

POLICY NUMBER: RX.PA.003.MPC REVISION DATE: 01/2021

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RX.PA.003.MPC ADAKVEO (CRIZANLIZUMAB-TMCA)

Description

Adakveo® (Crizanlizumab-tmca) is a selectin blocker

FDA Approved Indication(s)

To reduce the frequency of vasoocclusive crises (VOC) in adults and pediatric patients aged 16years and older with sickle cell disease (SCD).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinicalinformation) supporting that member has met all approval criteria.

I. Initial Approval Criteria

- A. Sickle Cell Disease (must meet all):
 - 1. Diagnosis of SCD with one of the following genotypes:
 - a. Homozygous hemoglobin S (HbSS);
 - b. Hemoglobin Sβ⁰-thalassemia;
 - c. Hemoglobin Sβ+-thalassemia;
 - d. Hemoglobin SC (HbSC);
 - 2. Age \geq 16 years;
 - 3. Prescribed by or in consultation with a hematologist, or other specialist with trainingin management of sickle cell disease;
 - 4. Hb level ≥ 4 g/dL;
 - 5. Member meets one of the following (a or b):
 - a. Member has experienced at least 2 VOC within the past 6 months while onhydroxyurea at up to maximally indicated doses
 - 6. Member has intolerance or contraindication to hydroxyurea and has experienced atleast 2 VOC within the past 12 months Failure of Lglutamine at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - 7. Documentation of baseline incidence of VOC over the last twelve months;
 - 8. Adakveo is prescribed concurrently with hydroxyurea, unless contraindicated orclinically significant adverse effects are experienced;
 - 9. Adakveo is not prescribed concurrently with Oxbryta®;
 - 10. Member is not concurrently being treated with chronic prophylactic blood transfusiontherapy
 - 11. Dose does not exceed 5 mg/kg doses on Day 1 and Day 15, followed by 5 mg/kgevery 4 weeks.



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Approval duration: 6 months

II. Continued Therapy

- Sickle Cell Disease (must meet all):Member is responding positively to therapy as evidenced by a documentedimprovement in the incidence of VOC from baseline;
- Adakveo is prescribed concurrently with hydroxyurea, unless contraindicated orclinically significant adverse effects are experienced;
- 3. Adakveo is not prescribed concurrently with Oxbryta;
- 4. If request is for a dose increase, new dose does not exceed 5 mg/kg every 4 weeks.

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
SCD	Administer 5 mg/kg by intravenous infusion	5 mg/kg
	over a period of 30 minutes on Week 0,	
	Week 2, and every 4 weeks thereafter.	

V. Product Availability

Single-dose vial for injection: 100 mg/10 mL (10 mg/mL)

VI. References

- Adakveo Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2019. Available at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/exjade.pdf. Accessed December 2, 2019.
- 2. 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 J Hematol. 2019;94:55-61.
- 3. Ataga K, Kutlar A, Kanter J, et al. Crizanlizumab for the Prevention of Pain Crises in SickleCell Disease. N Engl J Med. 2017 Feb 2;376(5):429-439.
- 4. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA. 2014 Sep10;312(10):1033-48.
- 5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, CO: ThomsonHealthcare. Updated periodically. Accessed December 4, 2019.

HCPCS Code(s) and ICD-10-CM Diagnosis Codes that Support Coverage



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Criteria The following is a list of diagnosis codes that support coverage for the

applicable coveredprocedure code(s).

