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## DRUG POLICY

# Orencia (abatacept)

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The intent of the Orencia drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Adalimumab-aacf, Enbrel, Entyvio Cosentyx, Otezla, Otulfi (ustekinumab-aauz), Rinvoq, Simponi, Skyrizi, Tremfya, Velsipity, and Xeljanz/Xeljanz XR/Xeljanz Oral Solution are the preferred products and will apply to members requesting treatment with subcutaneous Orencia for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan's preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication. Additionally for this program, Avsola, Inflectra, Entyvio, Ilumya, Otulfi (ustekinumab-aauz), Skyrizi, and Simponi Aria are the preferred products and will apply to members requesting treatment with intravenous Orencia for an indication that is FDA-approved for the preferred product. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis (RA) in adults
2. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age or older

3. Active psoriatic arthritis (PsA) in patients 2 years of age and older
4. Prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor

#### Compendial Uses

1. Oligoarticular juvenile idiopathic arthritis
2. Chronic graft versus host disease
3. Immune Checkpoint Inhibitor-related toxicity (given intravenously)

### **POLICY**

#### Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

#### **Rheumatoid arthritis (RA)**

1. For initial requests:
  - A. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
  - B. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

#### **Articular juvenile idiopathic arthritis (JIA):**

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

#### **Psoriatic arthritis (PsA):**

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

#### **Chronic graft versus host disease and Immune Checkpoint Inhibitor-Related Toxicity:**

1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

#### Preferred Drug Plan Design for subcutaneous Orencia requests

#### **Rheumatoid Arthritis (RA)**

1. Criteria for initial approval on rheumatoid arthritis will only apply when at least ONE of the following criteria are met:

- A. Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Adalimumab-aacf, Enbrel, Rinvoq, Simponi, and Xeljanz/Xeljanz XR)
- B. Member has a clinical reason to avoid TNF-inhibitors (Enbrel, Adalimumab-aacf, and Simponi) (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with the preferred products, Rinvoq AND Xeljanz/Xeljanz XR
- C. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

**Polyarticular Juvenile Idiopathic Arthritis (pJIA)**

- 1. Criteria for initial approval on polyarticular juvenile idiopathic arthritis will only apply when at least ONE of the following criteria are met:
  - A. Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Adalimumab-aacf, Enbrel, and Xeljanz/Xeljanz Oral Solution)
  - B. Member has a clinical reason to avoid Enbrel and Adalimumab-aacf (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with the preferred product Xeljanz or Xeljanz Oral Solution
  - C. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

**Psoriatic Arthritis (PsA)**

- 1. Criteria for initial approval on psoriatic arthritis will only apply when at least ONE of the following criteria are met:
  - A. Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Cosentyx, Enbrel, Adalimumab-aacf, Otezla, Rinvoq, Simponi, Skyrizi, Otulfi (ustekinumab-aauz), Tremfya, and Xeljanz/Xeljanz XR)
  - B. Member has a clinical reason to avoid TNF-inhibitors (Enbrel, Adalimumab-aacf, and Simponi) (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Cosentyx, Otezla, Skyrizi, Otulfi (ustekinumab-aauz), Tremfya, Rinvoq and Xeljanz/Xeljanz XR)
  - C. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

**Pediatric PsA**

- 1. Criteria for initial approval on psoriatic arthritis will only apply when at least ONE of the following criteria are met:
  - A. Member has had an inadequate response to treatment or intolerable adverse event with both of the preferred products (Cosentyx and Enbrel)
  - B. Member has a clinical reason to avoid Enbrel (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with Cosentyx.
  - C. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

Preferred Drug Plan Design for intravenous Orencia requests

**Rheumatoid Arthritis (RA)**

- 1. Criteria for initial approval on rheumatoid arthritis will only apply when at least ONE of the following criteria are met:

- A. Member has a documented inadequate response or intolerable adverse event with each of the following:
  - 1) Avsola
  - 2) Inflectra
  - 3) Simponi Aria
- B. Member has a documented clinical reason to avoid TNF inhibitors (See Appendix A)
- C. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

**Polyarticular Juvenile Idiopathic Arthritis (pJIA)**

- 1. Criteria for initial approval on polyarticular juvenile idiopathic arthritis will only apply when at least ONE of the following criteria are met:
  - A. Member has a documented inadequate response or intolerable adverse event to Simponi Aria
  - B. Member has a documented clinical reason to avoid TNF inhibitors (See Appendix A)
  - C. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

**Psoriatic Arthritis (PsA)**

- 1. Criteria for initial approval on psoriatic arthritis will only apply when at least ONE of the following criteria are met:
  - A. Member has a documented inadequate response or intolerable adverse event with each of the following:
    - 1) Avsola
    - 2) Inflectra
    - 3) Simponi Aria
    - 4) Skyrizi
  - B. Member has a documented clinical reason to avoid TNF inhibitors (See Appendix A)
  - C. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

Note: Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s) experienced, contraindication(s), or exclusion(s) to treatment with preferred product(s) is required (where applicable).

