Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Cimzia® (Certolizumab Pegol) Lyophilized Powder***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***December 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *December 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Cimzia® (certolizumab pegol) lyophilized powder.

Cimzia® (certolizumab pegol) lyophilized powder is indicated for:

- Treatment of adults with moderate-to-severe, active rheumatoid arthritis
- Reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderate-to-severe, active disease who have had an inadequate response to conventional therapy
- Treatment of adult patients with active psoriatic arthritis
- Treatment of adult patients with active ankylosing spondylitis
- Treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications.

This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Cimzia® (certolizumab pegol) lyophilized powder, is subject to the prior authorization process.

PROCEDURE

*****Please Note: When coverage of Cimzia is requested through the pharmacy benefit, please refer to policies RX.008.2 Exceptions Due to Medical Necessity and RX.011 Request for Non-Covered Medications. This policy, RX.PA.087.2.E (B), is for requests for Cimzia on the Medical Benefit only.*****

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Cimzia® lyophilized powder are subject to the preferred medical drug list program. This program applies to non-preferred autoimmune products used in the treatment of plaque psoriasis, inflammatory joint related conditions, or inflammatory bowel disease. Coverage for these products (those which are non-preferred and not covered for the prescribed indication) is provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication. Coverage for non-preferred products will continue in situations where the patient is currently receiving treatment.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Disease-modifying antirheumatic drugs for autoimmune conditions

	Products*
Preferred	• Remicade® **(infliximab)** • Simponi Aria® **(golimumab, intravenous)**
Non-preferred	• Actemra® **(tocilizumab)** • Cimzia® **(certolizumab pegol)** • Entyvio® **(vedolizumab)** • Ilumya® **(tildrakizumab-asmn)** • Inflectra® **(infliximab-dyyb)** • Renflexis® **(infliximab-abda)**

	• Stelara® **(ustekinumab)** • Orencia® **(abatacept)**

*If applicable for approved indication

Requests for Cimzia® on the Medical Benefit must meet one of the following exception criteria in addition to clinical criteria:

I. *EXCEPTION CRITERIA (Use for Non-Preferred Requests Only)*

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product(s) (as applicable).

Coverage for a non-preferred product is provided when ANY of the following criteria are met:

A. Actemra, Cimzia, Entyvio, Ilumya, Orencia and Stelara
    1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs
    2. Member has a documented inadequate response or intolerable adverse event with all of the preferred product(s) indicated for the condition being treated, unless there is a documented clinical reason to avoid TNF inhibitors
        i. History of demyelinating disorder
        ii. History of congestive heart failure
        iii. History of hepatitis B virus infection
        iv. Autoantibody formation/lupus-like syndrome
        v. Risk of lymphoma
    3. Requested product is Cimzia and member is currently pregnant or breastfeeding

B. Inflectra and Renflexis
    1. Member has a documented intolerable adverse event with the preferred product, Remicade

III. CLINICAL CRITERIA (*Use for ALL Autoimmune Drug Requests on the Medical Benefit*)

Must meet criteria for all diagnoses in addition to that listed under the respective diagnosis:

For All Diagnoses:

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.*TB* test (T-Spot)]
- Must currently not be using a tumor necrosis factor (TNF)-blocking agent or other biologic agents in combination with Cimzia®
- Must have no evidence of infection

1. Rheumatoid Arthritis:

- Must be prescribed by a rheumatologist
- Must be age 18 or older
- Must have a diagnosis of moderate-to-severe, active rheumatoid arthritis
- Must have an adequate trial (of at least 3 months) of methotrexate with an inadequate response or significant side effect/toxicity or must have a contraindication to this therapy
    - Members with significant side effects/toxicity or who have a contraindication to methotrexate must have an adequate trial (of at least 3 months) of leflunomide, hydroxychloroquine, or sulfasalazine with an inadequate response

2. Crohn's Disease:

- Must be prescribed by a gastroenterologist
- Must be age 18 or older
- Must have diagnosis of moderate-to-severe, active Crohn's disease
- Must have an adequate trial of conventional therapy including corticosteroids OR at least 3 months of immunosuppressants (e.g., azathioprine, 6-mercaptopurine) with an inadequate response, or significant side effects/toxicity, or have a contraindication to these therapies

3. Psoriatic Arthritis

- Must be prescribed by a rheumatologist or dermatologist
- Must be age 18 years or older
- Must have a diagnosis of active psoriatic arthritis
- For peripheral disease and dactylitis:
    - Must have an adequate trial (of at least 4 weeks) with a non-steroidal anti-inflammatory drug (NSAID) at an anti-inflammatory dose, with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
    - Must have an adequate trial (of at least 3 months) of a conventional systemic therapy (methotrexate, sulfasalazine, or leflunomide) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- For axial disease and enthesitis:
    - Must have an adequate trial (of at least 4 weeks each) with TWO NSAIDs at anti-inflammatory doses with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
- For skin or nail disease:
    - Must have an adequate trial of topical treatments, phototherapy, or

photochemotherapy with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have an adequate trial (of at least 3 months) of a conventional systemic therapy (methotrexate, cyclosporine, or acitretin) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

4. Ankylosing Spondylitis
- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of ankylosing spondylitis
- Must have an adequate trial (of at least 4 weeks) with TWO NSAIDs at anti-inflammatory doses, with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy

Plaque Psoriasis
- Must be prescribed by a dermatologist
- Must be age 18 years or older
- Must have a diagnosis of severe chronic plaque psoriasis
- Must have a minimum body surface area involvement of > 5% (Members with plaque psoriasis of palms, soles, head and neck, or genitalia are not required to have a minimum body surface area involvement)
- Must have an adequate trial of topical treatments, phototherapy, or photochemotherapy with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have an adequate trial (of at least 3 months) of a conventional systemic therapy (methotrexate, cyclosporine, or acitretin) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

Reauthorization Criteria:
All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy and there is no evidence of infection.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
All (vials)	2 vials per month • Rheumatoid Arthritis or Crohn's disease: a quantity of 6 vials per month are covered for the first month of treatment

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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4. *Lichtenstein GR,* Hanauer SB et al. American College of Gastroenterology Practice Guidelines on the Management of Crohn's Disease in Adults. *Am J Gastroenterol* 2009; 1-19.
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2. placebo-controlled phase 3 study. Ann Rheum Dis 2013; 1-9.
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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent

Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Criteria update	*10/16*
Preferred Product Update (effective 4/1/18)	*02/18*
Added procedural clarification	*6/18*
Indication update	*8/18*
Preferred Product Update (effective 1/1/19)	*12/18*