

# Medical and Behavioral Health Policy Activity

Policies Effective: February 1, 2021 Notification Posted: December 1, 2020

## Policies Developed

- **Medicare Advantage Part B Step Therapy, II-247**

**Note:**

- This policy applies to Medicare Advantage lines of business only.
- See table below for preferred products included in the Medicare Advantage Part B Step Therapy program. All other products in these drug classes are non-preferred.
- Medical necessity of the drug will be separately reviewed against the appropriate criteria.

Non-preferred products may be **reasonable and necessary** when ANY of the following criteria are met:

- Documentation of non-preferred therapy within the past 365 days;  
**OR**
- BOTH of the following:
  - Previous trial and failure of all preferred products resulting in minimal clinical response to therapy; AND
  - Documentation from the prescriber that clinical response is expected to be superior with the requested non-preferred product;  
**OR**
- ALL of the following:
  - Documented intolerance, FDA-labeled contraindication, or hypersensitivity to all preferred products; AND
  - For patients with a documented intolerance or hypersensitivity, BOTH of the following:
    - Documentation from the prescriber that the same intolerance or adverse event would not be expected to occur with the requested non-preferred product; AND
    - For patients who are unable to tolerate all preferred products, documentation from the prescriber clearly indicates the medical reason why the patient cannot use the preferred products.

**Table 1. Preferred Products Included in the Medicare Advantage Part B Step Therapy Program**

Drug Class	Preferred Products
Intra-articular hyaluronan injections for osteoarthritis	Synvisc®, Synvisc-One®, and Euflexxa®

## Policies Revised

- **Electroconvulsive Therapy, X-46**

I. **Initial Course**

Electroconvulsive therapy (ECT) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following are met:

- Age 12 or over; **AND**
- Diagnosis of ONE of the following:
  - Major depressive disorder (MDD); OR
  - Bipolar disorder, major depressive episode; OR
  - Bipolar disorder, manic episode; OR
  - Schizophrenia; OR
  - Schizoaffective disorder; OR
  - Neuroleptic malignant syndrome or malignant catatonia that is unresponsive to other treatments;  
**AND**

- Severity of illness considered severe as demonstrated by, but not limited to, the following:
  - Standardized rating scale indicates severe major depressive disorder (e.g., Hamilton Rating Scale for Depression, PHQ-9, or Montgomery-Asberg Depression Rating Scale); OR
  - Catatonia; OR
  - Nutritional compromise due to a psychiatric condition (i.e., sustained food or fluid refusal); OR
  - Psychotic illness; OR
  - Suicidal ideation or recent suicide attempt; OR
  - Unremitting self-injury or uncontrolled risk-taking behavior;
- AND**
- Pharmacotherapy is not an option due to ANY of the following:
  - Inadequate response, despite documented adherence, to medication trials of adequate dose and duration of at least two different therapeutic class of drugs: OR
  - Documented intolerance to medications; OR
  - Unacceptable medication risks due to potential side effects (e.g. elderly, pregnant); OR
  - Rapid response to treatment is needed (e.g., individual is suicidal).

## II. Continuation/Maintenance ECT

Continuation/maintenance ECT may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL of the following are met:

- Successful response to initial ECT; **AND**
- Sessions tapered to lowest frequency that maintains response (e.g., weekly, biweekly, monthly); **AND**
- Maintenance pharmacotherapy alone is insufficient to sustain remission.

## III. Reinitiating Treatment

Patient must meet criteria in Section I to reinitiate treatment after the completion of continuation/ maintenance ECT.

## IV. Investigative Uses

All other indications or procedures using ECT are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes, including but not limited to:

- Post-traumatic stress disorder (PTSD);
- Acute or chronic pain;
- Multiple-seizure ECT (MECT);
- Use of ketamine as a treatment for depression in combination with ECT.

