

# Medical Policy and Coding Updates

## November 3, 2022

### Special notices

## 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
- 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
- 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

- 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)
- Chromosomal microarray analysis may require additional review
- Specified the genes that must be included in panels for hematologic malignancy testing
- 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 mental health professionals who are state licensed to practice independently co-sign the letters
- 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 pre-surgery 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 to medical policy [7.01.557, Gender Transition/Affirmation Surgery and Related Services](#)
- Clarified that the policy does not apply to hysterectomy for gynecologic malignant conditions

### Miscellaneous Oncology Drugs, 5.01.540

#### Drugs added

- Elzonris™ (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
- 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 obsessive-compulsive 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**

- Age requirement reduced from 18 years and older to age 15 years and older
- The number of failed medication trials has been reduced from four to three
- 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
- 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
- Repeat full intensive course
- Short of brief intensive course

- Consecutive or overlapping courses of TMS for different conditions
- TMS with more than one provider at the same time
- 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™ (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

- 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)

## Effective November 4, 2022

### Authorization for Observation versus Inpatient Admission Level of Care, 10.01.534

#### New policy

Criteria and medical conditions added for observation stays for adults and children

### Immune Globulin Therapy, 8.01.503

#### Site of service review added

- Cutaquig® (immune globulin subcutaneous [human] - hipp)

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

#### Site of service review added

- Cutaquig® (immune globulin subcutaneous [human] - hipp)

## Medical policies

## New medical policies Effective November 1, 2022

### Surgical Left Atrial Appendage Occlusion Devices for Stroke Prevention in Atrial Fibrillation, 7.01.172

#### New policy

The use of surgical left atrial appendage occlusion devices, including the AtriClip® device, for stroke prevention in people with atrial fibrillation is considered investigational

## Revised medical policies Effective November 1, 2022

### Children's Therapeutic Positioning Equipment, 1.01.530

Medical necessity criteria added

Bath and/or toilet positioning equipment

### Pharmacy policies

## New pharmacy policies Effective November 1, 2022

### Pharmacologic Treatment of Psoriasis, 5.01.629

New policy

Drugs added

- Enbrel® (etanercept)
- Humira® (adalimumab)
- Infliximab (Janssen – unbranded)
- Inflectra® (infliximab-dyyb)
- Remicade® (infliximab)
- Taltz® (ixekizumab)
- Stelara® (ustekinumab)
- Skyrizi® (risankizumab-rzaa)
- Tremfya® (guselkumab)
- Otezla® (apremilast)
- Siliq™ (brodalumab)
- Cosentyx® (secukinumab)
- Cimzia® (certolizumab pegol)
- Renflexis™ (infliximab-abda)
- Avsola™ (infliximab-axxq)
- Ilumya™ (tildrakizumab-asmn)
  - The drugs listed above were moved from the policy Pharmacotherapy of Arthropathies, 5.01.550
  - Medical necessity criteria remain unchanged

**Drugs added**

- Vtama® (tapinarof)
- Zoryve® (roflumilast)
  - Treatment of plaque psoriasis

**Drug added**

- Spevigo® (spesolimab-sbzo)
  - Treatment of generalized pustular psoriasis (GPP) in adults age 18 years and older

## Revised pharmacy policies Effective November 1, 2022

### Drugs for Weight Management, 5.01.621

**Indication added**

- Qsymia® (phentermine/topiramate extended-release)
  - Treatment for chronic weight management in people age  $\geq 12$  and  $< 18$  years

**Drug added**

- Brand orlistat
  - Treatment for chronic weight management in adults and children

**Re-authorization criteria added**

- Qsymia® (phentermine/topiramate extended-release)
- Brand orlistat
- Xenical® (orlistat)
  - Ongoing treatment for people age  $\geq 12$  and  $< 18$  years

**Re-authorization criteria updated**

- All drugs in policy
  - For adults, the weight loss is a percentage from the baseline body weight
  - For people age  $\geq 12$  and  $< 18$  years, the weight loss is a percentage from the BMI

### Immune Checkpoint Inhibitors, 5.01.591

**Indication added**

- Imfinzi® (durvalumab)
  - Treatment of locally advanced or metastatic biliary tract cancer (BTC) in combination with gemcitabine and cisplatin

**Drug added**

- Opdualag® (nivolumab and relatlimab-rmbw)
  - Treatment of people age 12 years and older with melanoma that can't be surgically treated or that has spread to other parts of the body

**Medical necessity criteria updated**

- Keytruda® (pembrolizumab)
  - Indication: Locally advanced or metastatic esophageal or gastroesophageal junction (GEJ)*
    - The tumor must be of squamous cell histology
  - Indication: In combination with lenvatinib, for the treatment of endometrial carcinoma*
    - The requirement that the cancer must be microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) has been removed

