 <p>JOHNS HOPKINS M E D I C I N E JOHNS HOPKINS HEALTHCARE</p>	Johns Hopkins HealthCare LLC Pharmacy Public Medical Management Drug Policies	<i>Policy Number</i>	MMDP032
		<i>Effective Date</i>	08/01/2020
		<i>Review Date</i>	05/15/2020
	<i>Subject</i> Adakveo	<i>Revision Date</i>	11/10/2021
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Adakveo

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I. POLICY

Adakveo (crizanlizumab-tmca) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.


II. POLICY CRITERIA

- A. **Adakveo** may be approved for prevention of vaso-occlusive crises in patients meeting ALL the following:
1. Patient is 16 years of age or older
 2. Documented diagnosis of Sickle Cell Disease (SCD)
 3. Documentation has been submitted showing that the patient has experienced at least two sickle cell-related vaso-occlusive crisis within the past 12 months
 4. Patient has had inadequate response to optimally dosed hydroxyurea.* An adequate trial would consist of a stable dose of hydroxyurea for at least 3 months, unless the use of hydroxyurea is contraindicated, or clinically significant adverse reactions occur.
 5. The prescriber is, or has consulted with, a hematologist or sickle cell disease specialist

*Inadequate response to hydroxyurea may not be required for patients who are documented to have Sickle Hemoglobin-C Disease (HbSC) or Sickle Beta-Plus Thalassemia SCD genotypes.

III. AUTHORIZATION PERIOD/LIMITATIONS

- A. Initial approval will be for 12 months of therapy
- B. Approval for continuation of therapy may be extended in 12-month intervals with evidence of clinical improvement.
1. Clinical Improvement evidence should be demonstrated by a documented reduction in sickle-cell-related vaso-occlusive crisis medical treatment visits due to any of the following:
 - a. Acute episode of pain with no cause other than a vaso-occlusive event
 - b. Acute chest syndrome
 - c. Hepatic sequestration
 - d. Splenic sequestration

 <p>JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE</p>	Johns Hopkins HealthCare LLC Pharmacy Public Medical Management Drug Policies	<i>Policy Number</i>	MMDP032	
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- e. Priapism
2. Patient is not receiving concurrent prophylactic blood transfusion therapy

IV. EXCLUSIONS

- A. Adakveo will not be approved for the following;
 1. Patient is less than 16 years of age
 2. Concurrent use with Oxbryta (voxelotor)
 3. Any indications that are not FDA-approved, or clinical guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

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Medication	HCPCS/CPT Code
Adakveo Injection, crizanlizumab-tmca, 5 mg	J0791

VII. REFERENCES

1. Adakveo [Prescribing Information]; East Hanover, NJ; Novartis Pharmaceuticals Corp.; 2019 November.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
05/14/2020	Policy Creation
11/10/2021	Removed Priority Partners and EHP as applicable LOBs

Review Dates: 05/15/2020

Revision Dates: 05/14/2020, 11/10/2021