

Medical Policy and Coding Updates March 4, 2021

Special notices

Effective May 10, 2021

Updates to AIM Specialty Health® Clinical Appropriateness Guidelines

Effective for dates of service on and after May 10, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Molecular Testing of Solid and Hematologic Tumors and Malignancies

Updates by section

Conditions for which testing may be medically necessary (Table 1)

The following solid tumor markers were added:

- Cholangiocarcinoma: FGFR2 and FoundationOne® CDx
- Colorectal cancer: Praxis Extended RAS panel
- o Neuroblastoma: Chromosomal Microarray Analysis (CMA), MYCN, ALK
- o Non-small cell lung cancer (NSCLC): Oncomine Dx Target Test
- Ovarian cancer: myChoice® CDx
- Prostate cancer (Suspected): SelectMDx
- Prostate cancer: FoundationOne® CDx
- Tumor agnostic/all solid tumors: microsatellite instability (MSI) and FoundationOne® CDx

Breast Cancer Gene Expression Classifiers

- Criteria was clarified to confirm the patient has undergone surgery and full pathological staging
- A statement explaining testing is not medically necessary to guide decision making for extended endocrine therapy was added
- OncotypeDx Recurrence Score test: the definition of unfavorable histological features was clarified

Minimal Residual Disease (MRD)

Testing criteria was revised to require testing performed on bone marrow



Targeted Molecular Testing for NTRK Fusions

o Criteria were revised

Prostate Cancer (symptomatic cancer screening)

- Added criteria for SelectMDx (81479)
- o Criteria for PCA3 (81313), ExomeDx (0005U) and ConfirmMDx (81551) were revised

Effective May 6, 2021

Hereditary Angioedema, 5.01.587

Medical necessity criteria updated

- Berinert® (pdC1-INH)
 - Added coverage for acquired angioedema
- Cinryze® (pdC1-INH)
 - Added patient age, limits to danazol use, and acute HAE frequency requirements
- Firazyr® (icatibant)
 - Requires use of generic icatibant first
- Haegarda® (pdC1-INH)
 - Added limits to danazol use and acute HAE frequency requirements
- Ruconest® (rhC1-INH)
 - Age criteria revised to patients 13 and older
- Takhzyro ® (lanadelumab-flyo)
 - Added limits to danazol use, acute HAE frequency requirements, and quantity limit

Effective April 7, 2021

Immune Globulin Therapy, 8.01.503

Site of service review added

Xembify®

Miscellaneous Oncology Drugs, 5.01.540

New drug added to policy

- Jelmyto™ (mitomycin)
 - Treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC)

Site of Service Infusion Drugs and Biologic Agents, 11.01.523

Site of service review added

Xembify®



Effective March 14, 2021

Updates to AIM Specialty Health® Clinical Appropriateness Guidelines

Effective for dates of service on and after March 14, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Advanced Imaging

Updates by section

Brain Imaging

Ataxia, congenital or hereditary

o Combined with congenital cerebral anomalies to create one section

Acoustic neuroma

- o More frequent imaging for a watch and wait or incomplete resection
- New indication for neurofibromatosis type 2 (NF 2)
- More frequent imaging when MRI shows findings suspicious for recurrence
- o Single post-operative MRI following gross total resection
- Included pediatrics with known acoustics (rare but NF 2)

Tumor - not otherwise specified

o Repurposed for surveillance imaging of low grade neoplasms

Seizure disorder and epilepsy

- Limited imaging for the management of established generalized epilepsy
- Required optimal medical management (aligning adult and pediatric language) prior to imaging for management in epilepsy

Headache

- Removed response to treatment as a primary headache red flag
- o Included pregnancy as a red flag risk factor

Mental status change and encephalopathy

Added requirement for initial clinical and lab evaluation to assess for a more specific cause

Brain Imaging and Head and Neck Imaging

Hearing loss

 Added CT temporal bone for evaluation of sensorineural hearing loss in any pediatric patients or in adults for whom MRI is nondiagnostic or unable to be performed



- Higher allowed threshold for consecutive frequencies to establish SNHL
- Removed CT brain as an alternative to evaluating hearing loss based on ACR guidance

Tinnitus

Removed sudden onset symmetric tinnitus as an indication for advanced imaging

Chest Imaging and Head and Neck Imaging

Hoarseness, dysphonia, and vocal cord weakness/paralysis - primary voice complaint

