

# Medical Policy and Coding Updates December 1, 2022

#### **Special notices**

## **Effective April 9, 2023**

Updates to AIM Specialty Health® Clinical Appropriateness Guidelines

Effective for dates of service on and after April 9, 2023, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Advanced Imaging

## **Updates by section**

#### Abdominal and pelvic imaging

Abdominal and/or pelvic pain, undifferentiated Pancreatitis

Removed indication for MRI following non-diagnostic CT

#### **Brain imaging**

Bell's palsy (peripheral facial nerve palsy)

Limited the use of CT to when an MRI can't be performed

#### **Oncologic imaging**

Breast cancer screening

o Removed NBN gene mutation

#### Histiocytic neoplasms

 PET/CT surveillance frequency/duration is now aligned with National Comprehensive Cancer Network (NCCN) category 2A guidelines



#### Multiple myeloma

 Added restaging/treatment response, or follow-up every 12 months for bone marrow supply MRI with smoldering myeloma (SM) or solitary plasmacytoma (SP)

#### Prostate cancer

 Removed waiver that conventional imaging is not required for low-risk disease for PFT/CT

#### Thyroid cancer

- Removed medullary carcinoma FDG-PT/CT for diagnostic workup to align with National Comprehensive Cancer Network (NCCN) guidelines
- Added criteria for medullary carcinoma for diagnostic workup/management to align with NCCN guidelines

Effective for dates of service on and after April 9, 2023, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Advanced Imaging of the Heart

## **Updates by section**

#### **Cardiac Imaging**

Myocardial perfusion imaging (MPI) Perfusion PET Stress cardiac MRI Stress echocardiography (SE)

o Removed indication for suspected coronary artery disease for people without symptoms

Myocardial perfusion imaging (MPI)

Perfusion PET

Stress echocardiography (SE)

 Removed option of surveillance imaging following percutaneous coronary intervention (PCI)

#### Cardiac MRI

Coronary computed tomography angiography (CCTA)

 Added specific clinical scenarios for evaluation of suspected coronary artery congenital abnormalities



#### Fractional flow reserve – computed tomography (FFR-CT)

 Added specific medical necessity criteria, including ongoing symptoms even with maximum guideline-directed medical therapy

#### Resting transthoracic echocardiography (TTE)

 Evaluation for people who are stable after undergoing transcatheter placement of bioprosthetic valve has been revised from within the first 3 months to an annual review

Effective for dates of service on and after April 9, 2023, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Radiation Oncology

## **Updates by section**

#### **Radiation Therapy**

#### Skin cancer

 Added exclusion that image guidance radiation therapy is not medically necessary to guide superficial radiotherapy for non-melanoma skin cancer

## Effective March 1, 2023

#### Drugs for Rare Diseases, 5.01.576

#### Medical necessity criteria updated

- Lumizyme® (alglucosidase alfa)
  - Added dose limit of no more than 20 mg per kg of body weight administered every
     2 weeks

#### Site of service review added

- Mepsevii® (vestronidase alfa-vjbk)
- Naglazyme® (galsulfase)

#### **Drug added**

- Mepsevii® (vestronidase alfa-vjbk)
  - Treatment of mucopolysaccharidosis type VII (MPS VII; Sly syndrome)

#### Intravenous Iron Replacement Products, 5.01.630

#### New policy

#### **Drugs added**

Feraheme® (ferumoxytol)



- Generic ferumoxytol
- Injectafer® (ferric carboxymaltose) IV
- o Monoferric® (ferric derisomaltose) IV
  - Treatment of iron deficiency anemia (IDA) when criteria are met

#### Site of Service: Infusion Drugs and Biologic Agents, 11.01.523

#### Drugs added

- Mepsevii® (vestronidase alfa-vjbk)
- Naglazyme® (galsulfase)

## **Effective February 18, 2023**

Updates to AIM Specialty Health® Clinical Appropriateness Guidelines

Effective for dates of service on and after February 18, 2023, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Genetic Testing

## **Updates by section**

## Carrier Screening in the Prenatal Setting and Preimplantation Genetic Testing

- Clarified testing requirements for Fragile X Syndrome in patients with unexplained ovarian failure
- o Clarified carrier screening restrictions for autosomal recessive conditions
- Expanded selected relevant screening for patients at high risk based on ethnicity (e.g., Ashkenazi Jewish, French Canadian, Mennonite) and the conditions for which to test
- Expanded screening when one or both individuals do not have access to biological family history, and allowed preimplantation testing when reproductive donor is of unknown carrier risk

