

Medical Policy and Coding Updates June 3, 2021

Special notices

Effective September 12, 2021

Updates to AIM Specialty Health® Clinical Appropriateness Guidelines

Effective for dates of service on and after September 12, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Advanced Imaging

Updates by section

Advanced Imaging of the Spine

Congenital vertebral defects

Added new requirement for additional evaluation with radiographs

Scoliosis

- Defined presurgical planning criteria
- Added requirement for radiographs and new or progressive symptoms for postsurgical imaging

Spinal dysraphism

Tethered cord

- Revised diagnostic imaging strategy to limit CT use when MRI cannot be performed
- Added new requirement for ultrasound prior to advanced imaging for tethered cord in infants age 5 months or less

Multiple sclerosis

Added new criteria for imaging in initial diagnosis of MS

Spinal infection

 Aligned new diagnosis and management criteria with Infectious Disease Society of America (IDSA) and University of Michigan guidelines



Axial spondyloarthropathy

- o Added definition of inflammatory back pain
- Added diagnostic testing radiography requirements

Cervical injury

 Aligned pediatric cervical trauma criteria with American College of Radiology (ACR) guidelines

Thoracic or lumbar injury

- Revised diagnostic imaging strategy to include radiography and limited use of MRI for a known fracture
- Removed indication for follow-up imaging of progressively worsening pain without fracture or neurologic deficits

Syringomyelia

Removed surveillance imaging indication

Non-specific low back pain

 Aligned pediatric low back pain criteria with American College of Radiology (ACR) guidelines

Effective for dates of service on and after September 12, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Extremity Imaging

Updates by section

Advanced Imaging of the Extremities

Osteomyelitis or septic arthritis

Myositis

Removed CT as a follow-up to nondiagnostic MRI due to lower diagnostic accuracy of CT

Epicondylitis and Tenosynovitis – long head of biceps

Removed these sections due to lack of evidence supporting imaging for this diagnosis

Plantar fasciitis and fibromatosis

- Removed CT as a follow-up to nondiagnostic MRI due to lower diagnostic accuracy of CT
- Added specific conservative management requirements

Brachial plexus mass

Added specific requirement for suspicious findings on clinical exam or prior imaging



Morton's neuroma

Added requirements for focused steroid injection, orthoses, and plan for surgery

Adhesive capsulitis

 Added requirement for planned intervention (manipulation under anesthesia or lysis of adhesions)

Rotator cuff tear

Labral tear - shoulder

Labral tear - hip

- o Defined specific exam findings and updated duration of conservative management
- Updated recurrent labral tear to meet same criteria as an initial tear (shoulder only)

Triangular fibrocartilage complex tear

o Added requirement for radiographs and conservative management for chronic tear

Ligament tear - knee; meniscal tear

- o Added requirement for radiographs for specific scenarios
- Increased duration of conservative management for chronic meniscal tears

Ligament and tendon injuries - foot and ankle

Defined required duration of conservative management

Chronic anterior knee pain including chondromalacia patella and patellofemoral pain syndrome

 Increased duration of conservative management and specified requirement for chronic anterior knee pain

Intra-articular loose body

Added requirement for mechanical symptoms

Osteochondral lesion (including osteochondritis dissecans, transient dislocation of patella)

Added new requirement for radiographs

Entrapment neuropathy

Excluded carpal and cubital tunnel syndromes

Persistent lower extremity pain

- Defined duration of conservative management
- Excluded hip joint (addressed in other indications)

Upper extremity pain

Excludes shoulder joint (addressed in other indications)



 Revised diagnostic testing strategy to limit CT use when MRI cannot be performed or is nondiagnostic

Knee arthroplasty, presurgical planning

Limited to MAKO and robotic assist arthroplasty cases

Perioperative imaging, not otherwise specified

Require radiographs or ultrasound prior to advanced imaging

Effective for dates of service on and after September 12, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Vascular Imaging

Updates by section

Vascular Imaging

Added alternative non-vascular imaging approaches, where applicable

Hemorrhage, Intracranial

- Specified clinical scenario for subarachnoid hemorrhage
- Added pediatric intracerebral hemorrhage indication

Horner's syndrome; Pulsatile tinnitus; Trigeminal neuralgia

o Removed condition management indication for continued vascular evaluation

Stroke/TIA

Stenosis or occlusion (intracranial/extracranial)

