gravie

Effective January 1, 2025

Cigna: Precertification list for participating providers

Use this guide for precertification (also known as prior authorization or prior approval) with patients enrolled in Gravie health plans.

This document includes an overview of best practices for working with Gravie and Current Procedural Terminology (CPT®) codes for services, programs and prescriptions that require approval for coverage.

For more information on how to request a precertification request to Gravie, refer to the How to Request section.

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How to request precertification

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How to submit a precertification request

Medical precertification requests must be submitted at least seven (7) business days in advance. Please call Gravie Care® at 877.684.3984, weekdays, 7 a.m. to 7 p.m. CT to:

1. Determine whether precertification is required for any given procedure or service
2. Verify the specific Current Procedural Terminology (CPT®) codes for services, programs and prescriptions that require approval for coverage, and
3. Submit a precertification request

Precertification requests are required for the following services and programs:

- Inpatient admissions
- Outpatient and physician surgery
- Potentially cosmetic procedures
- Outpatient and physician diagnostic services
- Other labs and screenings
- Outpatient and physician - continuing care services
- **Please note:** precertification is required for any and all services and programs which are considered experimental or investigative.

All sections of a precertification submission are required. Failure to provide all of the medical records requested may cause delays in our review or result in a denial of coverage. You will be notified within five (5) calendar days that we've received your precertification request.

How to submit a medical precertification request for prescription drugs

Precertification requests for prescription drugs must be submitted to CVS Caremark® at least seven (7) business days in advance. There are two ways to submit a request:

1. Submit the request online here (quickest option).
2. Call CVS Caremark directly at 833.847.8881

All sections of a precertification submission are required. Failure to provide all of the medical records requested may cause delays in our review or result in denial of coverage. You will be notified within five (5) calendar days that we've received your precertification request.

What happens next

Once your request is submitted, we'll perform a clinical review. An initial coverage determination will be made within fifteen (15) calendar days.

If we determine your request is incomplete, you will receive a written notification explaining why.

Questions? We've got you covered.

If you have any questions about submitting a request, our precertification process, or eligibility, call our Provider Customer Service at 877.438.0009, weekdays, 7 a.m. to 7 p.m. CT. You can also visit us online at gravie.com/providers.

Drugs not covered

The following drugs are excluded from coverage effective 1/1/2025. Please refer to the Specialty Medications section of this document for alternatives.

Category	Drug Name	J Code	Effective Date
Autoimmune	Actemra	J3262	1/1/25
Anti-VEGF	Eylea	J0178	1/1/25
Anti-VEGF	Alymsys	Q5126	1/1/25
Infliximab	Remicade	J1745	1/1/25
Long-Acting GCSF	Rolvedon	J1449	1/1/25
Long-Acting GCSF	Udenyca	Q5111	1/1/25
Long-Acting GCSF	Nyvepria	Q5122	1/1/25
Long-Acting GCSF	Fylnetra	Q5130	1/1/25
Oncology	Avastin (except ophthalmologic)	J9035	1/1/25
Oncology	Rituxan	J9312	1/1/25
Oncology	Herceptin	J9355	1/1/25
Oncology	Vegzelma	Q5129	1/1/25
Oncology	Trazimera	Q5116	1/1/25
Short-Acting GCSF	Neupogen	J1442	1/1/25
Short-Acting GCSF	Granix	J1447	1/1/25
Short-Acting GCSF	Releuko	Q5125	1/1/25

Drugs covered by pharmacy benefit only

How to request | Drugs not covered | **Drugs covered** | Drugs policies

The following medications are covered on the Pharmacy Benefit ONLY and **will be excluded from coverage under the medical benefit effective 1/1/2025.** Please consult the Formulary and The CVS Specialty List for coverage. You can contact CVS for details at 833.847.8881.

Category	Drug Name	J Code	Effective Date
Alpha-1 Antitrypsin Deficiency	Glassia	J0257	1/1/2025
Alpha-Glucodidase Deficiency	Pombiliti	J1203	1/1/2025
Atopic Dermatitis	Adbry	J3490	1/1/2025
Bone Disorders	Voxzogo	J3490	1/1/2025
Botulinum Toxin	Dysport	J0586	1/1/2024
Botulinum Toxin	Xeomin	J0588	1/1/2024
Botulinum Toxin	Myobloc	J0587	1/1/2024
Botulinum Toxin	Daxxify	J0589	1/1/2025
Endocrine Disorders	Acthar	J0801	1/1/2025
Endocrine Disorders	Cortrophin	J0802	1/1/2025
Growth Hormone	Humatrope	J2941	1/1/2024
Growth Hormone	Zorbtive	J2941	1/1/2024
Growth Hormone	Genotropin	J2941	1/1/2024
Growth Hormone	Nutropin	J2941	1/1/2024
Growth Hormone	Norditropin Nordiflex	J2941	1/1/2024
Growth Hormone	Norditropin Flexpro	J2941	1/1/2024
Growth Hormone	Zomacton	J2941	1/1/2024
Growth Hormone	Sogroya	J2941	1/1/2024
Growth Hormone	Omnitrope	J2941	1/1/2024
Growth Hormone	Skytrofa	J2941	1/1/2024
Growth Hormone	Serostim	J2941	1/1/2024
Growth Hormone	Egrifta	J3490	1/1/2024
Growth Hormone	Saizen	J2941	1/1/2025
Growth Hormone	Increlex	J2170	1/1/2025
Growth Hormone	Saizenprep	J2941	1/1/2024

