Mass General Brigham
Health Plan

Orencia (abatacept)
Effective 01/01/2027

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 Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Orencia (abatacept) is a selective T cell co-stimulation modulator. It is available in intravenous (IV) and subcutaneous (SC) formulations. Both the IV and SC formulations are indicated for:

- Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA)
- Treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
- Treatment of patients 2 years of age and older with active psoriatic arthritis (PsA)

Additionally, the IV formulation is also approved for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorizations may be granted when all of the following diagnosis-specific criteria have been met:

Moderately to severely active rheumatoid arthritis (RA) (IV and SC)

1. Diagnosis of moderately to severely active rheumatoid arthritis (RA)
2. Trial and failure, contraindication, or intolerance to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Adalimumab-aaty, adalimumab-adaz, or Hadlima
    d. Rinvoq
    e. Simponi
3. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:

a. Methotrexate
b. Leflunomide
c. Sulfasalazine

Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) (IV and SC)

1. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
2. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses
    a. Leflunomide
    b. Methotrexate
3. Trial and failure, contraindication, or intolerance to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Adalimumab-aaty, adalimumab-adaz, or Hadlima
    d. Rinvoq or Rinvoq LQ

Active psoriatic arthritis (PsA) (IV and SC)

1. Diagnosis of active psoriatic arthritis (PsA)
2. ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement
3. Trial and failure, contraindication, or intolerance to TWO of the following:
    a. Cimzia
    b. Bimzelx
    c. Enbrel
    d. Adalimumab-aaty, adalimumab-adaz, or Hadlima
    e. Otezla or Otezla XR
    f. Rinvoq or Rinvoq LQ
    g. Simponi
    h. Skyrizi
    i. Selarsdi, Steqeyma, or Yesintek
    j. Taltz
    k. Tremfya

Prophylaxis for Acute Graft vs. Host Disease (aGVHD) (IV only)

1. Diagnosis of prophylaxis for acute Graft vs. Host disease (aGVHD)
2. Member is 2 years of age or older
3. Member will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor
4. Recommended antiviral prophylactic treatment for Epstein-Barrr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT
5. Medication will be used in combination with BOTH of the following:
    a. Calcineurin inhibitor (e.g., cyclosporine, tacrolimus)
    b. Methotrexate

Continuation of Therapy

Requests for reauthorization will be approved when all of the following criteria are met:

1. Submission of medical records (e.g., chart notes) documenting an improvement in the member's condition, as evidenced by low disease activity or improvement in signs and symptoms of the condition

Limitations

1. Initial approvals and reauthorizations will be granted for all diagnoses for 24 months
2. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Orencia IV	4 vials per 28 days
Orencia prefilled syringe	4 syringes per 28 days
Orencia autoinjector	4 autoinjectors per 28 days

References

1. 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.
2. Orencia (abatacept) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; May 2024.
3. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. 2008;59(6):762-784.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016;68(1)1-26.
5. 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.

Review History

11/01/2020 – Transitioned from SGM to Custom Criteria; Reviewed and Updated for 2021 strategy to be implemented 1/1/2021.
03/16/2022 – Reviewed and updated for March P&T; Added Rinvoq as preferred trial for PsA under pharmacy benefit. Updated to reflect Inflectra as preferred for Medical Benefit. Effective 05/01/2022.
11/15/2023 – Reviewed and Updated for Nov P&T; Updated preferred agents (consolidated pharmacy and medical benefit preferred drugs required). Removed Appendices. Removed TB requirement. For Psoriatic arthritis: Updated preferred agents to prior use of TWO of the following: Cimzia, Enbrel, Humira or biosimilars, Rinvoq, Simponi, Skyrizi, Stelara, Tremfya, Xeljanz/XR. removed conventional therapies and added examples of active PSA. Rheumatoid arthritis: updated conventional therapies to include methotrexate, leflunomide, sulfasalazine. Updated preferred agents to prior use of TWO of the following: Cimzia, Enbrel, Humira or biosimilars, Rinvoq, Simponi, Xeljanz/XR. Added indication of Prophylaxis for Acute Graft vs. Host Disease (aGVHD). Effective 1/1/2024.
09/11/2024 – Reviewed and updated for September P&T. Updated criteria for pJIA to include Rinvoq and Rinvoq LQ as previous treatment options. Updated PsA criteria to include Rinvoq LQ as a previous treatment option. Effective 11/1/2024.
10/09/2024 – Reviewed and updated at October P&T. For all diagnoses added Amjevita (Nuvaila) as a preferred adalimumab product. Updated criteria for psoriatic arthritis to include Otezla, Taltz and Wezlana as biologic step options. Updated pJIA criteria to include Cimzia as a biologic step option. Updated reauthorization criteria to require documentation of clinical response to therapy. Effective 1/1/2025.
06/11/2025 – Reviewed and Updated at June P&T. Added quantity limitations. Effective 07/01/2025.

09/10/2025 - Reviewed and updated at September P&T. Added Yesintek as an Ustekinumab trial option. Effective 10/15/2025.
10/08/2025 – Reviewed and updated at October P&T. Updated policy to reflect that Selarsdi, Steqeyma and Yesintek are the preferred Ustekinumab trial options. Updated policy to reflect that Humira, Hadlima, Simlandi and Yuflyma are the preferred adalimumab trial options. Updated policy to reflect that policy only applies to the pharmacy benefit. Effective 01/01/2026.
01/14/2026 – Reviewed and updated at January P&T. Effective 2/1/2026: Updated criteria for psoriatic arthritis to include Otezla XR as a previous trial option. Effective 4/1/2026: Updated policy to indicate that only the IV formulation will be approved for aGVHD.
03/11/2026 – Reviewed and updated for March P&T. Administrative update - changing verbiage in reauthorization criteria from “documentation is submitted” to “submission of medical records (e.g., chart notes…” and updating language for members who are new to the Plan. Effective 05/01/2026.
04/15/2026 – Reviewed and updated at April P&T. Updated criteria for psoriatic arthritis to include Sotyktu as a previous trial option. Effective 08/16/2026.
09/09/2026 – Reviewed and updated at September P&T. Updating preferred adalimumab products throughout policy. Updating psoriatic arthritis criteria to remove Sotyktu as a previous trial option. Effective 01/01/2027.
10/14/2026 – Reviewed and updated at October P&T. Removing Xeljanz/tofacitinib as a previous trial option. Adding Bimzelx as previous trial option for PsA. Effective 01/01/2027.