

**Pharmacy Policy**

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# Adakveo

**Policy Number:** 9.611

**Version Number:** 2.0

**Version Effective Date:** 3/1/2022

Product Applicability <input type="checkbox"/> <b>All Plan+ Products</b>	
<b>Well Sense Health Plan</b>	<b>Boston Medical Center HealthNet Plan</b>
<input type="checkbox"/> New Hampshire Medicaid	<input checked="" type="checkbox"/> MassHealth - MCO
	<input checked="" type="checkbox"/> MassHealth - ACO
	<input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice
	Direct
	<input type="checkbox"/> Senior Care Options
	<input type="checkbox"/> _____

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

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**Products Affected:**

- Adakveo (crizanlizumab-tmca)

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>• Concomitant chronic, prophylactic blood transfusion therapy</li> <li>• Concomitant Oxbryta (voxelotor) therapy</li> </ul>

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<b>Required Medical Information</b>	<ol style="list-style-type: none"> <li>1. Diagnosis of Sickle Cell Disease <b>AND</b></li> <li>2. Two (2) sickle cell-related vaso-occlusive crises within the previous 12 months <b>AND</b></li> <li>3. Current hydroxyurea therapy for at least 6 months with stable dose for at least 3 months OR documentation of previous treatment failure, intolerance, or contraindication to hydroxyurea. <b>AND</b></li> <li>4. Dosing is in accordance with the FDA approved labeling</li> </ol>
<b>Age Restriction</b>	16 year of age and older
<b>Prescriber Restriction</b>	Prescribed by or in consultation with a hematologist or sickle cell disease specialist
<b>Coverage Duration</b>	12 months
<b>Quantity Limit</b>	None
<b>Other criteria</b>	Reauthorization: <ol style="list-style-type: none"> <li>1. Attestation that the member has experienced a reduction in sickle cell-related vaso-occlusive crises <b>OR</b> a decrease in severity of sickle cell-related vaso-occlusive crises from pretreatment baseline</li> </ol>

**Applicable Coding:**

Code	Medication
J0791	Crizanlizumab-tmca, 5mg inj.

**Clinical Background Information and References**

1. Adakveo<sup>®</sup> [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation: Accessed Sept. 2021.
2. Ataga K, Kutlar A, Kanter A et. al. Crizanlizumab for the Prevention of Pain Crises in Sickle Cell Disease. N Engl J Med 2017; Feb 2; 20376:429-439 DOI: 10.1056/NEJMoa1611770.
3. Crizanlizumab: Drug information. Up To Date, Lexicomp. Topic 126184 Version 24.0. Accessed October 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

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<b>Policy Revisions History</b>			
<b>Review Date</b>	<b>Summary of Revisions</b>	<b>Revision Effective Date</b>	<b>Approved by</b>
12/1/2020	9.199 Adakveo Policy retired, new policy created. Replaced documentation with attestation for reauth	1/1/2021	P&T Committee
11/11/2021	Changed criteria: Changed the requirement of five vaso-occlusive crisis prior to treatment to two. Changed the duration of approval to 12 months for both initial and reauthorization.	3/1/2022	P&T Committee

**Next Review Date**

2022

**Other Applicable Policies**

None

**Reference to Applicable Laws and Regulations, If Any**

**Disclaimer Information**

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits;

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adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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Adakveo

4 of 4