Orencia (abatacept)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Orencia (abatacept) – Intravenous	4 vials per 28 days*
Orencia (abatacept) – Subcutaneous	4 syringes/autojectors per 28 days

*Initiation of intravenous therapy for Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (PJIA), or Psoriatic arthritis (PsA): May approve 4 (four) additional vials (250 mg/vial) in the first 28 days (4 weeks) of treatment. For Graft Versus Host Disease (GVHD): May approve up to 4 vials (250 mg/vial) per infusion for a total of 4 (four) infusions starting the day before transplantation (day -1), followed by administration on days 5, 14, and 28 after transplantation.

APPROVAL CRITERIA

Initial requests for Orencia (abatacept) may be approved if the following criteria are met:

I. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA;
   AND
   B. Documentation is provided that ifndividual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. Documentation is provided that if methotrexate is not tolerated , individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, hydroxychloroquine); **OR**
   D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;
      AND
   E. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred agents include – adalimumab-adbm, Enbrel (etanercept), Humira (adalimumab), or Simponi (golimumab)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
      AND
      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
      OR
      2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

F. Documentation is provided that individual has been receiving and is maintained on a stable dose of Orencia (abatacept). Medication samples/coupons/discount cards are excluded from consideration as a trial; **OR**

G. Documentation is provided that individual is unable to use the preferred agents due to:
   1. demyelinating disease or heart failure with documented left ventricular dysfunction;

*Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor. JAK inhibitor clinical criteria require a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents**.**

OR

II. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
   A. Individual has moderate to severe PJIA; **AND**
   B. Individual is 6 years of age or older for administration of intravenous infusion;
   OR
   C. Individual is 2 years of age and older for administration of subcutaneous injection;
   AND
   D. Individual has had an inadequate response toor is intolerant of conventional therapy [nonbiologic disease modifying antirheumatic drugs (DMARDs) (such as methotrexate) (ACR 2019); **OR**
   E. Individual has a contraindication to methotrexate;

   AND
   F. Documenation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Enbrel (etanercept) and Humira (adalimumab)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
      AND
      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
         OR
      2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

      OR

   G. Documenation is provided that individual has been receiving and is maintained on a stable dose of Orencia (abatacept). Medication samples/coupons/discount cards are excluded from consideration as a trial.;
   H. Documentation is provided that the individual has either concomitant clinical condition:
      1. Demyelinating disease; **OR**
      2. Heart failure with documented left ventricular dysfunction;

OR

III. Psoriatic arthritis (PsA) when each of the following criteria are met:
A. Individual is 2 years of age or older with moderate to severe PsA; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)] (ACR 2019); **OR**
C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

AND

D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira adalimumab), Otezla (apremilast), Simponi (golimumab), Stelara (ustekinumab), Tremfya guselkumab)*]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Orencia (abatacept)**.** Medication samples/coupons/discount cards are excluded from consideration as a trial.

*Note – Trial of Cosentyx (secukinumab) does not apply in states where not covered (CA, CO). Prior trial of Tremfya (guselkumab) not required in states where not covered (CA, CO, GA, IN, KY, ME, MO, NH, NY, OH, VA, WI];

*Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor. JAK inhibitor clinical criteria require a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents**.**

OR

III. Acute Graft Versus Host Disease (GVHD), prophylaxis, when each of the following criteria are met:
A. Individual is 2 years of age or older using for prophylaxis of acute GVHD; **AND**
B. Individual will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor; **AND**
C. Individual is using Orencia (abatacept) in combination with a calcineurin inhibitor and methotrexate;

OR

V. Chronic Graft-versus-host disease (GVHD) when each of the following criteria are met (NCCN 2A):
A. Individual has a diagnosis of steroid-refractory chronic GVHD; **AND**
B. Individual is initiating abatacept in combination with systemic corticosteroids;

OR

VI. Immune checkpoint inhibitor therapy-related toxicities when each of the following criteria are met (NCCN 2A):
   A. Individual is undergoing immune checkpoint inhibitor therapy for a cancer diagnosis; **AND**
   B. Individual is experiencing immunotherapy-related myocarditis; **AND**
   C. Myocarditis is unresponsive to high-dose systemic corticosteroids.

Continuation requests for Orencia (abatacept) may be approved if the following criterion is met:

I. Documentation is provided that individual has been receiving and is maintained on a stable dose of Orencia. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Orencia (abatacept) may **not** be approved for the following:

I. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
II. Tuberculosis or other active serious infections or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC-) and Prevention - recommended equivalent test to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors) **OR**
IV. When the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 11, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. Fraenkel L, Bathon JM, England BR et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021;73(7):924-939.
5. Menter A, Korman NJ, Elmets CA et al for the American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol*. 2011; 65: 137-174.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.
7. Ringold S, Weiss PF, Beukelman T, et al. 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 Rheum. 2013; 65(10):2499-2512.
8. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheum. 2019; 71(6):846-863.

9. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care & Research. 2011; 63(4):465.
10. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 13, 2023.
11. Management of Immunotherapy-related Toxicities. V3.2023. Revised October 11, 2023.
12. Hematopoietic Cell Transplantation. V3.2023. Revised October 9, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.