS.111.A)	Policy: III. B. 4. a.	Lesion size limit changed from "< 4 cm" to "< 5 cm".
Breast Cancer (RO.TXS.112.A)	POLICY: VI.	Palliation indication was changed from up to 10 fractions to up to 15 fractions.
Endometrial Cancer (RO.TXS. 114.A)	POLICY: I. D.	Now allows postoperative brachytherapy alone for stage II, grade 3.
Esophageal Cancer (RO.TXS.115.A)	POLICY: I.A./II.A./III.A.	Added option of IMRT.
Gastric Cancer (RO.TXS.116.A)	POLICY: I. A/II. A/III. A/IV. A.	Added option of IMRT.
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I	Burkitt's lymphoma, lymphoblastic lymphoma, and primary cutaneous B-cell lymphoma have been removed.
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Low-grade follicular lymphoma	Changed fractions and dose from up to 36 Gy in up to 20 fractions to 24-30 Gy in 12-20 fractions.
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. MALT lymphomas	Added minimum fraction number: Changed fractions to 12-20
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Mantle cell lymphoma	Added minimum fraction number: Changed fractions to 12-20
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Mantle cell lymphoma	Specified coverage is "for stage I or contiguous nonbulky stage II disease".
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Diffuse large B-cell lymphoma. A.	Added minimum fraction number: Changed fractions to 15-20
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Diffuse large B-cell lymphoma. B.	Changed from up to 20 fractions to 13-28 fractions. Dose increase from 36 Gy to 36-50 Gy.
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Diffuse large B-cell lymphoma. C.	Changed from up to 20 fractions and 36 Gy to 20-36 fractions and 40-55 Gy.
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Diffuse large B-cell lymphoma. D.	Added minimum fraction number: Changed fractions to 10-20
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Diffuse large B-cell lymphoma. E.	Changed from up to 20 fractions and 36 Gy to 13-20 fractions and 25-30 Gy.

Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Extranodal NK/T-cell lymphoma	Added minimum fraction number: Changed fractions to 25-30
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Peripheral T-cell lymphoma	New indications per NCCN.
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: I. Peripheral T-cell lymphoma	Added minimum fraction number: Changed fractions to 15-20
Non-Hodgkin Lymphoma (RO.TXS.122.A)	POLICY: II	Added specific higher dose palliative regimen for advanced or recurrent Extranodal NK/T-cell lymphoma that is felt not to be curative.
Non-Malignant Disorders (RO.TXS.123.A)	POLICY II. L and III. L/DISCUSSION I. AW	Updated Group 2 to specify "non-cutaneous neurofibromas" and added "cutaneous neurofibroma" to Group 3. Discussion I. AW. updated.
Non-Malignant Disorders (RO.TXS.123.A)	POLICY III. AG	Psoriasis was changed to an EIU indication with supporting updates made to the "Discussion" section.
Non-Malignant Disorders (RO.TXS.123.A)	POLICY III. AP	Warts was changed to an EIU indication with supporting updates made to the "Discussion" section.
Non-Small Cell Lung Cancer (RO.TXS.124.A)	Policy I.	Added "or T3N0 (T3 based on size)" to indication and removed "early stage".
Pancreatic Cancer (RO.TXS.127.A)	POLICY: I. A/B.	Removed chemo requirement for both and moved "unresectable" to the beginning of I. B.
Pancreatic Cancer (RO.TXS.127.A)	POLICY: III. A.	Added option of IMRT and removed "unresectable".
Pancreatic Cancer (RO.TXS.127.A)	POLICY: I. A/B.	Removed chemo requirement for both and moved "unresectable" to the beginning of I. B.
Pancreatic Cancer (RO.TXS.127.A)	POLICY: III. A.	Added option of IMRT and removed "unresectable".
Pancreatic Cancer (RO.TXS.127.A)	POLICY: III. E. 1.	SBRT information updated to state the following: "E. Stereotactic body radiation therapy (SBRT) using up to 5 fractions is considered medically necessary for curative treatment of unresectable/locally advanced cases and as preoperative treatment in borderline resectable cases. 1. SBRT is considered not medically necessary in the