- Added acute and subacute time frames
- Removed carotid/cardiac workup requirement for intracranial vascular evaluation
- Added condition management specifications
- Separated sections into anterior/posterior circulation (carotid artery and vertebral or basilar arteries, respectively)

Pulmonary Embolism

- Added non-diagnostic chest radiograph requirement for all indications
- Added pregnancy-adjusted YEARS algorithm

Peripheral Arterial Disease

 Added new post-revascularization indication to both upper and lower extremity PAD evaluation



Effective September 3, 2021

Alpha1-Proteinase Inhibitors, 5.01.624

New policy

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

- Aralast® NP (alpha1-proteinase inhibitor (PI) [human])
- Glassia® (alpha1-PI [human])
- Prolastin®-C (alpha1-PI [human])
- Zemaira® (alpha1-PI [human])
 - Treatment of adults with emphysema due to hereditary deficiency of alpha1-PI (alpha1-antitrypsin deficiency)

Drugs for Rare Diseases, 5.01.576

New drugs added to policy

- Aldurazyme® (laronidase)
 - Treatment of mucopolysaccharidosis type I (MPS I), including Hurler, Hurler-Scheie, and Scheie forms, in patients age 6 months and older
- o Brineura® (cerliponase alfa)
 - Treatment of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) in patients age 3 and older
- Gamifant™ (emapalumab-lzsg)
 - Treatment of adult and pediatric patients with primary hemophagocytic lymphohistiocytosis (HLH)
- Kanuma® (sebelipase alfa)
 - Treatment of lysosomal acid lipase (LAL) deficiency
- Naglazyme® (galsulfase)
 - Treatment of mucopolysaccharidosis type VI (MPS VI, also known as Maroteaux-Lamy syndrome), in patients age 3 months and older
- Sylvant® (siltuximab)
 - Treatment of patients with multicentric Castleman's disease (MCD) in patients age
 18 and older

Gonadotropin Releasing Hormone (GnRH) Analogs, 5.01.625

New policy

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

Breast cancer

- Zoladex® (goserelin)
 - Palliative treatment of advanced breast cancer in pre- and perimenopausal women



Central precocious puberty

- Fensolvi® (leuprolide acetate)
- Generic leuprolide
- Lupron Depot PED® (leuprolide acetate)
- Supprelin LA® (histrelin implant)
- Triptodur® (triptorelin),
- Vantas® (histrelin implant)
 - Treatment of children with abnormally early puberty

Endometriosis

- o Generic leuprolide
- Lupaneta Pack® (leuprolide/norethindrone)
- Lupron Depot® (leuprolide acetate)
- Zoladex® (goserelin)
 - Management of endometriosis, including pain relief and reduction of endometriotic lesions
- Orilissa® (elagolix)
 - Treatment of moderate to severe pain associated with endometriosis

Gender dysphoria

- Fensolvi® (leuprolide acetate)
- Generic leuprolide
- Lupron Depot® (leuprolide acetate)
- Lupron Depot PED® (leuprolide acetate)
- Supprelin LA® (histrelin implant)
- Trelstar® (triptorelin pamoate)
- Triptodur® (triptorelin)
- Vantas® (histrelin implant)
 - Treatment of gender dysphoria in adolescents

Prostate cancer

- Eligard® (leuprolide acetate)
- Firmagon® (degarelix)
- Generic leuprolide
- Lupron Depot® (leuprolide acetate)
- Orgovyx® (relugolix)
- Trelstar® (triptorelin pamoate)
- Zoladex® (goserelin)
 - Palliative treatment of metastatic prostate cancer
- Zoladex® (goserelin)
 - Treatment of locally confined Stage T2b-T4 (Stage B2-C) prostate cancer when used in combination with flutamide



Uterine fibroids

- o Generic leuprolide
- Lupron Depot® (leuprolide acetate)
 - Treatment of anemia due to uterine fibroids
 - To reduce the size of uterine fibroids prior to surgery
- Oriahnn® (elagolix/estradiol/norethindrone acetate)
 - Management of heavy bleeding related to uterine fibroids in premenopausal patients age 18 and older
- Zoladex® (goserelin)
 - Use as an endometrial-thinning agent prior to endometrial ablation for abnormal uterine bleeding

