

Medical Policy and Coding Updates February 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

- More frequent imaging for a watch and wait or incomplete resection
- New indication for neurofibromatosis type 2 (NF 2)
- o More frequent imaging when MRI shows findings suspicious for recurrence
- o Single post-operative MRI following gross total resection
- o 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
- Included pregnancy as a red flag risk factor

Mental status change and encephalopathy

o 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
- o 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

o 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



o Additional PET/CT management scenarios for cervical cancer, Hodgkin lymphoma

Cancer screening

New indication for pancreatic cancer screening

Breast cancer

 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

 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

- 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
- Removed "due to a medical contraindication" language
- 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

o 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)

Effective February 5, 2021

Services Reviewed Using InterQual® Criteria, 10.01.530

This policy is updated to remove reference to services replaced with individual policies that cover medical procedures and durable medical equipment.

The following policies are being reinstated and used to review medical necessity for dates of service starting February 5, 2021 and after:

- o Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses, 1.01.11
- o Artificial Pancreas Device Systems, 1.01.30

Medical necessity criteria updated

- The age for an artificial pancreas device system has been lowered from age 14 to age 6 and older
- The age for a hybrid closed loop insulin delivery system has been lowered from age
 7 to age 6 and older
- o Cochlear Implant, 7.01.05

Medical necessity criteria updated

- The age for bilateral hearing loss has been lowered from 12 months to 9 months or older
- Continuous Passive Motion in the Home Setting, 1.01.10
- Coronary Angiography for Known Suspected Coronary Artery Disease, 2.02.507
- o Deep Brain Stimulation, 7.01.63
- Hip Arthroplasty in Adults, 7.01.573
- Hospital Beds and Accessories, 1.01.520
- Knee Arthroplasty in Adults, 7.01.550



Knee Arthroscopy in Adults, 7.01.549

Medical necessity criteria updated

- Knee arthroscopy for a partial meniscectomy is considered not medically necessary for a degenerative tear(s) that do not result in functional impairment symptoms
- o Knee Orthoses (Braces), Ankle foot Orthoses and Knee-Ankle-Foot-Orthoses, 1.03.501
- o Mastectomy for Gynecomastia, 7.01.521
- Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions, 1.01.15
- Panniculectomy and Excision of Redundant Skin, 7.01.523
- Patient Lifts, Seat Lifts, and Standing Devices, 1.01.519
- Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation, 2.02.26
- o Power Operated Vehicle (Scooters) (excluding motorized wheelchairs), 1.01.527
- Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers,
 1.01.18
- o Reduction Mammoplasty for Breast Related Symptoms, 7.01.503
- Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy, 7.01.143
- o Rhinoplasty, 7.01.558
- o Semi-Implantable and Fully Implantable Middle Ear Hearing Aids, 7.01.84
- Spinal Cord and Dorsal Root Ganglion Stimulation, 7.01.546
- Transcatheter Aortic Valve Implantation for Aortic Stenosis, 7.01.132
- o Treatment of Varicose Veins, 7.01.519
- o Upper GI Endoscopy, 2.01.533

Medical necessity criteria updated

- Routine preoperative UGI is considered not medically necessary for individuals scheduled for bariatric surgery unless they meet the clinical criteria
- Vagus Nerve Stimulation, 7.01.20
- Wearable Cardioverter Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement, 2.02.506
- Wheelchairs (Manual or Motorized), 1.01.501

Medical policies

New medical policies Effective February 1, 2021



Nutrient/Nutritional Panel Testing, 2.04.136

New policy

Nutrient/nutritional panel testing is considered investigational for all indications

Whole Body Dual X-ray Absorptiometry to Determine Body Composition, 6.01.40

New policy

Dual energy x-ray absorptiometry body composition studies are considered investigational

Revised medical policies Effective February 1, 2021

Home Nutritional Support, 8.01.502

Medical necessity criteria added

RELiZORB™ immobilized lipase cartridge (B4105) may be considered medically necessary to add digestive enzymes to enteral formula when it is attached to an enteral feeding tube in patients with cystic fibrosis

Pharmacy policies

Revised pharmacy policies Effective February 1, 2021

Drugs for Rare Diseases, 5.01.576

New drugs added to policy

- Oxlumo™ (lumasiran)
 - Treatment of primary hyperoxaluria type 1 (PH1)
- Zokinvy™ (lonafarnib)
 - Treatment of Hutchinson-Gilford progeria syndrome (HGPS) and progeroid laminopathies