## Cell-free DNA Testing (Liquid Biopsy) for the Management of Cancer

 Removed specific language regarding the brand names of tests which are considered medically necessary, and generally does not specifically name the therapeutic agents which must be under consideration, allowing appropriate review of claims when new therapies or tests are approved by the FDA



#### **Genetic Testing for Inherited Conditions**

- Clarified criteria on cardiomyopathies for which testing is medically necessary
- o Allowed for broader panels for arrhythmia and cardiomyopathy syndromes

## **Hereditary Cancer Testing**

- Added condition-specific criteria based on National Comprehensive Cancer Network (NCCN) recommendations, as well as other clinical guidelines
- Limited testing in the following scenarios:
  - Prostate cancer (in select scenarios) for patients without additional familial risk
  - Patients with only a second-degree relative with ovarian cancer
  - Patients with breast cancer and family history in some select scenarios (e.g., lobular histology only plus personal or family history of gastric cancer)

#### **Pharmacogenomics Testing**

- o Limited testing for patients being treated with warfarin
- Specified biomarkers for which one-time testing is considered medically necessary

#### **Somatic Tumor Testing**

- Clarified criteria about tumor stage in cutaneous melanoma and cholangiocarcinoma, and about histology in non-small cell lung cancer, ovarian cancer (epithelial) and prostate cancer (adenocarcinoma)
- o Chromosomal microarray analysis may require additional review
- Specified the genes that must be included in panels for hematologic malignancy testing
- o Allowed testing for patients with metastatic uveal melanoma
- Removed specific language regarding the brand names of tests which are considered medically necessary, and generally does not specifically name the therapeutic agents which must be under consideration, allowing appropriate review of claims when new therapies or tests are approved by the FDA

### **Use of Polygenic Risk Scores in Genetic Testing**

Limited polygenic risk score testing



#### Whole Exome Sequencing and Whole Genome Sequencing

#### Whole exome sequencing

- Allowed analysis using the same criteria as the initial test
- Limited testing for congenital bilateral hearing loss of unknown etiology, developmental and epileptic encephalopathy, and single anomaly with positive family history

## **Effective February 3, 2023**

#### Gender Transition/Affirmation Surgery and Related Services, 7.01.557

#### **Standard Benefit Coverage**

Genital or "bottom surgery"

#### Surgery added

#### Site of service review added

Hysterectomy will be reviewed for medical necessity. Breast reduction, laparoscopic-assisted vaginal hysterectomy, rhinoplasty, and vaginal hysterectomy will also include site of service review.

#### Genital or "bottom surgery"

#### Note removed

Hysterectomies for gender transition/affirmation are not subject to medical necessity review

#### Hair removal (by laser or electrolysis) prior to genital surgery

#### Medical necessity criteria updated

Hair removal will be done by a physician, nurse practitioner, physician assistant, or by a professional who is licensed, certified, registered, or otherwise approved by the state for hair removal (e.g., a licensed aesthetician)

#### **Expanded Benefit Coverage**

#### Medical necessity criteria updated

Facial, body, or extremity hair removal not related to genital surgery now has separate criteria

## Recommendations by Licensed Mental Health Professionals

#### Section title expanded

Now includes "additional timing requirements for surgery and mental health recommendation letters, and for pre-surgery surgeon evaluations"

#### Medical necessity criteria updated

Removed requirement that psychiatrists are board-eligible or board-certified



- Evaluations may be performed by and letters written by state licensed master's and doctoral mental health clinicians who aren't licensed to practice independently if letters are co-signed by mental health professionals who are state licensed to practice independently
- Revised mental health recommendation letter content
  - Combined two criteria into documentation of the history of the person's gender dysphoria and gender identity transition to include assigned gender at birth, age of awareness of gender incongruence, symptoms of gender dysphoria, and actions taken to transition to the desired gender
  - Past and present treatment for gender dysphoric symptoms has been revised to any current or past psychiatric treatment
- Additional timing requirements for surgery and mental health recommendation letters, and pre-surgery surgeon evaluations now includes the statement: "for facial, body, or extremity hair removal not related to genital surgery, pre-procedure evaluations by either a referring medical provider or the hair removal provider are acceptable as the presurgery surgeon evaluations"

