Medical and Behavioral Health Policy Activity

Policies Effective: January 1, 2024 Notification Posted: November 1, 2023

Policies Developed

- **None**

Policies Revised

- **Hematopoietic Stem Cell Transplantation for Acute Myeloid Leukemia, II-115**
  Note: Acute myeloid leukemia for the purpose of this policy includes the following subtypes: Acute Myeloid Leukemia (AML), Acute Promyelocytic Leukemia (APL), and Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

  I. Allogeneic Hematopoietic Stem-Cell Transplantation

  - Allogeneic hematopoietic stem-cell transplantation (HSCT) using a myeloablative conditioning regimen may be considered MEDICALLY NECESSARY AND APPROPRIATE to treat:
    - Intermediate- to high-risk AML in remission; or
    - AML that is refractory to, or relapses following, standard induction chemotherapy; or
    - Any risk AML in remission for patients ≥ 60 years old.
  - Allogeneic HSCT using a reduced-intensity conditioning regimen may be considered MEDICALLY NECESSARY AND APPROPRIATE as a treatment of AML in patients who are in complete marrow and extramedullary remission, and who for medical reasons would be unable to tolerate a myeloablative conditioning regimen.

  II. Autologous Hematopoietic Stem-Cell Transplantation

  - Autologous hematopoietic stem-cell transplantation (HSCT) may be considered MEDICALLY NECESSARY AND APPROPRIATE to treat AML in first or second remission or relapsed AML if responsive to intensified induction chemotherapy in patients who are not candidates for allogeneic HSCT.

  III. Repeat Transplant

  - A second allogeneic hematopoietic stem-cell transplantation (HSCT) (myeloablative or reduced-intensity conditioning) may be considered MEDICALLY NECESSARY AND APPROPRIATE to treat:
    - AML in patients who have relapsed following a prior HSCT, ≥ 6 months after the initial HSCT.
  - A second allogeneic hematopoietic stem-cell transplantation (HSCT) is considered EXPERIMENTAL/INVESTIGATIVE for all other indications, including but not limited to refractory or progressive disease, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.
  - A second autologous hematopoietic stem-cell transplantation (HSCT) is considered EXPERIMENTAL/INVESTIGATIVE for all indications, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Continuous Glucose Monitoring Systems, VII-05**

  I. Professional (Short-Term) Continuous Glucose Monitoring (CGM) Systems

  - Use of a professional (short-term) CGM system for 3 to 5 days may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients with diabetes who meet **ONE** of the following criteria:

- Diabetes is poorly controlled, as evidenced by unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, or recurrent diabetic ketoacidosis; **OR**
- Prior to insulin pump initiation to determine basal insulin levels.

- All other uses of a professional (short-term) CGM system are considered **EXPERIMENTAL/ INVESTIGATIVE** due to the lack of evidence demonstrating an impact on improved health outcomes.

II. Personal (Long-term or Real-Time) Continuous Glucose Monitoring (CGM) Systems

- Use of a personal (long-term or real-time) CGM system may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients with diabetes who meet **ONE** of the following criteria:
  - Type 1 diabetes; **OR**
  - Type 2 diabetes AND ONE of the following:
    - Insulin dependent; **OR**
    - High risk for hypoglycemia (e.g., history of severe hypoglycemia requiring assistance to manage) and/or impaired awareness of hypoglycemia;

    OR
  - During pregnancy.
- All other uses of a personal (long-term or real-time) CGM system are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of evidence demonstrating an impact on improved health outcomes.

III. Closed-Loop Continuous Glucose Monitoring (CGM) and Insulin Pump Systems (Artificial Pancreas Device Systems)

- Use of an FDA-approved closed-loop CGM and insulin pump system (artificial pancreas device system) with a low-glucose suspend feature may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients with diabetes who meet **ALL** of the following criteria:
  - Type 1 or insulin-dependent type 2 diabetes; **AND**
  - Meets FDA-approved age requirements for the specific system being used; **AND**
  - Insulin injections are required 3 or more times per day or an insulin pump is used for maintenance of glucose control.
- All other uses of a closed-loop CGM and insulin pump system (artificial pancreas device system) are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of evidence demonstrating an impact on improved health outcomes.

IV. Implantable Interstitial Glucose Sensors

Use of an FDA-approved implantable interstitial glucose sensor is considered **EXPERIMENTAL/ INVESTIGATIVE** due to the lack of evidence demonstrating an impact on improved health outcomes.

