SENTARA HEALTH PLAN

MEDICAL PRIOR AUTHORIZATION 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

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:** _____

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

INFORMATIONAL NOTE:

Section A:

- 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 **Part A:**

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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**

❑ 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.

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: 12 months

Section B:

1. Prior to therapy initiation, member must meet **ALL** of the following:
   - ❑ The provider is, or has been in consultation with, a hematologist or specialist in treating sickle cell disease
   - ❑ Hemoglobin is > 4.0g/dL
   - ❑ Member is NOT planning to undergo an exchange transfusion during duration of treatment or is on a chronic transfusion program
   - ❑ Member is NOT receiving chronic anticoagulation therapy other than aspirin **(paid claims would be verified)**
   - ❑ Member has NOT been diagnosed with cancer (except non-melanoma skin and in situ cervical cancers) within the last 5 years
   - ❑ Member does NOT have a history of stroke within the past 2 year
   - ❑ Member is not concomitantly receiving Oxbryta™ (voxelotor) tablets or Endari® (L-glutamine oral powder) (verified by Pharmacy claims). If member is currently on Oxbryta™ or Endari® then Adakveo® will be denied

Section C:

2. Adakveo® is **medically necessary** to reduce the frequency of vaso-occlusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease who meet the following criteria:
   - ❑ Confirmed medical history or diagnosis of SCD has been confirmed by one of the following:
     - ❑ HbSS ❑ HbSC ❑ HbSB0-thalassemia ❑ HbSB+-thalassemia
     - ❑ Other: _____

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AND

- ❑ Member has experienced at least 2 vaso-occlusive crises (defined in Part A) within the preceding 12 months as determined by medical documentation with ICD codes.

AND

- ❑ Member had an insufficient response to at least 90 consecutive days of treatment with hydroxyurea of this request (defined as >2 VOC (VOC defined in Part A) while compliant on hydroxyurea/Droxia. **(Paid pharmacy claims for hydroxyurea and/or Droxia within the last 12 months will be verified)**

AND

- ❑ Member cannot take hydroxyurea due to contraindications of severe bone marrow depression (e.g., leukopenia [<2,500/mm3], thrombocytopenia [<100,000/mm3], or severe anemia that requires transfusion (Labs completed within the last 30 days documenting contraindication must be submitted)

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.

- Continuation of Adakveo® (crizanlizumab-tmca) will be approved for 12 months if the member meets **ALL** of the following:
  - ❑ Member continues to meet the criteria in section B;

AND

  - ❑ Provider must submit documentation that the member has had a decrease in the number of vaso-occlusive crises (VOC defined in Part A) from baseline since starting therapy with Adakveo® (documentation includes medical claims, chart notes and ICD codes from previous approval date to date of request)

AND

  - ❑ Absence of unacceptable toxicity from the drug (e.g. infusion-related reactions, interference with automated platelet counts (platelet clumping)

AND

****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**

(Continued on next page; signature page is required to process request.)

(Please ensure signature page is attached to form.)

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.*