#### Hysterectomy for Non-Malignant Conditions, 7.01.548

#### Policy notes updated

- Replaced statement that this policy does not apply to hysterectomy for gender transition/affirming surgeries to reference the medical policy Gender Transition/Affirmation Surgery and Related Services, 7.01.557
- Clarified that the policy does not apply to hysterectomy for gynecologic malignant conditions

#### Miscellaneous Oncology Drugs, 5.01.540

#### **Drugs added**

- Elzonris<sup>™</sup> (tagraxofusp-erzs)
  - Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and children age 2 years and older
- Onivyde® (irinotecan liposome injection)
  - Treatment of pancreatic cancer that has spread to other parts of the body
  - Treatment of bile duct cancer that has spread to other parts of the body

#### Site of Service: Select Surgical Procedures, 11.01.524

#### Policy added

**Gender Transition/Affirmation Surgery and Related Services, 7.01.557** added to policy to address breast reduction, laparoscopic-assisted vaginal hysterectomy, rhinoplasty, and vaginal hysterectomy.



#### Spravato® (esketamine) Nasal Spray, 5.01.609

Indication: Depression

#### Medical necessity criteria updated

- A trial and failure of four antidepressants from at least two different classes has been reduced to a trial and failure of three antidepressants from two different classes
- A trial and failure of three antidepressants from at least two different classes plus an augmenting agent has been reduced to two antidepressants from two different classes plus an augmenting agent
- No current substance use disorder unless in remission now includes definition of three months of complete abstinence

Indication: New course of Spravato® after previous treatment

#### Medical necessity criteria updated

No current substance use disorder unless in remission now includes definition of three months of complete abstinence

#### Investigational criteria updated

Use of Spravato® (esketamine) along with any other formulation of ketamine or with any psychedelic drug is considered investigational

#### All indications

#### Medical necessity criteria updated

Use of Spravato® (esketamine) with more than one provider/group/clinic at the same time is considered not medically necessary

#### Documentation requirements updated

- For failed medication trials, each medication that failed must be individually identified, along for the reason(s) for failure
- For each failed medication trial, there must be documentation of at least 30 continuous days with no or inadequate improvement unless stopped sooner because of intolerable adverse effects

## Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders, 2.01.526

#### Policy statements added

- Types of transcranial magnetic stimulation (TMS) covered
  - Deep transcranial magnetic stimulation of the brain
  - Standard/conventional repetitive transcranial magnetic stimulation of the brain
  - Theta burst stimulation of the brain
- o Specific medical conditions where TMS may be considered medically necessary
  - Major depression as a component of bipolar disorder



- Major depressive disorder
- Obsessive-compulsive disorder

#### Investigational criteria updated

- Added list of all other types of transcranial magnetic stimulation (TMS)
- Theta burst stimulation is considered investigational for the treatment of major depression as a component of bipolar disorder and the treatment of obsessivecompulsive disorder
- TMS for all other psychiatric conditions, for all substance use conditions, and for all neurologic conditions are considered investigational
- Use of TMS to boost the effectiveness of other treatment modalities, including but not limited to drugs or other devices, is considered investigational
- Technology computer-assisted TMS of the prefrontal cortex is considered investigational

#### Major depressive disorder

#### Medical necessity criteria updated

- o Age requirement reduced from 18 years and older to age 15 years and older
- o The number of failed medication trials has been reduced from four to three
- o Theta burst stimulation has been added as a type of TMS for this condition

#### Major depression as a component of bipolar disorder

#### Medical necessity criteria updated

- The number of failed medication trials has been increased from two to three
- o Theta burst stimulation is considered investigational for this condition

#### Obsessive-compulsive disorder

#### Indication added

#### Medical necessity criteria added

- Standard/conventional TMS and deep TMS may be considered medically necessary
- Theta burst stimulation is considered investigational for this condition

#### All indications

#### Contraindications added

- History of or presence of a brain tumor
- History of repetitive or severe head trauma/traumatic brain injury

#### Policy sections added

#### Medical necessity criteria added

- Course of full intensive TMS
- Extended intensive course or extended intensive phase (deep TMS)
- Extended taper
- Accelerated intensive TMS