- **Site of Service for Selected Specialty Medical Drugs, XI-06**

NOTE:

- **This policy applies to commercial health plan members only.**
- **See table below for medical drugs included in the site of service program.**
- **Medical necessity of the drug may be separately reviewed against the appropriate criteria.**
- **When policy criteria for use of a hospital outpatient facility are not met, a non-hospital outpatient setting (e.g., freestanding infusion center or home infusion) should be used.**

I. Use of a hospital outpatient facility for infusion or injection of a medical drug may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ANY** of the following criteria are met:

- Age <18 years; OR
- Nearest in-network non-hospital outpatient facility with supervised infusion or injection capabilities is >25 miles from patient's home AND patient is not eligible for home infusion; OR
- First dose or <60 days from the first dose; OR
- Reinitiating therapy after not being on therapy for ≥6 months (Note: this does not include maintenance therapy); OR
- History of a severe adverse event with prior infusion or injection therapy (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); OR
- History of adverse events with prior infusion or injection therapy (e.g., hypersensitivity or allergic reactions), which have not been successfully managed through standard premedications or infusion rate adjustments; OR
- Comorbidity or medical condition that increases the risk of an adverse event, including but not limited to the following:
  - Cardiopulmonary conditions; or
  - Inability to safely tolerate intravenous volume loads, including unstable renal function; or
  - Difficult or unstable vascular access;

  OR
- Physical or cognitive impairment such that infusion or injection in a non-hospital outpatient setting would present an unnecessary health risk; OR
- Concurrent treatment with medications that require a higher level of monitoring (e.g., intravenous cytotoxic chemotherapy, blood products); OR
- Member requests use of an outpatient facility.

II. Use of a hospital outpatient facility for infusion or injection of a medical drug when the criteria in section I are not met is considered **NOT MEDICALLY NECESSARY**.

Table 1. Specialty Medical Drugs Included in the Site of Service Program

Drug(s)	Policy #
Abatacept (Orencia®)	II-161
Agalsidase Beta (Fabrazyme®)	II-26
Alglucosidase Alfa (Lumizyme®)	II-186
Alpha-1 Proteinase Inhibitors • Alpha-1 Antitrypsin (Aralast NP™) • Alpha-1 Antitrypsin (Glassia®) • Alpha-1 Antitrypsin (Prolastin-C®) • Alpha-1 Antitrypsin (Zemaira®)	II-206
Anifrolumab (Saphnelo®)	II-255
Avalglucosidase Alpha (Nexviazyme®)	II-256
Belimumab (Benlysta®)	II-152
Benralizumab (Fasenra®)	II-203
Burosumab (Crysvita®)	II-212
Certolizumab Pegol (Cimzia®)	II-179
Eculizumab (Soliris®)	II-196
Efgartigimod alfa (Vyvgart™)	II-260
Edaravone (Radicava®)	II-178
Elosulfase alfa (Vimizim®)	II-218

Eteplirsen (Exondys 51®)	II-172
Galsufase (Naglazyme®)	II-217
Golimumab (Simponi Aria®)	II-180
Idursulfase (Elaprase®)	II-215
Immunoglobulin Therapy (e.g., Hizentra®, Gamunex®-C, Gammaked™, Gammagard Liquid®, Cuvitru™, HyQvia)	II-51
Inclisiran (Leqvio®)	II-258
Infliximab (Remicade®)	II-97
Intravenous Enzyme Replacement Therapy for Gaucher Disease • Imiglucerase (Cerezyme®) • Taliglucerase Alfa (Elelvso®) • Velaglucerase Alfa (Vpriv®)	II-214
Laronidase (Aldurazyme®)	II-216
Mepolizumab (Nucala®)	II-201
Natalizumab (Tysabri®)	II-49
Ocrelizumab (Ocrevus®)	II-185
Olipudase alfa (Xenpozyme®)	II-270
Omalizumab (Xolair®)	II-34
Patisiran (Onpattro™)	II-220
Pegloticase (Krystexxa®)	II-147
Pharmacologic Therapies for Hereditary Angioedema • C1 Esterase Inhibitor (Berinert®) • C1 Esterase Inhibitor (Cinryze®) • Ecallantide (Kalbitor®) • C1 Esterase Inhibitor (Ruconest®)	II-102
Ravulizumab (Ultomiris®)	II-229
Reslizumab (Cinqair®)	II-202
Risankizumab (Skyrizi®)	II-265
Rituximab (Rituxan®)	II-47
Romiplostim (Nplate®)	II-211
Sebelipase Alfa (Kanuma®)	II-200
Sutimlimab (Enjaymo™)	II-263
Tezepelumab (Tezspire™)	II-259
Tildrakizumab (Ilumya™)	II-222
Tocilizumab (Actemra™)	II-181
Ublituximab (Briumvi®)	II-275
Ustekinumab (Stelara®)	II-168
Vedolizumab (Entyvio®)	II-182
Velmanase Alfa (Lamzede®)	II-278
Vestronidase Alfa (Mepsevii™)	II-219
Vutrisiran (Amvuttra™)	II-264

- **Infliximab, II-97**
  NOTE: This policy is not to be used for reviews of infliximab (Remicade®, Inflectra®, Renflexis®, Avsola™, Ixifi™, unbranded infliximab) when administered in an inpatient setting.