 Required laryngoscopy for the initial evaluation of all patients with primary voice complaint

Head and Neck Imaging

Sinusitis/rhinosinusitis

- Added more flexibility for the method of conservative treatment in chronic sinusitis
- Required conservative management prior to repeat imaging for patients with prior sinus
 CT

Temporomandibular joint dysfunction

Removed requirement for radiographs/ultrasound

Cerebrospinal fluid (CSF) leak of the skull base

Added scenario for management of known leak with change in clinical condition

Oncologic Imaging

General content changes to align with current oncology recommendations

- Removal of indications/parameters not addressed by NCCN
- Average risk inclusion criteria for CT colonography
- New allowances for MRI Abdomen and/or MRI pelvis by tumor type, liver metastatic disease
- New indications for acute leukemia (CT, PET/CT), multiple myeloma (MRI, PET/CT), ovarian cancer surveillance (CT), bone sarcoma (PET/CT)
- Updated standard imaging pre-requisites prior to PET/CT for bladder/renal pelvis/ureter, colorectal, esophageal/GE junction, gastric and non-small cell lung cancers
- Additional PET/CT management scenarios for cervical cancer, Hodgkin lymphoma

Cancer screening

New indication for pancreatic cancer screening



 New PET/CT indication for restaging/treatment response for bone-only metastatic disease and limitation of post-treatment breast MRI after breast conserving therapy or unilateral mastectomy

Prostate Cancer

Breast cancer

o MRI pelvis: removal of TRUS biopsy requirement, allowance if persistent/unexplained elevation in PSA or suspicious DRE

Axumin PET/CT

 Updated inclusion criteria (removal of general MRI pelvis requirement, additional allowance for rising PSA with non-diagnostic mpMRI)

Effective for dates of service on and after March 14, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Advanced Imaging of the Heart

Updates by section

Evaluation of patients with cardiac arrhythmias

- o Updated repeat TTE criteria
- Added restrictions for patients whose initial echocardiogram shows no evidence of structural heart disease, and follow-up echocardiography is not appropriate for ongoing management of arrhythmia

Evaluation of signs, symptoms, or abnormal testing

 Added restrictions for TTE in evaluation of palpitation and lightheadedness based on literature

Effective for dates of service on and after March 14, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Radiation Oncology

Updates by section

Special Treatment Procedure

Removed IV requirement for chemotherapy



CNS cancer: IMRT for glioblastomas, other gliomas, brain metastases

- Eliminated the plan comparison requirement based on feedback from reviewers that essentially all cases were able to meet criteria - same change for high-grade and low-grade gliomas
- Added new indication for hippocampal sparing whole brain radiotherapy

Lung cancer: IMRT and SBRT for non-small cell, SBRT for small cell; fractionation for non-small cell

- Eliminated the plan comparison requirement for IMRT to treat stage III non-small cell lung cancer
- o Removed "due to a medical contraindication" language
- o Added new indication as an alternative to surgical resection when certain conditions apply
- o Adjusted fractions of thoracic radiotherapy for non-small cell lung cancer

Proton Beam Therapy

o Added new indication for hepatocellular carcinoma and intrahepatic cholangiocarcinoma

Effective March 3, 2021

Medical Necessity Criteria for Pharmacy Edits, 5.01.605

New policy section

Interferons

New drug added to policy

- Actimmune® (interferon gamma-1b)
 - Reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD)
 - Delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO)

Vascular Endothelial Growth Factor (VEGF) Receptor Inhibitors for Ocular Disorders, 5.01.620 New policy

The following brand drugs have been added and may be considered medically necessary when criteria are met:

- Beovu® (brolucizumab-dbll)
 - Treatment of neovascular (wet) age-related macular degeneration (AMD)
- Eylea® (aflibercept)
 - Treatment of neovascular (wet) age-related macular degeneration (AMD)
 - Treatment of macular edema following retinal vein occlusion (RVO)
 - Treatment of diabetic macular edema (DME)
 - Treatment of diabetic retinopathy (DR)



- Lucentis® (ranibizumab)
 - Treatment of neovascular (wet) age-related macular degeneration (AMD)
 - Treatment of macular edema following retinal vein occlusion (RVO)
 - Treatment of diabetic macular edema (DME)
 - Treatment of diabetic retinopathy (DR)
 - Treatment of myopic choroidal neovascularization (mCNV)
- Macugen® (pegaptanib)
 - Treatment of neovascular (wet) age-related macular degeneration (AMD)

