Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 40.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Orencia IV (abatacept)

I. Policy:
Orencia IV (abatacept)

II. Purpose/Objective:
To provide a policy of coverage regarding Orencia IV (abatacept)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
Orencia (abatacept) is a selective T-cell co-stimulation modulator that inhibits T-cell activation by binding to CD80 and CD86 which blocks interaction with CD28. The interaction provides a co-stimulatory signal necessary for full activation of T-lymphocytes. Activated T-lymphocytes are found in the synovium of patients with rheumatoid arthritis (RA) and are implicated in the pathophysiology of RA.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Orencia IV (abatacept) will be considered medically necessary when all of the following criteria are met:

1. Rheumatoid arthritis that is refractory to DMARD therapy, including TNF (Tumor necrosis factor) antagonists:
    - Documentation of a diagnosis of moderate to severe RA in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
    - Member must be at least 18 years old **AND**
    - Must be prescribed by a rheumatologist **AND**
    - Medical record documentation that Orencia is not being used concurrently with a TNF blocker or other biologic agent **AND**
    - Documentation of inadequate response to minimum 3 month trial of Humira*, Rinvoq*, OR Xeljanz*

2. Polyarticular Juvenile Idiopathic Arthritis (PJIA)
    - Insured individual is 6 years of age or older **AND**
    - Medical record documentation of a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis or juvenile rheumatoid **AND**
    - Must be prescribed by a rheumatologist **AND**
    - Medical record documentation that Orencia is not being used concurrently with a TNF blocker or other biologic agent **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 4 month trial of Humira*

3. Psoriatic Arthritis (PsA):
    - Prescription written by a rheumatologist **AND**
    - Medical record documentation of a diagnosis of moderate to severe active psoriatic arthritis which must include the following:
        - Documentation of either active psoriatic lesions OR a documented history of psoriasis **AND**
    - Medical record documentation of age ≥ 18 years of age **AND**
    - Medical record documentation that Orencia is not being used concurrently with a TNF blocker or other biologic agent **AND**
    - Medical record documentation of an inadequate response to a minimum 3 month trial of Humira* **AND** Cosentyx*

4. Prophylaxis of Acute Graft Versus Host Disease:
    - Prescription written by a hematologist, oncologist, or transplant specialist **AND**
    - Medical record documentation that the patient is 2 years of age and older **AND**
    - Medical record documentation that patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor **AND**
    - Medical record documentation Orencia will be used in combination with a calcineurin inhibitor (i.e. cyclosporine, tacrolimus) and methotrexate **AND**
    - Medical record documentation that the member is receiving an FDA approved dose**

*Prior authorization required

**Note: The FDA approved dose for prophylaxis of acute graft versus host disease:
- For patients 2 years to less than 6 years old: 15 mg/kg IV on the day before transplantation (Day -1), followed by 12mg/kg IV on Days 5, 14, and 28 after transplantation
- For patients 6 years and older: 10 mg/kg (maximum of 1,000 mg) IV on the day before transplantation (Day -1), followed by administration on Days 5, 14, and 28 days after transplantation

AUTHORIZATION DURATION:

Prophylaxis of Acute Graft Versus Host Disease:

Authorization for prophylaxis of Acute Graft Versus Host Disease should not exceed the FDA-approved treatment duration of 28 days after transplantation. For requests exceeding 1 month auth duration, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

All other Indications:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or a lack of progression in the signs and symptoms of the targeted disease state at six (6) months of Orencia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the targeted disease state while on Orencia therapy.

LIMITATIONS: The concomitant use of Orencia with other potent immunosuppressants [e.g. biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 08/02/06

Revised: 11/09; 02/14 (add indications, update auth period), 09/16/14; 12/30/14 (updated formulary alternatives for both indications), 09/15/15 (removed joint counts), 9/19/17 (PsA indication), 3/20/18 (form alt, duplicate therapy), 4/24/18 (per DHS, grandfather), 9/18/18 (formulary alt), 1/21/20 (RA form alt), 5/17/22 (GVHD, duration), 9/20/22 (updated limitations), 9/20/23 (Medicaid business segment)

Reviewed: 12/10; 02/12, 9/13/16, 7/31/17, 1/19/21, 1/13/22