Category	Drug Name	J Code	Effective Date
Hemophilia	Advate	J7192	1/1/2024
Hemophilia	Ixinity	J7213	1/1/2024
Hemophilia	Adynovate	J7207	1/1/2024
Hemophilia	Jivi	J7208	1/1/2024
Hemophilia	Afstyla	J7210	1/1/2024
Hemophilia	Koate	J7190	1/1/2024
Hemophilia	Alphanate	J7186	1/1/2024
Hemophilia	Kogenate	J7192	1/1/2024
Hemophilia	AlphaNine SD	J7193	1/1/2025
Hemophilia	Kovaltry	J7211	1/1/2024
Hemophilia	Alprolix	J7201	1/1/2024
Hemophilia	NovoSeven RT	J7189	1/1/2025
Hemophilia	Altuviiio	J7214	1/1/2025
Hemophilia	Novoeight	J7182	1/1/2024
Hemophilia	Benefix	J7195	1/1/2024
Hemophilia	Nuwiq	J7209	1/1/2024
Hemophilia	Beqvez	J3490	1/1/2024
Hemophilia	Obizur	J7188	1/1/2024
Hemophilia	Coagadex	J7175	1/1/2025
Hemophilia	Profilnine	J7194	1/1/2025
Hemophilia	Eloctate	J7205	1/1/2024
Hemophilia	Rebinyn	J7203	1/1/2024
Hemophilia	Esperoct	J7204	1/1/2024
Hemophilia	Recombinate	J7192	1/1/2024
Hemophilia	Feiba	J7198	1/1/2025
Hemophilia	RiaSTAP	J7178	1/1/2025
Hemophilia	Fibryga	J7177	1/1/2025
Hemophilia	Rixubis	J7200	1/1/2025
Hemophilia	Hemgenix	J1411	1/1/2024
Hemophilia	Sevenfact	J7212	1/1/2025
Hemophilia	Hemlibra	J7170	1/1/2024
Hemophilia	Tretten	J7181	1/1/2025

Category	Drug Name	J Code	Effective Date
Hemophilia	Hemofil M	J7190	1/1/2024
Hemophilia	Vonvendi	J7179	1/1/2025
Hemophilia	Humate-P	J7187	1/1/2024
Hemophilia	Wilate	J7183	1/1/2024
Hemophilia	Idelvion	J7202	1/1/2024
Hemophilia	Xyntha	J7185	1/1/2024
Hereditary Angioedema	Berinert	J0597	1/1/2024
Hereditary Angioedema	Kalbitor	J1290	1/1/2025
Hereditary Angioedema	Cinryze	J0598	1/1/2024
Hereditary Angioedema	Ruconest	J0596	1/1/2024
Hereditary Angioedema	Haegarda	J0599	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Durolane	J7318	1/1/2024
Hyaluronic Acid Derivatives (HAD)	OrthoVisc	J7324	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Euflexxa	J7323	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Supartz FX	J7321	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Gel-One	J7326	1/1/2024
Hyaluronic Acid Derivatives (HAD)	SynoJoynt	J7331	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Gelsyn-3	J7328	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Synvisc	J7325	1/1/2024
Hyaluronic Acid Derivatives (HAD)	GenVisc 850	J7320	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Synvisc One	J7325	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Hyalgan	J7321	1/1/2024
Hyaluronic Acid Derivatives (HAD)	TriVisc	J7329	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Hymovis	J7322	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Triluron	J7332	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Monovisc	J7327	1/1/2024
Hyaluronic Acid Derivatives (HAD)	Visco-3	J7321	1/1/2024
Inflammatory	Stelara (SC dosing only)	J3357	1/1/2024