I. <u>Initial Review for Infliximab (Remicade®, Inflectra®, Renflexis®, Avsola™, Ixifi™, Unbranded Infliximab)</u>

Infliximab (Remicade®, Inflectra®, Renflexis®, Avsola™, Ixifi™, unbranded infliximab) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Perianal fissuring/chronic fistulizing Crohn's disease in a patient 6 years of age or older; OR
  - Moderately to severely active rheumatoid arthritis in a patient 18 years of age or older **AND** ONE of the following:
    - Previously failed another biologic immunomodulator with FDA approval for the same indication; or
    - Used one conventional agent prerequisite for the indication (see table 2 below); or
    - Documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL conventional agents; OR
  - Moderately to severely active Crohn's disease in a patient 6 years of age or older **AND** ONE of the following:
    - Previously failed another biologic immunomodulator with FDA approval for the same indication; or
    - Used one conventional agent prerequisite for the indication (see table 2 below); or
    - Documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL conventional agents for the indication; OR
  - Moderately to severely active ulcerative colitis in a patient 6 years of age or older **AND** ONE of the following:
    - Previously failed another biologic immunomodulator with FDA approval for the same indication; or
    - Used one conventional agent prerequisite for the indication (see table 2 below); or
    - Documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL conventional agents for the indication; OR
  - Active ankylosing spondylitis in a patient 18 years of age or older **AND** ONE of the following:
    - Previously failed another biologic immunomodulator with FDA approval for the same indication; or
    - Used at least two NSAIDs (see table 2 below); or
    - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least two NSAIDs; OR
  - Moderate to severe plaque psoriasis in a patient 18 years of age or older **AND** ONE of the following:
    - Previously failed another biologic immunomodulator with FDA approval for the same indication; or
    - Used one conventional agent prerequisite for the indication (see table 2 below); or
    - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at ALL conventional agents for the indication; or
    - First line treatment for severe active plaque psoriasis (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritis); or
    - First line treatment for moderate to severe plaque psoriasis with concomitant severe active psoriatic arthritis (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to psoriatic arthritis, long term damage that interferes with function [i.e., joint deformities], rapid progressive); OR
  - Active psoriatic arthritis in a patient 18 years of age or older **AND** ONE of the following:
    - Previously failed another biologic immunomodulator with FDA approval for the same indication; or
    - Used one conventional agent prerequisite for the indication (see table 2 below); or
    - Documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL conventional agents for the indication; or

- First line treatment for severe active psoriatic arthritis (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to psoriatic arthritis, long term damage that interferes with function [i.e., joint deformities], rapid progressive); or
- First line treatment for active psoriatic arthritis with concomitant severe psoriasis (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritis); OR

- Moderately to severely active juvenile idiopathic arthritis in a patient 2 years of age or older **AND** ONE of the following:
  - Previously failed another biologic immunomodulator with FDA approval for the same indication; or
  - Used one conventional agent prerequisite for the indication (see table 2 below); or
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL conventional agents for the indication; OR
- Chronic, recurrent, treatment-refractory, or vision-threatening non- infectious uveitis **AND** ONE of the following:
  - Previously failed another biologic immunomodulator with FDA approval for the same indication; or
  - Used at least 2 conventional agent prerequisites for the indication (see table 2 below); or
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least two conventional agents for the indication from two different drug classes;
- Immune checkpoint inhibitor related toxicity and ALL of the following:
  - ONE of the following toxicities related to immunotherapy:
    - Moderate (grade 2) to severe (grade 3-4) diarrhea or colitis;
    - Severe (grade 3-4) pneumonitis refractory to methylprednisolone after 48 hours of therapy;
    - Severe (grade 3) or life-threatening (grade 4) elevated serum creatinine/ acute kidney injury that is refractory to at least 1 week of therapy with corticosteroids;
    - Uveitis (grade 3-4) that is refractory to high-dose systemic corticosteroids;
    - Suspected myocarditis if no improvement within 24 hours of starting pulse-dose corticosteroids;
    - Severe inflammatory arthritis as additional disease-modifying therapy refractory to high-dose corticosteroids after 7 days of treatment or if unable to taper corticosteroids by day 14;
    - Moderate, severe or life-threatening steroid-refractory myalgias or myositis; AND
  - Receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, etc.);

AND

- For commercial health plan members only, ONE of the following:
  - Previously tried and failed Remicade®, Inflectra®, Renflexis®; and unbranded infliximab; OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to Remicade®, Inflectra®, Renflexis®; and unbranded infliximab; **OR**
- For Medicaid health plan members only, ONE of the following:
  - Previously tried and failed Inflectra®, Renflexis®; and Avsola™; OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to Inflectra®, Renflexis®; and Avsola™.

