



**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

<b>ESA (erythropoetin, Aranesp, Mircera, Retacrit)</b>	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
<b>Fabrazyme (agalsidase)</b>	J0180
<b>Factor products</b>	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 (Rebinyon), J7205 (Eloctate), J7207 (Adynovate), J7208 (Jivi), J7209 (Nuwiq), J7210 (Afstyl), J7211 (Kovaltry), J7213 (Ixinity)
<b>Fasenra (benralizumab)</b>	J0517
<b>Feraheme (ferumoxytol)</b>	Q0138 (non-ESRD) Q0139 (ESRD)
<b>Hyaluronan Intra-articular Injections</b>	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
<b>Ilaris (canakinumab)</b>	J0638
<b>Immune Globulin (Intravenous)</b>	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
<b>Immune Globulin (Subcutaneous)</b>	Cutaquiq J1551 Cuvitru J1555 Hizentra J1559 Hyqvia J1575 Xembify J1558
<b>Inflectra (infliximab-dyyb)</b>	Q5103
<b>Injectafer (ferric carboxymaltose)</b>	J1439
<b>Lemtrada (alemtuzumab)</b>	J0202

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

<b>Ultomiris (ravulizumab-cwvz)**</b>	J1303
<b>Ventavis (iloprost)</b>	Q4074
<b>VPRIV (velaglucerase alfa)</b>	J3385
<b>Xiaflex (collagenase clostridium histolyticum)**</b>	J0775
<b>Xolair (omalizumab)</b>	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 or Health Help (criteria available on the marketing portal at [www.essencehealthcare.com](http://www.essencehealthcare.com) under Resources and Downloads/Other Plan Information/Clinical Criteria)
3. \*\*Lumeris (see criteria below)

**Approval Timeframes (for NCD/LCD/InterQual)**

- One year approval timeframe with the exception of the following:
  - Iron Infusions (Injectafer, Feraheme, Monoferic) – 3 months
  - Hyaluronan Intra-articular Injections – 3 months
  - ESA (Perioperative use) – 1 month
  - Stelara – 3-month IV induction dose only
  - Skyrizi – 3-month IV induction dose only

# Prior Authorization Criteria for Medicare Part B Drugs

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# DIABETES TESTING SUPPLIES: Benefit Exception for 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.

## References:

Health Plan Evidence of Coverage

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



3/26/24	Update to clarify this is a benefit exception criteria
4/16/24	Approved by MMC on 4/16/24

# ULTOMIRIS (ravulizumab-cwvz) J1303

## Purpose

In its administration of Medicare Advantage plans (Health Plans), the Company shall determine benefits in accordance with the requirements of the Centers for Medicare & Medicaid Services (CMS). Where CMS has established a national coverage policy on an item or service or a local Medicare contractor has done so as authorized by CMS, the Company follows the Medicare coverage criteria. In the absence of fully established Medicare coverage criteria, the Company may develop and implement internal criteria based on current evidence in widely used treatment guidelines or clinical literature. Internal criteria are reviewed and approved by the Pharmacy Oversight Committee and the Medical Management Committee and are made publicly accessible.

CMS has not established coverage criteria for Ultomiris. Therefore, the Company has developed and implemented this coverage criteria to ensure that patients receive clinically appropriate, medically necessary care at the appropriate level, which allows for the best clinical outcome. The purpose of this policy is to describe the circumstances under which treatment with Ultomiris would be considered medically necessary.

## 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**

Last Updated 4/16/2024



- 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 (Medicare criteria not fully established):**

Ultomiris prescribing information

MedImpact Plus Medicare Part D Formulary Prior Authorization Guidelines

**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
3/26/24	Added statement of criteria purpose in compliance with CMS requirements
4/16/24	Approved by MMC on 4/16/24

# XIAFLEX (collagenase clostridium histolyticum) J0775

## Purpose

In its administration of Medicare Advantage plans (Health Plans), the Company shall determine benefits in accordance with the requirements of the Centers for Medicare & Medicaid Services (CMS). Where CMS has established a national coverage policy on an item or service or a local Medicare contractor has done so as authorized by CMS, the Company follows the Medicare coverage criteria. In the absence of fully established Medicare coverage criteria, the Company may develop and implement internal criteria based on current evidence in widely used treatment guidelines or clinical literature. Internal criteria are reviewed and approved by the Pharmacy Oversight Committee and the Medical Management Committee and are made publicly accessible.

CMS has not established coverage criteria for Xiaflex. Therefore, the Company has developed and implemented this coverage criteria to ensure that patients receive clinically appropriate, medically necessary care at the appropriate level, which allows for the best clinical outcome. The purpose of this policy is to describe the circumstances under which treatment with Xiaflex would be considered medically necessary.

## 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):
<ol style="list-style-type: none"><li>1. Treatment of adult patients with Dupuytren's contracture with a palpable cord</li><li>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.</li></ol>

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 Dupuytren's 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

#### 2. 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 (Medicare criteria not fully established):

Xiaflex prescribing information

MedImpact Plus Medicare Part D Formulary Prior Authorization Guidelines

### 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
3/26/24	Added statement of criteria purpose in compliance with CMS requirements
4/16/24	Approved by MMC on 4/16/24