Category	Drug Name	J Code	Effective Date
Lysosomal Storage Disorder	Aldurazyme	J1931	1/1/2025
Lysosomal Storage Disorder	Naglazyme	J1458	1/1/2025
Lysosomal Storage Disorder	Cerezyme	J1786	1/1/2024
Lysosomal Storage Disorder	Nexviazyme	J0219	1/1/2025
Lysosomal Storage Disorder	Elaprase	J1743	1/1/2025
Lysosomal Storage Disorder	Opfolda	J1202	1/1/2025
Lysosomal Storage Disorder	Elelyso	J3060	1/1/2024
Lysosomal Storage Disorder	Vimizim	J1322	1/1/2025
Lysosomal Storage Disorder	Fabrazyme	J0180	1/1/2025
Lysosomal Storage Disorder	Vpriv	J3385	1/1/2024
Lysosomal Storage Disorder	Kanuma	J2840	1/1/2025
Lysosomal Storage Disorder	Xenpozyme	J0218	1/1/2025
Lysosomal Storage Disorder	Lumizyme	J0221	1/1/2025
Pulmonary Arterial Hypertension	epoprostenol sodium	J1325	2/1/2024
Pulmonary Arterial Hypertension	treprostinil sodium	J3285	2/1/2024
Pulmonary Arterial Hypertension	Flolan	J1325	2/1/2024
Pulmonary Arterial Hypertension	Remodulin	J3285	2/1/2024
Pulmonary Arterial Hypertension	Veletri	J1325	2/1/2024
Specialty Asthma	Dupixent	J3490	1/1/2025
Specialty Asthma	Nucala	J2182	1/1/2024
Specialty Asthma	Cinqair	J2786	1/1/2024
Specialty Asthma	Tezspire	J2356	1/1/2024
Specialty Asthma	Fasenra	J0517	1/1/2024
Specialty Asthma	Xolair	J2357	1/1/2024

Change Log

Effective Date	Change	CPT Codes
3/8/2024	Added Codes	0425U, 0426U, 0803T, 0813T, 0823T, 0824T, 0825T, 0865T, 0866T, 22836, 22837, 22838, 27278, 61889, 61891, 63011, 63020, 63045, 64596, 64597, 64598, 81457, 81458, 81459, 81462, 81463, 81464, E0492, E0530, E0678, E0679, E0680, E0682
	Deleted Codes	0424T, 0715T, 0775T, 0809T, 75580, 81407, 81408, C9771, K1001, K1024, K1025, K1032, K1033
5/31/2024	Added Codes	0443U, 0445U, 0448U, 0449U, 0707T, 22595, 22610, 22800, A4271, C9796, E0468, E0736, E0738, E0739
	Deleted Codes	0378U, 36299, 64598, 81210, 81233, 81288, 81309, 88299
8/16/24	Deleted Codes	J0585 (from pharmacy-only benefit)
8/31/24	Added Codes	0020M, 0457U, 0459U, 0464U, 0467U, 0469U, 0471U, 0473U, 0869T, 0889T, 0898T, 0899T, 0900T, 32855, 32856, 33930, 33933, 33940, 33944, 44137, 47133, 50300, 50323, 63082, 86950, A9506, C9791, H0045, J0885, J1449, J3315, J9196, J9216, Q4331, Q4332, Q5106, Q5115, Q5119, Q5123, Q5125, S0148, S5150, S5151, T1005
	Deleted Codes	22595, 22610, 22800, A4271, C7516, C7517, C7518, C7519, C7520, C7521, C7522, C7523, C7524, C7525, C7526, C7527, C7528, C7529, E0656, E0657, E0670, Q4210, S8035
12/20/24	Added Effective 1/1/25	**Drugs Covered by Pharmacy Benefit:** J0180, J0218, J0219, J0221, J0257, J0589, J0801, J0802, J1202, J1203, J1290, J1322, J1458, J1743, J1931, J2170, J2840, J2941, J3357, J7175, J7177
		Excluded Drugs: J0178, J1442, J1447, J1449, J3262, J1745, J9035, J9312, J9355, Q5111, Q5116, Q5122, Q5125, Q5126, Q5129, Q5130

Medical drug policies

The following pages contain medical drug policies for the following:

- Acute Hepatic Porphyria (AHP)
- Hereditary transthyretin amyloidosis (hATTR)
- Hemgenix
- Intravenous Iron
- Lyfgenia
- Multiple Sclerosis
- Muscular Atrophy
- Myasthenia Gravis
- Primary Hyperoxaluria Type 1 (PH1)
- Roctavian
- Specialty Asthma
- Spinal Muscular Atrophy
- Vyjuvek (beremagene geperpavec-svdt)
- Zynteglo

MEDICAL POLICY

Acute Hepatic Porphyria (AHP)