## 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. Patient age
2. Clinical notes describing the diagnosis and clinical features of the diagnosis
3. Symptoms of disease that describe severity of illness
4. Previous medications prescribed, including dose and duration, adherence, and patient response
5. If medication trials of at least two different therapeutic classes have not been attempted, rationale for use of electroconvulsive therapy as a first-line treatment
6. Previous trial of electroconvulsive therapy and response, if applicable

## Renewal Review

1. Documentation of prior approval through the initial review process
2. Documentation supporting positive clinical response
3. Documentation of tapering to lowest frequency that maintains response
4. Relapses that have occurred on maintenance pharmacotherapy alone after ECT, if applicable

### • **Steroid-Eluting Devices for Maintaining Sinus Ostial Patency, IV-140**

The use of implantable steroid-eluting sinus devices, including stents and implants, is considered **EXPERIMENTAL/INVESTIGATIVE** for **ALL** indications, including but not limited to the following, due to a lack of clinical evidence demonstrating an impact on improved health outcomes:

- Maintain sinus patency following endoscopic sinus surgery;
- Treatment of sinonasal polyps.

### • **Balloon Ostial Dilation, VI-01**

**I** Balloon sinus ostial dilation of the frontal, maxillary or sphenoid sinuses may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of either of the following:
  - Recurrent acute rhinosinusitis defined as 4 or more documented, medically managed episodes in 1 year with symptom-free intervals between episodes; or
  - Chronic sinusitis defined as greater than 12 weeks duration with medical management;

**AND**

- Two or more of the following signs/symptoms:
  - Mucopurulent nasal drainage;
  - Nasal obstruction;
  - Facial pain, pressure and/or fullness over the affected sinus;
  - Decreased sense of smell;

**AND**

- Other etiologies of symptoms have been ruled out or treated appropriately (e.g., allergies, nasal decongestant spray abuse [Afrin<sup>®</sup>], nasal septal deviation, dental pathology, immune disorders, intranasal tumors, polyps); **AND**
- **ONE** of the following:
  - Tried and failed medical management for a minimum of 12 weeks including **ALL** of the following:
    - Nasal saline irrigation or nasal saline spray; and
    - Intranasal corticosteroids for a minimum of 8 weeks; and
    - Antihistamine nasal spray or decongestant (oral or nasal); and
    - Two courses of oral antibiotics or one prolonged course of oral antibiotics for at least 21 days;

**OR**

- Documented intolerance, contraindication, or hypersensitivity to nasal saline, intranasal corticosteroids, antihistamine nasal spray/decongestants and antibiotics.

**AND**

- Evidence of abnormal findings on computerized tomography (CT) confirming diagnosis, including **ALL** of the following:
  - CT image is obtained **AFTER** maximum medical therapy; and
  - Image is read by a board-certified radiologist; and
  - Findings include **ONE** or **MORE** of the following:
    - Mucosal thickening >3 mm; or
    - Opacified sinus; or
    - Obstruction of the ostiomeatal complex;

**AND**

- Will be performed on the sinus identified by abnormal CT findings, as noted above.
- II. Balloon sinus ostial dilation is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to a lack of clinical evidence demonstrating an impact on improved health outcomes, including, but not limited to:
  - Isolated ethmoid sinus disease;
  - Nasal polyposis, as a stand-alone treatment;
  - Repeat balloon procedure in any of the sinuses to be treated;
  - Samter's triad (chronic condition defined by asthma, sinus inflammation with recurring nasal polyps, and aspirin sensitivity);
  - Severe sinusitis secondary to autoimmune or connective tissue disorders including but not limited to sarcoidosis, granulomatosis with polyangiitis;
  - Severe sinusitis secondary to ciliary dysfunction including but not limited to cystic fibrosis, Kartagener's syndrome;
  - Suspected or known benign or malignant sinonasal tumors.

