curative

TITLE:	ABATACEPT (ORENCIA) POLICY
POLICY #:	MM-PNP-048
VERSION #:	01
DEPARTMENT:	MEDICAL MANAGEMENT
ORIGINAL EFFECTIVE DATE:	4/12/2024
CURRENT REVISION DATE:	N/A

1. PURPOSE

This policy will be used to inform medical necessity decisions related to authorization requests for Abatacept (Orencia).

2. SCOPE

Medical UM Department

3. DEFINITION

As defined in Curative's policies, health care services are not medically necessary when they are more costly than alternative services that are at least as likely to produce equivalent therapeutic or diagnostic results. Orencia IV (intravenous abatacept) is more costly to Curative than other targeted immune modulators for certain indications. There is a lack of reliable evidence that Orencia IV (intravenous abatacept) is superior to other lower cost targeted immune modulators for the medically necessary indications listed below. Therefore, Curative considers Orencia IV (intravenous abatacept) to be medically necessary only for members who have a contraindication, intolerance, or ineffective response to the available equivalent alternative targeted immune modulators per criteria below:

- **Moderately to severely active rheumatoid arthritis (RA)**

  Orencia intravenous (IV) formulation only: for the treatment of moderately to severely active RA, member has a contraindication, intolerance, or ineffective response to all of the following available equivalent alternative targeted immune modulators (one-month trial each): Simponi Aria and Avsola or Inflectra.

- **Active psoriatic arthritis (PsA)**

  Orencia intravenous (IV) formulation only: for the treatment of PsA, member has a contraindication, intolerance, or ineffective response to all the following available equivalent alternative targeted immune modulators (one-month trial each): Simponi Aria and Avsola or Inflectra

4. RESPONSIBILITIES

Medical UM Department

5. POLICY

Note: Requires Precertification:

Precertification of intravenous abatacept (Orencia IV) is required of all Curative participating providers.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis and articular juvenile idiopathic arthritis: rheumatologist.
- Psoriatic arthritis: rheumatologist or dermatologist.
- Prophylaxis of acute graft versus host disease (aGVHD), chronic GVHD, and immune checkpoint inhibitor-related toxicity: oncologist or hematologist.

Criteria for Initial Approval

Curative considers abatacept (Orencia) medically necessary for the following indications, where the patients has a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray) **Footnotes:** within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB:

Rheumatoid arthritis (RA)

1. For adult patients who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active RA; *or*
2. For adult patients for treatment of moderately to severely active RA when *all* the following criteria are met:
    1. Patients meet *either* of the following criteria:

Patients have been tested for either of the following biomarkers and the test was positive:

a) Rheumatoid factor (RF); *or*

b) Anti-cyclic citrullinated peptide (anti-CCP); *or*

The patient has been tested for ***all*** the following:

a) RF; *and*

b) Anti-CCP; *and*

c) C-reactive protein (CRP and/or erythrocyte sedimentation rate (ESR); *and*

*d) The p*atient meets *either* of the following criteria:

The patient has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 15 mg/week); *or*

1. The patient has intolerance or contraindication to methotrexate.

Articular juvenile idiopathic arthritis (JIA)

1. For patients 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active articular juvenile idiopathic arthritis; *or*
2. For patients 2 years of age or older for treatment of moderately to severely active articular juvenile idiopathic arthritis when *any* of the following criteria is met:
    a. The patient has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration; *or*

b. The patient has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and *one* of the following risk factors for poor outcome:

- Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ); *or*
- Presence of erosive disease or enthesitis; *or*
- Delay in diagnosis; *or*
- Elevated levels of inflammation markers; *or*
- Symmetric disease; *or*

- The patient has risk factors for disease severity and potentially a more refractory disease course and members also meet *one* of the following:
  - High-risk joints are involved (e.g., cervical spine, wrist, or hip); *or*
  - Has high disease activity; *or*
  - It is judged to be at high risk for disabling joint disease.

Psoriatic arthritis (PsA)

1. For patients 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis; *or*
2. For patients 2 years of age or older for treatment of active psoriatic arthritis when *either* of the following criteria is met:
    1. The patient has mild to moderate disease and meets *one* of the following criteria:
    - The patient has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration; *or*
    - The patient has an intolerance or contraindication to methotrexate or leflunomide
        1. A), or another conventional synthetic drug (e.g., sulfasalazine); *or*
        2. The patient has enthesitis; *or*
        3. The patient has severe disease.

Prophylaxis of acute graft versus host disease (aGVHD)

For prophylaxis of acute graft versus host disease in members 2 years of age or older when *both* of the following criteria are met:

i. Patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor; *and*
ii. The requested medication will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate.

Chronic graft versus host disease

For treatment of chronic graft versus host disease when *either* of the following criteria is met:

iii. The patient has experienced an inadequate response to systemic corticosteroids; *or*

iv. The patient has intolerance or contraindication to corticosteroids.

Immune checkpoint inhibitor-related toxicity

For the treatment of immune checkpoint inhibitor-related toxicity when the member has myocarditis and meets *either* of the following:

1. The patient has experienced an inadequate response to systemic corticosteroids; *or*
2. The patient has intolerance or contraindication to corticosteroids.

Curative considers all other indications as experimental and investigational (for additional information, see Experimental and Investigational and Background sections).

Continuation of Therapy

Curative considers continuation of abatacept (Orencia) therapy medically necessary for the following indications:

A. Rheumatoid arthritis (RA)

For all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

A. Articular juvenile idiopathic arthritis (JIA)

For all members 2 years of age or older (including new members) who are using the requested medication for moderately to severely active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in *any* of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion); *or*
2. Number of joints with limitation of movement; *or*
3. Functional ability.

A. Psoriatic arthritis (PsA)

For all members 2 years of age or older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in *any* of the following from baseline:

1. Number of swollen joints; *or*
2. Number of tender joints; *or*
3. Dactylitis; *or*
4. Enthesitis; *or*
5. Skin and/or nail involvement.

A. Prophylaxis of acute graft versus host disease, chronic graft versus host disease, and immune checkpoint inhibitor-related toxicity

For all members (including new members) who meet all initial authorization criteria.

Footnotes* If the screening test for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB

infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

7.1. All Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

Curative reserves the right to require that additional documentation be made available as part of its coverage determination; documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service or other practice that is inappropriate or excessive.

10. REFERENCE DOCUMENTS AND MATERIALS

10.1. Regulatory Authority - N/A

11. COLLABORATING DEPARTMENTS

N/A

12. DOCUMENT CONTROL

APPROVED BY:		
Charles,Brandon	4/16/2024	DocuSigned by: Charles,Brandon DE2813BF834C49A...
(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A:

N/A