Last review date: 6/17/2024

Applicable Products:
Givlaari (givosiran)
Panhematin (hemin)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Must be age 18 years or older; **AND**
- Must be prescribed by a physician who specializes in porphyria treatment (e.g., hematologist, gastroenterologist); **AND**
- Must have a diagnosis of acute hepatic porphyria (AHP); **AND**
- Active disease has been documented with at least 2 porphyria attacks requiring hospitalization, urgent healthcare visit, or intravenous hemin administration at home, within the past 6 months; **AND**
- Must provide chart documentation showing member has been counseled on known triggers of porphyria attacks (e.g., alcohol, smoking, hypocaloric diet/fasting, certain medications) and that the member avoids the applicable triggers; **AND**
- Must provide current weight and have a requested dose that falls within the recommended dosing guidelines from the manufacturer; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Improvement in the member's condition as evidenced by chart documentation showing a reduction in porphyria attacks requiring hemin administration, hospitalization, or urgent healthcare visits (e.g., emergency department visit); **AND**
- Absence of unacceptable toxicity

Length of Authorization:

12 months

MEDICAL POLICY

Hereditary transthyretin amyloidosis (hATTR)

Last review date: 6/17/2024

Applicable Products:
Amvuttra (vutrisiran) Onpattro (patisiran)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Patient is > 18 years old; **AND**
- Confirmed diagnosis of hATTR-PN with documentation of a mutation in the TTR gene; **AND**
- Currently experiencing signs and symptoms of polyneuropathy, including peripheral or autonomic; **AND**
- Baseline polyneuropathy disability (PND) score <IIIb; **AND**
- Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of amyloidosis; **AND**
- Patient is not on a TTR-lowering agent, including Tegsedi and Onpattro/Amvuttra; **AND**
- Patient has no prior or planned liver transplantation; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Documentation of clinical response to therapy, such as an improvement, stabilization, or slowing of progression of hATTR-PN manifestations; **AND**
- Absence of unacceptable toxicity

Length of Authorization:

12 months

MEDICAL POLICY

Hemgenix

Last review date: 5/20/2024

Applicable Products:
Hemgenix (etranacogene dezaparvovec-drlb)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Patient has a diagnosis of moderately severe or severe congenital factor IX deficiency, as confirmed by blood coagulation testing, for which the subject is on continuous routine factor IX prophylaxis, unless there is a contraindication or intolerance; **AND**
- Patient is at least 18 years of age; **AND**
- Must be prescribed by or in consultation with a hematologist; **AND**
- Patient has not received prior hemophilia AAV-vector–based gene therapy; **AND**
- Patient has at least one of the following:
    - Currently use Factor IX prophylaxis therapy;
    - Have current or historical life-threatening hemorrhage;
    - Have repeated, serious spontaneous bleeding episodes*;* **AND**
- Patient has been tested and found negative for Factor IX inhibitor titers (if test result is positive, re-test within approximately 2 weeks. If re-test is also positive, Hemgenix should not be given); **AND**
- Patient Factor IX activity will be monitored periodically (e.g., weekly for 3 months) as well as presence of inhibitors if bleeding is not controlled; **AND**
- Patient will discontinue Factor IX prophylaxis therapy upon achieving FIX levels of 5% from Hemgenix treatment; **AND**
- Prescriber attests they have performed liver health assessments, including enzyme testing and hepatic ultrasound and elastography; **AND**
- Patient has all of the following:
    - Patient does not have an active infection with hepatitis B virus or hepatitis C virus; **AND**
    - Patient is not currently receiving antiviral therapy for a prior hepatitis B virus or C virus exposure; **AND**
    - Patient does not have uncontrolled human immunodeficiency virus (*Note: A patient testing positive for human immunodeficiency virus can still qualify for Hemgenix if controlled on antiviral therapy with CD4+ counts ≥ 200/μL or by a viral load of ≤ 200 copies/mL)*; **AND**
- Patient will have liver function assessed after therapy, weekly for at least 3 months; **AND**
- Patients with preexisting risk factors for hepatocellular carcinoma will have abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:
None

Length of Authorization:
1 dose per lifetime

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.

