Essence Healthcare

Prior Authorization Criteria

for Medicare Part B Drugs

2024 Part B Drugs Requiring Prior Authorization

Drug	HCPC code
Actemra (tocilizumab) IV	J3262
Aduhelm (aducanumab-avwa)	J0172
Avsola (infliximab-axxq)	Q5121
Benlysta (belimumab)	J0490
Botulinum toxins (Botox, Dysport, Myobloc, Xeomin)	Botox J0585 Dysport J0586 Myobloc J0587 Xeomin J0588
Cerezyme (imiglucerase)	J1786
Cinqair (reslizumab)	J2786
Diabetes Testing Supplies (non-preferred)**	A4253, E0607
Duopa (carbidopa/levodopa)**	J7340
Entyvio (vedolizumab)	J3380
Epoprostenol (Flolan, Veletri)	J1325
ESA (erythropoetin, Aranesp, Mircera, Retacrit)	Epogen/Procrit non-ESRD J0885 Epogen/Procrit ESRD Q4081

	Aranesp non-ESRD J0881 Aranesp ESRD J0882 Mircera non-ESRD J0888 Mircera ESRD J0887 Retacrit non-ESRD Q5106 Retacrit ESRD Q5105
Fabrazyme (agalsidase)	J0180
Factor products	J7170 (Hemlibra), J7179 (Vonvendi), J7180 (Corifact), J7181 (Tretten), J7182 (Novoeight), J7183 (Wilate), J7185 (Xyntha), J7186 (Alphanate/VWF complex), J7187 (Humate-P), J7189 (NovoSeven RT), J7190 (Koate-DVI, Hemofil M)), J7192 (Factor VIII Advate, Kogenate FS, Recombinate), J7193 (AlphaNine SD), J7194 (Profilnine/Profilnine SD), J7195 (BeneFix), J7198 (Feiba/Feiba NF), J7200 (Rixubis), J7201 (Alprolix), J7202 (Idelvion), J7203 (Rebinyn), J7205 (Eloctate), J7207 (Adynovate), J7208 (Jivi), J7209 (Nuwiq), J7210 (Afstyla), J7211 (Kovaltry), J7213 (Ixinity)
Fasenra (benralizumab)	J0517
Feraheme (ferumoxytol)	Q0138 (non-ESRD) Q0139 (ESRD)
Hyaluronan Intra-articular Injections	Durolane J7318 Euflexxa J7323 Gel-one J7326 Gelsyn-3 J7328 GenVisc 850 J7320 Hyalgan J7321

	Hymovis J7322 Monovisc J7327 Orthovisc J7324 Supartz J7321 Synojoynt J7331 Synvisc/Synvisc-One J7325 Triluron J7332 Trivisc J7329 Visco-3 J7321
Ilaris (canakinumab)	J0638
Immune Globulin (Intravenous)	Asceniv J1554 Bivigam J1556 Flebogamma/Flebogamma DIF J1572 Gammagard J1569 Gammagard S/D J1566 Gammaked/Gamunex-C J1561 Gammaplex J1557 Octagam J1568 Panzyga J1599 Privigen J1459
Immune Globulin (Subcutaneous)	Cutaquiq J3590 Cuvitru J1555 Hizentra J1559 Hyqvia J1575 Xembify J1558
Inflectra (infliximab-dyyb)	Q5103
Injectafer (ferric carboxymaltose)	J1439
Lemtrada (alemtuzumab)	J0202

Leqembi (lecanemab-irmb)	J0174
Monoferric (ferric derisomaltose)	J1437
Nplate (romiplostim)	J2796
Ocrevus (ocrelizumab)	J2350
Orencia (abatacept)	J0129
Radicava (edaravone)	J1301
Remicade (infliximab)	J1745
Remodulin (treprostinil)	J3285
Renflexis (infliximab –abda)	Q5104
Revatio (sildenafil)	J3490
Simponi Aria (golimumab)	J1602
Soliris (eculizumab)	J1300
Stelara (ustekinumab)	J3358 (IV injection)
Skyrizi (risankizumab-rzaa)	J2327
Tysabri (natalizumab)	J2323
Tyvaso (treprostinil)	J7686

Ultomiris (ravulizumab-cwvz)**	J1303
Ventavis (iloprost)	Q4074
VPRIV (velaglucerase alfa)	J3385
Xiaflex (collagenase clostridium histolyticum)**	J0775
Xolair (omalizumab)	J2357

This list is used for the purposes of utilization management of drugs covered under Medicare Part B.

Hierarchy for review:

1. Medicare National Coverage Determination (NCD)/Local Coverage Determination (LCD) (visit CMS.gov for criteria)
2. InterQual (criteria available on the marketing portal at www.essencehealthcare.com under Resources and Downloads/Other Plan Information/Clinical Criteria)
3. **Lumeris (see criteria below)

Last updated December 5, 2023

Contents

DIABETES TESTING SUPPLIES: Non-Preferred Blood Glucose Meters and Test Strips

Covered Uses:

*Refer to client specific coverage for which brand is covered.

