CareSource

PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Adakveo (crizanlizumab-tmca)
BILLING CODE	J0791 (1 unit = 5 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient Hospital/Office/Infusion Site
COVERAGE REQUIREMENTS	Prior authorization required (Non-preferred product) Alternative product includes hydroxyurea QUANTITY LIMIT – Weight based dosing
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Adakveo (crizanlizumab-tmca) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

SICKLE CELL DISEASE

For **initial** authorization:

1. Member must be 16 years of age or older; AND
2. Medication must be prescribed by or in consultation with a hematologist or a physician who has experience in treating sickle cell disease; AND
3. Chart notes have been provided with documentation of at least TWO vaso-occlusive pain crises in the past 12 months; AND
4. Member has tried and failed 90-day of hydroxyurea, unless contraindicated or intolerant; AND
5. Medication will not be used concurrently with Oxbryta (voxelotor) therapy.
6. **Dosage allowed**: 5 mg/kg intravenously at week 0, week 2, and every 4 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided to show that the member has experienced a reduction in frequency of vaso-occlusive crises since starting treatment.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Adakveo (crizanlizumab-tmca) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
04/17/2020	New policy for Adakveo created.
06/18/2020	New J Code added
08/21/2020	Removed Endari from trial requirement.

References:

1. Adakveo [Package Insert]. East Hanover, NJ: Novartis; November 2019.

2. Ataga KI, Kutlar A, Kanter J, et al. Crizanlizumab for the prevention of pain crises in sickle cell disease. *N Engl Med*. 2017;376(5):429-439.
3. Evidence-Based Management of Sickle Cell Disease. US Department of Health and Human Services. 2014.
4. Niihara Y, Miller ST, Kanter J, et al. A phase 3 trial of L-glutamine in sickle cell disease. *N Engl Med*. 2018;379:226-235.
5. Reprixys Pharmaceutical Corporation. Study to Assess Safety and Impact of SelG1 With or Without Hydroxyurea Therapy in Sickle Cell Disease Patients With Pain Crises (SUSTAIN). NLM Identifier: NCT01895361.
6. Kutlar A, Kanter J, Liles DK, et al. Effect of crizanlizumab on pain crises in subgroups of patients with sickle cell disease: A SUSTAIN study analysis. Am. 2019;94(1):55-61.
7. Bradt P, Spackman E, Synnott PG, Chapman R, Beinfeld M, Rind DM, Pearson SD.
8. Crizanlizumab, Voxelotor, and L-Glutamine for Sickle Cell Disease: Effectiveness and Value. Institute for Clinical and Economic Review, January 23, 2020. https://icer-review.org/material/sickle-cell-disease-draft-evidence-report/.
9. Voskaridou E, Christoulas D, Bilalis A, et al. The effect of prolonged administration of hydroxyurea on morbidity and mortality in adult patients with sickle cell syndromes: results of a 17-year, single-center trial (LaSHS). *Blood*. 2010;115(12):2354-2363.
10. Rodgers GP, George A. Hydroxyurea use in sickle cell disease. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on August 21, 2020).

Effective date: 12/01/2020
Revised date: 08/21/2020