### **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:

- Clinical notes describing the following:
  1. Signs/symptoms of chronic or acute rhinosinusitis including duration of symptoms; AND
  2. Work up that has excluded other etiologies for sinus symptoms; AND
  3. Specific treatments, including duration and results.
- Report of sinus computerized tomography (CT) imaging on the sinus intended for the procedure, performed after all maximum medical therapy.
- Confirmation that the CT imaging report was read by a board-certified radiologist.

- **Mepolizumab, II-201**

- I. **Initial Review for Mepolizumab (Nucala®)**

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

- Diagnosis of **ONE** of the following:
  - **Severe eosinophilic asthma** AND ALL of the following:
    - Age 6 years or older; **AND**
    - Blood eosinophil level is **ONE** of the following:
      - ≥150 cells/μL prior to initiating therapy; or
      - ≥300 cells/μL within the previous 12 months;
    - AND**
    - Used as add-on therapy for patients currently receiving regular maintenance treatment with **BOTH** of the following:
      - Maximally tolerated inhaled corticosteroid OR documented intolerance, FDA labeled contraindication, or hypersensitivity to inhaled corticosteroids; and
      - An additional asthma controller medication (long-acting beta-2 agonist, leukotriene receptor antagonist, long-acting muscarinic antagonist, or theophylline) OR documented intolerance, FDA labeled contraindication, or hypersensitivity to controller medications;
    - AND**
    - **ONE** of the following:
      - History of 2 or more asthma exacerbations requiring systemic corticosteroid treatment within the

- previous 12 months; or
- Serious asthma exacerbation requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the previous 12 months; or
- Require daily oral corticosteroid therapy in addition to regular maintenance treatment, as defined above; or
- Controlled asthma that worsens when the doses of inhaled or systemic corticosteroids are tapered; or
- Pretreatment forced expiratory volume in 1 second (FEV<sub>1</sub>) <80% predicted;

**AND**

- Prescribed by or in consultation with a pulmonologist, allergist, or immunologist;

**OR**

- **Eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome) AND ALL of the following:**

- Age 18 years or older; **AND**
- History or presence of asthma; **AND**
- Blood eosinophil level is ONE of the following:
  - ≥10% of leukocytes; or
  - Absolute eosinophil count >1,000 cells/μL;

**AND**

- TWO OR MORE of the following:
  - Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation;
  - Neuropathy;
  - Pulmonary infiltrates;
  - Sinonasal abnormalities;
  - Cardiomyopathy;
  - Glomerulonephritis;
  - Alveolar hemorrhage;
  - Palpable purpura;
  - Antineutrophil cytoplasmic antibody (ANCA)-positive;

**AND**

- Used as add-on therapy for patients currently receiving maximally tolerated oral corticosteroid therapy OR documented intolerance, FDA labeled contraindication, or hypersensitivity to oral corticosteroid therapy; **AND**
- Previously tried and failed an immunosuppressant (e.g., azathioprine, methotrexate) OR documented intolerance, FDA labeled contraindication, or hypersensitivity to immunosuppressants; **AND**
- Prescribed by or in consultation with a pulmonologist, rheumatologist, allergist, or immunologist;

**OR**

- **Hypereosinophilic syndrome (HES) AND ALL of the following:**

- Age 12 years or older; **AND**
- History of hypereosinophilic syndrome (HES) for ≥ 6 months; **AND**
- Absence of non-hematologic secondary HES (e.g. drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1-PDGFR $\alpha$  kinase-positive HES; **AND**
- Blood eosinophil level is ≥ 1,000 cells/μL; **AND**
- Used as add-on therapy for patients currently receiving regular maintenance treatment for HES (e.g. oral corticosteroids, immunosuppressive, or cytotoxic therapy) OR documented intolerance, FDA labeled contraindication, or hypersensitivity to HES therapy; **AND**
- Prescribed by or in consultation with a hematologist, allergist, or immunologist;

