PREFERRED STEP THERAPY POLICY

POLICY: Sickle Cell Disease – Hydroxyurea Products Preferred Step Therapy Policy
- Droxia® (hydroxyurea capsules – Bristol-Meyers Squibb)
- Siklos® (hydroxyurea tablets – Medunik)

REVIEW DATE: 08/17/2022

OVERVIEW

Both Droxia and Siklos are indicated **in patients with sickle cell anemia** with recurrent moderate to severe painful crises for the following uses:[1,2]
- **Reduce** the **frequency of painful crises**.
- **Reduce the need for blood transfusions.**

Siklos is indicated for use in adults and pediatric patients ≥ 2 years of age. The safety and effectiveness of Droxia in pediatric patients have not been established, but the National Institutes of Health – National Heart, Lung, and Blood Institute Evidence-Based Management of Sickle Cell Disease, Expert Panel Report (2014) recommends hydroxyurea for use in pediatric patients and adults.[3]

Droxia capsules should be swallowed whole; patients should not open, break, or chew the capsules.[1] Droxia is available as 200 mg, 300 mg, and 400 mg capsules. Siklos tablets can be swallowed whole or dispersed (immediately before use) in a small quantity of water in a teaspoon.[2] Siklos is available as 100 mg and 1,000 mg functionally scored tablets. The 100 mg tablets can be split into two parts (each part is 50 mg). The 1,000 mg tablets have three score lines and can be split into four parts (each part is 250 mg). The two tablet strengths can be used to deliver doses of 50 mg, 100 mg, 250 mg, 500 mg, 750 mg, and 1,000 mg and combinations thereof. Both Droxia and Siklos are cytotoxic medications and caregivers/patients should follow applicable special handling and disposal procedures. Avoid exposure to crushed tablets/capsules.

Guidelines

The National Institutes of Health – National Heart, Lung, and Blood Institute issued the Evidence-Based Management of Sickle Cell Disease, Expert Panel Report in 2014.[3] The report notes that there are only two currently proven disease-modifying treatments for patients with sickle cell disease: hydroxyurea and chronic blood transfusions. Hydroxyurea therapy is recommended in adults and children with sickle cell disease to reduce sickle cell disease-related complications. Clinical response to hydroxyurea therapy may take 3 to 6 months; a 6-month trial on the maximum tolerated dose is required prior to considering discontinuation due to treatment failure. Long-term hydroxyurea therapy is indicated in patients with clinical response.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: Droxia

Step 2: Siklos

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. If the patient requires the Siklos 100 mg or 1,000 mg tablets to achieve a dosage that cannot be achieved with the available strengths of Droxia, approve Siklos.

3. If the patient cannot swallow or has difficulty swallowing Droxia capsules, approve Siklos.

4. No other exceptions are recommended.

REFERENCES

1. Droxia® capsules [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; September 2021.
2. Siklos® tablets [prescribing information]. Bryn Mawr, PA: Medunik; December 2021.
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 August 12, 2022.