

**Orencia (abatacept)**  
**Effective 05/01/2022**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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. This interaction provides a costimulatory signal necessary for full activation of T lymphocytes. Activated T lymphocytes are implicated in the pathogenesis of RA and PsA and are found in the synovium of patients with RA and PsA.

### Coverage Guidelines

#### Moderately to severely active rheumatoid arthritis (RA)

Authorization may be granted for members new to the plan who have previously received Orencia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis.

#### 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. If requesting under the **Medical Benefit**: the member has experienced an intolerance, inadequate response or contraindication to Inflectra and Simponi Aria
3. If requesting under the **Pharmacy Benefit**: the member has experienced intolerance, inadequate response or contraindication to Enbrel, Humira and Rinvoq
4. The member meets ONE of the following:
  - a. The member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
  - b. The member has an intolerance or contraindication to methotrexate (see Appendix).

### **Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)**

Authorization may be granted for members new to the plan who have previously received Orenzia excluding when these products have been obtained via physician samples or patient assistant program

**OR**

Authorization may be granted when the following criteria is met:

- a. The member has a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA)
- b. The member experienced an intolerance, inadequate response, or contraindication to BOTH methotrexate AND an NSAID (see Appendix A)
- c. ONE of the following:
  - a. If requesting under the **Medical Benefit** - the member has had intolerance, inadequate response (defined as a 3-month trial) or contraindication to Inflectra
  - b. If requesting under the **Pharmacy Benefit** - the member has had intolerance, inadequate response (defined as a 3-month trial) or contraindication to Enbrel and Humira

### **Active psoriatic arthritis (PsA)**

Authorization may be granted for members new to the plan who are currently receiving treatment with Orenzia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

Authorization may be granted when the following criteria are met:

1. The member has a diagnosis of active psoriatic arthritis (PsA)
2. If requesting under the **Medical Benefit**: the member has had intolerance, inadequate response, or contraindication to Inflectra and Simponi Aria
3. If requesting under the **Pharmacy Benefit**: the member has had intolerance, inadequate response, or contraindication to Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, and Rinvoq

### **Continuation of Therapy**

Authorization of 24 months may be granted for members who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Orenzia 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. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
  - a. Note: Members who have received Orenzia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

### **Appendix**

#### **Examples of Contraindications to Methotrexate**

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia



9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

### 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.