AND

- No FDA labeled contraindications to infliximab (see table 1 below); **AND**
- Not currently being treated with another biologic therapy; **AND**
- For patients not currently receiving infliximab, the patient has been screened for hepatitis B infection and has begun therapy if appropriate; **AND**
- For patients not currently receiving infliximab, the patient has been screened for latent tuberculosis (TB) and started on TB therapy if the patient tests positive; **AND**
- Requested dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications (see table 3 below); **AND**
- For commercial health plan members only, infliximab is administered in accordance with site of service criteria (see policy XI-06); **AND**

- For commercial and Medicaid health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

II. Renewal Review for Infliximab (Remicade®, Inflectra®, Renflexis®, Avsola™, Ixifi™, Unbranded Infliximab)

Infliximab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for infliximab through the initial review process; **AND**
- Continued positive clinical response to infliximab therapy (e.g., stabilization and/or slowing of disease progression, or decrease in symptom severity and/or frequency); **AND**
- No FDA labeled contraindications to infliximab (see table 1 below); **AND**
- Not currently being treated with another biologic therapy; **AND**
- Requested dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications (see table 3 below); **AND**
- For commercial health plan members only, infliximab is administered in accordance with site of service criteria (see policy XI-06).

III. Experimental/Investigative Uses

All other uses of infliximab are considered **EXPERIMENTAL/INVESTIGATIVE**, including but not limited to intra-articular injections and treatment of the following conditions, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- Age-related macular degeneration
- Alcoholic hepatitis
- Arthritis (other than rheumatoid arthritis, psoriatic arthritis, and juvenile idiopathic arthritis)
- Behcet syndrome
- Cancer cachexia
- Depression
- Diabetic macular edema
- Endometriosis
- Erythrodermic or exfoliative psoriasis
- Giant cell arteritis
- Graft-versus-host disease
- Hidradenitis suppurativa
- Kawasaki syndrome
- Polyarteritis nodosa
- Polymyalgia rheumatica
- Renal cell carcinoma
- Sacroiliitis
- Sarcoidosis
- Sclerosing cholangitis
- Sjogren syndrome
- Systemic lupus erythematosus
- Systemic necrotizing vasculitides
- Systemic sclerosis
- Takayasu's arteritis

- Wegener's Granulomatosis

Table 1. FDA Labeled Contraindications

Agent	FDA Labeled Contraindications
Infliximab	Doses >5 mg/kg in moderate to severe heart failure Hypersensitivity

Table 2. Conventional Agent Prerequisites

FDA Labeled Indications	Conventional Agent Prerequisites
Rheumatoid arthritis (RA)	methotrexate leflunomide sulfasalazine hydroxychloroquine
Psoriatic arthritis (PsA)	methotrexate leflunomide sulfasalazine hydroxychloroquine cyclosporine
Psoriasis (Ps)	methotrexate topical corticosteroids coal tar products anthralin calcipotriene calcitriol acitretin tazarotene cyclosporine methoxsalen tacrolimus pimecrolimus PUVA (phototherapy)
Crohn's disease (CD)	methotrexate corticosteroids (including budesonide EC capsule) azathioprine 6-mercaptopurine
Ulcerative colitis (UC)	methotrexate

	aminosalicylates corticosteroids (including budesonide EC capsule) azathioprine 6-mercaptopurine cyclosporine
Ankylosing spondylitis	NSAIDs, prescription strength, (ibuprofen, ketoprofen, celecoxib)
Off Label Indications	**Conventional Agent Prerequisites**
Juvenile idiopathic arthritis (JIA)	methotrexate leflunomide sulfasalazine hydroxychloroquine
Non-infectious uveitis	methotrexate azathioprine cyclosporine mycophenolate tacrolimus

Table 3. Dosing

NOTE: See documentation submission requirements below if the requested dose is outside of the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Rheumatoid arthritis	3 mg/kg at weeks 0, 2, and 6 followed by 3 mg/kg every 8 weeks. May go up to 10 mg/kg every 4 weeks.
Crohn's disease - adult	IV induction: 5 mg/kg at weeks 0, 2, and 6. May go up to 10 mg/ kg. IV maintenance: 5 mg/kg every 8 weeks. May go up to 10 mg/ kg every 4 weeks. If no response by 14 weeks, discontinue
Crohn's disease – pediatric (≥6 years)	IV induction: 5 mg/kg at weeks 0, 2, and 6. May go up to 10 mg/ kg. IV maintenance: 5 mg/kg every 8 weeks. May

	go up to 10 mg/ kg every 4 weeks.
Ulcerative colitis – adult and pediatric (≥6 years)	IV induction: 5 mg/kg at weeks 0, 2, and 6. May go up to 10 mg/ kg. IV maintenance: 5 mg/kg every 8 weeks. May go up to 10 mg/ kg every 4 weeks.
Ankylosing spondylitis	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 6 weeks
Psoriatic arthritis and plaque psoriasis	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 8 weeks
Off Label Indications	**Dosing**
Juvenile idiopathic arthritis	3 to 6 mg/kg at weeks 0, 2, and 6 followed by 3 to 6 mg/kg every 8 weeks.
Non-infectious uveitis	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 8 weeks
Management of Immune Checkpoint Inhibitor Related Toxicity	5 mg/ kg at weeks 0 and 2

IV (intravenous)

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization. In addition, the following documentation must also be submitted:

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. For patients not currently receiving infliximab, laboratory results for hepatitis B and latent tuberculosis (TB) screening. If either test was positive, describe follow-up therapy.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
5. For commercial health plan members only, the site of service for infliximab administration is specified, including CMS place of service code (see policy XI-06). If infliximab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06
6. For commercial and Medicaid health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review

1. Documentation of prior approval for infliximab through the initial review process.

2. Documentation, since most recent approval, supporting continued positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
5. For commercial health plan members only, the site of service for infliximab administration is specified, including CMS place of service code (see policy XI-06). If infliximab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.

