RX.PA.052.MPC Orencia IV (abatacept)

PURPOSE

The purpose of this policy is to define the prior authorization process for Orencia IV (abatacept).

Orencia (abatacept) is indicated for the following:

- **Rheumatoid arthritis**, for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely disease. In RA, Orencia intravenous may be used as monotherapy or concomitantly with disease-modifying antirheumatic drugs (DMARDs) other than tumor necrosis factor inhibitors (TNFis).
- **Juvenile idiopathic arthritis**, for reducing signs and symptoms in pediatric patients ≥ 2 years of age with moderately to severely active polyarticular disease. In juvenile idiopathic arthritis, Orencia intravenous may be used alone or in combination with methotrexate (MTX).
- **Psoriatic arthritis**, in adults with active disease.
- **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.

PROCEDURE

A. Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Rheumatoid Arthritis.** Approve for the duration noted if the patient meets the following:
   Initial Therapy. Approve for 3 months if the patient meets the following criteria:
   - Patient is ≥ 18 years of age; AND
   - Patient has tried at least TWO traditional systemic agents for at least 3 months or has documented intolerance to at least TWO traditional systemic agents; AND
   - Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
   - Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with Xeljanz (tofacitinib)
   - Patient has a documented intolerance, contraindication to, or failed treatment for at least 3 months with Actemra (Tocilizumab)
   - Dose does not exceed FDA approved label dosing for indication

- The agent is prescribed by or in consultation with a rheumatologist

- Patient must not be concurrently using Orencia with other biologic disease-modifying antirheumatic drugs (DMARDs)
    - Note: Examples of biologic DMARDs consist of infliximab products, Rinvoq, etc.

Patient is Currently Receiving Orencia (Intravenous or Subcutaneous). Approve for 1 year if the patient meets ONE of the following:
MPC Renewal

- Patient has received an MPC prior authorization and has been established on therapy for at least 3 months; AND
    - Note: A patient who has received < 3 months of therapy or who is restarting therapy with Orencia is reviewed under criterion Initial Therapy.
- Patient meets at least one of the following:
    - Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR

      Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
    - Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.
- Patient must not be concurrently using Orencia with other biologic disease-modifying antirheumatic drugs (DMARDs).
    - Note: Examples of biologics DMARDs consist of infliximab products, Rinvoq, etc.

OR

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), of have been receiving medication samples, should be considered under criterion Initial Authorization Criteria
- Patient has been established on therapy for at least 3 months; AND
- Patient meets at least one of the following (a or b):
    - Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR

      Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).

- Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

2. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset). Approve for the duration noted if the patient meets the following:

Initial Therapy. Approve for 3 months if the patient meets the following criteria:

- Patient has tried at least TWO systemic agents for this condition for at least 3 months or has a documented intolerance to at least TWO other agents
  - Note: Examples of therapies which could have been tried include methotrexate, sulfasalazine, or leflunomide, and a nonsteroidal anti-inflammatory drug (NSAID).
- Patient has aggressive disease, as determined by the prescriber; AND
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with Xeljanz (tofacitinib)
- Dose does not exceed FDA approved label dosing for indication
- The agent is prescribed by or in consultation with a rheumatologist.
- Patient must not be concurrently using Orencia with other biologic disease-modifying antirheumatic drugs (DMARDs).
  - Note: Examples of biologic DMARDs consist of infliximab products, Rinvoq, etc.

Patient is Currently Receiving Orencia (Intravenous or Subcutaneous). Approve for 1 year if the patient meets ONE of the following:

MPC Renewal

- Patient has received an MPC prior authorization and has been established on therapy for at least 3 months; AND
  - Note: A patient who has received < 3 months of therapy or who is restarting therapy with Orencia is reviewed under criterion Initial Therapy.
- Patient meets at least one of the following:
  - When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline; OR

    Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis

Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

- Compared with baseline, patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

- Patient must not be concurrently using Orencia with other biologic disease-modifying antirheumatic drugs (DMARDs).
  - Note: Examples of biologic DMARDs consist of infliximab products, Rinvoq, etc.

OR

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion Initial Authorization Criteria
- Patient has been established on therapy for at least 3 months; AND
- Patient meets at least one of the following:
  - When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline; OR
    Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
  - Compared with baseline, patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

3. Psoriatic Arthritis. Approve for the duration noted if the patient meets the following:
Initial Therapy. Approve for 3 months if the patient meets the following criteria:

- Patient is ≥ 18 years of age; AND

- Patient has tried TWO conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months or has documented intolerance to at least TWO conventional synthetic DMARDs
  - Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with Xeljanz (tofacitinib)
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with a preferred Ustekinumab product (Yesintek, Pyzchiva, Steqeyma)
- Dose does not exceed FDA approved label dosing for indication
- The agent is prescribed by or in consultation with a rheumatologist or a dermatologist
- Patient must not be concurrently using Orencia with other biologic disease-modifying antirheumatic drugs (DMARDs).
  - Note: Examples of biologic DMARDs consist of infliximab products, Rinvoq, etc.

<u>Patient is Currently Receiving Orencia (Intravenous or Subcutaneous).</u> Approve for 1 year if the patient meets ONE of the following:
<u>MPC Renewal</u>

- Patient has received an MPC prior authorization and has been established on therapy for at least 3months; AND
  - Note: A patient who has received < 3 months of therapy or who is restarting therapy with Orencia is reviewed under criterion Initial Therapy.
- Patient meets at least one of the following:
  - When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline; OR
    Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
  - Compared with baseline, patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.
- Patient must not be concurrently using Orencia with other biologic disease-modifying antirheumatic drugs (DMARDs).
  - Note: Examples of biologic DMARDs consist of infliximab products, Rinvoq, etc.