**Medical Necessity Criteria for Pharmacy Edits, 5.01.605***Anticonvulsants***Medical necessity criteria updated**

- Fintepla® (fenfluramine)
  - The specific drug names have been removed from the criterion that the individual has tried four anti-seizure medications
  - The dosing limit criterion now requires the use of this drug with clobazam plus Diacomit® (stiripentol)

**Indication added**

- Qudexy XR® (topiramate extended-release capsules)
- Brand topiramate extended-release capsules
- Trokendi XR® (topiramate extended-release capsules)
  - Preventive treatment of migraines in people age 12 years and older

**Drug added**

- Zonisamide (zonisamide oral suspension)
  - Treatment of partial-onset seizures in people age 16 years and older

*Heart Failure Agents***Medical necessity criteria updated**

- Camzyos™ (mavacamten)
  - People receiving concurrent therapy require a beta-blocker (BB) or a calcium channel blocker (CCB)
  - Using both types of drugs (BB and CCB) is no longer required

## Miscellaneous Oncology Drugs, 5.01.540

### Indication removed

- Zejula® (niraparib)
  - Treatment of adults patients with advanced homologous recombination deficiency-positive ovarian cancer after more than 3 lines of chemotherapy

### Indication added

- Retevmo™ (selpercatinib)
  - Treatment of RET fusion-positive solid tumors that are locally advanced or have spread to other parts of the body

### Drug added

- Lytgobi® (futibatinib)
  - Treatment of intrahepatic bile duct cancer

### Indication added

- Pemazyre™ (pemigatinib)
  - Treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement

## MTOR Kinase Inhibitors, 5.01.533

### Drug added

- Hyftor™ (sirolimus topical gel)
  - Treatment of facial angiofibroma associated with tuberous sclerosis complex (TSC) in people age 6 years and older

## Pharmacotherapy of Arthropathies, 5.01.550

### *Plaque Psoriasis*

### Policy section moved to another policy

### Drugs removed

- Enbrel® (etanercept)
- Humira® (adalimumab)
- Infliximab (Janssen – unbranded)
- Inflectra® (infliximab-dyyb)
- Remicade® (infliximab)
- Taltz® (ixekizumab)
- Stelara® (ustekinumab)
- Skyrizi® (risankizumab-rzaa)
- Tremfya® (guselkumab)
- Otezla® (apremilast)
- Siliq™ (brodalumab)
- Cosentyx® (secukinumab)

- Cimzia® (certolizumab pegol)
- Renflexis™ (infliximab-abda)
- Avsola™ (infliximab-axxq)
- Ilumya™ (tildrakizumab-asmn)
  - The drugs listed above have been moved to the policy [Pharmacologic Treatment of Psoriasis, 5.01.629](#)
  - Medical necessity criteria unchanged

### Pharmacotherapy of Type I and Type II Diabetes Mellitus, 5.01.569

#### *Glucagon-like Peptide-1 (GLP-1) Receptor Agonists*

##### Drug added to preferred

- Victoza® (liraglutide)

##### Medical necessity criteria updated

- Adlyxin® (lixisenatide)
  - Victoza® (liraglutide) has been added to the list of drugs that must be tried before the above drug may be prescribed

### Prostate Cancer Targeted Therapies, 5.01.544

#### Drug with new indication

- Nubeqa® (darolutamide)
  - Treatment of metastatic hormone-sensitive prostate cancer (mHSPC)

### Use of Granulocyte Colony-Stimulating Factors (G-CSF), 5.01.551

#### Drugs added

- Rolvedon™ (eflapegrastim-xnst)
  - Treatment of adults ages 18 years and older who are receiving myelosuppressive anti-cancer treatments and who are at risk of severe febrile neutropenia
- Stimufend® (pegfilgrastim-fpgk)
  - Treatment of people less than age 18 years and adults ages 18 years and older who are receiving myelosuppressive anti-cancer treatments and who are at risk of severe febrile neutropenia

### 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

### **Effective November 1, 2022**

#### **Bioengineered Skin and Soft Tissue Substitutes, 7.01.113**

Now requires review for investigational.

A2014, A2015, A2016, A2017, A2018

**Cranial Electrotherapy Stimulation and Auricular Stimulation, 8.01.58**

Now requires review for investigational.

A4596

**Immune Checkpoint Inhibitors, 5.01.591**

Now requires review for medical necessity and prior authorization.

J9298

## **Revised codes Effective November 4, 2022**

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

No longer requires review for prior authorization. Review for medical necessity still required.

J1551

## **Removed codes Effective January 6, 2023**

**Total Ankle Replacement, 7.01.577**

No longer requires review.

27703

## **Effective November 1, 2022**

**Balloon Dilation of the Eustachian Tube, 7.01.158**

No longer requires review.

C9745