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Section:	Prescription Drugs	**Effective Date:**	September 26, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	September 26, 2025
Subject:	Xromi	**Page:**	1 of 5

Last Review Date: December 12, 2025

Xromi

Description

Xromi (hydroxyurea)

Background
Sickle cell anemia is a genetically inherited condition which causes red blood cells to become sickle shaped. These “sickled” red blood cells can cause many complications including infections, hypertension, renal disease, stroke, retinopathy, and other chronic conditions. Painful crises are an acute condition caused by chronic sickle cell disease that causes much distress to people with sickle cell anemia. Hydroxyurea has been used to prevent these acute painful crises from occurring, as well as to improve survival and reduce other complications. Xromi is a newer formulation of hydroxyurea specifically designed for use in sickle cell patients to decrease the need for blood transfusions as well as decrease the frequency of painful crises (1-2).

Regulatory Status
FDA-approved indication: Xromi is an antimetabolite indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients 6 months of age and older with sickle cell anemia with recurrent moderate to severe painful crises (2).

Xromi carries boxed warnings for myelosuppression and malignancies. Do not give Xromi if bone marrow function is markedly depressed. Blood counts should be monitored at baseline and throughout treatment. Interrupt treatment and reduce dose as necessary. Hydroxyurea is carcinogenic. Sun protection should be advised, and patients should be monitored for malignancy (2).

Initiation of therapy is started at 15 mg/kg/day and is based on the patient's actual body weight. Dosing adjustments are made based on blood counts and therefore it is imperative to monitor patients' CBCs during therapy (2).

Xromi can cause fetal harm when administered to pregnant women. Verify the pregnancy status of females of reproductive potential prior to initiating Xromi therapy. Females of reproductive potential should be advised to use effective contraception during and after treatment with Xromi for at least 6 months after therapy. Males with female partners of reproductive potential should be advised to use effective contraception during and after treatment with Xromi for at least 1 year after therapy (2).

Safety and effectiveness in pediatric patients 6 months of age and older have been established (2).

Related policies
Adakveo, Endari, Siklos

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xromi may be considered **medically necessary** if the conditions indicated below are met.

Xromi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 6 months through 17 years of age

Diagnosis

Patient must have following:

Sickle Cell Disease (SCD)

AND ALL of the following:

1. History of moderate to severe painful crises

2. Inadequate treatment response, intolerance, or contraindication to generic hydroxyurea
3. Prescriber agrees to monitor blood counts at least every 4 weeks throughout therapy and adjust dose accordingly
4. Prescriber agrees to monitor for the development of secondary malignancies
5. Female patients of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for at least 6 months after therapy
6. Male patients with partners of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for at least 1 year after therapy
7. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Age 6 months through 17 years of age

Diagnosis

Patient must have following:

Sickle Cell Disease (SCD)

AND ALL of the following:

1. Decrease in number of painful crises
2. Prescriber agrees to monitor blood counts at least every 4 weeks throughout therapy and adjust dose accordingly
3. Prescriber agrees to monitor for the development of secondary malignancies
4. Female patients of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for at least 6 months after therapy
5. Male patients with partners of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for at least 1 year after therapy
6. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Painful crises are an acute condition caused by chronic sickle cell disease that causes much distress to people with sickle cell anemia. Hydroxyurea has been used to prevent these acute painful crises from occurring, as well as to improve survival and reduce other complications. Xromi is indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients with sickle cell anemia with recurrent moderate to severe painful crises (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Xromi while maintaining optimal therapeutic outcomes.

References

1. National Heart, Lung, and Blood Institute (NHLBI): Evidence-Based Management of Sickle Cell Disease. Expert Panel Report, 2014. Published by U.S. Department of Health and Human Services, National Institutes of Health. https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf
2. Xromi [package insert]. Franklin, TN: Rare Disease Therapeutics, Inc.; December 2024.

Policy History

Date	Action
September 2025	Addition to PA

Keywords

This policy was effective with interim approval on September 26, 2025 and will be reviewed by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025.