

Medical Policy

Adakveo® (crizanlizumab_tmca)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-065
ORIGINAL EFFECTIVE DATE	May 24, 2021
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	<i>Individual Family Plan: All Plans Small Group: All Plans Medicare Advantage: All Plans</i>

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.

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Adakveo® (crizanlizumab-tmca) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Initial coverage for Adakveo will be for 6 months. Continued coverage will be for 12 months.

Initial Therapy

1. Patient is 16 years of age or older; **AND**
2. Patient has a diagnosis of a sickle cell disease, including, but not limited to, homozygous hemoglobin S [HbSS], sickle hemoglobin C disease [HbSC], sickle beta0 thalassemia, and sickle beta+ thalassemia; **AND**

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3. Patient has previously experienced two or more sickle cell-related vasoocclusive crises within the previous 12 months; **AND**
4. Patient is currently receiving hydroxyurea therapy; **OR**
5. Patient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy; **AND**
6. Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy; **AND**
7. Patient is not receiving concomitant Oxbryta (voxelotor) therapy; **AND**
8. Adakveo is prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease.

Continuation Therapy

1. Patient has a diagnosis of a sickle cell disease, including, but not limited to, homozygous hemoglobin S [HbSS], sickle hemoglobin C disease [HbSC], sickle beta0 thalassemia, and sickle beta+ thalassemia; **AND**
2. Patient has experienced a reduction in sickle cell-related vasoocclusive crises and/or a decrease in severity of sickle cell related vasocculsive crises from pretreatment baseline while on Adakveo; **AND**
3. Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy; **AND**
4. Patient is not receiving concomitant Oxbryta (voxelotor) therapy; **AND**
5. Adakveo is prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease.

LIMITATIONS/EXCLUSIONS

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

BACKGROUND

Adakveo (crizanlizumab-tmca) is a selectin blocker humanized IgG2 kappa monoclonal antibody that binds to P-selectin and is indicated to reduce the frequency of vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease.

DEFINITIONS

1. ADAKVEO (crizanlizumab-tmca) injection, for intravenous use. Initial U.S. Approval: 2019
 - a. ADAKVEO (crizanlizumab-tmca) injection is a sterile, clear to opalescent, colorless to slightly brownish-yellow solution for intravenous infusion supplied as:
 - i. Carton containing one 100 mg/10 mL (10 mg/mL) single-dose vial

CODING

Applicable NDC Codes

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00078-0883-61	Adakveo 100 mg/10 mL single-dose vial
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Applicable Procedure Code	
J0791	Injection, crizanlizumab-tmca, 5 mg (Adakveo)

Applicable ICD-10 Codes	
D57.0	Hb-SS disease with crisis
D57.00	Hb-SS disease with crisis unspecified
D57.01	Hb-SS disease with acute chest syndrom
D57.02	Hb-SS disease with splenic sequestration
D57.1	Sickle cell disease without crisis
D57.2	Sickle cell/Hb-C disease
D57.20	Sickle cell/Hb-C disease without crisis
D57.21	Sickle cell/Hb-C disease with crisis
D57.211	Sickle cell/Hb-C disease with acute chest syndrome
D57.212	Sickle cell/Hb-C disease with splenic sequestration
D57.219	Sickle cell/Hb-C disease with crisis, unspecified
D57.4	Sickle cell thalassemia
D57.40	Sickle cell thalassemia without crisis
D57.41	Sickle cell thalassemia with crisis
D57.411	Sickle cell thalassemia with acute chest syndrome
D57.412	Sickle cell thalassemia with splenic sequestration
D57.419	Sickle cell thalassemia with crisis, unspecified
D57.8	Other sickle cell disorders
D57.80	Other sickle cell disorders without crisis
D57.81	Other sickle cell disorders with crisis
D57.811	Other sickle cell disorders with acute chest syndrome
D57.812	Other sickle cell disorders with splenic sequestration
D57.819	Other sickle cell disorders with crisis unspecified

EVIDENCE BASED REFERENCES

1. Adakveo [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; November 2019.

POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021: Annual review – no changes made. P&T Approved November 8, 2022: Annual review – no changes made. P&T Approved March 1, 2023 – Adopted by MA UMC January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

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