

Medical Policy and Coding Updates May 6, 2021

Special notices

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)
- 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)

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
- Neuroblastoma: Chromosomal Microarray Analysis (CMA), MYCN, ALK
- 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

- Criteria were revised

Prostate Cancer (symptomatic cancer screening)

- Added criteria for SelectMDx (81479)
- 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

Medical policies

Revised medical policies Effective May 1, 2021

Amniotic Membrane and Amniotic Fluid, 7.01.583

New product added to policy

- Affinity®
 - Treatment of non-healing diabetic lower-extremity ulcers

Investigational products updated

The table of products that are considered investigational has several product additions and deletions

Bariatric Surgery, 7.01.516

Policy statement revised

The timeframe for patient participation in a physician-administered weight reduction program before surgery is considered has been reduced:

- From at least 6 continuous months within a 2-year period
- To 3 continuous months within a 12-month period

Designated Centers of Excellence: Total Knee or Total Hip Replacement, 7.01.568

Note added to policy statement

If the patient has not met specific pre-operative goals, case-by-case reviews will be performed if the healthcare provider has documented the patient's efforts to improve. Pre-operative goals include:

- Body Mass Index (BMI) less than 40
- Cessation of nicotine products at least 4 weeks prior to surgery
- Hemoglobin A1c less than 8% in diabetic patients

Hospital Beds and Accessories, 1.01.520

Non-covered criteria updated

Safety, enclosure, or canopy-type beds have been removed from not medically necessary accessories and are no longer covered

Temporomandibular Joint Disorder, 2.01.535

Investigational criteria updated

Platelet concentrates have been added to the list of non-surgical treatments that are considered investigational

Pharmacy policies

Revised pharmacy policies Effective May 1, 2021

Continuity of Coverage for Maintenance Medications, 5.01.607

Medical necessity criteria updated

Continuation of maintenance drugs for patients who are new health plan members

- Member must have been receiving the drug for 90 or more days
- Documentation is required to explain why an adverse clinical outcome would be expected if the member is switched to a preferred therapeutic alternative that is on the member's new drug formulary

Medical necessity criteria added

Continuation of maintenance drugs for patients who are current health plan members

Hetlioz® (tasimelteon), 5.01.552

New drug added to policy

- Hetlioz LQ™ (tasimelteon) oral suspension
 - Treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients between the ages of 3 and 15

Drug with new indication

- Hetlioz® (tasimelteon) (capsules)
 - Treatment of nighttime sleep disturbances in Smith Magenis Syndrome (SMS) in patents age 16 and older

Medical necessity criteria updated

- Hetlioz® (tasimelteon) (capsules)

- Age and dosage limits added for the treatment of non-24-hour sleep-wake disorder

Immune Checkpoint Inhibitors, 5.01.591

Drugs with new indications

- Keytruda® (pembrolizumab)
 - Treatment of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) cancer
- Libtayo® (cemiplimab)
 - Treatment of locally advanced or metastatic basal cell cancer
 - Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) in patients who aren't surgical candidates or can't have chemotherapy combined with radiation therapy
- Opdivo® (nivolumab)
 - First-line treatment of patients with advanced renal cell cancer (RCC) when used with Cabometyx® (cabozantinib)

Drugs with indications removed

- Imfinzi® (durvalumab)
 - The indication for urothelial cancer has been removed from the policy
- Keytruda® (pembrolizumab)
 - The indication for metastatic small-cell lung cancer (SCLC) has been removed from the policy
- Tecentriq® (atezolizumab)
 - The indication for metastatic urothelial cancer during or following the use of platinum-containing chemotherapy has been removed from the policy

Medical Necessity Criteria for Pharmacy Edits, 5.01.605

Antifungals

New drugs added to policy

- Noxafil® (posaconazole)
 - Treatment of fungal infections in patients age 13 and older
- Tolsura® (itraconazole)
 - Treatment of fungal infections in patients age 18 and older

Antiprotozoal Agents

New policy section

New drug added to policy

- Alinia® (nitazoxanide)
 - Treatment of diarrhea caused by Giardia lamblia or Cryptosporidium parvum in patients 12 months and older

Brand Topical Acne or Rosacea Products

New drugs added to policy

- Retin-A®
 - Treatment of acne or rosacea
- Retin-A Micro®
 - Treatment of acne or rosacea

Heart Failure Agents

New drug added to policy

- Verquvo™ (vericiguat)
 - Treatment of chronic heart failure (NYHA Class II to IV) in patients age 18 and older

Ulcerative Colitis Agents

Policy statement added

The requirement to use two generic drugs first is exempt when Pentasa® (mesalamine) is used to treat inflammatory bowel disease of the small intestine

Multiple Receptor Tyrosine Kinase Inhibitors, 5.01.534

New drugs added to policy

- Fotivda® (tivozanib)
 - Treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC)
- Tepmetko® (tepotinib)
 - Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC)

Pharmacologic Treatment of Duchenne Muscular Dystrophy, 5.01.570

New drug added to policy

- Amondys 45® (casimersen)
 - Treatment of patients up to age 21 with Duchenne Muscular Dystrophy that is amenable to exon 45 skipping

Pharmacologic Treatment of High Cholesterol, 5.01.558

New drugs added to policy

- Evkeeza™ (evinacumab-dgnb)
 - Treatment of homozygous familial hypercholesterolemia (for primary prevention) in patients age 12 and older
- Generic icosapent ethyl
 - To reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization
 - Treatment of severe hypertriglyceridemia

Pharmacotherapy of Cushing's Disease and Acromegaly, 5.01.548

New drug added to policy

- Mycapssa® (octreotide)
 - Treatment of acromegaly in adults age 18 and older

Medical necessity criteria updated

- Signifor® LAR (pasireotide)
- Somavert® (pegvisomant)
 - For the treatment of acromegaly, patients must be age 18 and older
 - The acromegaly diagnosis must be documented by lab tests

Pharmacotherapy of Multiple Sclerosis, 5.01.565

New drug added to policy

- Ponvory™ (ponesimod)
 - Treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

Phosphoinositide 3-kinase (PI3K) Inhibitors, 5.01.592

New drug added to policy

- Ukoniq™ (umbralisib)
 - Treatment of relapsed or refractory marginal zone lymphoma (MZL) in adults
 - Treatment of relapsed or refractory follicular lymphoma (FL) in adults

Archived policies

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

Effective May 1, 2021

Placental and Umbilical Cord Blood as a Source of Stem Cells, 7.01.50

Vagus Nerve Blocking Therapy for Treatment of Obesity, 7.01.150

Deleted policies

No updates this month

Coding updates

Added codes Effective May 1, 2021

Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome, 9.03.29

Now requires review for investigative.

0507T

Glaucoma, Invasive Procedures, 9.03.510

Now requires review for medical necessity.

66174, 66175, 0191T, 0253T

Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring, 1.01.536

Now requires review for medical necessity.

93792, 93793

Laryngeal Injection for Vocal Cord Augmentation, 2.01.541

Now requires review for medical necessity.

31573, 31574

Spinal Orthosis, 1.03.502

Now requires review for medical necessity.

A4467

Steroid-Eluting Sinus Stents, 7.01.134

Now requires review for investigative.

J7402

Transient Elastography, 2.01.536

Now requires review for medical necessity.

76981, 76982, 76983

Revised codes Effective May 1, 2021

Amniotic Membrane and Amniotic Fluid, 7.01.583

Now requires review for medical necessity and prior authorization.

Q4159

Hospital Beds and Accessories, 1.01.520

No longer covered.

E0316