Medical policies

New medical policies Effective March 1, 2021

Radiofrequency Coblation Tenotomy for Musculoskeletal Conditions, 7.01.165

New policy

Radiofrequency coblation tenotomy is considered investigational as a treatment for musculoskeletal conditions

Revised medical policies Effective March 1, 2021

Skilled Hourly Nursing Care in the Home, 11.01.522

Medical necessity criteria updated

The following clarifying statements have been added to the policy:

- "The skilled nursing services are performed in the home as an alternative to a more acute care setting (eg, hospital, skilled nursing facility), or to assist with a transition of care from an acute care setting."
- o "There is a primary caregiver in the home who is willing and has the ability to be trained to care for the patient and assume and be responsible for the patient's care when the nurse is not in the home or once the patient's condition has stabilized."

Documentation requirements updated

The following documentation requirement has been added: "The specific number of skilled nursing hours being requested as well as the anticipated duration of the skilled nursing services to be provided."



Pharmacy policies

Revised pharmacy policies Effective March 1, 2021

Drugs for Rare Diseases, 5.01.576

New drug added to policy

- o Imcivree[™] (setmelanotide)
 - Treatment of chronic weight management due to POMC, PCSK1, or LEPR deficiency

Medical necessity criteria updated

- Firdapse® (amifampridine)
 - Age limitation of age 18 or older has been removed
 - Patient must have tried Ruzurgi® (amifampridine) first
- o Ruzurgi® (amifampridine)
 - The age limitation of age 18 and older has been removed

Epidermal Growth Factor Receptor (EGFR) Inhibitors, 5.01.603

Drug with new indication

- Tagrisso® (osimertinib)
 - Treatment after surgery in patients with non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations

Herceptin® (trastuzumab) and Other HER2 Inhibitors, 5.01.514

New drugs added to policy

- Generic lapatinib
 - Treatment of HER2-positive breast cancer
- o Margenza™ (margetuximab-cmkb)
 - Treatment of metastatic HER2-positive breast cancer

Drug with new indication

- Enhertu® (fam-trastuzumab deruxtecan-nxki)
 - Treatment of gastric or gastroesophageal junction adenocarcinoma

Medical necessity criteria updated

- Tykerb® (lapatinib)
 - Patient must have tried and failed generic lapatinib first



Medical Necessity Criteria for Pharmacy Edits, 5.01.605

Anticonvulsants

Medical necessity criteria updated

o The initial authorization period for all anticonvulsant drugs has been updated to 3 years

Brand Gabapentin Products

Drug with new indication

- Gralise® (gabapentin extended-release)
 - Treatment of neuropathic pain

Brand Topical Acne or Rosacea Products

New drugs added to policy

- o Arazlo™
- Atralin®
- Soolantra®

Cystic Fibrosis

New policy section

New drug added to policy

- Bronchitol® (mannitol)
 - Treatment of cystic fibrosis in adults age 18 or older

Archived policies

An archived policy is one that's no longer active and is not used for reviews.

No updates this month

Deleted policies

No updates this month



Coding updates

Added codes Effective March 3, 2021

Medical Necessity Criteria for Pharmacy Edits, 5.01.605

Now requires review for medical necessity and prior authorization.

J9216

Vascular Endothelial Growth Factor (VEGF) Receptor Inhibitors for Ocular Disorders, 5.01.620 Now requires review for medical necessity and prior authorization.

J0178, J0179, J2503, J2778

Effective March 1, 2021

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions, 7.01.48

Now requires review for medical necessity and prior authorization as well as site of service.

S2112

Bioengineered Skin and Soft Tissue Substitutes, 7.01.582

Now requires review for investigative.

Q4104

Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors, 7.01.92

Now requires review for investigative and prior authorization.

20983

Wheelchairs (Manual or Motorized), 1.01.501

Now requires review for medical necessity and prior authorization.

E0988, E1002, E1003, E1004, E1005, E1006, E1007, E1008, E1009, E1010, E1011, E1110, E1280



Revised codes Effective March 1, 2021

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease, 2.01.38 Now requires review for investigative and prior authorization.

43236

Removed codes Effective March 1, 2021

 $Bioengineered\,Skin\,and\,Soft\,Tissue\,Substitutes, 7.01.582$

No longer requires review for investigative.

Q4114