SmartHealth Ascension

Abatacept

(Orencia®) J0129 (10mg)

Covered with prior authorization

Abatacept (Orencia®) may be authorized when the following criteria are met:

Graft-Versus-Host Disease – Prevention

Individual meets ALL of the following criteria:

- Individual is ≥ 2 years of age.
- Orencia® is being used for prevention of acute graft-versus-host disease.
- Individual will also receive a calcineurin inhibitor (e.g., cyclosporine and tacrolimus) for prevention of acute graft-versus-host disease.
- Individual will also receive methotrexate for prevention of acute graft-versus-host disease.
- Individual will undergo hematopoietic stem cell transplantation from one of the following donors:
  - Matched, unrelated donor
  - 1-allele-mismatched, unrelated donor
- Medication is prescribed by, or in consultation with, an oncologist, a hematologist, or a physician affiliated with a transplant center.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Individual meets ALL of the following criteria:

- Individual is ≥ 6 years of age; **AND**
- Individual has tried and had an inadequate response to one conventional agent (ie methotrexate, leflunomide) used in the treatment of PJIA for at least 3 months; **OR**
- Intolerance or hypersensitivity to one of the conventional agents used in the treatment of PJIA or individual has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PJIA.
- Prescribed by, or in consultation with, a rheumatologist or a prescriber who specializes in PJIA.

Psoriatic arthritis

Individual meets ALL of the following criteria:

- Documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE disease-modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide and sulfasalazine).
  - ***NOTE:*** *An exception to this requirement can be made if the individual has already tried a biologic. These individuals are not required to "step back" and try a DMARD.*
- Prescribed by, or in consultation with, a rheumatologist, dermatologist or a prescriber who specializes in psoriatic arthritis.

Rheumatoid arthritis

Individual meets ALL of the following criteria:

- Documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE disease-modifying, anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide and sulfasalazine).
    - ***NOTE****: An exception to this requirement can be made if the individual has already tried a biologic. These individuals are not required to "step back" and try a conventional synthetic DMARD.*
- Prescribed by, or in consultation with, a rheumatologist or a prescriber who specializes in rheumatoid arthritis.

Exclusion criteria:

- Concomitant use with any other biologic including all non-tumor necrosis factor (non-TNF) biologics, anti-TNF biologics, or oral immunomodulatory agents (e.g., Otezla or Xeljanz/Xeljanz XR)
- The individual has been tested for latent tuberculosis (TB) AND if positive the has not begun therapy for latent TB
- Ankylosing Spondylitis (AS)
- Inflammatory Bowel Disease (i.e., Crohn's Disease [CD], Ulcerative Colitis [UC])
- Psoriasis
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use

Initial approval duration:

- **Graft-Versus-Host Disease – Prevention:** Authorization is for 4 doses
- **PJIA, psoriatic arthritis, and rheumatoid arthritis:** Initial authorization is up to 12 months

Reauthorization approval duration:

- **PJIA, psoriatic arthritis, and rheumatoid arthritis:** Reauthorization for up to 12 months

Reauthorization Criteria:

- **PJIA, psoriatic arthritis, and rheumatoid arthritis:** Orencia® is considered medically necessary for continued use when the individual has had a positive response to abatacept intravenous

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Orencia intravenous, a selective T-cell costimulation modulator, is indicated for the following uses:

- Juvenile idiopathic arthritis, in patients ≥ 2 years of age with moderately to severely active polyarticular disease.
- Psoriatic arthritis, in adults with active disease.
- Rheumatoid arthritis, in adults with moderately to severely active disease.
- 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, unrelated donor or 1 allele-mismatched, unrelated donor.

Orencia® is not recommended for use concomitantly with other potent immunosuppressants such as biologics or Janus kinase inhibitors. Orencia® is available as an intravenous infusion that is dosed on body weight. There is also a subcutaneous injection available in prefilled syringes. Some patients initiating therapy with Orencia® subcutaneous will receive a single loading dose with Orencia® intravenous.

References:

1. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022
2. Orencia® for injection [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2019
3. 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 nonsystemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019 Apr 25.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. Arthritis Care Res (Hoboken). 2019;71(1):2-29

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.