Dupixent® (dupilumab), 5.01.575

Medical necessity criteria updates

- Dupixent® (dupilumab)
 - Treatment of chronic rhinosinusitis with nasal polypsosis (CRSwNP)
 - Patient must have tried and failed one intranasal corticosteroid
 - Patient must have used systemic corticosteroids in the last 2 years



• This drug must be prescribed by or in consultation with an allergist/immunologist or otolaryngologist

Excessively High Cost Drug Products with Lower Cost, 5.01.560

Medical necessity criteria updated

- o Generic tavaborole
 - Documented diagnosed of onychomycosis based on lab test and fungal culture
 - Patient must have tried and failed generic ciclopirox (topical) and generic terbinafine or itraconazole
 - Therapy is no longer than 48 weeks
- Jublia® (efinaconazole)
 - Patient must have tried and failed generic tavaborole
- Kerydin® (tavaborole)
 - Patient must have tried and failed generic tavaborole

Removed from policy

The following topical lidocaine products have been removed:

- o Anastia
- Astero
- o Kamdoy
- o Lido-K
- o Lidorx
- Lidotral
- Lidovex
- Lidtopic Max
- Numbonex
- Suvicort
- Tranzarel
- Vexasyn

Hereditary Angioedema, 5.01.587

New drug added to policy

- Orladeyo® (berotralstat)
 - Prevention of acute angioedema attacks in patients 12 years and older

Immune Checkpoint Inhibitors, 5.01.591

Drugs with new indications

- Keytruda® (pembrolizumab)
 - Treatment of patients with inoperable or metastatic triple-negative breast cancer (TNBC)
- Opdivo® (nivolumab) and Yervoy® (ipilimumab)



 Treatment of metastatic or recurrent non-small cell lung cancer (NSCLC) when used together and with two cycles of platinum-doublet chemotherapy

Indication removed

- Opdivo® (nivolumab)
 - Metastatic small cell lung cancer (SCLC)

Medical necessity criteria updated

- Keytruda® (pembrolizumab)
 - Adult patient criteria have been separated from pediatric patients for classical Hodgkin lymphoma (cHL)
 - Prior lines of therapy have been reduced for pediatric patients with classical Hodgkin lymphoma (cHL)

Medical Necessity Criteria for Pharmacy Edits, 5.01.605

Anticonvulsants

New drug added to policy

- o Generic rufinamide
 - Treatment of seizures associated with Lennox-Gastaut syndrome

New indication added

- Vimpat® (lacosamide)
 - Treatment of generalized tonic-clonic seizures

Medical necessity criteria updated

- o Banzel® (rufinamide) oral suspension
 - Patient must have tried generic rufinamide oral suspension

Brand Oral Antibiotics and Their Generics

New drug added to policy

- Helidac® (bismuth subsalicylate, metronidazole, tetracycline)
 - Treatment of Helicobacter pylori infection and duodenal ulcer disease

Brand Topical Acne or Rosacea Agents

Drugs removed from policy

- Adapalene/Benzoyl Peroxide/Clindamycin
- o Adapalene/Benzoyl Peroxide/Niacinamide
- o Benzoyl Peroxide/Clindamycin/Niacinamide
- o Benzoyl Peroxide/Clindamycin/Tretinoin
- Clindamycin/Niacinamide
- Clindamycin/Niacinamide/Spironolactone/Tretinoin



- Dapsone/Niacinamide
- o Dapsone/Niacinamide/Spironolactone
- Niacinamide/Spironolactone/Tretinoin

Crohn's Disease Agents

New policy section

New drugs added to policy

- Entocort® EC (budesonide delayed-release capsules)
 - Treatment of Crohn's disease
- o Ortikos™ (budesonide extended-release capsules)
 - Treatment of Crohn's disease

Corticosteroids, Topical Brand

Drug removed from policy

Tovet®

Intranasal Brand Corticosteroid Products

New indication added

Nasal polyps for all drugs listed in this section

Drugs removed from policy

- Ticanase[™]
- Ticaspray®

Ulcerative Colitis Agents

New drug added to policy

- Uceris® (budesonide extended-release tablets)
 - Treatment of ulcerative colitis

Miscellaneous Oncology Drugs, 5.01.540

New drugs added to policy

- Danyelza® (naxitamab-gqgk)
 - In combination with GM-CSF for the treatment of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow
- Gavreto[™] (pralsetinib)
 - Treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)
 - Treatment of adult and pediatric patients with advanced or metastatic RET-mutant medullary thyroid cancer (MTC)
 - Treatment of adult and pediatric patients with advanced or metastatic RET fusionpositive thyroid cancer



