MVP Health Care Medical Policy

Medicare Part B: Abatacept

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**02/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**
Related Policies:	**Infliximab, Risankizumab, Secukinumab, Ustekinumab, Golimumab, Tocilizumab, Certolizumab**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

Drugs Requiring Prior Authorization under the medical benefit

J0129 abatacept, 10mg (Orencia IV)

Overview/Summary of Evidence

Abatacept is a fully human recombinant fusion protein categorized as a costimulatory or second-signal blocker of T cell activation. It is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA), in patients 2 years of age and older with active psoriatic arthritis (PsA), and in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Abatacept is also indicated as prophylaxis of acute graft versus host disease, in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem-cell transplantation from a matched or 1 allele-mismatched unrelated donor. Members should be screened for immunologic and infectious disease prior to initiating therapy.

Indications/Criteria

A. For all indications, Abatacept IV (Orencia) may be considered for **medical** coverage when:
   - Prescribed for an FDA approved indication **AND**

- Ordered by or with consult from a rheumatologist/immunologist **AND**
- Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy

B. **Rheumatoid Arthritis**

Abatacept may be considered for coverage for Rheumatoid Arthritis when the above criteria are met **AND**:

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where Abatacept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. **Juvenile Idiopathic Arthritis**

Abatacept to treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where Abatacept IV (Orencia) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Psoriatic Arthritis**
Abatacept may be considered for coverage for Psoriatic Arthritis when the above criteria are met **AND**:

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes are provided documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where Abatacept IV (Orencia) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Acute graft versus host disease (GVHD) prophylaxis**
Abatacept may be considered for coverage for GVHD when the above criteria are met **AND** documentation that the member is undergoing hematopoietic stem-cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where Abatacept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

Exclusions

The use of Abatacept will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

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References

1. Clinical Pharmacology. Abatacept. Revised 12/21/2021. Accessed 01/05/2023.
2. Orencia (abatacept) for injection. Prescribing information. Bristol-Myers Squibb Princeton, NJ. Revised 05/2024.
3. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf
5. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).