- **MS Drug Policy Updates:**
  - **Alemtuzumab, II-184**

I. Initial Review for Alemtuzumab (Lemtrada®)

Alemtuzumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of a relapsing form of multiple sclerosis (MS) (i.e., relapsing-remitting MS [RRMS], secondary-progressive MS [SPMS] with relapses); **AND**
- ONE of the following:
  - Tried and failed natalizumab (Tysabri®), or ocrelizumab (Ocrevus®), or ublituximab (Briumvi®) for MS; OR
  - Tried and failed at least two preferred, self-administered, disease-modifying therapies for MS (see table 2a or 2b below); OR
  - Documented intolerance, FDA-labeled contraindication, or hypersensitivity to ALL preferred, self-administered, disease-modifying therapies for MS (see table 2a or 2b below).

  AND
- Alemtuzumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- No FDA-labeled contraindications to therapy (see table 1 below); **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below); **AND**
- For commercial and Medicaid health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

II. Renewal Review for Alemtuzumab (Lemtrada®)

Alemtuzumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for alemtuzumab through the initial review process; **AND**
- Continued positive clinical response to alemtuzumab therapy (e.g., stabilization and/or slowing of disease progression, or decrease in symptom severity and/or frequency); **AND**
- No FDA-labeled contraindications to therapy (see table 1 below); **AND**
- Alemtuzumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below).

III. Experimental/Investigative Uses

All other uses of alemtuzumab are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Table 1. FDA Labeled Contraindications

Agent	FDA Labeled Contraindications
Alemtuzumab	Infection with human immunodeficiency virus (HIV) Known hypersensitivity or anaphylactic reactions to alemtuzumab or any of the excipients Active infection

Table 2a. Conventional Agent Prerequisites for Alemtuzumab (Lemtrada®) – Commercial

FDA Labeled Indications	Conventional Agent Prerequisites
Multiple sclerosis – Relapsing forms	Cladribine (Mavenclad) Dimethyl fumarate (generic) Diroximel fumarate (Vumerity) Fingolimod (generic) Glatiramer (generic, Glatopa) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron) Ofatumumab (Kesimpta) Ozanimod (Zeposia) Peginterferon beta-1a (Plegridy) Siponimod (Mayzent) Teriflunomide (generic)

Table 2b. Conventional Agent Prerequisites for Alemtuzumab (Lemtrada®) – Medicaid

FDA Labeled Indications	Conventional Agent Prerequisites
Multiple sclerosis – Relapsing forms	Cladribine (Mavenclad) Dimethyl fumarate (Tecfidera) Diroximel fumarate (Vumerity) Fingolimod (Gilenya) Glatiramer acetate (Copaxone, Glatopa) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron, Extavia) Monomethyl fumarate (Bafiertam)

	Ofatumumab (Kesimpta) Ozanimod (Zeposia) Peginterferon beta-1a (Plegridy) Ponesimod (Ponvory) Siponimod (Mayzent) Teriflunomide (Aubagio)

Table 3. Dosing

NOTE: See documentation submission requirements below if the requested dose is outside of the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Multiple sclerosis – Relapsing forms	12 mg/day for two treatment courses: · First treatment course: 12 mg/day on 5 consecutive days (60 mg total dose) · Second treatment course: 12 mg/day on 3 consecutive days (36 mg total dose) administered 12 months after the first treatment course Subsequent treatment courses: 12mg/day on 3 consecutive days (36 mg total) administered at least 12 months after the last dose of any prior treatment courses.

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
3. The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
4. For commercial and Medicaid health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review

1. Documentation of prior approval for alemtuzumab through the initial review process.
2. Documentation, since most recent approval, supporting continued positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the

medications.

4. The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.

- **Natalizumab, II-49**

I. Initial Review for Natalizumab (Tysabri®) for Multiple Sclerosis

Natalizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of a relapsing form of multiple sclerosis (MS) (i.e., relapsing-remitting MS [RRMS], secondary-progressive MS [SPMS] with relapses, and clinically isolated syndrome); **AND**
- ONE of the following:
  - Tried and failed alemtuzumab (Lemtrada®), ocrelizumab (Ocrevus®), or ublituximab (Briumvi®) for MS; OR
  - Tried and failed at least one preferred, self-administered, disease-modifying therapy for MS (see table 1a or 1b below); OR
  - Documented intolerance, FDA-labeled contraindication, or hypersensitivity to ALL preferred, self-administered, disease-modifying therapy for MS (see table 1a or 1b below); OR
  - First line treatment for patients with a significant burden of disease or presentation of an aggressive form of multiple sclerosis, as defined by ONE of the following:
    - MRI findings showing spinal cord lesions, brainstem lesions, gadolinium-enhancing lesions, or new, enlarging, or high burden of T2 lesions, OR
    - Expanded Disability Status Scale (EDSS) score ≥ 4; OR
    - One or more relapses with incomplete resolution in the past year;

