

Targeted Immunomodulators
Orencia IV (abatacept)
Effective 06/01/2025

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

Overview

Orencia (abatacept) is a selective T cell co-stimulation modulator indicated for:

- Moderately to severely active Rheumatoid Arthritis (RA)
- Moderately to severely active polyarticular Juvenile Idiopathic Arthritis (pJIA)
- Active Psoriatic Arthritis (PsA)
- Acute Graft Versus Host Disease (aGVHD) Prophylaxis

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with Orencia excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Rheumatoid Arthritis (RA) and Polyarticular juvenile idiopathic arthritis (pJIA)

1. Diagnosis of **ONE** of the following:
 - a. Moderate to severe rheumatoid arthritis
 - b. Moderate to severe polyarticular juvenile idiopathic arthritis
2. **ONE** of the following:
 - a. Inadequate response or adverse reaction to at least **ONE** traditional DMARD or contraindication to **ALL** traditional DMARDs
 - b. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. Appropriate dosing

Psoriatic Arthritis

1. Diagnosis of psoriatic arthritis
2. **ONE** of the following:
 - a. Inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication
 - b. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication
3. Appropriate dosing

Acute Graft Versus Host Disease (aGVHD) Prophylaxis (aGVHD)

1. Indication of acute graft versus host disease prophylaxis
2. Member is ≥ 2 years of age
3. Orencia will be used in combination with **BOTH** of the following:
 - a. A calcineurin inhibitor
 - b. methotrexate
4. Appropriate dosing (weight required)

Requests for More Frequent or Higher Doses

Requests for more frequent or higher doses of injectable biologics, may be approved if **ALL** of the following is provided:

1. Documentation of severe disease
2. **ONE** of the following:
 - a. Inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication
 - b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

Continuation of Therapy

Resubmission by prescriber for any of the following FDA-approved diagnoses will infer a positive response to therapy and request can be recertified if dosing is appropriate.

Limitations

1. Initial approvals will be for:
 - a. All other indications: **6 months**.
 - b. Acute Graft Versus Host Disease (aGVHD) Prophylaxis: **up to 1 month** past anticipated date of transplantation
2. Reauthorizations will be for:
 - a. All other indications: **up to 12 months**.
 - b. Acute Graft Versus Host Disease (aGVHD) Prophylaxis: reviewed on a case by case basis

References

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; December 2024.
2. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis*. 2017;0:1-18.
3. Mease P, Genovese MC, Gladstein G, et al. Abatacept in the treatment of patients with psoriatic arthritis: results of a six-month, multicenter, randomized, double-blind, placebo-controlled, phase II trial. *Arthritis Rheum* 2011; 63:939.



4. 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 Res.* 2011;63(4):465-482.
5. Ruperto N, Lovell DJ, Quartier P, et al. Abatacept in children with juvenile idiopathic arthritis: a randomised, double-blind, placebo-controlled withdrawal trial. *Lancet* 2008; 372:383.

Review History

06/26/06 – Reviewed and revised

08/15/06 – Effective

02/25/08 – Reviewed

02/23/09 – Reviewed

02/22/10 – Reviewed

02/28/11 – Reviewed

10/24/11 – Reviewed and revised (09/12/11 drug file Orenzia SQ)

02/27/12 – Reviewed

02/25/13 – Reviewed

02/24/14 – Reviewed

02/23/15 – Reviewed

02/22/16 – Reviewed

02/27/17 – Reviewed and revised (adopted SGM & ST) in P&T Meeting

03/01/18 – Reviewed and revised (adopted MH RS)

02/20/19 – Reviewed in P&T Meeting

10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021

06/22/2022 – Reviewed and updated for June P&T; matched MH UPPL. Added criteria and approval limitations for newly FDA-approved indication (aGVHD). Continuation of therapy language was updated. Added Appendix B for Requests for More Frequent or Higher Doses. Updated Appendix A: Dosing and References. Effective 08/01/2022.

01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members. Effective 3/1/23.

05/15/25 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Updated formatting and references. Moved “Requests for More Frequent or Higher Doses” criteria into coverage guidelines section. Effective 6/1/25