- Maintenance TMS
- o Repeat full intensive course
- Short of brief intensive course
- o Consecutive or overlapping courses of TMS for different conditions
- o TMS with more than one provider at the same time
- o TMS along with Spravato® (esketamine), or ketamine, or any other psychedelic drug
- TMS along with other types of neuromodulation

## **Effective January 6, 2023**

Services Reviewed Using InterQual® Criteria, 10.01.530

Acute adult

See InterQual® for medical necessity criteria

#### Services added

- Electroconvulsive therapy (ECT)
- Total ankle replacement

**Total Ankle Replacement, 7.01.577** 

Policy deleted

Now included in Services Reviewed Using InterQual® Criteria, 10.01.530

## Effective December 1, 2022

**Botulinum Toxins**, 5.01.512

New policy replaces InterQual® criteria

#### **Drugs added**

- Botox® (onabotulinumtoxinA)
  - Prevention of chronic migraine headaches in adults age 18 years and older
  - Treatment of overactive bladder (OAB) in adults age 18 years and older
  - Treatment of urinary incontinence due to overactivity of the detrusor muscle in adults age 18 years and older
  - Treatment of neurogenic detrusor overactivity (NDO) in patients age 5 to 17 years of age
  - Treatment of cervical dystonia in adults age 18 years and older
  - Treatment of adults with dystonia that results in functional impairment and/or pain
  - Treatment of blepharospasm with dystonia in patients age 12 years and older
  - Treatment of chronic anal fissure
  - Treatment of esophageal achalasia
  - Treatment of Hirschsprung disease



- Treatment of lower and upper limb spasticity in patients age 2 years and older
- Treatment of strabismus in patients age 12 years and older
- Dysport® (abobotulinumtoxinA)
  - Treatment of cervical dystonia in adults age 18 years and older
  - Treatment of adults with dystonia that results in functional impairment and/or pain
  - Treatment of chronic anal fissure
  - Treatment of esophageal achalasia
  - Treatment of Hirschsprung disease
  - Treatment of lower and upper limb spasticity in patients age 2 years and older
- Jeuveau<sup>™</sup> (prabotulinumtoxinA-xvfs)
  - For cosmetic use and not covered
- Myobloc® (rimabotulinumtoxinB)
  - Treatment of cervical dystonia in adults age 18 years and older
  - Treatment of adults with dystonia that results in functional impairment and/or pain
  - Treatment of chronic hypersalivation in adults
- Xeomin® (incobotulinumtoxinA)
  - Treatment of upper limb spasticity in patients age 2 to 17 years
  - Treatment of cervical dystonia in adults age 18 years and older
  - Treatment of adults with dystonia that results in functional impairment and/or pain
  - Treatment of blepharospasm in patients age 18 years and older
  - Treatment of chronic anal fissure
  - Treatment of chronic hypersalivation in patients age 2 years and older
  - Treatment of esophageal achalasia
  - Treatment of Hirschsprung disease
  - Treatment of upper limb spasticity in adults

#### Pharmacologic Treatment of Gout, 5.01.616

#### Medical necessity criteria updated

Krystexxa® (pegloticase) must be given with oral methotrexate 15 mg weekly, unless there is a medical reason why methotrexate can't be taken

#### Pharmacotherapy of Inflammatory Bowel Disorder, 5.01.563

#### Medical necessity criteria updated

- Tysabri® (natalizumab)
  - Patient must have tried and failed treatment with one or more TNF blockers

#### Temporomandibular Joint Disorder, 2.01.535

- Botulinum toxin is considered investigational as a nonsurgical treatment for temporomandibular joint disorder
- For dates of service starting on and after December 1, 2022, codes for botulinum toxin will require review for medical necessity and prior authorization (see also the **Coding** updates section)



#### Treatment of Hyperhidrosis, 8.01.519

- o Botulinum toxin is considered:
  - Medically necessary as a treatment for primary focal hyperhidrosis when criteria are met
  - Investigational as a treatment for severe secondary gustatory hyperhidrosis
- For dates of service starting on and after December 1, 2022, codes for botulinum toxin will require review for medical necessity and prior authorization (see also the **Coding** updates section)

#### **Medical policies**

No updates this month

#### **Pharmacy policies**

## New pharmacy policies Effective December 1, 2022

Gene Therapies for Thalassemia, 5.01.42

New policy

Drug added

- Zynteglo® (betibeglogene autotemcel)
  - Treatment of people with beta thalassemia who are dependent on blood transfusions