  AND
- Documented negative JCV antibody test within the past 6 months; **AND**
- No FDA-labeled contraindications to therapy (see table 2 below); **AND**
- Natalizumab will be used as single agent therapy, and not in combination with antineoplastic, immunosuppressant, or immunomodulatory therapy; **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below); **AND**
- For commercial health plan members only, natalizumab is administered in accordance with site of service criteria (see policy XI-06).
- For commercial and Medicaid health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

I. Initial Review for Natalizumab (Tysabri®) for Crohn's Disease

Natalizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- 18 years of age or older; **AND**
- Diagnosis of moderately to severely active Crohn's disease (CD) with evidence of inflammation; **AND**
- ONE of the following:
  - Tried and failed at least one TNF-alpha inhibitor (e.g., adalimumab, infliximab, certolizumab pegol) AND at least one conventional agent prerequisite for CD (see table 1a. below); OR
  - Documented intolerance, FDA-labeled contraindication, or hypersensitivity to BOTH a TNF-alpha

inhibitor and a conventional agent for CD;
AND

- Documented negative JCV antibody test within the past 6 months; **AND**
- No FDA labeled contraindications to therapy (see table 2 below); **AND**
- Natalizumab will not be used in combination with immunosuppressants (excluding systemic corticosteroids) (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or TNF-alpha inhibitors; **AND**
- The dose is within the FDA labeled dose for the indication (see table 3 below); **AND**
- For commercial health plan members only, natalizumab is administered in accordance with site of service criteria (see policy XI-06).
- For commercial and Medicaid health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

II. Renewal Review for Natalizumab (Tysabri®) for Multiple Sclerosis or Crohn's Disease

Natalizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; **AND**
- Continued positive clinical response to natalizumab therapy (e.g., stabilization and/or slowing of disease progression, or decrease in symptom severity and/or frequency); **AND**
- No FDA-labeled contraindications to therapy (see table 2 below); **AND**
- ONE of the following:
  - In patients with MS, natalizumab will be used as single agent therapy, and not in combination with antineoplastic, immunosuppressant, or immunomodulatory therapy; OR
  - In patients with CD, natalizumab will not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or TNF-alpha inhibitors;

  AND
- Documented negative JCV antibody test within the past 6 months; **AND**
- The dose is within the FDA labeled dose for the indication (see table 3 below); **AND**
- For commercial health plan members only, natalizumab is administered in accordance with site of service criteria (see policy XI-06).

III. Experimental / Investigative Uses

All other uses of natalizumab are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Table 1a. Prerequisite Agents for Natalizumab (Tysabri®) - Commercial

FDA Labeled Indications	Conventional Agent Prerequisites
Multiple sclerosis – Relapsing forms	Cladribine (Mavenclad) Dimethyl fumarate (generic) Diroximel fumarate (Vumerity) Fingolimod (generic) Glatiramer (generic, Glatopa) Interferon beta-1a (Avonex, Rebif)

	Interferon beta-1b (Betaseron) Ofatumumab (Kesimpta) Ozanimod (Zeposia) Peginterferon beta-1a (Plegridy) Siponimod (Mayzent) Teriflunomide (generic)
Crohn's disease	Azathioprine Corticosteroids (including budesonide EC capsule) Methotrexate 6-mercaptopurine

Table 1b. Prerequisite Agents for Natalizumab (Tysabri®) – Medicaid

FDA Labeled Indications	Conventional Agent Prerequisites
Multiple sclerosis – Relapsing forms	Cladribine (Mavenclad) Dimethyl fumarate (Tecfidera) Diroximel fumarate (Vumerity) Fingolimod (Gilenya) Glatiramer acetate (Copaxone, Glatopa) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron, Extavia) Monomethyl fumarate (Bafiertam) Ofatumumab (Kesimpta) Ozanimod (Zeposia) Peginterferon beta-1a (Plegridy) Ponesimod (Ponvory) Siponimod (Mayzent) Teriflunomide (Aubagio)

Table 2. FDA-Labeled Contraindications

Agent	FDA Labeled Contraindications
Natalizumab	Current or prior history of progressive multifocal leukoencephalopathy (PML) Hypersensitivity

Table 3. Dosing

NOTE: See documentation submission requirements below if the requested dose is outside of the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Multiple sclerosis – Relapsing forms	300 mg every 4 weeks
Crohn's disease	300 mg every 4 weeks NOTE: discontinue in patients who have not experienced therapeutic benefit by 12 weeks of induction therapy, and in patients who cannot discontinue chronic concomitant steroids within 6 months of starting therapy

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
3. The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
4. For commercial health plan members only, the site of service for natalizumab administration is specified, including CMS place of service code (see policy XI-06). If natalizumab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.
5. For commercial and Medicaid health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review

1. Documentation of prior approval for natalizumab through the initial review process.
2. Documentation, since most recent approval, supporting continued positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.

