Adakveo® (crizanlizumab-tmca)

When requesting Adakveo® (crizanlizumab-tmca), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Adakveo is indicated to reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease.

Coverage Guidelines

Sickle Cell Disease (SCD)

The individual must meet ALL of the following criteria for initial authorization:

- Is 16 years of age or older;
- Has had at least one sickle cell-related crisis in the previous 12 months;
- Meets one of the following:
    - Is currently receiving hydroxyurea;
    - Has had inadequate efficacy or significant intolerance with hydroxyurea;
    - Is not a candidate for hydroxyurea (i.e., pregnant or planning to become pregnant, has immunosuppressive condition [e.g., cancer])
- Adakveo is prescribed by or in consultation with a physician who specializes in the treatment of sickle cell disease (e.g., a hematologist)

The individual must meet ALL of the following criteria for re-authorization:

- Is 16 years of age or older;
- Is receiving clinical benefit from Adakveo therapy (e.g., reduction in the number of vaso-occlusive crises/sickle cell-related crises, delay in time to sickle cell-related crisis, reduction in number of days in the hospital);
- Adakveo is prescribed by or in consultation with a physician who specializes in the treatment of sickle cell disease (e.g., a hematologist)

Approval duration (initial and renewal): 12 months

Dosing Recommendation

The recommended dose of Adakveo is 5 mg/kg by intravenous infusion over a period of 30 minutes at Week 0, Week 2, and every 4 weeks thereafter.

References

1. Adakveo® injection for intravenous use [prescribing information]. East Hanover, NJ: Novartis; June 2024.
2. Ataga KI, Kutlar J, Kanter K, et al. Crizanlizumab for the prevention of pain crises in sickle cell disease. *N Engl J Med*. 2017;376(5):429-439.

3. Brandow AM, Carroll CP, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. *Blood Adv*. 2020;4:2656-2701.
4. The National Institutes of Health – National Heart, Lung, and Blood Institute Evidence-Based Management of Sickle Cell Disease, Expert Panel Report 2014. Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed on January 8, 2025.
5. Droxia® capsules [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; July 2021.
6. Siklos® tablets [prescribing information]. Bryn Mawr, PA: Medunik; November 2023.
7. Xromi oral solution [prescribing information]. Franklin, TN: Rare Disease Therapeutics; April 2024.
8. López Rubio M and Argüello Marina M. The current role of hydroxyurea in the treatment of sickle cell anemia. *J Clin Med*. 2024;13(21)L6404.