Effective August 6, 2021

Pharmacologic Treatment of Duchenne Muscular Dystrophy, 5.01.570

Site of service review added

Vyondys 53® (golodirsen)

Pharmacotherapy of Cushing's Disease and Acromegaly, 5.01.548

New drugs added to policy

- Bynfezia® Pen (octreotide)
- o Generic octreotide
- Sandostatin® (octreotide)
- Sandostatin® LAR Depot (octreotide)
- Somatuline® Depot (lanreotide)
 - Treatment of acromegaly in adults age 18 and over
 - Treatment of adults with inoperable, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
 - Treatment of adults with carcinoid syndrome
 - Treatment of adults with profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas)

Site of Service: Infusion Drugs and Biologic Agents, 11.01.523

Site of service review added

Vyondys 53® (golodirsen)



Medical policies

New medical policies Effective June 1, 2021

Surgical Interruption of Pelvic Nerve Pathways for Chronic Pelvic Pain, 4.01.502

New policy

Uterine nerve ablation or presacral neurectomy for the treatment of chronic pelvic pain is considered investigational

Revised medical policies Effective June 1, 2021

Colorectal Cancer Screening, 10.01.519

Coverage statement updated

Age range of 50-75 years has been added for preventive screen colonoscopy

New section added

Other covered preventive screening methods, including the following stool-based and direct visualization tests:

- Fecal immunochemical test (FIT)
- o FIT-DNA test
- Guaiac-based fecal occult blood test (gFOBT)
- CT colonography
- Flexible sigmoidoscopy
- Flexible sigmoidoscopy with FIT

Removed from policy

List of conditions that are considered not medically necessary for diagnostic colonoscopy

Electrical Stimulation Devices, 1.01.507

Investigational criteria updated

The following devices are considered investigational for all indications:

- Electrical sympathetic stimulation therapy
- o Galvanic or high-voltage galvanic stimulation
- H-wave stimulation
- Microcurrent electrical nerve stimulation (MENS)
- Pulsed electrical stimulation and pulsed electromagnetic therapy
- Remote electrical neuromodulation (REN)
- Transcutaneous electrical modulation pain reprocessing (TEMPR)



o Transcutaneous supraorbital electrical nerve stimulator

Pharmacy policies

Revised pharmacy policies Effective June 1, 2021

Antibody-Drug Conjugates, 5.01.582

New drug added to policy

- Zynlonta® (loncastuximab tesirine-lpyl)
 - Treatment of adult patients with relapsed or refractory large B-cell lymphoma

Immune Checkpoint Inhibitors, 5.01.591

New drug added to policy

- Jemperli® (dostarlimab-gxly)
 - Treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC)

Drugs with new indications

- Keytruda® (pembrolizumab)
 - First-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma
- Opdivo® (nivolumab)
 - Treatment of advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma

Medical Necessity Criteria for Pharmacy Edits, 5.01.605

Anticonvulsants

Medical necessity criteria updated

- Brand topiramate extended-release capsules
- Qudexy XR® (topiramate extended-release capsules)
 - The age limit has been reduced from 6 years to 2 years and older for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome

Atopic Dermatitis

New drugs added to policy

- Elidel® (pimecrolimus)
- Protopic® (tacrolimus)



Treatment of atopic dermatitis in patients age 2 and older

Brand Drugs for ADHD and Stimulants for Other Psychiatric Conditions

New drug added to policy

- Qelbree[™] (viloxazine extended-release)
 - Treatment of attention deficit hyperactivity disorder (ADHD) in patients age 6 to 17 years of age

Brand Oral Antibiotics and Their Generics

New drugs added to policy

- o Omeclamox-Pak® (omeprazole, clarithromycin, amoxicillin)
 - Treatment of Helicobacter pylori infection and duodenal ulcer disease in adults
- Talicia® (omeprazole, amoxicillin, rifabutin)
 - Treatment of Helicobacter pylori infection in adults

Brand Oral Corticosteroids

New policy section

New drugs added to policy

- Alkindi® Sprinkle (hydrocortisone)
- Cortef® (hydrocortisone)
- Dxevo® (dexamethasone)
- Hemady® (dexamethasone)
- Medrol® (methylprednisolone)
- Orapred ODT® (prednisolone)
- Pediapred® (prednisolone)
- Taperdex® (dexamethasone)
- Zcort® (dexamethasone)