**AND**

- No current infections requiring systemic treatment; **AND**
- Not used in combination with reslizumab (Cinqair<sup>®</sup>), benralizumab (Fasenra<sup>®</sup>), omalizumab (Xolair<sup>®</sup>), or dupilumab (Dupixent<sup>®</sup>); **AND**
- No FDA labeled contraindications to mepolizumab (see table 1 below); **AND**
- The dose is within the FDA labeled dose for the indication (see table 2 below); **AND**
- For commercial health plan members only, mepolizumab is administered in accordance with site of service



- criteria (see policy XI-06); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

**II. Renewal Review for Mepolizumab (Nucala®)**

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

- Previously approved for mepolizumab through the initial review process; **AND**
- Demonstrated positive clinical response to mepolizumab therapy. Examples include:
  - For patients with severe eosinophilic asthma, decreased use of rescue medications, decreased frequency of exacerbations, increase in percent predicted FEV<sub>1</sub>, reduction in asthma-related symptoms;
  - For patients with eosinophilic granulomatosis with polyangiitis (EGPA), decreased frequency and/or severity of relapses, reduction or discontinuation of corticosteroid therapy, disease remission, reduction in EGPA-related symptoms; **AND**
  - For patients with hypereosinophilic syndrome (HES), reduction of maintenance therapy for HES (e.g. oral corticosteroids, immunosuppressive, or cytotoxic therapy), reduction in HES-related symptoms;
- AND**
- Used as add-on therapy for patients currently receiving standard maintenance treatment with the following:
  - For patients with severe eosinophilic asthma, currently receiving regular maintenance treatment with a maximally tolerated inhaled corticosteroid **AND** an additional asthma controller medication (long-acting beta-2 agonist, leukotriene receptor antagonist, long-acting muscarinic antagonist, or theophylline) **OR** documented intolerance, FDA labeled contraindication, or hypersensitivity to inhaled corticosteroids and controller medications;
  - For patients with EGPA, currently receiving maximally tolerated oral corticosteroid therapy **OR** documented intolerance, FDA labeled contraindication, or hypersensitivity to oral corticosteroid therapy;
  - For patients with HES, currently receiving regular maintenance treatment for HES (e.g. oral corticosteroids, immunosuppressive, or cytotoxic therapy) **OR** documented intolerance, FDA labeled contraindication, or hypersensitivity to HES therapy;
- AND**
- No current infections requiring systemic treatment; **AND**
- Prescribed by or in consultation with a pulmonologist, rheumatologist (EGPA only), hematologist (HES only), allergist, or immunologist; **AND**
- Not used in combination with reslizumab (Cinqair®), benralizumab (Fasenra®), omalizumab (Xolair®), or dupilumab (Dupixent®); **AND**
- No FDA labeled contraindications to mepolizumab (see table 1 below); **AND**
- The dose is within the FDA labeled dose for the indication (see table 2 below); **AND**
- For commercial health plan members only, mepolizumab is administered in accordance with site of service criteria (see policy XI-06).

**III. Experimental/Investigative Uses**

All other uses of mepolizumab 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
Mepolizumab	History of hypersensitivity to mepolizumab or excipients in the formulation

**Table 2. Dosing**

FDA Labeled Indications	Dosing
Severe eosinophilic asthma—adults and adolescents (≥12 years)	100 mg once every 4 weeks by subcutaneous injection
Severe eosinophilic asthma—pediatric patients (6-11 years)	40 mg once every 4 weeks by subcutaneous injection
Eosinophilic granulomatosis with polyangiitis	300 mg once every 4 weeks by subcutaneous injection as 3 separate 100-mg injections
Hypereosinophilic syndrome (HES)	300 mg once every 4 weeks by subcutaneous injection as 3 separate 100-mg injections.

