

Policy: MBP 130.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Mircera (methoxy polyethylene glycol-epoetin beta)

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
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

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 5 years or greater **AND**
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients 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, a repeat Hgb no greater than 3 months old should be submitted.

For continuation of therapy 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 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

For continuation of therapy in pediatric patients:

- Medical record documentation of age 5 years or greater **AND**
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients 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

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.

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.

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)

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