Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Orencia (abatacept) Intravenous**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***March 2014 (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 Orencia (abatacept) Intravenous.

Orencia (abatacept) Intravenous is indicated for:

- Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adults with moderately to severely active Rheumatoid Arthritis (RA). Abatacept (Orencia) may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.
- Reducing signs and symptoms in pediatric patients 2 years of age and older with moderately to severely active Polyarticular Juvenile Idiopathic Arthritis. Abatacept (Orencia) may be used as monotherapy or concomitantly with methotrexate.
- Treatment of active psoriatic arthritis in adults

DEFINITIONS

evolent HEALTH

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, Orencia (abatacept) Intravenous, is subject to the prior authorization process.

PROCEDURE

*****Please Note: When coverage of Orencia 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.055.2.E (B), is for requests for Orencia Intravenous on the Medical Benefit only.*****

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Orencia® are subject to the preferred medical drug list program. This program applies to non-preferred autoimmune products used in the treatment of psoriatic arthritis, juvenile idiopathic arthritis, or rheumatoid arthritis. 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 Orencia® on the Medical Benefit must meet one of the following exception criteria in addition to clinical criteria:

II. *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 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 Orencia (abatacept)
- Must have no evidence of infection

1. Rheumatoid Arthritis:

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

2. Juvenile Idiopathic Arthritis without systemic symptoms, includes polyarticular juvenile arthritis (PJIA):

- Must be prescribed by a rheumatologist
- Must be age 2 or older
- Must have a diagnosis of moderately to severely active juvenile idiopathic arthritis
- 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 methotrexate or leflunomide with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy

3. Psoriatic Arthritis

- 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 be prescribed by a rheumatologist
- 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 these therapies
    - Must have an adequate trial of at least 3 months, of a conventional systemic therapy (e.g., 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 for at least 4 weeks each with 2 non-steroidal anti-inflammatory drugs (NSAIDs) at anti-inflammatory doses with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
- For Skin and 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 (e.g., 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 one-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

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

REFERENCES

1. Orencia (abatacept) [package insert] Princeton, NJ: Bristol-Myers Squibb Company; June 2017.
2. Genovese MC, Becker JC, Schiff M, Luggen M, Sherrer Y, Kremer J, Birbara C, Jane Box J, Natarajan K, Nuamah I , Li T, Aranda R, Hagerty DT, Dougados M. Abatacept for Rheumatoid Arthritis Refactory to Tumor Necrosis Inhibition. N Engl J Med 2005;353(21): 1114-23
3. Saag KG, Teng GG, Patkar NM et al. American college of rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum* 2008;59(6):762-784
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6. Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection. http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.htm. Accessed 10/29/2012.
7. Ringold S, Weiss PF, Beukelman T, DeWitt EM, Ilowite NT, Kimura Y, Laxer RM, Lovell DJ, Nigrovic PA, Robinson AB and Vehe RK (2013), 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. Arthritis Care Res, 65: 1551–1563
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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, 07/17*
New Indication	*09/17*
Preferred Product Update (effective 4/1/18)	*02/18*
Added procedural clarification	*6/18*

Preferred Product Update (effective 1/1/19)	*12/18*