RX.PA.003.CCH ADAKVEO (CRIZANLIZUMAB®-TMCA)

The purpose of this policy is to define the prior authorization process for Adakveo® (crizanlizumab-tmca).

Adakveo® (crizanlizumab-tmca) is indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Adakveo® (crizanlizumab-tmca), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must have a diagnosis of sickle cell disease with one of the following genotypes:
  - Homozygous hemoglobin S (HbSS)
  - Hemoglobin Sβ0-thalassemia
  - Hemoglobin Sβ+-thalassemia
  - Hemoglobin SC (HbSC)
- Must be age 16 years or older
- Must be prescribed by or in consultation with a hematologist, or other specialist with training in management of sickle cell disease
- Must have Hb level ≥ 4 g/dL
- Must provide baseline frequency of vasoocclusive crises (VOCs) over the last 12 months
- Member meets one of the following (a or b):
  a. Member has experienced at least 2 VOC within the past 6 months while on hydroxyurea at up to maximally indicated doses
  b. Member has intolerance or contraindication to hydroxyurea and has experienced at least 2 VOC within the past 12 months Failure of L-glutamine at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced

- Adakveo is prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced
- Adakveo is not prescribed concurrently with Oxbryta®
- Member is not concurrently being treated with chronic prophylactic blood transfusion therapy
- Dose does not exceed 5 mg/kg doses on Day 1 and Day 15, followed by 5 mg/kg every 4 weeks

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy and documentation of a reduction in frequency of vasoocclusive crises.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J0791	ADAKVEO	INJECTION, CRIZANLIZUMAB-TMCA, 5 MG

REFERENCES

1. Adakveo prescribing information. Sage Therapeutics, Cambridge, MA, June 2019.
2. Brandow AM, Caroll P, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. *Blood Adv* (2020) 4(12):2656-2701.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial Review	3/22
Updated initial approval duration 1 year	2/23

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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