5. For commercial health plan members only, the site of service for natalizumab administration is specified, including CMS place of service code (see policy XI-06). If natalizumab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.

- **Ocrelizumab II-185**

I. Initial Review for Ocrelizumab (Ocrevus®) for Relapsing Forms of Multiple Sclerosis

Ocrelizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of a relapsing form of MS (i.e., relapsing-remitting MS [RRMS], secondary-progressive MS [SPMS] with relapses, and clinically isolated syndrome); **AND**
- ONE of the following:
  - Tried and failed natalizumab (Tysabri®), alemtuzumab (Lemtrada®), or ublituximab (Briumvi®) for MS; OR
  - Tried and failed at least one preferred, self-administered, disease-modifying therapy for MS (see table 1a or 1b below); OR
  - Documented intolerance, FDA-labeled contraindication, or hypersensitivity to ALL preferred, self-administered, disease-modifying therapy for MS (see table 1a or 1b below); OR
  - First line treatment for patients with a significant burden of disease or presentation of an aggressive form of multiple sclerosis, as defined by ONE of the following:
    - MRI findings showing spinal cord lesions, brainstem lesions, gadolinium-enhancing lesions, or new, enlarging, or high burden of T2 lesions, OR
    - Expanded Disability Status Scale (EDSS) score ≥ 4; OR
    - One or more relapses with incomplete resolution in the past year;

  AND
- No FDA-labeled contraindications to therapy (see table 2 below); **AND**
- For patients not currently receiving ocrelizumab, the patient has been screened for hepatitis B infection; **AND**
- Ocrelizumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below); **AND**
- For commercial health plan members only, ocrelizumab is administered in accordance with site of service criteria (see policy XI-06); **AND**
- For commercial and Medicaid health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement.

II. Initial Review for Ocrelizumab (Ocrevus®) for Primary Progressive Forms of Multiple Sclerosis

Ocrelizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of a primary-progressive form of MS (PPMS); **AND**
- No FDA-labeled contraindications to therapy (see table 2 below); **AND**
- For patients not currently receiving ocrelizumab, the patient has been screened for hepatitis B infection; **AND**
- Ocrelizumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below); **AND**
- For commercial health plan members only, ocrelizumab is administered in accordance with site of service

criteria (see policy XI-06).

III. Renewal Review for Ocrelizumab (Ocrevus®) for Relapsing or Primary Progressive Forms of Multiple Sclerosis

Ocrelizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; **AND**
- Continued positive clinical response to ocrelizumab therapy (e.g., stabilization and/or slowing of disease progression, or decrease in symptom severity and/or frequency); **AND**
- No FDA-labeled contraindications to therapy (see table 2 below); **AND**
- Ocrelizumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- The dose is within the FDA labeled dose for the indication (see table 3 below); **AND**
- For commercial health plan members only, ocrelizumab is administered in accordance with site of service criteria (see policy XI-06).

IV. Experimental / Investigative Uses

All other uses of ocrelizumab are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Table 1a. Prerequisite Agents for Ocrelizumab (Ocrevus®) – Commercial

FDA Labeled Indications	Conventional Agent Prerequisites
Multiple sclerosis – Relapsing forms	Cladribine (Mavenclad) Dimethyl fumarate (generic) Diroximel fumarate (Vumerity) Fingolimod (generic) Glatiramer (generic, Glatopa) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron) Ofatumumab (Kesimpta) Ozanimod (Zeposia) Peginterferon beta-1a (Plegridy) Siponimod (Mayzent) Teriflunomide (generic)

Table 1b. Prerequisite Agents for Ocrelizumab (Ocrevus®) – Medicaid

FDA Labeled Indications	Conventional Agent Prerequisites
	Cladribine (Mavenclad) Dimethyl fumarate (Tecfidera)

Multiple sclerosis – Relapsing forms	Diroximel fumarate (Vumerity) Fingolimod (Gilenya) Glatiramer acetate (Copaxone, Glatopa) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron, Extavia) Monomethyl fumarate (Bafiertam) Ofatumumab (Kesimpta) Ozanimod (Zeposia) Peginterferon beta-1a (Plegridy) Ponesimod (Ponvory) Siponimod (Mayzent) Teriflunomide (Aubagio)

Table 2. FDA-Labeled Contraindications

Agent	FDA Labeled Contraindications
Ocrelizumab	Active hepatitis B virus infection History of life-threatening infusion reaction to ocrelizumab

Table 3. Dosing

NOTE: See documentation submission requirements below if the requested dose is outside of the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Multiple sclerosis – Relapsing forms	Initial dose: 300 mg followed 2 weeks later by 300 mg Subsequent doses: 600 mg every 6 months
Multiple sclerosis – Primary progressive forms	Initial dose: 300 mg followed 2 weeks later by 300 mg Subsequent doses: 600 mg every 6 months

Documentation Submission

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
3. For patients not currently receiving ocrelizumab, laboratory results for hepatitis B screening.
4. The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
5. For commercial health plan members only, the site of service for ocrelizumab administration is specified, including CMS place of service code (see policy XI-06). If ocrelizumab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.
6. For commercial and Medicaid health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review

1. Documentation of prior approval for ocrelizumab through the initial review process.
2. Documentation, since most recent approval, supporting continued positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
5. For commercial health plan members only, the site of service for ocrelizumab administration is specified, including CMS place of service code (see policy XI-06). If ocrelizumab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.

