Mass General Brigham
Health Plan

Adakveo® (crizanlizumab-tmca)
Endari® (l-glutamine)
Oxbryta® (voxelotor)
Reblozyl® (luspatercept-aamt)
Siklos® (hydroxyurea tablet)
Effective 10/02/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Adakveo and Reblozyl are only available through the medical benefit.		

Overview

No PA	Drugs that require PA
Droxia (hydroxyurea capsule) Hydrea # (hydroxyurea capsule)	Adakveo (crizanlizumab-tmca)[MB]
	Endari (l-glutamine)
	Oxbryta(voxelotor)
	Reblozyl (luspat ercept-aamt)[MB]
	Siklos (hydroxyurea tablet)

This designates a brand-name drug with FDA "A"-rated generic equivalents. Prior authorization is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who new to the plan who are currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if the member meets all following criteria and documentation has been submitted:

Adakveo® (crizanlizumab-tmca)
ALL of the following:

1. Diagnosis of sickle cell disease
2. Member is ≥ 16 years of age
3. Prescriber is a hematologist or consult notes from a hematologist are provided
4. Member has experienced two or more sickle cell crises in the previous 12 months
5. **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response to hydroxyurea therapy at the maximally tolerated (up to a max of 35 mg/kg/day or until mild myelosuppression [e.g., ANC 2,000/uL to 4,000/uL, platelet count < 80,000/uL, reticulocyte count < 80 x 10^9/L]) dose for at least three months
    b. Adverse reaction or contraindication to hydroxyurea
6. Member's current weight

Endari® (l-glutamine)
ALL of the following:

1. Diagnosis of sickle cell disease
2. Member is ≥ 5 years of age
3. Prescriber is a hematologist or consult notes from a hematologist are provided
4. Member has experienced two or more sickle cell crises in previous 12 months
5. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to hydroxyurea
6. Member's current weight

Oxbryta® (voxelotor)
ALL of the following:

1. Diagnosis of sickle cell disease
2. Member is ≥ 4 years of age
3. Prescriber is a hematologist or consult notes from a hematologist are provided
4. Member has experienced at least **ONE** sickle cell crisis in the previous 12 months
5. **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response to hydroxyurea therapy at the maximally tolerated (up to a max of 35 mg/kg/day or until mild myelosuppression [e.g., ANC 2,000/uL to 4,000/uL, platelet count < 80,000/uL, reticulocyte count < 80 x 10^9/L]) dose for at least three months
    b. Adverse reaction or contraindication to hydroxyurea
6. Member has a baseline hemoglobin level ≤ 10.5 g/dL (Lab work should be drawn within the last 60 days)
7. If request is for Oxbryta® 300 mg tablets for oral suspension, medical necessity for the requested formulation as noted by **ONE** of the following:
    a. Member is < 13 years of age
    b. Member utilizes tube feeding (G-tube/J-tube)
    c. Member has a swallowing disorder or condition affecting ability to swallow
8. Appropriate dosing

Reblozyl® (luspatercept-aamt)
<u>Beta-thalassemia</u>
ALL of the following:

1. Documentation is submitted supporting a diagnosis of transfusion-dependent β-thalassemia (e.g., genetic test, medical records noting requirement of regular blood transfusions and/or chronic iron chelator use)
2. Member is ≥ 18 years of age
3. Prescriber is a hematologist or consult notes from a hematologist supporting the use of Reblozyl are provided
4. Member's current weight

Myelodysplastic syndromes with ring sideroblasts or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS-RS or MDS/MPN-RS-T)

ALL of the following:

1. Appropriate diagnosis
2. Member is ≥ 18 years of age
3. **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** erythropoiesis stimulating agent (e.g., epoetin, darbepoetin)
    b. Contraindication to **ALL** erythropoiesis stimulating agents
4. Documentation that member has required RBC transfusions in the past 8 weeks
5. Prescriber is a hematologist or consult notes from a hematologist supporting use of Reblozyl are provided
6. Member's current weight

Siklos® (hydroxyurea tablet)

ALL of the following:

1. Diagnosis of sickle cell disease
2. Member is ≥ 2 years of age
3. Prescriber is a hematologist or consult notes from a hematologist are provided
4. Medical necessity for the use of tablet formulation as noted by one of the following:
    a. Member is < 13 years of age
    b. Member utilizes tube feeding (G-tube/J-tube)
    c. Member has a swallowing disorder or condition affecting ability to swallow
5. Member's current weight

Continuation of Therapy

Adakveo: Reauthorization will require physician documentation of positive response to therapy as evidenced (e.g., decrease in VOCs, reduction in need for pain management, decrease in hospitalizations).

Endari or **Siklos**: Reauthorization by physician will infer a positive response to therapy. For Siklos, if member was previously approved for medical necessity based on age and member is now ≥ 13 years of age, request must meet other criteria for medical necessity for reauthorization.

Oxbryta: Reauthorization will require physician documentation of positive response to therapy as evidenced (e.g., decrease in VOCs, increase in Hgb >1 g/dL from baseline, reduction in laboratory markers associated with hemolysis [e.g., indirect bilirubin, absolute reticulocyte count, lactate dehydrogenase level]).

Reblozyl: Reauthorization will require physician documentation of a positive response to therapy (decrease in transfusion requirements).

Limitations

1. Initial approvals will be granted for:
    a. Oxbryta: 3 months
    b. Adakveo, Endari, Reblozyl, Siklos: 6 months
2. Reauthorization may be granted for:
    a. Adakveo, Oxbryta, Reblozyl: 6 months
    b. Endari, Siklos: 12 months
3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
5. The following quantity limits apply:

Oxbryta 300mg	150 tablets per 30 days
Oxbryta 500mg	90 tablets per 30 days

References

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16. Droxia® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 2021 Sep.
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Review History

03/18/2020 – Created and Reviewed P&T Mtg (effective 6/1/20)
11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes
01/11/23 - Reviewed and updated for Jan P&T. Matched MH UPPL criteria. Added criteria for drugs: Endari, Oxbryta, Reblozyl, Siklos. Updated Adakveo criteria. Effective 4/1/23.
09/13/23 – Reviewed and updated for P&T. Updated Oxbryta tablets for oral suspension for age due to medical necessity for consistency. Brand preferred and mandatory generic language was added under Limitations. Effective 10/2/23.