

Medical Drug Clinical Criteria

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| Subject: | Adakveo (crizanlizumab) | | |
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Overview

This document addresses the use of Adakveo (crizanlizumab). Crizanlizumab 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.

Other Uses

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

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.

Clinical Criteria

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.

Adakveo (crizanlizumab)

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; **AND**
- IV. Individual is not using in combination with voxelotor (Oxbryta).

Continuation requests for Adakveo (crizanlizumab) may be approved if the following criterion is met:

- I. Documentation is provided that 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.

Requests for Adakveo (crizanlizumab) may not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Adakveo (crizanlizumab) Quantity Limits

| Drug | Limit |
|--|------------------------|
| Adakveo (crizanlizumab) 10 mg/ ml vial* | 5 mg/ kg every 4 weeks |
| Override Criteria | |
| *Initiation of therapy for Adakveo: May approve 5mg/kg at week 0 and week 2. | |

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

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

ICD-10 Diagnosis

D57.00-D57.819 Sickle Cell Disease

Document History

Revised: 05/19/2023

Document History:

- 5/19/2023 – Annual Review: Wording and formatting updates. Remove approval durations. Coding Reviewed: No changes.
- 5/20/2022 – Annual Review: Update criteria with continuation criteria and approval durations. Coding Reviewed: No changes.
- 08/01/2021 – Administrative update to add documentation.
- 05/21/2021– Annual Review: No changes. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: Update criteria regarding combination use with Oxbryta (voxelotor) and add may not be approved section. Coding Reviewed: Added HCPCS code J0791 (Effective 7/1/2020), Deleted C9399, J3590, J3490, C9053 (6/30/2020). All Dx pend removed 6/30/2020
- 12/09/2019 – Annual Review: Add new clinical criteria document for Adakveo (crizanlizumab). Coding Reviewed: Added HCPCS J3490, J3590, C9399, C9053. Added ICD-10 dx codes D57.00-D57.819. 3/31/2020 Deleted C9399. 4/1/2020 C9053 Effective

References

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 policies may take precedence over the application of this clinical criteria.

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