Bright HealthCare

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

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

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

- 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.

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 ≥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

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

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)

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.

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