AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Orencia	Page:	1 of 8
Effective Date:	2/1/2024	Last Review Date:	11/2023

Applies to:	☐Illinois	☐Florida	☒Florida Kids
	☐New Jersey	☐Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Orencia under the patient's prescription drug benefit.

Description:

A. FDA-Approved Indications
   1. Moderately to severely active rheumatoid arthritis in adults
   2. Moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age or older
   3. Active psoriatic arthritis in adults
   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

B. Compendial Uses
   1. Oligoarticular juvenile idiopathic arthritis
   2. Chronic graft versus host disease
   3. Immune checkpoint inhibitor-related toxicity

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Non-preferred: Orencia

Policy/Guideline:

Documentation for all indications:
The patient is unable to take a preferred adalimumab product, Enbrel and Rinvoq, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

A. **Rheumatoid arthritis (RA)**
   1. Initial requests:
      i. 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.

ii. 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. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. **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.

C. **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.

D. **Chronic graft versus host disease:** 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.

Prescriber Specialty:
This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis and articular juvenile idiopathic arthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Prophylaxis of acute graft versus host disease (aGVHD), chronic GVHD, and immune checkpoint inhibitor-related toxicity: oncologist or hematologist

Criteria for Initial Approval:
A. Rheumatoid arthritis (RA)
1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug 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:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   ii. Member meets either of the following criteria:
      a. 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).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. 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 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 is met:
   i. Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
   ii. 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:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis
      c. Delay in diagnosis
      d. Elevated levels of inflammation markers
      e. Symmetric disease

iii. Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and member also meets one of the following:
   a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
   b. Has high disease activity.
   c. Is judged to be at high risk for disabling joint disease.

C. Psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug indicated for active psoriatic arthritis.

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis or predominantly axial disease.
   ii. Member has severe disease.

D. Prophylaxis of acute graft versus host disease

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:

1. Member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.
2. The requested medication will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate.

E. Chronic graft versus host disease

Authorization of 12 months may be granted for treatment of chronic graft versus host disease when either of the following criteria is met:

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

F. Immune checkpoint inhibitor-related toxicity

Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has cardiac toxicity.

Continuation of Therapy:

A. Rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all adult 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.

B. Articular juvenile idiopathic arthritis (JIA)

Authorization of 12 months may be granted for all members 2 years of age and older (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:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

C. Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for 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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement

D. Prophylaxis of acute graft versus host disease, chronic graft versus host disease, and immune checkpoint inhibitor-related toxicity

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

Other Criteria:
Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs 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. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

Appendix A: Examples of Contraindications to Methotrexate or Leflunomide
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 B: Risk factors for articular juvenile idiopathic arthritis
1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

Approval Duration and Quantity Restrictions:
Approval:
Initial Approval: Prophylaxis of acute graft versus host disease and immune checkpoint inhibitor-related toxicity = 1 month; others = 12 months

Renewal Approval: Prophylaxis of acute graft versus host disease and immune checkpoint inhibitor-related toxicity = 1 month; others = 12 months

Quantity Level Limit:

Medication	Standard Limit	Exception Limit*
Orencia (abatacept) subcutaneous injection: 50 mg per 0.4 mL syringe	4 syringes per 28 days	N/A
Orencia (abatacept) subcutaneous injection: 87.5 mg per 0.7 mL syringe	4 syringes per 28 days	N/A
Orencia (abatacept) subcutaneous injection: 125 mg per mL syringe/autoinjector	4 syringes per 28 days	N/A
Orencia (abatacept) intravenous: 250 mg single-use vial	4 vials every 28 days	16 vials per 29 days

*Exception limits apply to loading doses.

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