OR

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion Initial Authorization Criteria
- Patient has been established on therapy for at least 3 months; AND
- Patient meets at least one of the following:
    - When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Orencia); OR Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
    - Compared with baseline (prior to initiating Orencia), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

4. Prophylaxis of Acute Graft Versus Host Disease (aGVHD). Approve for the duration noted if the patient meets the following:
Initial Therapy. Approve for 2 months if the patient meets the following criteria:

- Patient must be 2 years of age or older
- Patient must weigh ≥ 20kg
- Patient is undergoing a hematopoietic stem cell transplant (HSCT) from a matched or 1 allele-mismatched unrelated donor
- Patient has been diagnosed with a high-risk hematologic malignancy
    - Includes: AML, ALL, CML, MDS, NHL, HL
- Orenica (abatacept) will not be used for aGVHD treatment
- Documentation that the patient will use Orencia (abatacept) in combination with a calcineurin inhibitor (cyclosporine, tacrolimus) and methotrexate
- The agent is prescribed by or in consultation with an oncologist, hematologist, or transplant specialist
- Patient must not be concurrently using Orencia with other biologic disease-modifying antirheumatic drugs (DMARDs)
    - Note: Examples of biologic DMARDs consist of infliximab products, Rinvoq, etc.
- Provider attestation that the patient will be evaluated for

cytomegalovirus (CMV) and Epstein-Barr Virus (EBV) reactivation during treatment

Provider attestation that the patient will receive antiviral prophylactic treatment for Epstein-Barr Virus (EBV) and will continue for six months following HSCT.

Patient is Currently Receiving Orencia

No reauthorization allowed for aGVHD

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Orencia will be considered investigational or experimental for any other use and will not be covered.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months aGVHD: 2 months
Reauthorization	Up to 1 year aGVHD: No Reauthorization allowed

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

APPLICABLE CODES:	
CODE	**DESCRIPTION**
J0129	Injection, abatacept, 10mg

REFERENCES

1. Orencia® for injection [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2019.
2. 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.
3. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):717-734.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. Arthritis Care Res (Hoboken). 2019;71(1):2-29.
5. Song IH, Heldmann F, Rudwaleit M, et al. Treatment of active ankylosing spondylitis with abatacept: an open-label, 24-week pilot study. Ann Rheum Dis. 2011;70(6):1108-1110.
6. Furst DE, Keystone EC, Braun J, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2011. Ann Rheum Dis. 2012;71 Suppl 2:i2-i45.
7. Xeljanz® tablets [prescribing information]. New York, NY: Pfizer Inc; December 2017.

8. Sandborn WJ, Colombel JF, Sands BE, et al. Abatacept for Crohn's disease and ulcerative colitis. Gastroenterology. 2012;143(1):62-69.e4.
9. Abrams JR, Lebwohl MG, Guzzo CA, et al. CTLA4Ig-mediated blockade of T-cell costimulation in patients with psoriasis vulgaris. J Clin Invest. 1999;103:1243-1252.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Revision *Throughout the policy, references to Humira, Enbrel, and Rituxan were reworded as adalimumab, etanercept, and rituximab products, respectively, with the innovator names listed as examples of these products. Renflexis and Erelzi were also added as respective examples of infliximab and etanercept products.*	*05/09/2018*
Annual Revision *Rheumatoid Arthritis: Truxima was added as an example of a rituximab product. To align with the Medical Policy, the duration of approval for patients currently taking Orencia IV or SC was changed to 1 year (previously was 3 years).* *Juvenile Idiopathic Arthritis: Actemra SC was added as an example of an agent which may have been previously tried. To align with the Medical Policy, the duration of approval for patients currently taking Orencia IV or SC was changed to 1 year (previously was 3 years).* *Psoriatic Arthritis: To align with the Medical Policy, the duration of approval for patients currently taking Orencia IV or SC was changed to 1 year (previously was 3 years).*	*06/05/2019*

Annual Revision *Rheumatoid Arthritis: Examples of conventional synthetic disease-modifying antirheumatic drugs were moved to a Note (previously listed as examples within the criteria). Examples of biologics for Rheumatoid Arthritis were moved to be included in the Appendix (previously listed in a Note in the criteria section). Examples of a response to therapy were moved to a Note (previously listed as examples within the criteria).* *Juvenile Idiopathic Arthritis: Examples of therapies that could have been tried prior to Orencia were moved to a Note (previously listed as examples within the criteria). Examples of biologics were moved to be included in the Appendix (previously listed in a Note in the criteria section). Examples of a response to therapy were moved to a Note (previously listed as examples within the criteria). For the exception applying to patients with aggressive disease, wording was updated to more generally allow this determination by the prescriber (criteria previously specified this was according to the prescribing physician).* *Psoriatic Arthritis: Examples of a response to therapy were moved to a Note (previously listed as examples within the criteria).*	*06/17/2020*
MPC Revision *Addition of treatment failure requirements of Humira and Enbrel for applicable indications. Clarification of systemic treatment failure agents and addition of FDA dosing requirements. Addition of specialist requirement for prescribing.*	*02/2022*
Selected Revision *Expansion of initial authorization criteria; Addition of MPC vs Non-MPC renewal; Additional requirement of treatment failure with Xeljanz for RA, PsA and JIA*	*11/2022*
Annual Review	*02/2023*
Annual Review *Change in Non-MPC renewal to renewal from previous insurer*	*02/2024*
Annual Review	*02/2025*
Selected Revision *Addition of criteria requirements for the prophylaxis of acute graft vs host disease (aGVHD)*	*06/2025*
Annual Review	*02/2026*


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