Mass General Brigham
Health Plan

Orencia (abatacept)
Effective 03/01/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Orencia IV is only available under the medical benefit.		

Overview
Orencia (abatacept) is a selective T cell co-stimulation modulator indicated for:
- Moderately to severely active Rheumatoid Arthritis (RA)
- Moderately to severely active polyartricular 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)**
Prescriber provides documentation of **ALL** of the following:
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. Paid claims or physician documented inadequate response or adverse reaction to at least **ONE** traditional DMARD or contraindication to **ALL** traditional DMARDs
    b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. Appropriate dosing †

Psoriatic Arthritis
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of psoriatic arthritis
2. **ONE** of the following:
    a. Paid claims or physician documented 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)
Prescriber providers documentation of **ALL** of the following:

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 – See Appendix B

New members currently stable on Orencia® can be approved without documentation of failed trials with the conventional therapies.

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
3. The following quantity limits apply:

Orencia Inj 50mg/0.4mL Orencia Inj 87.5mg/0.7mL Orencia 125mg/mL Orencia Inj 250mg	4 units per 28 days

Appendix A: Dosing

<table>
<tr><th></th><th>Pediatric Dosing</th><th>Other Dosing</th></tr>
<tr><td>Orencia®
(abatacept)</td><td>Juvenile Idiopathic Arthritis (≥ 6 years old, weight < 75 kg): 10 mg/kg IV at weeks 0, 2, and 4, then every 4 weeks thereafter

Juvenile Idiopathic Arthritis (≥ 6 years old, weight > 75 kg): Refer to adult IV dosing regimen. Maximum dose: 1,000 mg.

Juvenile Idiopathic Arthritis (≥ 2 years old, weight 10 kg to 25 kg): 50 mg SQ every week

Juvenile Idiopathic Arthritis (≥ 2 years old, weight 25 to 50 kg): 87.5 mg SQ every week

Juvenile Idiopathic Arthritis (≥ 2 years old, weight ≥50 kg): 125 mg SQ every week

Acute Graft versus Host prophylaxis ((≥ 6 years old): 10 mg/kg (maximum dose: 1,000 mg) IV over 60 minutes on the day before transplantation, followed by Days 5, 14, and 28 after transplantation

Acute Graft versus Host prophylaxis (2 to < 6 years old): 15 mg/kg IV over 60 minutes on the day before transplantation, followed by 12 mg/kg IV over 60 min on Days 5, 14, and 28 after transplantation</td><td>Rheumatoid arthritis or Psoriatic Arthritis (IV regimen): Dose based on weight infused over 30 minutes at week 0, 2, and 4, then every 4 weeks thereafter.
<table>
<tr><th>Body weight of patient</th><th>Dose</th><th>Number of vials</th></tr>
<tr><td><60 kg</td><td>500 mg</td><td>2</td></tr>
<tr><td>60 to 100 kg</td><td>750 mg</td><td>3</td></tr>
<tr><td>>100 kg</td><td>1 gm</td><td>4</td></tr>
</table>
Rheumatoid arthritis or Psoriatic Arthritis (SQ regimen): Weight-based IV loading dose (as per above), then 125 mg SQ within 1 day, followed by 125 mg SQ once weekly.

<u>Unable to receive an IV infusion:</u>
Initiate weekly SQ injections without an IV loading dose.
<u>Transitioning from IV to SQ</u>: administer the first SQ dose instead of the next scheduled IV dose.</td></tr>
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Appendix B: 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

References

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; December 2021.
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 Orencia 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.