Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 130.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Mircera (methoxy polyethylene glycol-epoetin beta)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Mircera (methoxy polyethylene glycol-epoetin beta)

II. Purpose/Objective:
To provide a policy of coverage regarding Mircera (methoxy polyethylene glycol-epoetin beta)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Mircera (methoxy polyethylene glycol-epoetin beta) is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Mircera (methoxy polyethylene glycol-epoetin beta) will be considered medically necessary for commercial, exchange, CHIP, and Medicare lines of business when all of the following criteria are met:

For initial authorization in adult patients:
- Medical record documentation of age 18 years or greater **AND**
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis **AND**
- Hemoglobin (Hgb) less than 10 g/dL for new starts **AND**
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

For initial authorization in pediatric patients:
- Medical record documentation of age 3 months or greater **AND**
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients on dialysis and patients not on dialysis **AND**
- Medical record documentation that patient's hemoglobin has stabilized on and patient is converting to Mircera from another erythropoiesis-stimulating agent **AND**
- Hemoglobin (Hgb) less than 11 g/dL for new starts **AND**
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

For continuation of therapy in adult and pediatric patients:
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis **AND**
- Hemoglobin (Hgb) less than 11 g/dL for continuation of therapy **AND**
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

GENERAL GUIDANCE:
- For continuation of therapy, a repeat Hgb no greater than 3 months old should be submitted.
- In individuals whose Hgb is greater than or equal to 12gm/dL or rises by 1gm/dL in any two-week period, additional doses should be withheld or reduced (Except when being used for reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery).
- For initiation or continuation of therapy, a ferritin level no greater than 3 months old and/ or transferrin saturation level no greater than 6 months old should be submitted.
- The member should receive supplemental iron if serum ferritin is less than 100ng/mL and transferrin saturation is less than 20 percent

AUTHORIZATION DURATION: Each authorization period (initial and re-authorization) will be defined as a period of 12 months. Re-authorization will be considered based on continuation of therapy criteria listed above.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Mircera [prescribing information]. Gallen, Switzerland: Vifor (International) Inc; June 2024.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/19/15

Revised: 11/20/18 (pediatric), 11/15/22 (Medicaid Business Segment, LOB carve out, iron chelation, continuation criteria), 12/31/23 (references added), 10/18/24 (age change & dialysis peds, added general guidance, combined continuation criteria, deleted Medicaid business segment, LOB table, taglines)

Reviewed: 3/31/16, 3/30/17, 3/29/18, 11/18/19, 11/16/20, 10/4/21, 9/1/22, 10/26/23

MA UM Committee approval: 12/31/23, 11/8/24