

SENTARA COMMUNITY PLAN (MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to 1-844-305-2331. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization can be delayed.

Drug Requested: Adakveo[®] (crizanlizumab-tmca) Injection (**Medical**) (J0791/C9053)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

- Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Maximum Approved Dose: 5mg/kg IV at week 0, week 2 and every 4 weeks thereafter

INFORMATIONAL NOTE:

- Based on the FDA labeled package insert, Adakveo[®] (crizanlizumab-tmca) has the potential to cause fetal harm when administered to a pregnant woman. There are insufficient human data on Adakveo[®] (crizanlizumab-tmca) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Advise pregnant women of the potential risk to a fetus. Adakveo[®] (crizanlizumab-tmca) should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the fetus

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- **Vaso-occlusive crises (VOC):** as an event prompting either a visit or outreach to the provider (date and outcome would need to be documented within progress notes) which results in a diagnosis of VOC being made necessitating subsequent interventions such as narcotic pain management, non-steroidal anti-inflammatory therapy, hydration, etc. ICD codes and progress notes with date and outcome intervention for VOC and pharmacy claims would be verified within last 12 months.
- **ICD CODES for Crisis while in ER/INPATIENT: 282.42, 282.62, 282.64, 282.69, D57.0, D57.00, D57.01, D57.02, D57.21, D57.211, D57.212, D57.219, D57.41, D57.411, D57.419 D57.3, D57.412, D57.81, D57.811, D57.812, D57.819**

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization Approval: 6 months

1. Is the drug being prescribed by or in consultation with an oncologist, hematologist or sickle cell specialist?
 Yes No
2. Does the patient have a diagnosis of Sickle Cell Disease presenting as one of following (HbSS, HbSC, HbS β^0 -thalassemia, or HbS β^+ -thalassemia)?
 Yes No
3. Is the medication dose proper for the patient's age or other conditions affecting the dose, according to the product package insert approved by the FDA?
 Yes No
4. Has the member had an insufficient response to a minimum 3-month trial of hydroxyurea (unless contraindicated or intolerant)?
 Yes No
5. Patient has experienced **TWO** or more vaso-occlusive crises (VOC) in the previous year despite adherence to hydroxyurea therapy?
 Yes No

Reauthorization Approval: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

1. Does the member continue to meet the above criteria?
 Yes No
2. Does the member have disease response improvement with treatment?
 Yes No
3. Is the member's response compared to pre-treatment baseline evidenced by a decrease in the frequency of vaso-occlusive crises (VOC) necessitating treatment, reduction in number or duration of hospitalizations, and/or reduction in severity of VOC?
 Yes No

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**NOTE: Other uses of Adakveo (crizanlizumab-tmca) are considered investigational

Medication being provided by (check box below that applies):

Location/site of drug administration:

NPI or DEA # of administering location: _____

OR

Specialty Pharmacy – PropriumRx

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

******Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.******

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****