- Onureg® (azacitidine)
 - Treatment of adult patients with acute myeloid leukemia (AML)

Drug with new indication

- Xpovio[™] (selinexor)
 - Treatment of adult patients with multiple myeloma (MM)

Medical necessity criteria updated

- Leukine® (sargramostim)
 - In combination with Danyelza® (naxitamab-gqgk) for the treatment of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow

Pharmacotherapy of Miscellaneous Autoimmune Diseases, 5.01.564

Drug with new indication

- Benlysta® (belimumab)
 - Treatment of adult patients with active lupus nephritis

Xolair® (omalizumab), 5.01.513

New indication

Add-on maintenance treatment in adults with nasal polyps

Archived policies

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

Effective February 1, 2021

Allergy Testing, 2.01.500

Deleted policies

No updates this month



Coding updates

Added codes Effective February 8, 2021

Effective for dates of service on and after February 8, 2021, the following will apply to the AIM Specialty Health® Clinical Appropriate Guidelines for Genetic Testing

0017M

Effective February 5, 2021

Coronary Angiography for Known or Suspected Coronary Artery Disease, 2.02.507 Now requires review for medical necessity and prior authorization.

93460, 93461

Deep Brain Stimulation, 7.01.63

Now requires review for medical necessity and prior authorization.

61868

Hospital Beds and Accessories, 1.01.520

Now requires review for medical necessity and prior authorization.

E0265, E0266, E0296, E0297, E0300, E0912

Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions, 1.01.15

Now requires review for medical necessity and prior authorization.

E0481

Pharmacotherapy of Spinal Muscular Atrophy (SMA), 5.01.574

Now requires review for medical necessity and prior authorization.

E0642, E0985



Power Operated Vehicle (Scooters) (excluding motorized wheelchairs), 1.01.527

Now requires review for medical necessity and prior authorization.

E1230, K0899

Spinal Cord and Dorsal Root Ganglion Stimulation, 7.01.546

Now requires review for medical necessity.

C1767, C1778, C1787, C1820, C1822, C1883, C1897

Spinal Cord and Dorsal Root Ganglion Stimulation, 7.01.546

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

63661, 63662, 63664, 63688

Treatment of Varicose Veins, 7.01.519

Now requires review for medical necessity and prior authorization.

0524T, 36482, 36483, 37500, 37700, 37718, 37722, 37735, 37760, 37761, 37765, 37766, 37780, 37785

Treatment of Varicose Veins, 7.01.519

Now requires review for investigative.

36473, 36474

Wearable Cardioverter Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement, 2.02.506

Now requires review for medical necessity.

93292, 93745

Wheelchairs (Manual or Motorized), 1.01.501

Now requires review for medical necessity and prior authorization.

E1012, E1014, E1050, E1060, E1070, E1083, E1084, E1085, E1086, E1087, E1088, E1089, E1090, E1100, E1160, E1170, E1171, E1172, E1180, E1190, E1195, E1200, E1220, E1221, E1223, E1224, E1229, E1240, E1250, E1260, E1270, E1285, E1290, E1295, E2227, E2228, E2230, E2292, E2295, E2300, E2310, E2311, E2331, E2341, E2342, E2343, E2351, E2398, E2610, E2620, E2621, E2622, E2623, K0004, K0009, K0010, K0011, K0012, K0014, K0830, K0831, K0898, K0900



Effective February 1, 2021

Diagnosis and Treatment of Sacroiliac Joint Pain, 6.01.23

Now requires review for investigative.

64625, G0259, G0260

Diagnosis and Treatment of Sacroiliac Joint Pain, 6.01.23

Now requires review for medical necessity and prior authorization.

27280

Pharmacologic Treatment of Infertility, 5.01.610

Now requires review for medical necessity and prior authorization.

S0128

Removed codes Effective February 5, 2021

Knee Orthoses (Braces), Ankle foot Orthoses and Knee-Ankle-Foot-Orthoses, 1.03.501 No longer requires review for medical necessity and prior authorization.

L1907, L1940, L1950, L1960, L1970, L1980, L1990, L2000, L2005, L2010, L2020, L2030, L2034, L2036, L2037, L2038, L2106, L2108, L2126, L2128

Effective February 1, 2021

Effective for dates of service on and after February 1, 2021, the following will no longer apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Radiation Oncology

20555

Allergy Testing, 2.01.500

No longer requires review for medical necessity. Policy archived.

90506