**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. Laboratory documentation of blood eosinophil level.
4. The dose being requested, including the patient's weight if the diagnosis requires weight-based dosing. If the requested dose is higher or more frequent than the dosing guidelines 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 mepolizumab administration is specified, including CMS place of service code (see policy XI-06). If mepolizumab 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 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 mepolizumab through the initial review process.
2. Documentation supporting positive clinical response.
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 diagnosis requires weight-based dosing. If the requested dose is higher or more frequent than the dosing guidelines 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 mepolizumab administration is specified, including CMS place of service code (see policy XI-06). If mepolizumab 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.

- **Golimumab, II-180**

**NOTE: This policy revision will be effective January 1, 2021.**

**NOTE: This policy addresses intravenous golimumab (Simponi Aria®) only. When golimumab will be administered by subcutaneous injection, please refer to applicable pharmacy benefit plan.**

**I. Initial Review for Golimumab (Simponi Aria®)**

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

- Diagnosis of **ONE** of the following:
  - Moderately to severely active rheumatoid arthritis in a patient 18 years of age or older **AND ONE** of the following:
    - Previously failed another biologic therapy 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
  - Active psoriatic arthritis in a patient 2 years of age or older **AND ONE** of the following:
    - Previously failed another biologic therapy 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
    - 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
  - 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
  - Active polyarticular 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;

**AND**

- No FDA labeled contraindications to intravenous golimumab (see table 1 below); **AND**
- Not currently being treated with another biologic therapy; **AND**
- For patients not currently receiving intravenous golimumab, 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 (see table 3 below); **AND**
- For commercial health plan members only, golimumab (Simponi Aria) is administered in accordance with site of service criteria (see policy XI-06); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions



(see policy II-242: Step Therapy Supplement).

**II. Renewal Review for Golimumab (Simponi Aria®)**

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

- Previously approved for intravenous golimumab through the initial review process; **AND**
- Demonstrated positive clinical response to intravenous golimumab therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency); **AND**
- No FDA labeled contraindications to intravenous golimumab (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 (see table 3 below); **AND**
- For commercial health plan members only, golimumab (Simponi Aria) is administered in accordance with site of service criteria (see policy XI-06).

**III. Experimental/Investigative Uses**

All other uses of intravenous golimumab 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
Intravenous golimumab	None

**Table 2. Conventional Agent Prerequisites**

FDA Labeled Indications	Conventional Agent Prerequisites
Rheumatoid arthritis (RA)	methotrexate leflunomide sulfasalazine hydroxychloroquine
Psoriatic arthritis (PsA)	methotrexate leflunomide cyclosporine sulfasalazine hydroxychloroquine
Ankylosing spondylitis	NSAIDs, prescription strength, (ibuprofen, ketoprofen, celecoxib)

Polyarticular juvenile idiopathic arthritis (PJIA)	methotrexate leflunomide sulfasalazine hydroxychloroquine
--	--

**Table 3. Dosing**

**NOTE:** See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Rheumatoid arthritis	2 mg/kg at weeks 0 and 4, then every 8 weeks
Psoriatic arthritis – adult	2 mg/kg at weeks 0 and 4, then every 8 weeks
Psoriatic arthritis – pediatric (≥2 years)	80 mg/m <sup>2</sup> at weeks 0 and 4, then every 8 weeks
Ankylosing spondylitis	2 mg/kg at weeks 0 and 4, then every 8 weeks
Polyarticular juvenile idiopathic arthritis	80 mg/m <sup>2</sup> at weeks 0 and 4, then every 8 weeks

**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. For patients not currently receiving intravenous golimumab, laboratory results for latent tuberculosis (TB) screening. If the 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 higher or more frequent than the dosing guidelines 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 golimumab (Simponi Aria) administration is specified, including CMS place of service code (see policy XI-06). If golimumab (Simponi Aria) 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 care criteria provided in policy XI-06.
6. For commercial 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 intravenous golimumab through the initial review process.
2. Documentation supporting 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 higher or more frequent than the dosing guidelines 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 golimumab (Simponi Aria) administration is specified, including CMS place of service code (see policy XI-06). If golimumab (Simponi Aria) 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**