MEDICAL POLICY

Intravenous Iron

Last review date: 6/18/2024

Applicable Products:	
Feraheme (ferumoxytol)	Injectafer (ferric carboxymaltose)
Ferrlecit (sodium ferric gluconate complex)	Monoferric (ferric derisomaltose)
Ferumoxytol	Venofer (iron sucrose)
INFeD (iron dextran)	

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Patient is at least 18 years of age; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**
- Other causes of anemia (e.g., vitamin B-12 deficiency, thalassemia, sideroblastic anemia, etc.) have been ruled out; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list; **AND**

Iron deficiency anemia in non-dialysis-dependent chronic kidney disease (NDD-CKD)

- Patient must not be receiving hemodialysis; **AND**
- Patient has chronic renal impairment with eGFR between 15-59 mL/min; **AND**
- Patient has iron-deficiency anemia with a Hemoglobin (Hb) ≤11 g/dL; **AND**
  - Ferritin ≤100 ng/mL; **OR**
  - Ferritin ≤300 ng/mL when transferrin saturation (TSAT) ≤30%; **OR**

Iron deficiency anemia in patients intolerant to or who have had unsatisfactory response to oral iron

- Patient had an intolerance or inadequate response to a minimum of 14 days of oral iron; **AND**
- Patient has iron-deficiency anemia with a Hemoglobin (Hb) ≤11 g/dL; **AND**
  - Ferritin <100 ng/mL; **AND**
  - Transferrin saturation (TSAT) <20%

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity

Length of Authorization:

35 days

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.

MEDICAL POLICY

Lyfgenia

Last review date: 3/26/2024

Applicable Products:
Lyfgenia (lovotibeglogene autotemcel)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Patient has a diagnosis of sickle cell disease and a history of vaso-occlusive events; **AND**
- Patient is at least 12 years of age; **AND**
- For patients with α-thalassemia trait (-α3.7/-α3.7), both of the following:
    - Patient does not have more than 2 α-globin gene deletions; **AND**
    - Prescriber will monitor for anemia with erythroid dysplasia following treatment as it may require chronic red blood cell transfusions; **AND**
- Must be prescribed by or in consultation with a hematologist; **AND**
- Prescriber attests to monitor for all of the following:
    - Hematologic malignancies by monitoring complete blood count (with differential) at least every 6 months for at least 15 years after treatment with Lygenia, and integration site analysis at months 6, 12, and as warranted; **AND**
    - Thrombocytopenia and bleeding by frequently monitoring platelet counts until platelet engraftment and platelet recovery are achieved; **AND**
    - Neutrophil engraftment failure (defined as failure to achieve three consecutive absolute neutrophil counts (ANC) ≥ 0.5 × 109 cells/L obtained on different days by Day 43 after treatment) by monitoring neutrophil counts until engraftment has been achieved; **AND**
    - Renal and hepatic function prior to treatment; **AND**
- Patient will not use any of the following:
    - Hydroxyurea for at least 2 months prior to mobilization; **AND**
    - Iron chelators for 6 months post-treatment; **AND**
    - Anti-retroviral medications for at least one month prior to mobilization; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

None

Length of Authorization:

1 dose per lifetime

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.

MEDICAL POLICY

Multiple Sclerosis Agents

Last review date: 6/19/2024

Applicable Products:	
Briumvi (Ublituximab-xiiy)	Tyruko (natalizumab-sztn)
Lemtrada (alemtuzumab)	Tysabri (natalizumab)
Ocrevus (ocrelizumab)	

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Drug-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Briumvi

- Patient is 18 years of age or older; **AND**
- A diagnosis of a relapsing form of MS to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; **AND**
- Documentation of an MRI of the brain showing abnormalities consistent with MS; **AND**
- Prescribed by a neurologist or a provider who specializes in MS; **AND**
- Briumvi will not be used in combination with any disease modifying therapies

Lemtrada

- Patient is 18 years of age or older; **AND**
- A diagnosis of a relapsing form of MS to include relapsing-remitting disease and active secondary progressive disease; **AND**
- Documentation of an MRI of the brain showing abnormalities consistent with MS; **AND**
- Prescribed by a neurologist or a provider who specializes in MS; **AND**
- Lemtrada will not be used in combination with any disease modifying therapies; **AND**
- Due to its safety profile, patient has had an inadequate response to two or more drugs indicated for the treatment of MS

Ocrevus

- Patient is 18 years of age or older; **AND**
- A diagnosis of one of the following:
    - A relapsing form of MS to include relapsing-remitting disease and active secondary progressive disease; **OR**
    - Primary progressive MS**; AND**
- Documentation of an MRI of the brain showing abnormalities consistent with MS; **AND**
- Prescribed by a neurologist or a provider who specializes in MS; **AND**
- Ocrevus will not be used in combination with any disease modifying therapies

