Mass General Brigham
Health Plan

Orencia (abatacept)
Effective 01/01/2024

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	N/A		

Overview
Abatacept, a selective costimulation modulator, inhibits T cell (T lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28.

Orencia IV and SC are FDA approved for:
1. Rheumatoid arthritis (RA)
2. Polyarticular juvenile idiopathic arthritis (PJIA)
3. Psoriatic arthritis (PsA)

Orencia IV is also indicated for:
1. Prophylaxis for Acute Graft vs. Host Disease (aGVHD)

Coverage Guidelines

Moderately to severely active rheumatoid arthritis (RA)
Authorization may be granted 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 when the following criteria is met:
1. The member has a diagnosis of moderate to severely active rheumatoid arthritis (RA)
2. Member has trial and failure, contraindication or intolerance to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira, Adalimumab-adaz, Adalimumab-fkjp, or Hadlima
    d. Rinvoq
    e. Simponi
    f. Xeljanz or Xeljanz XR

3. Member has had 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. Leflunamide
    c. sulfasalazine

Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
Authorization may be granted 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 when the following criteria is met:
1. The member has a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA)
2. Minimum duration of a 6-week trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses
    a. Leflunomide
    b. Methotrexate
3. Member has trial and failure, contraindication or intolerance to TWO of the following:
    a. Enbrel
    b. Humira, Adalimumab-adaz, Adalimumab-fkjp, or Hadlima
    c. Xeljanz or Xeljanz XR

Active psoriatic arthritis (PsA)
Authorization may be granted 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 when the following criteria is met:
1. The member has a diagnosis of active psoriatic arthritis (PsA)
2. Trial and failure, intolerance, or contraindication to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp
    d. Rinvoq
    e. Simponi
    f. Skyrizi
    g. Stelara
    h. Tremfya
    i. Xeljanz/XR
3. The member has ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

Prophylaxis for Acute Graft vs. Host Disease (aGVHD)
Authorization may be granted 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 when the following criteria is met:

1. The member has a 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

Authorization of 24 months may be granted for members who achieve or maintain positive clinical response after at least 3 months of therapy with Orencia 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

References

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; June 2017.
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. 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.
4. 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.
5. 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.

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