		palliative setting, postoperative setting, or for planned neoadjuvant treatment when the primary tumor is otherwise fully resectable". Removed chemo requirement.
Primary Craniospinal Tumors and Neurologic Conditions (RO.TXS.128.A)	POLICY: I/II/III	Removed option of complex isodose technique.
Primary Craniospinal Tumors and Neurologic Conditions (RO.TXS.128.A)	POLICY: I.	For WHO grade I tumors, changed from up to 30 fractions to 25 to 30.
Primary Craniospinal Tumors and Neurologic Conditions (RO.TXS.128.A)	POLICY: II	For WHO grade II tumors, changed from up to 30 fractions to 25 to 33.
Primary Craniospinal Tumors and Neurologic Conditions (RO.TXS.128.A)	POLICY: III.	For WHO grade III-IV tumors, changed from up to 33 fractions to 30 to 33.
Primary Craniospinal Tumors and Neurologic Conditions (RO.TXS.128.A)	POLICY: III.	For WHO grade III-IV tumors in individuals with poor performance status, changed from 10 to 20 fractions to 5 to 15 fractions.
Rectal Cancer (RO.TXS.130.A)	POLICY: III. A.	Changed from "25-30" to "25-33" fractions.
Skin Cancer- Non-Melanoma (RO.TXS.132.A)	POLICY: Extramammary Paget Disease (EMPD) and Discussion updated accordingly.	Added EMPD to this policy from the Non-Malignant policy and expounded on indications, techniques, and doses, noting the following: "Extramammary Paget Disease (EMPD) A. For the curative treatment of EMPD in the inoperable or postoperative setting, up to 33 fractions of electron beam or superficial radiation therapy is considered medically necessary. B. 3D conformal radiation is considered medically necessary when irradiating the regional lymph nodes. C. Intensity-modulated radiation therapy (IMRT) is considered medically necessary when irradiating the inguinal lymph nodes. D. For the palliative treatment of EMPD, up to 15 fractions of electron beam or superficial radiation therapy is considered medically necessary".
Small Cell Lung Cancer (RO.TXS.133.A)	Policy I.C.	Changed upper limit of hypofractionation to 15.

Small Cell Lung Cancer (RO.TXS.133.A)	Policy II.	Added indications for stage I or node-negative stage IIA LS-SCLC in the adjuvant setting.
Small Cell Lung Cancer (RO.TXS.133.A)	Policy V.	Updated to specify "consolidative thoracic" rather than just "definitive" and added options of 30 Gy in 10 fractions and 45 Gy in 15 fractions. Also added "systemic therapy" and "technique".
Small Cell Lung Cancer (RO.TXS.133.A)	Policy VIII.	Added statement "Hippocampal-avoidance PCI (HA-PCI) is considered not medically necessary".
Soft Tissue Sarcomas (RO.TXS.134.A)	POLICY: I.A.1 and 2.	New indications for sarcomas of the extremity, trunk, head, and neck.
Soft Tissue Sarcomas (RO.TXS.134.A)	POLICY: I. B. 3.	Changed allowable fractions from 33-38 to "33 fractions".
Soft Tissue Sarcomas (RO.TXS.134.A)	POLICY: I.B.4.	Changed allowable fractions from 35-41 to "35-38 fractions".
Soft Tissue Sarcomas (RO.TXS.134.A)	POLICY: I.B.4.	IMRT is now allowed in the postoperative setting with gross residual disease.
Soft Tissue Sarcomas (RO.TXS.134.A)	POLICY: I.B.5.	New indication for unresectable tumors.
Soft Tissue Sarcomas (RO.TXS.134.A)	POLICY: I.C.	Added option of IMRT for proximal lower extremity.
Soft Tissue Sarcomas (RO.TXS.134.A)	POLICY: I.D.	New indication for oligometastatic sarcomas.
Soft Tissue Sarcomas (RO.TXS.134.A)	POLICY: Brachytherapy: A.	Added an indication for monotherapy.
Thymoma and Thymic Cancer (RO.TXS.136.A)	POLICY: I. A/B/C	Post-operative indication updated and expanded to state the following: "External beam photon radiation therapy is considered medically necessary: I. In the postoperative treatment of A. Stage IIB-IVA thymoma and thymic carcinoma with negative surgical margins to a dose of 45 to 50 Gy using 25-28 fractions of 3D conformal radiation therapy (3DCRT) B. Stage I-IVA thymoma and thymic carcinoma with microscopic positive surgical margins to a dose of 54 Gy using 30 fractions of 3DCRT C. Stage I-IVA thymoma and thymic carcinoma with macroscopic positive surgical margins or gross residual