The health plan covers*:

- Ascensia glucose meters and strips through network pharmacies, including CONTOUR® NEXT EZ, CONTOUR® NEXT, CONTOUR® NEXT ONE, and CONTOUR®. **OR**
- Abbott glucose meters and strips through network pharmacies, including FREESTYLE LITE and FREESTYLE FREEDOM LITE.

The health plan may make an exception to cover non-Ascensia or non-Abbott products through pharmacies if the criteria listed below are met.

Coverage Duration:

If all conditions are met, the plan may authorize coverage for non-preferred meter and test strips for **Lifetime approval for visual impairment/voice meter and 1 year for all other meters and test strips**. For this policy, the term "inadequate response" means lack of therapeutic effect, and/or inability to tolerate due to adverse effects, or contraindication to therapy.

Required Medical Information:

1. Member has visual impairment and requires a voice meter, and there is no voice meter in the preferred suite of products, **OR**
2. Member requires a meter that communicates with an insulin pump, and there is no such meter in the preferred suite of products, **OR**
3. Requests for other reasons will be considered on a case-by-case basis.

Last Reviewed Date	Updates / Revisions
3/3/17	Addition of newly covered meter
2/12/18	Update to covered products
3/5/19	None
2/10/20	None
2/17/21	None
11/10/21	Update to approval time frame
11/23/22	None
3/23/22	None
1/27/23	Added covered meters/strips by plan

DUOPA (carbidopa/levodopa enteral suspension) J7340

Covered Uses:

FDA-approved indications and off-label indications as specified in NCD or LCD, or supported in the medical compendia. Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Coverage Duration:

If all conditions are met, Essence may authorize coverage for Duopa (carbidopa/levodopa) for **one year**. For this policy, the term "inadequate response" means lack of therapeutic effect, and/or inability to tolerate due to adverse effects, or contraindication to therapy.

FDA Approved Indication(s):
Duopa (carbidopa/levodopa) is a combination of carbidopa (an aromatic amino acid decarboxylation inhibitor) and levodopa (an aromatic amino acid) indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease (PD).

Required Medical Information:

1. Treatment of motor fluctuations in patients with advanced Parkinson's disease (PD), **AND**
2. The prescriber is a neurologist, **AND**
3. Documented idiopathic PD based on the presence of bradykinesia and at least one other cardinal PD feature (i.e. tremor, rigidity, postural instability), **AND**
4. Documented response to L-dopa (i.e. with clearly defined "On" periods), **AND**
5. Documented persistent motor complications with disabling "Off" periods for a minimum of 3 hours/day, despite adequate medical therapy with levodopa-carbidopa, and at least one other class of anti-PD therapy (i.e. COMT inhibitor or MAO-B inhibitor)

Reauthorization:

1. Patient is being treated for an FDA approved indication, or indication supported by NCD, LCD, or medical compendia **AND** physician attestation of improvement or stabilization.

Exclusion Criteria:

1. Atypical Parkinson's syndrome ("Parkinson's Plus" syndrome) or secondary Parkinson's
2. Non-levodopa responsive PD
3. Contraindication to percutaneous endoscopic gastro-jejunal (PEG-J) tube placement or long-term use of a PEG-J
4. Contraindicated in patients taking nonselective monoamine oxidase (MAO) inhibitors
5. Coverage excluded for any indications that are not supported in FDA labeling, NCD, LCD, or medical compendia.

Version History

Last Reviewed Date	Updates / Revisions
1/1/18	Addition to part B criteria with effective date 1/1/18
8/20/18	Update to exclusion criteria

3/5/19	None
2/10/20	None
2/17/21	Addition of reauthorization criteria
3/23/22	None
3/7/23	None

ULTOMIRIS (ravulizumab-cwvz) J1303

Covered Uses:

FDA-approved indications and off-label indications as specified in NCD or LCD, or supported in the medical compendia. Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Coverage Duration:

If all conditions are met, the plan may authorize coverage for Ultomiris (ravulizumab-cwvz) for **6 months (initial – PNH, gMG) and 12 months (initial and reauthorization – aHUS and reauthorization – PNH, gMG).** For this policy, the term "inadequate response" means lack of therapeutic effect, and/or inability to tolerate due to adverse effects, or contraindication to therapy.

FDA Approved Indication(s):
Ultomiris (ravulizumab-cwvz) is a complement inhibitor indicated for: • The treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH) • Treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA) • Treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive

Required Medical Information:

1. **Paroxysmal nocturnal hemoglobinuria**
    a. Patient has confirmed PNH as demonstrated by ALL of the following via flow cytometry:
        i. At least 2 different GPI-protein deficiencies (i.e. CD55, CD59) on at least 2 cell lineages (i.e. erythrocytes, granulocytes)
        ii. PNH granulocyte clone size of 10% or higher, **AND**
    b. Prescribed by or in consultation with a hematologist, **AND**
    c. Prescriber must be enrolled in the ULTOMIRIS REMS program, **AND**
    d. Patient must be immunized with meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risks of developing a meningococcal infection, **AND**
    e. Patient is one month of age or older, **AND**
    f. The patient is not using concurrent complement inhibitor therapy (e.g., Soliris, Empaveli), **AND**
    g. Patient meets ONE of the following:
        i. The patient is transitioning from Soliris to Ultomiris **OR**
        ii. The patient has evidence of intravascular hemolysis (e.g., lactate dehydrogenase [LDH] level greater than or equal to 1.5 X ULN, hemoglobinuria), AND presence of at least one PNH-related sign or symptom (e.g., history of blood transfusion due to PNH, symptoms of anemia, history of major adverse vascular event from thromboembolism)

2. **Atypical hemolytic uremic syndrome**
    a. Patient is one month of age or older, **AND**
    b. Prescriber must be enrolled in the ULTOMIRIS REMS program, **AND**

c. Patient must be immunized with meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risks of developing a meningococcal infection.

3. **Generalized myasthenia gravis (gMG)**
    a. Patient is anti-acetylcholine receptor (AChR) antibody-positive, **AND**
    b. Prescriber must be enrolled in the ULTOMIRIS REMS program, **AND**
    c. Patient must be immunized with meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risks of developing a meningococcal infection, **AND**
    d. The patient is 18 years of age or older, **AND**
    e. Therapy is prescribed by or in consultation with a neurologist, **AND**
    f. The patient is Myasthenia Gravis Foundation of America class II, III, or IV, **AND**
    g. The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone), **AND**
    h. The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate)

Reauthorization:

1. **Paroxysmal nocturnal hemoglobinuria**
    a. Diagnosis of PNH AND physician attestation of benefit (i.e. reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels) compared to baseline
    b. The patient is not using concurrent complement inhibitor therapy (e.g., Soliris, Empaveli)
2. **Atypical hemolytic uremic syndrome**
    a. Diagnosis of aHUS AND physician attestation of benefit
3. **Generalized myasthenia gravis (gMG)**
    a. Diagnosis of gMG and the patient had clinical benefit compared to baseline (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

Exclusion Criteria:

- Ultomiris is contraindicated in patients with unresolved *Neisseria meningitidis* infection and in patients who are not currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying treatment outweigh the risks of developing a meningococcal infection.
- Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- Coverage excluded for any indications that are not supported in FDA labeling, NCD, LCD, or medical compendia.

References:

Ultomiris prescribing information

Version History

Last Reviewed Date	Updates / Revisions

2/17/2021	Addition to part B criteria with effective date 9/1/2021
11/10/21	Update to FDA approved indication and required medical information. Addition of new required criteria.
8/23/22	Addition to FDA approved indication; update to approval time frame
11/2/22	Update to initial authorization time frame for gMG; Update to initial and reauthorization criteria
12/5/23	Addition to reauthorization criteria

XIAFLEX (collagenase clostridium histolyticum) J0775

Covered Uses:

FDA-approved indications and off-label indications as specified in NCD or LCD, or supported in the medical compendia. Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Coverage Duration:

If all conditions are met, the plan may authorize coverage for Xiaflex (collagenase clostridium histolyticum) for **one year**. For this policy, the term "inadequate response" means lack of therapeutic effect, inability to tolerate due to adverse effects, or contraindication to therapy.

FDA Approved Indication(s):
1. Treatment of adult patients with Dupuytren's contracture with a palpable cord 2. Treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. Because of the risks of corporal rupture or other serious penile injury, Xiaflex is available only through a restricted program under a REMS called the Xiaflex REMS Program. Prescribers and health care sites must be certified with the program.

Required Medical Information:

1. **Dupuytren's contracture**
    a. Documented diagnosis of Dupuytren's contracture with palpable cord, **AND**
    b. Provider must be a healthcare provider who is experienced with injection procedures of the hand and in treatment of Dupuytrens contracture (i.e. orthopedic physician/hand specialist), **AND**
    c. Patient must be 18 years old or older, **AND**
    d. The prescriber has completed Xiaflex training as provided by the Risk Evaluation and Mitigation Strategy (REMS) program

1. **Peyronie's disease in men**
    a. Palpable plaque, **AND**
    b. Curvature deformity of at least 30 degrees, **AND**
    c. Administered by a healthcare provider experienced in the treatment of male urological diseases, **AND**
    d. Patient must be 18 years old or older, **AND**
    e. The prescriber has completed Xiaflex training as provided by the Risk Evaluation and Mitigation Strategy (REMS) program

Exclusion Criteria:

1. Treatment of Peyronie's plaques that involve the penile urethra
2. History of hypersensitivity to Xiaflex or to collagenase used in any other therapeutic applications
3. Coverage excluded for any indications that are not supported in FDA labeling, NCD, LCD, or medical compendia.

References:
Xiaflex prescribing information

Version History

Last Reviewed Date	Updates / Revisions
12/6/16	None
12/18/17	Update to required information for Peyronie's Disease
11/5/18	None
12/10/19	None
11/10/20	None
11/10/21	None
11/2/22	Update to required medical information
12/5/23	None