Commercial PA Criteria

Effective: January 1, 2019

Prior Authorization: Orencia

Products Affected: Orencia (abatacept) subcutaneous solution

Medication Description: Orencia (abatacept) is a biological response modifier that displays anti-inflammatory affects by downregulating T cell activation. Abatacept is indicated for reducing signs and symptoms, inducing major clinical response, slowing progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. It may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists. There was an increased frequency of infections and serious infections in patients on abatacept plus a TNF antagonists compared with TNF antagonists alone and no increased clinical benefit. Therefore, abatacept should not be used with a TNF antagonists. The safety and efficacy of abatacept concomitantly with other biologic rheumatoid arthritis agents (eg, anakinra) have not been evaluated, and therefore, such use is not recommended. Clinical trials demonstrated the efficacy of abatacept as in adjunct in patients with active rheumatoid arthritis who failed methotrexate or tumor necrosis factor inhibitors. No comparative studies are available comparing abatacept to other disease modifying agents for rheumatoid arthritis. Abatacept may be a treatment option for individuals who do not respond to existing agents, may not be candidates for the other agents, or unable to tolerate other agents.

Covered Uses:

1. **Juvenile idiopathic arthritis**, in patients ≥ 2 years of age with moderately to severely active polyarticular disease.
2. **Psoriatic arthritis**, in adults with active disease.
3. **Rheumatoid arthritis**, in adults with moderately to severely active disease.
4. **Graft-versus-host disease (GVHD),** for prophylaxis of acute GVHD in combination with a calcineurin inhibitor and methotrexate, in patients ≥ 2 years of age undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated donor.

Exclusion Criteria:

1. Concurrent use with a Biologic or DMARD
2. IBD (Crohn's/Ulcerative Colitis)
3. Ankylosing Spondylitis
4. Psoriasis

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed
3. Current medication regimen

Age Restrictions:

Rheumatoid Arthritis: 18 years of age or older
Juvenile Idiopathic Arthritis: 2 years of age or older
Psoriatic Arthritis: 18 years of age or older
Graft-versus-host-disease: 2 years of age or older

Prescriber Restrictions:
Rheumatoid Arthritis/Juvenile Idiopathic Arthritis: Must be prescribed by, or in consultation with, a rheumatologist.
Psoriatic Arthritis: Must be prescribed by, or in consultation with, a rheumatologist or dermatologist.
Graft-versus-host-disease: The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

Coverage Duration:
Initial: 4 doses or 6 months (contingent on criteria)
Continuation: 1 year

Other Criteria:
Initiation

1. **Graft-versus-host-disease – Prevention**
   Approve for 4 doses if the patient meets ALL of the following (A, B, C, D, E, **AND** F):
   A. Patient is ≥ 2 years of age; **AND**
   B. Orencia is being used for prevention of acute graft-versus-host disease; **AND**
   C. Patient will also receive a calcineurin inhibitor for prevention of acute graft-versus-host disease; **AND**
      Note: Examples of calcineurin inhibitors include cyclosporine and tacrolimus.
   D. Patient will also receive methotrexate for prevention of acute graft-versus-host disease; **AND**
   E. Patient will undergo hematopoietic stem cell transplantation from one of the following donors (i **OR** ii):
      i. Matched unrelated donor; **OR**
      ii. 1-allele-mismatched unrelated donor; **AND**
   F. The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

2. **Juvenile Idiopathic Arthritis (JIA) [or juvenile rheumatoid arthritis] {regardless of type of onset}.**
   Initial Therapy: Approve if the patient meets the following criteria
   A. Patient has tried one other agent for this condition; **OR**
      Note: Examples of other systemic therapies for JIA include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of one biologic other than the requested medication also counts as a trial of one systemic therapy for JIA. A biosimilar of the requested biologic does not count.
   B. Patient will be starting on adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide; **OR**
   C. Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; **OR**
      Note: Examples of contraindications to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias.
   D. Patient has aggressive disease, as determined by the prescriber **AND**

E. Prescribed by or in consultation with a rheumatologist **AND**
F. Patient has a documented failure of, or intolerance to, **TWO** of the following medications **OR**
Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz tablets and Xeljanz oral solution) collectively counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product. A trial of Actemra intravenous, Orencia intravenous, an infliximab product (e.g., Remicade, biosimilars), or Simponi Aria also counts [documentation required].