- **Ublituximab, II-275**

I. Initial Review for Ublituximab (Briumvi®)

Ublituximab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Age ≥ 18 years; **AND**
- Diagnosis of a relapsing form of MS (i.e., relapsing-remitting MS [RRMS], secondary progressive MS [SPMS] with relapses, and clinically isolated syndrome); **AND**
- ONE of the following:
  - Tried and failed natalizumab (Tysabri®), alemtuzumab (Lemtrada®), or ocrelizumab (Ocrevus®) for MS; OR
  - Tried and failed at least one preferred, self-administered, disease-modifying therapy for MS (see table 1a or 1b below); OR
  - Documented intolerance, FDA-labeled contraindication, or hypersensitivity to ALL preferred, self-administered, disease-modifying therapy for MS (see table 1a or 1b below);

AND

- For patients not currently receiving ublituximab, the patient has been screened for hepatitis B infection; **AND**
- Not used in combination with another disease-modifying therapy for MS; **AND**

- No FDA labeled contraindications to therapy (see table 2 below); **AND**
- The dose is within the FDA labeled dose (see table 3 below); **AND**
- For commercial health plan members only, ublituximab is administered in accordance with site of service criteria (see policy XI-06); **AND**
- For commercial and Medicaid health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

II. Renewal Review for Ublituximab (Briumvi®)

Ublituximab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; **AND**
- Continued positive clinical response to ublituximab therapy (e.g., stabilization and/or slowing of disease progression, or decrease in symptom severity and/or frequency); **AND**
- Not used in combination with another disease-modifying therapy for MS; **AND**
- No FDA labeled contraindications to therapy (see table 2 below); **AND**
- The dose is within the FDA labeled dose for the indication (see table 3 below); **AND**
- For commercial health plan members only, ublituximab is administered in accordance with site of service criteria (see policy XI-06).

III. Experimental / Investigative Uses

All other uses of ublituximab are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Table 1a. Prerequisite Agents for Ublituximab (Briumvi®) – Commercial

FDA Labeled Indications	Conventional Agent Prerequisites
Multiple sclerosis – Relapsing forms	Cladribine (Mavenclad) Dimethyl fumarate (generic) Diroximel fumarate (Vumerity) Fingolimod (generic) Glatiramer (generic, Glatopa) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron) Ofatumumab (Kesimpta) Ozanimod (Zeposia) Peginterferon beta-1a (Plegridy) Siponimod (Mayzent) Teriflunomide (generic)

Table 1b. Prerequisite Agents for Ublituximab (Briumvi®) – Medicaid

FDA Labeled Indications	Conventional Agent Prerequisites
Multiple sclerosis – Relapsing forms	Cladribine (Mavenclad) Dimethyl fumarate (Tecfidera) Diroximel fumarate (Vumerity) Fingolimod (Gilenya) Glatiramer acetate (Copaxone, Glatopa) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron, Extavia) Monomethyl fumarate (Bafiertam) Ofatumumab (Kesimpta) Ozanimod (Zeposia) Peginterferon beta-1a (Plegridy) Ponesimod (Ponvory) Siponimod (Mayzent) Teriflunomide (Aubagio)

Table 2. FDA Labeled Contraindications

Agent	FDA Labeled Contraindications
Ublituximab	Active hepatitis B virus infection. History of life-threatening infusion reaction to ublituximab.

Table 3. Dosing

NOTE: See documentation submission requirements below if the requested dose is outside of the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Multiple sclerosis – Relapsing forms	Administer via intravenous infusion. First infusion: 150 mg. Second infusion: 450 mg administered two weeks after the first infusion. Subsequent infusions: 450 mg administered 24 weeks after the first infusion and every 24 weeks thereafter.

Documentation Submission

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
3. For patients not currently receiving ublituximab, laboratory results for hepatitis B screening.
4. The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
5. For commercial health plan members only, the site of service for ublituximab administration is specified, including CMS place of service code (see policy XI-06). If ublituximab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.
6. For commercial and Medicaid health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review

1. Documentation of prior approval for ublituximab through the initial review process.
2. Documentation, since most recent approval, supporting continued positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
5. For commercial health plan members only, the site of service for ublituximab administration is specified, including CMS place of service code (see policy XI-06). If ublituximab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.

Policies Delegated to eviCore
None

Policies Inactivated
None