		disease to a dose of 60-70 Gy using 30-35 fractions of 3DCRT or intensity-modulated radiation therapy (IMRT)". This change includes adding IMRT as an option for I. C. as well as increasing the allowable fraction number for microscopic positive surgical margins to 30.
Thymoma and Thymic Cancer (RO.TXS.136.A)	POLICY: I. A.	This indication previously allowed "up to 27 fractions" and has been changed to allow "25-28 fractions".
Thymoma and Thymic Cancer (RO.TXS.136.A)	POLICY: II	Specified indication for unresectable disease as definitive treatment and added option of IMRT. Updated to state, "II. In the definitive treatment of unresectable disease to a dose of 60-70 Gy using 30-35 fractions of 3DCRT or IMRT". Removed "gross residual disease from this indication. Added dosage.
Thymoma and Thymic Cancer (RO.TXS.136.A)	POLICY: III	Specified indication for treatment of isolated recurrence as definitive. Updated to state, "In the definitive treatment of an isolated local recurrence without distant metastatic disease to a dose of 60-70 Gy using 30-35 fractions of 3DCRT or IMRT" which adds option of IMRT and specifies dosage.
Thymoma and Thymic Cancer (RO.TXS.136.A)	POLICY: V	Added the following in regards to IMRT: "IMRT is considered medically necessary for treatment in the curative setting which overlaps with a previously irradiated area". IMRT was previously considered not medically necessary.
Urethral Cancer and Cancers of the Ureter and Renal Pelvis (RO.TXS.137.A)	POLICY: Cancers of the ureter and renal pelvis	Removed radiation as an option before surgery for cancers of the ureter and renal pelvis.
177Lu-dotatate (Lutathera®) (RO.RX.140.A)	POLICY: I. B.	Added pheochromocytomas and paragangliomas to I. B.
177Lu-dotatate (Lutathera®) (RO.RX.140.A)	POLICY criteria: I.A.	Added the following criteria: "OR well-differentiated G3 neuroendocrine tumors with a Ki-67 < 55%".
Pluvicto (RO.RX.144.A)	Throughout Document	New policy

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→ Select appropriate RADIATION ONCOLOGY→ *Search Health Plan* by typing in Highmark→Click on Highmark and then click on magnifying glass→ Click on FUTURE→ Select appropriate guideline.

Coverage Guidelines Revised for Belimumab (Benlysta)

NEWS FOR ALL PROVIDER TYPES

Highmark's Medicare Advantage products have revised criteria for belimumab (Benlysta) to add reauthorization criteria along with the initial and reauthorization period of 12 months. The reauthorization criteria include that the individual meets all initial authorization criteria and has demonstrated disease stability or a beneficial response to therapy.

MA MEDICARE ADVANTAGE

This revised Medical Policy will apply to professional providers and facility claims. The effective date is October 24, 2022.

Please refer to Medical Policy I-195, Belimumab (Benlysta), for additional information.

Criteria Established for Vutrisiran (Amvuttra)

NEWS FOR ALL PROVIDER TYPES

Highmark's Medicare Advantage products has/have established new guidelines for Vutrisiran (Amvuttra). Vutrisiran (Amvuttra) may be considered medically necessary for the treatment of individuals aged 18 years of age and older with a diagnosis of hereditary TTR amyloidosis (TTR amyloidosis, hATTR or ATTR) when **ALL** of the following criteria are met:

MA MEDICARE ADVANTAGE

- Diagnosis of polyneuropathy associate with hereditary TTR amyloidosis; **and**
- Documented mutation in TTR gene as confirmed by genetic testing; **and**
- Has adequate liver function (AST and ALT less than or equal to 2.5 times upper limit of normal, total bilirubin within normal limits and INR less than or equal to two (2)); **and**
- Has adequate renal function (Serum Creatinine level less than or equal to two (2) times upper limit of normal or creatinine clearance greater than 30 mls/min); **and**
- Individual is not simultaneously utilizing other gene targeted therapy for polyneuropathy of hATTR.
- Initial authorization will be for a 12-month period.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is August 1, 2022.

Please refer to Medical Policy I-201, Treatment of Hereditary Amyloidosis, 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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