Prescriber Specialties (initial approvals only)

This medication must be prescribed by or in consultation with one of the following:

- 1. Rheumatoid arthritis and articular juvenile idiopathic arthritis: rheumatologist
- 2. Psoriatic arthritis: rheumatologist or dermatologist
- 3. Prophylaxis of acute graft versus host disease (aGVHD), chronic GVHD, and immune checkpoint inhibitor-related toxicity: oncologist or hematologist

Criteria for Initial Approval

**Moderately to severely active rheumatoid arthritis (RA)**

- 1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
- 2. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:

- A. Member meets either of the following criteria:
  - 1) Member has been tested for either of the following biomarkers and the test was positive/elevated:
    - a. Rheumatoid factor (RF)
    - b. Anti-cyclic citrullinated peptide (anti-CCP)
  - 2) Member has been tested for ALL of the following biomarkers:
    - a. Rheumatoid factor (RF)
    - b. Anti-cyclic citrullinated peptide (anti-CCP)
    - c. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- B. Member meets either of the following criteria:
  - 1) Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
  - 2) Member has an intolerance or contraindication to methotrexate (see Appendix B).

**Moderately to severely active articular juvenile idiopathic arthritis (JIA)**

- 1. Authorization of 12 months may be granted for members 2 years of age and older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active articular juvenile idiopathic arthritis.
- 2. Authorization of 12 months may be granted for members 2 years of age and older for treatment of moderately to severely active articular juvenile idiopathic arthritis when any of the following criteria are met:
  - A. The member had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
  - B. The member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
    - 1) Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
    - 2) Presence of erosive disease or enthesitis
    - 3) Delay in diagnosis
    - 4) Elevated levels of inflammation marker
    - 5) Symmetric disease
  - C. The member has risk factors for disease severity and potentially a more refractory disease course (See Appendix C) and the member also meets one of the following:
    - 1) High-risk joints are involved (e.g., cervical spine, wrist, or hip).
    - 2) Has high disease activity.
    - 3) Are judged to be at high risk for disabling joint disease.

**Psoriatic arthritis (PsA)**

- 1. Authorization of 12 months may be granted for members 2 years of age and older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.
- 2. Authorization of 12 months may be granted for members 2 years of age and older for treatment of active psoriatic arthritis when either of the following criteria is met:
  - A. Member has mild to moderate disease and meets one of the following criteria:
    - 1) Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
    - 2) Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix B), or another conventional synthetic drug (e.g., sulfasalazine).

- 3) Member has enthesitis or predominantly axial disease.
- B. Member has severe disease.

### **Prophylaxis of acute graft versus host disease**

1. Authorization of 1 month may be granted for prophylaxis of acute graft versus host disease in members 2 years of age and older when both of the following criteria are met:
  - A. Member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.
  - B. The requested medication will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate.

### **Chronic graft versus host disease**

1. Authorization of 12 months may be granted for treatment of chronic graft versus host disease when either of the following criteria is met:
  - A. Member has experienced an inadequate response to systemic corticosteroids.
  - B. Member has an intolerance or contraindication to corticosteroids.

### **Immune checkpoint inhibitor-related toxicity**

1. Authorization of 1 month (intravenous Orencia only) may be granted for the treatment of Immune checkpoint inhibitor (e.g., CTLA-4, PD-L1 inhibitor) toxicity when ALL of the following are met:
  - A. Member has been diagnosed with one of the following severe (G3) or life threatening (G4) immune checkpoint-related cardiac toxicities:
    - 1) Myocarditis
    - 2) Pericarditis
    - 3) Arrhythmias
    - 4) Impaired ventricular function
    - 5) Conduction abnormalities
  - B. Member has had an inadequate response to corticosteroids.
  - C. Member has recently received immune checkpoint inhibitor therapy [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)].
  - D. Treatment will not exceed 5 doses (i.e., 500mg IV every 2 weeks, for a total of 5 doses).

### Continuation of Therapy

#### **Moderately to severely active rheumatoid arthritis (RA)**

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

#### **Moderately to severely active articular juvenile idiopathic arthritis (JIA)**

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
  - A. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
  - B. Number of joints with limitation of movement
  - C. Functional ability

#### **Psoriatic arthritis (PsA)**

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain a positive

clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- A. Number of swollen joints
- B. Number of tender joints
- C. Dactylitis
- D. Enthesitis
- E. Axial disease
- F. Skin and/or nail involvement

**Prophylaxis of acute graft versus host disease, Immune Checkpoint Inhibitor-Related Toxicity, and Chronic Graft Versus Host Disease**

1. All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Other

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])\* within 12 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs associated with an increased risk of TB.

\* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer abatacept to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of abatacept.

For all indications: Member cannot use Orencia concomitantly with any other biologic DMARD or targeted synthetic DMARD.

Orencia is considered **not medically necessary** for members who do not meet the criteria set forth above.

*Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.*

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Trade Name	Generic Name	Quantity Limit
Orencia®	Abatacept	4 vials or syringes/auto-injectors per 28 days

Appendix

**Appendix A: Clinical reasons to avoid TNF-inhibitors**

1. History of demyelinating disorder
2. History of congestive heart failure
3. History of hepatitis B infection
4. Autoantibody formation/lupus-like syndrome
5. Risk of lymphoma

**Appendix B: Examples of Contraindications to Methotrexate**

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

### Appendix C: Risk factors for articular juvenile idiopathic arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

## PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0129 Injection, abatacept, 10 mg

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\*Some content reprinted from CVSHealth

## POLICY HISTORY

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