Injection, crizanlizumab-tmca, 5mg Injection Description	HCPCS Code	Description
D57.0 Hb-SS disease with crisis unspecified D57.00 Hb-SS disease with crisis unspecified D57.01 Hb-SS disease with crisis unspecified D57.02 Hb-SS disease with acute chest syndrome D57.03 Hb-SS disease with splenic sequestration D57.09 Hb-SS disease with crisis with other specified complication D57.09 Hb-SS disease with crisis with other specified complication D57.1 Sickle-cell disease without crisis D57.20 Sickle-Cell/Hb-C disease without crisis D57.21 Sickle-cell/Hb-C with crisis D57.21 Sickle-cell/Hb-C with crisis D57.21 Sickle-cell/Hb-C with splenic sequestration D57.212 Sickle-cell/Hb-C with splenic sequestration D57.213 Sickle-cell/Hb-C with other specified complication D57.219 Sickle-cell/Hb-C with unspecified complication D57.219 Sickle-cell/Hb-C with unspecified with crisis D57.41 Sickle-cell thalassemia D57.41 Sickle-cell thalassemia, unspecified with crisis D57.41 Sickle-cell thalassemia, unspecified with acute chest syndrome D57.41 Sickle-cell thalassemia, unspecified with splenic sequestration D57.413 Sickle-cell thalassemia, unspecified with cerebral vascularinvolvement D57.418 Sickle-cell thalassemia, unspecified with other specifiedcomplication D57.419 Sickle-cell thalassemia, unspecified with other specifiedcomplication D57.42 Sickle-cell thalassemia beta zero with other specified cell thalassemia beta zero with crisis D57.43 Sickle-cell thalassemia beta zero with crisis D57.43 Sickle-cell thalassemia beta zero with splenic sequestration D57.43 Sickle-cell thalassemia beta zero with splenic sequestration D57.43 Sickle-cell thalassemia beta zero with creebral vascularinvolvement D57.43 Sickle-cell thalassemia beta zero with other specified complication D57.43 Sickle-cell thalassemia beta zero with other specified complication	J0791	Injection, crizanlizumab-tmca, 5mg
D57.00 Hb-SS disease with crisis unspecified D57.01 Hb-SS disease with acute chest syndrome D57.02 Hb-SS disease with splenic sequestration D57.03 Hb-SS disease with cerebral vascular involvement D57.09 Hb-SS disease with crisis with other specified complication D57.1 Sickle-cell disease without crisis D57.20 Sickle-Cell/Hb-C disease without crisis D57.21 Sickle-cell/Hb-C with crisis D57.21 Sickle-cell/Hb-C with crisis D57.21 Sickle-cell/Hb-C with acute chest syndrome D57.212 Sickle-cell/Hb-C with splenic sequestration D57.213 Sickle-cell/Hb-C with other specified complication D57.218 Sickle-cell/Hb-C with other specified complication D57.219 Sickle-cell with acute chest syndrome D57.219 Sickle-cell thalassemia D57.41 Sickle-cell thalassemia D57.41 Sickle-cell thalassemia, unspecified with crisis D57.41 Sickle-cell thalassemia, unspecified with acute chest syndrome D57.412 Sickle-cell thalassemia, unspecified with splenic sequestration D57.413 Sickle-cell thalassemia, unspecified with cerebral vascularinvolvement D57.418 Sickle-cell thalassemia, unspecified with other specified complication D57.419 Sickle-cell thalassemia, unspecified with other specified complication D57.42 Sickle-cell thalassemia beta zero with crisis D57.43 Sickle-cell thalassemia beta zero with crisis D57.43 Sickle-cell thalassemia beta zero with splenic sequestration D57.43 Sickle-cell thalassemia beta zero with other specified complication	ICD-10-CM Code	Description
D57.01 Hb-SS disease with acute chest syndrome D57.02 Hb-SS disease with splenic sequestration D57.03 Hb-SS disease with cerebral vascular involvement D57.09 Hb-SS disease with crisis with other specified complication D57.1 Sickle-cell disease without crisis D57.20 Sickle-Cell/Hb-C disease without crisis D57.21 Sickle-cell/Hb-C with crisis D57.21 Sickle-cell/Hb-C with crisis D57.21 Sickle-cell/Hb-C with acute chest syndrome D57.212 Sickle-cell/Hb-C with splenic sequestration D57.213 Sickle-cell/Hb-C with cerebral vascular involvement D57.214 Sickle-cell/Hb-C with other specified complication D57.215 Sickle-cell/Hb-C with unspecified complication D57.216 Sickle-cell thalassemia D57.217 Sickle-cell thalassemia D57.219 Sickle-cell thalassemia D57.219 Sickle-cell thalassemia, unspecified with crisis D57.210 Sickle-cell thalassemia, unspecified with acute chest syndrome D57.21 Sickle-cell thalassemia, unspecified with splenic sequestration D57.21 Sickle-cell thalassemia, unspecified with cerebral vascular involvement D57.410 Sickle-cell thalassemia, unspecified with cerebral vascular involvement D57.418 Sickle-cell thalassemia, unspecified with crisis D57.42 Sickle-cell thalassemia beta zero with crisis D57.43 Sickle-cell thalassemia beta zero with crisis D57.43 Sickle-cell thalassemia beta zero with splenic sequestration D57.43 Sickle-cell thalassemia beta zero with splenic sequestration D57.43 Sickle-cell thalassemia beta zero with splenic sequestration D57.43 Sickle-cell thalassemia beta zero with other specified vascular involvement D57.43 Sickle-cell thalassemia beta zero with other specified complication	D57.0	Hb-SS disease with crisis