Juvenile Idiopathic Arthritis (TWO of the following)
Enbrel
Adalimumab Product
Actemra SC
Xeljanz tablets/ Xeljanz oral solution
Rinvoq/Rinvoq LQ

G. According to the prescriber, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder.

3. Psoriatic Arthritis

Initial Therapy: Approve if the patient meets the following criteria

A. Patient has clinically diagnosed psoriatic arthritis **AND**
B. Prescribed by or in consultation with a rheumatologist or dermatologist **AND**
C. Patient is ≥ 18 years of age and has a documented failure of, or intolerance to, **TWO** of the following medications **OR**
Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts [documentation required].

Psoriatic Arthritis (TWO of the following)
Tremfya
Enbrel
Adalimumab Product
Stelara SC
Xeljanz/XR
Otezla
Taltz
Skyrizi SC
Rinvoq/ Rinvoq LQ

D. Patient is < 18 years of age AND has a documented failure of, or intolerance to **ONE** of the following medications; **OR**
Note: A trial of another TNFi counts towards a trial of Enbrel [documentation required]. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product.

Psoriatic Arthritis (ONE of the following)
Enbrel
Stelara SC
Rinvoq/ Rinvoq LQ

E. According to the prescriber, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, **OR** a demyelinating disorder

4. Rheumatoid Arthritis

Initial Therapy: Approve if the patient meets the following criteria

A. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD **AND**
Note: Examples include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial with at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for rheumatoid arthritis is not required to "step back" and try a conventional synthetic DMARD.

B. The medication is prescribed by or in consultation with a rheumatologist **AND**

C. Patient has a documented failure of, or intolerance to, **TWO** of the following medications **OR**
Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of Actemra intravenous, Cimzia, an infliximab product (e.g., Remicade, biosimilars), Kevzara, or Simponi (Aria or subcutaneous) also counts [documentation required].

Rheumatoid Arthritis (TWO of the following)
Enbrel
Adalimumab Product
Actemra SC
Xeljanz/XR
Rinvoq

D. According to the prescriber, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, **OR** a demyelinating disorder.

Continuation

A. Patient meets all initial authorization criteria, **AND**

B. Patient achieves or maintains a positive clinical response after at least 90 days of therapy with Orencia as evidenced by low disease activity or improvement in signs and symptoms of the condition.
Note: A patient who has received < 90 days of therapy or who is restarting therapy is reviewed under Initial Therapy criterion

References:

1. Orencia® subcutaneous injection [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; October 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019
2	Policy Update	Update	Coverage Duration: Continuation Update to 3 years	07/01/2019
3	Policy Update	Added Rinvoq as a preferred product for RA	Other Criteria	10/18/2019
4	Policy Update	Added Dosing Limitations according to FDA label	Other Criteria	5/5/2020
5	Policy Update	Added Otezla as a preferred option for PsA diagnosis	Other Criteria	8/1/2020
6	Policy Update	Removed Actemra SQ as a preferred product for RA & JIA Added Taltz as a preferred product for PsA Removed Cosentyx as preferred product for PsA Added Tremfya as preferred product for PsA Added Xeljanz/XR as preferred product for JIA	Other Criteria	1/1/2021
7	Policy Update	Added Rinvoq, and Skyrizi as preferred agents on PsA indication. Added Actemra SQ as a preferred product for RA and JIA	Other Criteria	02/17/2022
8	Policy Update	Replaced “Humira” with “Adalimumab” in Other Criteria	Other Criteria	05/11/2023

9	Policy Update	Update Exclusion Criteria Remove Dosage Limitations Removal of*Emblem does not consider alcohol use to be a clinical reason to use Orencia over methotrexate. Removed current criteria for - Rheumatoid Arthritis, Psoriatic Arthritis, Polyarticular juvenile idiopathic arthritis and replaced with Select criteria for implementation to label use Addition of Step Requirements for approval	Exclusion Criteria Prescriber Restriction Other Criteria	12/19/2023
10	Update	Addition of Graft-versus-host disease (GVHD) For Juvenile Idiopathic Arthritis, Rinvoq/LQ was added as a Step 2 Product that may have been tried prior to Orencia subcutaneous. For Psoriatic Arthritis, Rinvoq LQ was added as a Step 2 Product that may have been tried prior to Orencia subcutaneous. Documentation of previous trials remains required. For Rheumatoid Arthritis, Juvenile Idiopathyic Arthritis, and Psoriatic Arthritis, Simlandi and adalimumab-ryvk were added to the list of Preferred adalimumab products that may have been tried prior to Orencia Subcutaneous.	Covered used Age Restriction Prescriber Restriction Other criteria	6/7/2024