STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOXY PEG-EPOETIN BETA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOXY PEG-EPOETIN BETA	MIRCERA	35005		GPI-10 (8240104010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, continue to #3.

3. Is the patient between 5 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is on hemodialysis
   - The patient is converting from another erythropoiesis-stimulating agent (ESA) (i.e., epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHOXY PEG-EPOETIN BETA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for approval:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
B. **If you are 18 years of age or older, approval also requires**:
   1. You have tried the preferred medication: Retacrit
   2. You have a hemoglobin level (type of blood test) of less than 10g/dL
C. **If you are between 5 and 17 years of age, approval also requires:**
   1. You are on hemodialysis (process of removing excess water, toxins from the blood)
   2. You are changing from another erythropoiesis-stimulating agent (ESA; epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 11g/dL (if on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, continue to #3.

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METHOXY PEG-EPOETIN BETA

RENEWAL CRITERIA (CONTINUED)

3. Is the patient between 5 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is currently receiving dialysis treatment
   - The patient has a hemoglobin level of less than 11g/dL OR the patient has a hemoglobin level that has reached 11g/dL and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for renewal:
   A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   B. **If you are 18 years of age or older, renewal also requires ONE of the following:**
      1. You have a hemoglobin level (type of blood test) of less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
      2. The patient has a hemoglobin level that has reached 11g/dL (if you are on dialysis) and your dose is being reduced/interrupted to decrease the need for blood transfusions
      3. You have a hemoglobin level (type of blood test) of less than 10g/dL if you are not on dialysis
      4. You have a hemoglobin level that has reached 10g/dL (if you are not on dialysis) and your dose is being reduced/interrupted to decrease the need for blood transfusions
   C. **If you are between 5 and 17 years of age, renewal also requires:**
      1. You are currently receiving dialysis treatment (process of removing excess water, toxins from the blood)
      2. You have ONE of the following:
         a. A hemoglobin level (type of blood test) of less than 11g/dL
         b. A hemoglobin level that has reached 11g/dL and your dose is being reduced/interrupted to decrease the need for blood transfusions

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHOXY PEG-EPOETIN BETA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mircera.

REFERENCES

- Mircera [Prescribing Information]. St. Gallen, Switzerland: Vifor, August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 02/11
Client Approval: 03/23
P&T Approval: 01/21