POLICY – MPP – Crizanlizumab (Adakveo)

Department/Team	Medical Management/Medical Payment Policy (MPP)
Approval By	HQUM
Approval Date	3/29/2021
Effective Date	4/10/2020
Line of Business	☒ Virginia Premier (Medicaid) ☒ D-SNP

PURPOSE

This policy outlines guidelines and criteria for coverage determination of Adakveo (crizanlizumab-tmca) for the prevention of pain crises in individuals with sickle cell disease.

DESCRIPTION

Crizanlizumab (Adakveo) is a humanized monoclonal antibody that binds to P-selectin and blocks its interaction with P-selectin glycoprotein ligand 1 (PSGL-1). Crizanlizumab is indicated to reduce the frequency of vaso-occlusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.

Sickle cell pain crises are a major morbidity and cause repeated hospitalizations for individuals with sickle cell disease. The cause of pain crises is complex, however vaso-occlusion which is caused by the adhesion of sickle erythrocytes and leukocytes to the endothelium is believed to be a major contributing factor. The degree of sickle erythrocyte adhesion correlates with vaso-occlusion and increased severity of disease. P-selectin initiates the leukocyte adhesion process during inflammation. P-selectin that is expressed on the surface of the endothelium mediates abnormal rolling and static adhesion of sickle erythrocytes to the vessel surface in vitro. By blocking P-selectin, Crizanlizumab reduces leukocyte recruitment thus reducing adhesion of sickle erythrocytes to vessels and the development of vascular occlusion.

GUIDELINES/INSTRUCTIONS

Virginia Premier Health Plan considers Adakveo (crizanlizumab-tmca) to be medically necessary for the prevention of pain crises in the following conditions:

<u>Initial Therapy</u>

1) Member has diagnosis of sickle cell disease of any genotype (including HbSS, HbSC, HbSβ 0 -thalassemia or HbSβ + -thalassemia) by medical history.
2) Member is age 16 to 65 years.
3) If member is a female who has childbearing potential, the member:
    a. Has had a negative urine pregnancy test prior to authorization of Adakveo
    b. Has received counseling on appropriate birth control methods for the duration of Adakveo infusions
    c. Will have routine urine pregnancy testing prior to receiving Adakveo
4) Member is not breastfeeding
5) Member must be taking, be intolerant of, or have a contraindication to hydroxyurea

6) Member must not be on chronic transfusion therapy or Adakveo will be administered with the intent of stopping chronic transfusion therapy
7) Member is not receiving concomitant Oxbryta (voxelotor) therapy or Oxbryta therapy will be stopped at onset of Adakveo therapy
8) Member must not have hemoglobin A level that is greater than 20 % of the total hemoglobin
9) Member must have experienced at least 2 sickle cell-related pain crises within the preceding 12 months by medical history
10) Adakveo dosing will follow the FDA approved labeling (5 mg/kg on week 0, week 2, and every 4 weeks thereafter)

Initial authorization 6 months.

Continuation of Therapy

Virginia Premier Health Plan considers continuation of crizanlizumab-tmca (Adakveo) to be medically necessary for the prevention of pain crises when the following criteria are met:

1) The member continues to meet criteria 1-8 for initial therapy.
2) The member has experienced a reduction in the frequency of vaso-occlusive crises which has been maintained since initiation of therapy.
3) Adakveo dosing will follow the FDA approved labeling (5 mg/kg on week very 4 weeks)

A face-to-face visit within 60 days of the requested date of service supporting the above criteria must be submitted for continuation of therapy.

Subsequent authorizations 12 months.

Virginia Premier Health Plan considers Adakveo to be investigational and experimental for any member who does not meet the above criteria.

CODING

HCPCS codes covered if selection medical necessity is met:
J0791 Injection, crizanlizumab-tmca, 5 mg

CPT code covered if selection medical necessity is met:
CPT 36965 Intravenous infusion for therapy, prophylaxis, or diagnosis, initial, up to 1 hour

ICD-10 Codes which justify medical necessity

D57.0 – D57.1 Sickle cell disease without crisis
D57.2 – D57.219 Sickle cell/Hb-C disease
D57.4 – D57.419 Sickle-cell Thalassemia

REFERENCES

1) https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761128s000lbl.pdf Accessed 3/16/2021
2) Kenneth I. Ataga, M.B., B.S., Abdullah Kutlar, M.D., Julie Kanter, M.D., Darla Liles, M.D., Rodolfo Cancado, M.D., Ph.D., João Friedrisch, M.D., Ph.D., Troy H. Guthrie, M.D., Jennifer Knight-Madden, M.B., B.S., Ph.D., Ofelia A. Alvarez, M.D., Victor R. Gordeuk, .D., Sandra Gualandro, M.D., Ph.D., Marina P. Colella, M.D., Ph.D., et al. Crizanlizumab for the Prevention of Pain Crises in Sickle Cell Disease. N Engl J Med 2017; 376:429-439 DOI: 10.1056/NEJMoa1611770
3) https://www.hcp.novartis.com/products/adakveo/sickle-cell-disease/ Accessed 3/16/2021
4) https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/adakveo-crizanlizumab-tmca.pdf Accessed 3/16/21

Related Documents

Revision History		
Date	**By**	**Description**
3/16/2021	Dr. Tamar Springel	Annual update
11/16/2022	Amy Ridolphi	Updates to the template