Calcium Channel Blockers

New drugs added to policy

- Azor® (amlodipine/olmesartan)
- Caduet® (amlodipine/ atorvastatin)
- Exforge® (amlodipine/valsartan)
- Exforge® HCT (amlodipine/valsartan/hydrochlorothiazide)
- Lotrel® (amlodipine/benazepril)
- Tarka® (verapamil/trandolapril)
- Tribenzor® (amlodipine/olmesartan/hydrochlorothiazide)
- Twynsta® (amlodipine/telmisartan)

New drug added to policy

- o Prestalia® (amlodipine/perindopril)
 - Treatment of hypertension



Miscellaneous Oncology Drugs, 5.01.540

New drugs added to the policy

- Cosela[™] (trilaciclib)
 - To decrease chemotherapy-induced myelosuppression in adult patients with extensive-stage small cell lung cancer
- Pepaxto® (melphalan flufenamide)
 - Treatment of relapsed or refractory multiple myeloma in patients age 18 and older

Drugs with new indications

- Darzalex Faspro™ (daratumumab and hyaluronidase-fihj)
 - Treatment of adult patients with light chain (AL) amyloidosis when used in combination with bortezomib, cyclophosphamide, and dexamethasone as first-line therapy
 - Treatment of adult patients with multiple myeloma when used in combination with bortezomib, thalidomide, and dexamethasone as first-line therapy in patients who are eligible for autologous stem cell transplant
- Sarclisa® (isatuximab-irfc)
 - Treatment of multiple myeloma when given in combination with Kyprolis® (carfilzomib) and dexamethasone
- Trodelvy (sacituzumab govitecan-hziy)
 - Treatment of urothelial cancer

Medical necessity criteria updated

- Trodelvy (sacituzumab govitecan-hziy)
 - Inoperable locally advanced triple-negative breast cancer has been added to the breast cancer indication

Pharmacologic Treatment of Idiopathic Pulmonary Fibrosis, 5.01.555

New drugs added to policy

- Actemra® (tocilizumab)
 - Treatment of interstitial lung disease associated with systemic sclerosis (SSc-ILD) in patients age 18 and older
- Tyvaso® (treprostinil)
 - Treatment of pulmonary hypertension associated interstitial lung disease (PH-ILD) in patients age 18 and older

Pharmacotherapy of Miscellaneous Autoimmune Diseases, 5.01.564

New drugs added to policy

- Kineret® (anakinra)
 - Treatment of deficiency of interleukin-1 receptor antagonist (DIRA)
 - Treatment of cryopyrin-associated periodic syndromes (CAPS)
- Lupkynis™ (voclosporin)



• Treatment of adult patients with active lupus nephritis

Medical necessity criteria updated

- Benlysta® (belimumab)
 - The requirement of no previous use of Benlysta® (belimumab) in the past 12 months has been removed
 - A requirement has been added that Benlysta® (belimumab) is not used at the same time as Lupkynis™ (voclosporin) for the treatment of active lupus nephritis

Archived policies

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

Effective June 1, 2021

Cardiac Rehabilitation in the Outpatient Setting, 8.03.08

Keratoprosthesis, 9.03.01

Outpatient Pulmonary Rehabilitation, 8.03.05

Deleted policies

No updates this month

Coding updates

Added codes Effective September 3, 2021

The following codes will require review for medical necessity and prior authorization for services on or after September 3, 2021

American Society of Addiction Medicine (ASAM)

0362T, 0905, 0912, 97151, 97153, 97154, 97155, 97156, 97158, H0015, H0017, H0035, S9480



Arthrotomy Hip, InterQual® Criteria 27269

Spinal Orthosis, 1.03.502 L0622, L0623, L0624

Specialty Rx Non-Oncology Alpha 1- Proteinase Inhibitor, InterQual® Criteria

J0256

Surgical Dressings and Wound Care Supplies, 9.01.511A6205

Wound Debridement, InterQual® Criteria 11008

Revised codes Effective June 1, 2021

AIM Specialty Health® Clinical Appropriateness Guidelines for Genetic Testing

No longer requires review for medical necessity and prior authorization.

81545

Keratoprosthesis, 9.03.01

No longer requires review for medical necessity and prior authorization. Policy archived.

65770, L8609

Keratoprosthesis, 9.03.01

No longer requires review for medical necessity. Policy archived.

C1818