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Sequestration		
D57.413 Sickle-cell thalassemia, unspecified with cerebral vascularinvolvement D57.418 Sickle-cell thalassemia, unspecified with other specified complication D57.419 Sickle-cell thalassemia, unspecified with crisis D57.42 Sickle-cell thalassemia beta zero without crisis D57.43 Sickle-cell thalassemia beta zero with crisis D57.431 Sickle-cell thalassemia beta zero with acute chest syndrome D57.432 Sickle-cell thalassemia beta zero with splenic sequestration D57.433 Sickle-cell thalassemia beta zero with cerebral vascularinvolvement D57.438 Sickle-cell thalassemia beta zero with other specified complication	D57.412	
D57.418 Sickle-cell thalassemia, unspecified with other specifiedcomplication D57.419 Sickle-cell thalassemia, unspecified with crisis D57.42 Sickle-cell thalassemia beta zero without crisis D57.43 Sickle-cell thalassemia beta zero with crisis D57.431 Sickle-cell thalassemia beta zero with acute chest syndrome D57.432 Sickle-cell thalassemia beta zero with splenic sequestration D57.433 Sickle-cell thalassemia beta zero with cerebral vascularinvolvement D57.438 Sickle-cell thalassemia beta zero with other specified complication		
D57.418 Sickle-cell thalassemia, unspecified with other specifiedcomplication D57.419 Sickle-cell thalassemia, unspecified with crisis D57.42 Sickle-cell thalassemia beta zero without crisis D57.43 Sickle-cell thalassemia beta zero with crisis D57.431 Sickle-cell thalassemia beta zero with acute chest syndrome D57.432 Sickle-cell thalassemia beta zero with splenic sequestration D57.433 Sickle-cell thalassemia beta zero with cerebral vascularinvolvement D57.438 Sickle-cell thalassemia beta zero with other specified complication	D57.413	·
Specifiedcomplication	D== 440	
D57.419 Sickle-cell thalassemia, unspecified with crisis D57.42 Sickle-cell thalassemia beta zero without crisis D57.43 Sickle-cell thalassemia beta zero with crisis D57.431 Sickle-cell thalassemia beta zero with acute chest syndrome D57.432 Sickle-cell thalassemia beta zero with splenic sequestration D57.433 Sickle-cell thalassemia beta zero with cerebral vascularinvolvement D57.438 Sickle-cell thalassemia beta zero with other specified complication	D57.418	
D57.42 Sickle-cell thalassemia beta zero without crisis D57.43 Sickle-cell thalassemia beta zero with crisis D57.431 Sickle-cell thalassemia beta zero with acute chest syndrome D57.432 Sickle-cell thalassemia beta zero with splenic sequestration D57.433 Sickle-cell thalassemia beta zero with cerebral vascularinvolvement D57.438 Sickle-cell thalassemia beta zero with other specified complication	DE7 440	
D57.431 Sickle-cell thalassemia beta zero with crisis D57.431 Sickle-cell thalassemia beta zero with acute chest syndrome D57.432 Sickle-cell thalassemia beta zero with splenic sequestration D57.433 Sickle-cell thalassemia beta zero with cerebral vascularinvolvement D57.438 Sickle-cell thalassemia beta zero with other specified complication		
D57.431 Sickle-cell thalassemia beta zero with acute chest syndrome D57.432 Sickle-cell thalassemia beta zero with splenic sequestration D57.433 Sickle-cell thalassemia beta zero with cerebral vascularinvolvement D57.438 Sickle-cell thalassemia beta zero with other specified complication		
D57.432 Sickle-cell thalassemia beta zero with splenic sequestration D57.433 Sickle-cell thalassemia beta zero with cerebral vascularinvolvement D57.438 Sickle-cell thalassemia beta zero with other specified complication		
D57.433 Sickle-cell thalassemia beta zero with cerebral vascularinvolvement D57.438 Sickle-cell thalassemia beta zero with other specified complication		
D57.438 Sickle-cell thalassemia beta zero with other specified complication		
D57.438 Sickle-cell thalassemia beta zero with other specified complication	D57.433	
complication	DE7 420	
	D57.438	
	D57 439	
complication	507.400	
D57.44 Sickle-cell thalassemia beta plus without crisis	D57.44	<u> </u>
D57.45 Sickle-cell thalassemia beta plus with crisis		
D57.451 Sickle-cell thalassemia beta plus with acute chest syndrome		
D57.452 Sickle-cell thalassemia beta plus with splenic sequestration		



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D57.453	Sickle-cell thalassemia beta plus with cerebral	
	vascularinvolvement	
D57.458	Sickle-cell thalassemia beta plus with other specified	
	complication	
D57.459	Sickle-cell thalassemia beta plus with unspecified	
	complication	
D57.80	Other sickle-cell disorders without crisis	
D57.81	Other sickle-cell disorders with crisis	
D57.811	Other sickle-cell disorders with acute chest syndrome	
D57.812	Other sickle-cell disorders with splenic sequestration	
D57.813	Other sickle-cell disorders with cerebral vascular involvement	
ICD-10-CM Code	Description	
D57.818	Other sickle-cell disorders with other specified complication	
D57.819	Other sickle-cell disorders with unspecified complication	

Reviews, Revisions, and Approvals	Date	P&T Approva IDate
Policy created.	01/28/2021	