Tyruko/Tysabri

- Patient is 18 years of age or older; **AND**
- A diagnosis of one of the following:
    - A relapsing form of MS to include relapsing-remitting disease and active secondary progressive disease; **AND**
        - Documentation of an MRI of the brain showing abnormalities consistent with MS; **AND**
        - Prescribed by a neurologist or a provider who specializes in MS; **AND**
        - Tyruko/Tysabri will not be used in combination with any disease modifying therapies; **OR**
    - Moderate to severe Crohn's Disease; **AND**
        - Patient has had an inadequate response to conventional therapy with one of the following:
            - Corticosteroids
            - 6-mercaptopurine/azathioprine
            - 5 aminosalicylates

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Absence from unacceptable toxicity

Length of Authorization:

12 months

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MEDICAL POLICY

Myasthenia Gravis

Last review date: 6/24/2024

Applicable Products:	
Rystiggo (rozanolixizumab)	Vyvgart (efgartigimod alfa)
Soliris (eculizumab)	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc
Ultomiris (ravulizumab)	
Uplizna (Inebilizumab)	

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Disease-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Atypical Hemolytic Uremic Syndrome (aHUS) (Soliris, Ultomiris)

- Patient is 1 month of age or older (Ultomiris only); **AND**
- Agent will not be used for the treatment of Shiga toxin E. coli related to hemolytic uremic syndrome (STEC-HUS); **AND**
- Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (i.e., ADAMTS-13 activity level ≥ 10%); **AND**
- Patient shows signs of thrombotic microangiopathy (TMA)

Generalized Myasthenia Gravis (gMG) (Rystiggo, Soliris, Ultomiris, Vyvgart, Vyvgart Hytrulo)

- Patient is 18 years of age or older; **AND**
- Patient is positive for antiacetylcholine receptor (AchR) (or anti-muscle-specific tyrosine kinase (MuSK) antibodies for Rystiggo only); **AND**
- Patient meets Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II – IV; **AND**
- Patient meets Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 3; **AND**
- Patient has tried and failed treatment with two (2) or more classes of agents (e.g., acetylcholinesterase inhibitor, steroids and non-steroidal immunosuppressants)

Paroxysmal Nocturnal Hemoglobinuria (PNH) (Soliris, Ultomiris)

- Patient is 1 month of age or older (Ultomiris only); **AND**
- Patient has laboratory evidence of significant intravascular hemolysis (i.e., LDH ≥1.5 x ULN) with symptomatic disease; **AND**
- Diagnosis is confirmed by detection of PNH clones of at least 10% by flow cytometry diagnostic testing

Neuromyelitis Optica Spectrum Disorder (NMOSD) (Soliris, Ultomiris, Uplizna)

- Patient is 18 years of age or older; **AND**
- Patient is positive for anti-aquaporin-4 (AQP4) antibody; **AND**
- Patient has at least one of the following clinical signs:
    - Acute optic neuritis
    - Acute myelitis
    - Area postrema syndrome (APS)
    - Acute brainstem syndrome
    - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
    - Acute cerebral syndrome with NMOSD-typical brain lesions

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Vyvgart Hytrulo)

- Patient is 18 years of age or older

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Patient has shown a clinical response; **AND**
- Absence of unacceptable toxicity

Length of Authorization:

6 months

MEDICAL POLICY

Primary Hyperoxaluria Type 1 (PH1)

Last review date: 6/20/2024

Applicable Products:
Oxlumo (lumasiran)
Rivfloza (nedosiran)

Initial Approval Criteria:

- Drug-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Oxlumo

- Patient is 6 years of age or older; **AND**
- Patient has primary hyperoxaluria type 1 (PH); **AND**
- Patient has an underlying AGXT gene mutation; **AND**
- Prescribed by a nephrologist or provider specializing in PH1

Rivfloza

- Patient is 9 years of age or older; **AND**
- Patient has primary hyperoxaluria type 1 (PH); **AND**
- Patient has relatively preserved kidney function, e.g., eGFR ≥30 mL/min/1.73 m^2; **AND**
- Prescribed by a nephrologist or provider specializing in PH1

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity

Length of Authorization:

12 months

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MEDICAL POLICY

Roctavian

Last review date: 3/25/2024

Applicable Products:
Roctavian (valoctocogene roxaparvovec)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Patient has severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test; **AND**
- Patient is 18 years of age or older; **AND**
- Evidence of any bleeding disorder NOT related to hemophilia A has been ruled out; **AND**
- Patient is on a stable dose of regularly administered exogenous factor VIII for the prevention and control of bleeding episodes; **AND**
- Patient does not have an active infection, either acute (such as acute respiratory infections or acute hepatitis) or uncontrolled chronic (such as chronic active hepatitis B); **AND**
- Roctavian will not be administered concurrently with live vaccines while on immunosuppressive therapies; **AND**
- Patient does not have significant hepatic fibrosis (stage 3 or 4) or cirrhosis; **AND**
- Patient has not received prior hemophilia AAV-vector–based gene therapy; **AND**
- Patient is adeno-associated virus serotype 5 (AAV5) antibody negative as determined by an FDA-approved or CLIA-compliant test; **AND**
- Patient has been tested and found negative for active factor VIII inhibitors (i.e., results from a Bethesda assay or Bethesda assay with Nijmegen modification of less than 0.6 Bethesda Units (BU) on 2 consecutive occasions at least one week apart within the past 12 months) and is not receiving a bypassing agent (e.g., Feiba); **AND**
- Post administration monitoring of patient serum ALT levels will be performed according to the monitoring schedule outlined in the product labeling with corticosteroids (or other immunosuppressive therapy) administered in response to elevations; **AND**
- Patients with preexisting risk factors for hepatocellular carcinoma will have regular (e.g., annually) liver ultrasounds performed and will be tested for alpha-fetoprotein (AFP) elevations following administration; **AND**
- Provider attests that the patient has been counseled or educated on both of the following:
    - Abstain from alcohol for at least one year following treatment; **AND**
    - Will not use any medications, herbal products, or supplements that are hepatotoxic; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

None

Length of Authorization:
1 dose per lifetime

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MEDICAL POLICY

Specialty Asthma

Last review date: 6/20/2024

Applicable Products:	
Cinqair (reslizumab)	Tezspire (tezepelumab-ekko)
Fasenra (benralizumab)	Xolair (omalizumab)
Nucala (mepolizumab)	

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Disease-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Severe Asthma (Cinqair, Fasenra, Nucala, Tezspire)

- Agent is used for add-on maintenance treatment of severe asthma with an eosinophilic phenotype; **AND**
- Agent will not be used for the treatment of for the relief of acute bronchospasm or status asthmaticus; **AND**
- Agent will not be used for the treatment of other eosinophilic conditions**; AND**
- One of the following:
    - Patient is 6 years of age or older (Nucala and Fasenra only)
    - Patient is 18 years of age or older (Cinqair only)
    - Patient is 12 years of age or older (Tezspire only); **AND**
- Patient is currently using a medium or high dose inhaled corticosteroid, a long-acting beta agonist (LABA), and an additional asthma controller medications (LAMA, LTRA)

Asthma (Xolair)

- Patient is 6 years of age or older; **AND**
- Diagnosis of moderate to severe persistent asthma with a positive skin test or in vitro reactivity to a perennial aeroallergen; **AND**
- Patient's symptoms have been inadequately controlled with inhaled corticosteroids

Chronic Rhinosinusitis with Nasal Polyps (Nucala, Xolair)

- Patient is 18 years of age or older; **AND**
- Agent will be used as add-on maintenance treatment for chronic rhinosinusitis with nasal polyps (CRSwNP); **AND**
- Patient had an inadequate response to nasal corticosteroids

Eosinophilic Granulomatosis with Polyangiitis (Nucala)

- Patient is 18 years of age or older; **AND**
- Patient has a history of relapsing disease; **AND**

- Patient will use Nucala in addition to glucocorticoid treatment (prednisone or prednisolone), with or without immunosuppressive therapy (cyclosporine, leflunomide, azathioprine etc.)

Hypereosinophilic Syndrome (Nucala)

- Patient is 12 years of age or older; **AND**
- Patient has hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause; **AND**
- Patient does not have FIP1L1-PDGFRα kinase-positive HES; **AND**
- Patient is on standard HES therapy prior to starting Nucala (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy)

IgE-Mediated Food Allergy (Xolair)

- Patient is 1 year of age or older; **AND**
- Patient has Type 1 allergic reactions, including anaphylaxis, that can occur with exposure to one or more foods; **AND**
- Patient will continue to avoid food allergens while using Xolair; **AND**
- Xolair will not be used as an emergency treatment of allergic reactions, including anaphylaxis

Chronic Spontaneous Urticaria (Xolair)

- Patient is 12 years of age or older; **AND**
- Patient has chronic spontaneous urticaria (CSU) and remain symptomatic despite H1 antihistamine treatment

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity

Length of Authorization:

12 months

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MEDICAL POLICY

Spinal Muscular Atrophy

Last review date: 6/15/2024

Applicable Products:
Spinraza (nusinersen)
Zolgensma (onasemnogene abeparvovec-xioi)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Drug-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Spinraza