## Revised pharmacy policies Effective December 1, 2022

Chimeric Antigen Receptor Therapy for Leukemia and Lymphoma, 8.01.63

#### Indication added

- Kymriah™ (tisagenlecleucel)
  - Treatment of adults age 18 years and older with follicular lymphoma that has come back or has not responded to treatment



#### Indication added

- Breyanzi® (lisocabtagene maraleucel)
  - Treatment of adults with large B-cell lymphoma that does not respond to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy, or does not respond to first-line chemoimmunotherapy or relapses after first-line chemoimmunotherapy and the person is not able to have a blood stem cell transplant due to medical problems or the person's age

#### Documentation requirements updated

Adequate organ and bone marrow function has been revised to "stable renal, liver, pulmonary, cardiac, and bone marrow function"

#### Drugs for Rare Diseases, 5.01.576

#### **Drug added**

- Xenpozyme<sup>™</sup> (olipudase alfa-rpcp)
  - Treatment of non-central nervous system symptoms of acid sphingomyelinase deficiency (ASMD)

#### Dupixent® (dupilumab), 5.01.575

#### Indication added

Treatment of people age 18 years and older with pruigo nodularis (PN)

#### Pharmacologic Treatment of Psoriasis, 5.01.629

#### Drug added

- Sotyktu<sup>™</sup> (deucravacitinib)
  - Treatment of moderate to severe plaque psoriasis in adults age 18 years and older

## Use of Vascular Endothelial Growth Factor Receptor (VEGF) Inhibitors and Other Angiogenesis Inhibitors in Oncology Treatment, 5.01.517

#### **Drugs added**

- Alymsys® (bevacizumab-maly)
- Vegzelma® (bevacizumab-adcd)
  - Treatment for people who haven't responded to or can't tolerate Avastin® (bevacizumab) or Zirabev® (bevacizumab-bvzr)

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

#### Drug added

- Cimerli® (ranibizumab-egrn)
  - Treatment of neovascular (Wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy (DR), and myopic choroidal neovascularizatoin (mCNV)



#### Medical necessity criteria updated

- Beovu® (brolucizumab-dbll)
- Eylea® (aflibercept)
- Macugen® (pegaptanib)
- Susvimo<sup>™</sup> (ranibizumab)
- Vabysmo<sup>™</sup> (faricimab-svoa)
  - Cimerli® (ranibizumab-eqrn) has been added to the list of drugs that may not be used in combination with the drugs listed above

#### Note updated

The names of the specific biosimilars bevacizumab-adcd and bevacizumab-maly have been added to references to bevacizumab

#### **Archived policies**

No updates this month

#### **Deleted policies**

No updates this month

#### **Coding updates**

## Added codes Effective January 6, 2023

See also the **Special notices** section above

#### Services Reviewed Using InterQual® Criteria, 10.01.530

Now requires review for medical necessity and prior authorization.

90870



## Effective December 1, 2022

See also the **Special notices** section above

**Botulinum Toxins**, 5.01.512

Now requires review for medical necessity and prior authorization.

J0585, J0586, J0587, J0588

#### Temporomandibular Joint Disorder, 2.01.535

Now requires review for medical necessity and prior authorization.

J0585, J0586, J0587, J0588

#### Treatment of Hyperhidrosis, 8.01.519

Now requires review for medical necessity and prior authorization.

J0585, J0586, J0587, J0588

Use of Vascular Endothelial Growth Factor Receptor (VEGF) Inhibitors and Other Angiogenesis Inhibitors in Oncology Treatment, 5.01.517

Now requires review for medical necessity.

C9142

## Revised codes Effective December 1, 2022

#### Amyloid Antibodies for the Treatment of Alzheimer's Disease, 5.01.626

No longer requires review for medical necessity. Now requires review for investigational. Prior authorization still required.

J0172



## Removed codes Effective January 6, 2023

**Total Ankle Replacement, 7.01.577** 

No longer requires review.

27703

## **Effective December 1, 2022**

#### Therapeutic Radiopharmaceuticals in Oncology, 6.01.525

No longer requires review for medical necessity. Now requires review for investigational. Prior authorization still required.

A9593, A9594, A9595, A9596, A9800