

Medical Policy

Orencia® (abatacept)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-099
CURRENT VERSION EFFECTIVE DATE	1/1/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Orencia® (abatacept) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Orencia will be provided for 6 months and may be renewed unless otherwise specified. Therapy for the Management of Immune-Checkpoint Inhibitor Related Toxicity may not be renewed.

- Max Units (per dose and over time):
 - o Management of Immune-Checkpoint Inhibitor Related Toxicity: 50 billable units per 2 weeks for a total of 5 doses
 - o Prophylaxis for aGVHD: 100 billable units for a total of 4 doses
 - o All other indications
 - Loading: 100 billable units at weeks 0, 2, & 4

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- Maintenance: 100 billable units per 4 weeks

Initial

- A. Patient is 18 years of age or older, unless otherwise specified; **AND**
- B. Provider has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- C. Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- D. Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment; **AND**
- E. Patient has been evaluated and screened for the presence of latent TB (tuberculosis) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- F. Patient does not have an active infection, including clinically important localized infections; **AND**
- G. Patient will not receive live vaccines during therapy; **AND**
- H. Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); **AND**

Rheumatoid Arthritis (RA)

- A. Patient has a documented diagnosis of moderate to severe active disease; **AND**
- B. Patient has had at least a 3-month trial and failure of previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.; **AND**
- C. Orencia may be used as a single agent or in combination with other non-biologic DMARDs (e.g., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine, etc.).

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

- A. Patient is at least 2 years of age (*6 years of age for the IV formulation*); **AND**
- B. Patient has a documented diagnosis of moderate to severe active polyarticular disease; **AND**
- C. Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR an oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.); **AND**
- D. Orencia may be used as single agent or in combination with methotrexate.

Psoriatic Arthritis (PsA)

- A. Patient has a documented diagnosis of moderate to severe active disease; **AND**
 - a. For patients with predominantly axial disease OR active enthesitis, patient has had a trial and failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; **OR**
 - b. For patients with peripheral arthritis or dactylitis, patient has had a trial and failure of at least a 3-month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc.

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- B. Orencia may be used as a single agent or in combination with other non-biologic DMARDs (e.g., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine, etc.).

Chronic Graft Versus Host Disease (cGVHD)

- A. Patient has received a hematopoietic stem cell transplant (HSCT); **AND**
 - a. Used for steroid-refractory chronic GVHD; **AND**
 - b. Used in combination with systemic corticosteroids as additional therapy following no response to first-line therapies; **OR**
- B. Patient is undergoing a hematopoietic stem cell transplant (HSCT) from a matched or 1allele-mismatched unrelated-donor; **AND**
 - a. Used for prophylaxis of acute graft versus host disease (aGVHD) (IV formulation only); **AND**
 - b. Patient is at least 2 years of age; **AND**
 - c. Used in combination with a calcineurin inhibitor and methotrexate; **AND**
 - d. Patient will receive antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation and prophylaxis will continue for 6 months post-transplantation; **AND**
 - e. Patient will be monitored for both EBV reactivation and cytomegalovirus (CMV) infection/reactivation

Management of Immune Checkpoint Inhibitor Related Toxicity (*IV formulation only*)

- A. Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, dostarlimab, etc.); **AND**
- B. Patient has had no improvement within 24 hours of starting pulse-dose methylprednisolone; **AND**
- C. Orencia will be used as additional therapy for the management of suspected myocarditis.

Renewal

- A. Patient continues to meet the Initial criteria; **AND**
- B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious infections, severe hypersensitivity reactions, respiratory adverse events in those with predisposing conditions, etc.; **AND**

Rheumatoid Arthritis

- A. Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more or a $\geq 20\%$ improvement on the American College of Rheumatology-20 (ACR20) criteria].

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

- A. Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g., an improvement on a composite scoring index such as

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Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables].

Psoriatic Arthritis

- A. Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria.]

Treatment of Chronic Graft Versus Host Disease (cGVHD)

- A. Response to therapy with an improvement in one or more of the following:
 - a. Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score, etc.)
 - b. Patient-reported symptoms (e.g., Lee Symptom Scale, etc.)

Management of Immune Checkpoint Inhibitor Related Toxicity

- A. May not be renewed

Prophylaxis of Acute Graft Versus Host Disease (aGVHD)

- A. May not be renewed

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

- A. ORENCIA (abatacept) injection, for subcutaneous use. Initial U.S. Approval: 2005
 - a. ORENCIA (abatacept) for injection is a white lyophilized powder for intravenous infusion after reconstitution and dilution. It is supplied as an individually packaged, single-dose vial (one may use less than the full contents of the vial or use more than one vial) with a silicone-free disposable syringe, providing 250 mg of abatacept
 - b. ORENCIA (abatacept) for injection is a white lyophilized powder for intravenous infusion after reconstitution and dilution. It is supplied as an individually packaged, single-dose vial (one may use less than the full contents of the vial or use more than one vial) with a silicone-free disposable syringe, providing 250 mg of abatacept

CODING

Applicable NDC Codes	
00003-2187-13	Orencia 250 mg single-use vial
00003-2188-51	Orencia ClickJect 125 mg/mL Autoinjector

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00003-2188-11	Orencia ClickJect 125 mg/mL prefilled syringe
00003-2814-11	Orencia prefilled syringe 50 mg/0.4 mL
00003-2818-11	Orencia prefilled syringe 87.5 mg/0.7 mL

Applicable Procedure Code

J0129	Injection, Abatacept, 10 mg; 1 billable unit = 10 mg (Code may be used for Medicare when drug is administered under the direct supervision of a physician; NOT for use when drug is self-administered)
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Applicable ICD-10 Codes

D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
I30.8	Other forms of acute pericarditis
I30.9	Acute pericarditis, unspecified
I40.8	Other acute myocarditis
I40.9	Acute myocarditis, unspecified
I44.0	Atrioventricular block, first degree
I44.1	Atrioventricular block, second degree
I44.2	Atrioventricular block, complete
I44.3	Other and unspecified atrioventricular block
I44.30	Unspecified atrioventricular block
I44.39	Other atrioventricular block
I45.0	Right fascicular block
I45.10	Unspecified right bundle-branch block
I45.19	Other right bundle-branch block
I45.2	Bifascicular block
I45.3	Trifascicular block
I45.4	Nonspecific intraventricular block
I45.5	Other specified heart block
I45.6	Pre-excitation syndrome
I45.81	Long QT syndrome
I45.89	Other specified conduction disorders
I45.9	Conduction disorder, unspecified

EVIDENCE BASED REFERENCES

1. Product Information: ORENCIA(R) intravenous, subcutaneous injection, abatacept intravenous, subcutaneous injection. Bristol-Myers Squibb Company (per FDA), Princeton, NJ, 2020.

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POLICY HISTORY

Original Effective Date	1/1/2022
Revised Date	March 1, 2023 - Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	3/21/2022