Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Crizanlizumab-tmca (Adakveo®)	MP-RX-FP-118-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of *Crizanlizumab-tmca (Adakveo®),* a selectin blocker approved by the Food and Drug Administration (FDA) to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.

Background Information

Crizanlizumab-tmca is a monoclonal antibody that binds to and inhibits P- selectin, an adhesion protein found on the surface platelets and endothelial cells. In those with sickle cell disease, P-selectin promotes blood vessels "sticking" with sickle cells, which causes inflammation and pain crises also called Vaso-occlusive crises (VOCs). VOCs, are unpredictable, acute episodes of severe pain that can lead to serious life-threatening complications and death in people with sickle cell disease.

Adakveo® is administered as a once monthly infusion based on the individual's weight. Adkaveo may be used with or without hydroxyurea.

Definitions and Measures

- Sickle cell disease (SCD) - affects about 100,000 patients in the United States (US) and primarily affects African Americans, Latinos, and other minorities. It results in a host of acute and chronic complications, including vasoocclusion and hemolysis. Patients with this genetic disorder have an average life expectancy of 40 to 60 years.
- Monoclonal antibody: A protein developed in the laboratory that can locate and bind to specific substances in the body and on the surface of cancer cells.
- Sickle Cell Crises - defined as admission to an emergency room (ER) department or medical facility for Sickle Cell Crises -related pain that was treated with a parenterally-administered narcotic or parenterally-administered ketorolac in the previous year.

Approved Indications

A. To reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.

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Other Uses

i. There is currently limited to no data to support the safety and efficacy of concomitant use of voxelotor (Oxbryta) with crizanlizumab- tmca (Adakveo).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J0791	Injection, crizanlizumab-tmca, 5 mg (Adakveo) (Effective 7/1/2020)

ICD-10	Description
D57.00-D57.819	Sickle Cell Disease

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Crizanlizumab-tmca (Adakveo®)

A. Criteria For Initial Approval

Initial requests for Adakveo (crizanlizumab) may be approved if the following criteria are met:

i. Individual is 16 years of age or older; **AND**
ii. Individual has a diagnosis of sickle cell disease; **AND**
iii. Documentation is provided that individual had at least two episodes of sickle cell related pain crises in the past 12 months**.**

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B. Criteria For Continuation of Therapy

i. MMM considers continuation of Crizanlizumab-tmca (Adakveo®) therapy medically necessary in members requesting reauthorization if the following information is provided:
   A. Documentation indicating that the individual experienced a reduction in acute complications of sickle cell disease (e.g. reduction in the number of vaso-occlusive episodes, acute chest syndrome episodes) since initiation Adakveo.

C. Authorization Duration

i. Initial Approval Duration: 12 months
ii. Reauthorization Approval Duration: 12 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Adakveo (crizanlizumab) may not be approved when the above criteria (section A: Criteria for Initial Approval) are not met and for the following:
   A. Individual is using in combination with Oxbryta (voxelotor) (Absiola 2022).

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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Drug	Recommended Dosing Schedule
Adakveo® (crizanlizumab) 10 mg/ml vial	5 mg/kg by intravenous infusion over a period of 30 minutes at Week 0, Week 2, and every 4 weeks thereafter.
Exceptions	
• Dose should be calculated based on actual body weight.	

Reference Information

1. Ataga KI, Kutlar A, Kanter J, et al. Crizanlizumab for the prevention of pain crises in sickle cell disease. *N Engl J Med*. 2017;376(5):429-439.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 12/10/2024	Update may not approved criteria. Minor wording and formatting changes. Coding reviewed: no changes.	3/20/2025	4/2/2025
Policy Inception 1/24/2024	Elevance Health's Medical Policy adoption	N/A	6/28/2024