

Adakveo® (crizanlizumab-tmca)

When requesting Adakveo® (crizanlizumab-tmca), the individual requiring treatment must be diagnosed with an 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 authorization:

- Is 16 years of age or older; AND
- Has had at least one sickle cell-related crisis in the previous 12 months; AND
- Meets one of the following:
 - a. is currently receiving hydroxyurea; OR
 - b. has had inadequate efficacy or significant intolerance with hydroxyurea; OR
 - c. is not a candidate for hydroxyurea (i.e., pregnant or planning to become pregnant, 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; AND
- Is receiving clinical benefit (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); AND
- 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: 12 months

Dosing Recommendation

Approve up to 5 mg/kg administered by intravenous infusion at week 0, week 2, and then not more frequently than once every 4 weeks.

References

1. Adakveo® injection for intravenous use [prescribing information]. East Hanover, NJ: Novartis; July 2021.
2. Piel FB, Steinberg MH. Sickle cell disease. *N Engl J Med*. 2017;376:1561-1573.
3. 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 November 4, 2021.