- Spinraza is prescribed by a neurologist or neuromuscular specialist with expertise in the treatment of SMA; **AND**
- One of the following:
    - Individual has had SMA diagnostic test results confirming 0 copies of SMN1; **OR**
    - Molecular genetic testing of 5q SMA for one of the following: homozygous gene deletion, homozygous conversion mutation, compound heterozygote; AND
- Patient has not previously received gene therapy and will not concomitantly receive Zolgensma; **AND**
- Patient must not have advanced disease (complete limb paralysis, permanent ventilation support, etc.); **AND**
- Patient must have the following laboratory tests at baseline and prior to each administration:
    - Platelet count
    - Prothrombin time
    - Activated partial thromboplastin time
    - Quantitative spot urine protein testing

Zolgensma

- Patient has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene; **AND**
- Zolgensma is prescribed by a neurologist or neuromuscular specialist with expertise in the treatment of SMA; **AND**
- Diagnosis of SMA by a neurologist with expertise in the diagnosis of SMA; **AND**
- Patient has 4 copies or less of SMN2 gene; **AND**
- One of the following:
    - Patient is less than 2 years of age; **OR**
    - For use in a neonatal patient born prematurely, the full-term gestational age has been reached; **AND**

- Patient does not have advanced SMA (i.e., Invasive ventilation or tracheostomy, complete limb paralysis); **AND**
- Patient will not receive routine concomitant SMN modifying therapy (e.g., Spinraza); **AND**
- Physician attests that the patient will not receive Zolgensma if the most recent pre-treatment anti-AAV9 antibody titer is above 1:50; **AND**
- The following laboratory tests will be evaluated prior to administration of Zolgensma:
    - Liver function tests (normal clinical exam, total bilirubin, and prothrombin results, and ALT and AST levels below 2 × ULN); **AND**
    - Complete blood count, including platelet counts; **AND**
    - Patient has undergone a renal function assessment within the last 30 days and has a creatinine level < 1.0 mg/dL

Renewal Criteria:

- None for Zolgensma
- Spinraza:
    - Patient continues to meet Initial Approval Criteria; **AND**
    - Absence of unacceptable toxicity

Length of Authorization:

Zolgensma - 1 dose per lifetime
Spinraza – 6 months

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MEDICAL POLICY

Vyjuvek (beremagene geperpavec-svdt)

Last review date: 6/17/2024

Applicable Products:
Vyjuvek (beremagene geperpavec-svdt)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Must have a diagnosis of Dystrophic Epidermolysis Bullosa (DEB); **AND**
- Member meets ALL of the following - documentation must be provided:
    - Mutation in the collagen type VII alpha 1 chain (COL7A1) gene
    - Wound to be treated is open and clean with adequate granulation tissue, excellent vascularization, and no appearance of active infection
    - The member does not have current evidence or a history of squamous cell carcinoma in the area to be treated
    - The member does not have evidence of an active systemic infection
    - The member has not received a skin graft in the past 3 months
    - Treatment is prescribed by or in consultation with a specialist (dermatologist, geneticist)
    - The dose does not exceed one single dose vial (containing 5x109 plaque forming units (PFU) per mL) every 7 days; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- The member had a beneficial response to treatment with evidence of improved wound healing (closure or reduction in wound area from baseline); **AND**
- Absence of unacceptable toxicity

Length of Authorization:

6 months

MEDICAL POLICY

Zynteglo

Last review date: 3/23/2024

Applicable Products:
Zynteglo (betibeglogene autotemcel)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Must have a diagnosis of transfusion-dependent β-thalassemia confirmed by both of the following:
    - Genetic testing confirming diagnosis of β-thalassemia; **AND**
    - Documentation of transfusion-dependent disease defined as one of the following:
        - History of ≥ 8 transfusions of packed red blood cells (pRBC) per year in the previous two years; **OR**
        - History of ≥ 100 mL/kg/year of pRBCs in the previous two years; **AND**
- Must be prescribed by or in consultation with a hematologist; **AND**
- Must be age 4 years or older; **AND**
- Patient does not currently have an active bacterial, viral, fungal, or parasitic infection as determined by the prescribing physician; **AND**
- One of the following:
    - For patients 18 years of age or older: Must have an attestation from the provider that the member is eligible to undergo hematopoietic stem cell transplant (HSCT); **OR**
    - For patients 17 years of age or younger: Must have an attestation from the prescriber that a suitable and willing fully matched sibling donor is not available for allogeneic hematopoietic stem cell transplant (HSCT); **AND**
- Patient must not have any of the following:
    - Cardiomyopathy or severe congestive heart failure (NYHA class III or IV)
    - Advanced liver disease
    - Advanced kidney disease
    - Hypersplenism
    - Evidence of active infection including hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV)
    - Prior HSCT or gene therapy; **AND**
- Must be administered at a Zynteglo Qualified Treatment Center (QTC); **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

None

Length of Authorization:

1 dose per lifetime

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