Orencia (abatacept)
Effective February 20, 2019

Plan	☐ MassHealth ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis in adults
2. Moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age or older for subcutaneous use and 6 years of age and older for IV use.
3. Active psoriatic arthritis

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 24 months may be granted for members who are currently receiving treatment with Orencia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

2. Authorization of 24 months may be granted for treatment of moderately to severely active RA when one of the following criteria is met:
    a. Member has experienced an inadequate response or intolerance to BOTH Enbrel and Humira

b. Member has a contraindication to BOTH Enbrel and Humira and meets one of the following:
    i. 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).
    ii. Member has an intolerance or contraindication to methotrexate (see Appendix A).

Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)

1. Authorization of 24 months may be granted for members who have previously received Orencia or Actemra.

2. Authorization of 24 months may be granted for treatment of active pJIA when any of the following criteria is met:
    a. Member has experienced an inadequate response to at least a 3-month trial of a TNF inhibitor.
    b. Member has intolerance or contraindication to a TNF inhibitor.

Active psoriatic arthritis (PsA)

1. Authorization of 24 months may be granted for members who are currently receiving treatment with Orencia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

2. Authorization of 24 months may be granted for treatment of active psoriatic arthritis (PsA) if any of the following criteria is met:
    a. Member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla and Stelara).
    b. Member has a contraindication to all the preferred agents AND BOTH of the following criteria is met:
        a) One of the following:
            1) Member has had an inadequate response to at least a 3-month trial of at least one TNF inhibitor indicated for PsA (see Appendix B).
            2) Member has experienced an intolerance to a trial of at least one TNF inhibitor indicated for PsA.
            3) All TNF inhibitors indicated for PsA are not appropriate for the member (e.g., due to comorbidities or a history of infections).

        AND

        b) One of the following:
            1) Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
            2) Patient has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or has a contraindication to sulfasalazine.

<u>Continuation of Therapy</u>

Reauthorizations may be granted for all members (including new members) who meet all initial authorization criteria and 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. Approvals will be granted 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).

   Note: Members who have received Orencia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.
3. The following quantity limits apply:

ORENCIA INJ 250MG	1000 mg (4 vials) every 4 weeks
ORENCIA INJ 250MG	1000 mg (4 vials) every 4 weeks
ORENCIA INJ 125MG/ML	4 per 28 days
ORENCIA CLCK INJ 125MG/ML	4 per 28 days
ORENCIA INJ 50/0.4	4 per 28 days
ORENCIA INJ 87.5/0.7	4 per 28 days

Appendix

A: 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

B: Examples of TNF Inhibitors Indicated for PsA

1. Cimzia
2. Enbrel
3. Humira
4. Inflectra (infliximab-dyyb)
5. Renflexis (infliximab-abda)
6. Remicade
7. Simponi

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. 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 & Revised
02/25/08 – Reviewed
02/23/09 – Reviewed
02/22/10 – Reviewed
02/28/11 – Reviewed
10/24/11 – 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 – Adopted SGM & Step
02/26/18 – Reviewed & Revised
02/20/19 – Reviewed & Revised

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