

Erythropoiesis Stimulating Agents (ESAs): Mircera[®] (methoxy polyethylene glycol-epoetin beta) (Intravenous/Subcutaneous)

NON-DIALYSIS

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I. Length of Authorization

- Coverage will be provided for 45 days and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- One syringe (30 mcg, 50 mcg, 75 mcg, 100 mcg, 120 mcg, 150 mcg) every 2 weeks
- One syringe (200 mcg, 250 mcg, 360 mcg) every 4 weeks

B. Max Units (per dose and over time) [Medical Benefit]:

- 360 billable units every 28 days

III. Initial Approval Criteria

Mircera is covered for the following indication(s):

- Patient must be 18 years or older; **AND**
- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Prior to initiation of therapy, patient should have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) $\geq 20\%*$; **AND**
- Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) $< 30\%$; **AND**
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**

Anemia secondary to chronic kidney disease (non-dialysis patients) †

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Last dose less than 60 days ago; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: pure red cell aplasia, severe allergic reactions (anaphylaxis, angioedema, bronchospasm, Stevens-Johnson syndrome/toxic epidermal necrolysis, etc.), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, uncontrolled hypertension), seizures, etc. ; **AND**
- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Hemoglobin (Hb) <11 g/dL and/or Hematocrit (Hct) <33%; **AND**
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
- Adequate iron stores, as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) $\geq 20\%$, measured within the previous 3 months*

* Intravenous iron supplementation may be taken into account when evaluating iron status

V. Dosage/Administration

Indication	Dose
CKD – Non-dialysis	<u>Starting dose:</u> 0.6 mcg/kg IV or SC once every 2 weeks. <u>Maintenance dose:</u> Once monthly dosing at twice the every-two-week dose once Hb has been stabilized. Most commonly 120 to 360 mcg every 4 weeks
<ul style="list-style-type: none">– Dose increases of 25% can be considered if after 4 weeks of initial therapy the hemoglobin has increased less than 1 g/dL and the current hemoglobin level is less than the indication specific level noted above– Dose decreases of 25% or more can be considered if the hemoglobin rises rapidly by more than 1 g/dL in any 2-week period– Avoid frequent dose adjustments. Do not increase the dose more frequently than once every 4 weeks; decreases can occur more frequently.– Dose and frequency requested are the minimum necessary for the patient to avoid RBC transfusions. If patients fail to respond over a 12-week dose escalation period, further dose increases are unlikely to improve response and discontinuation of therapy should be considered.	

VI. Billing Code/Availability Information

Jcode:

- J0888 – Injection, epoetin beta, 1 microgram, (for non esrd use); 1 billable unit = 1 mcg

NDC:

- Mircera 30 mcg/0.3 mL single-dose prefilled syringe: 59353-0400-xx
- Mircera 50 mcg/0.3 mL single-dose prefilled syringe: 59353-0401-xx
- Mircera 75 mcg/0.3 mL single-dose prefilled syringe: 59353-0402-xx
- Mircera 100 mcg/0.3 mL single-dose prefilled syringe: 59353-0403-xx
- Mircera 120 mcg/0.3 mL single-dose prefilled syringe: 59353-0407-xx
- Mircera 150 mcg/0.3 mL single-dose prefilled syringe: 59353-0404-xx
- Mircera 200 mcg/0.3 mL single-dose prefilled syringe: 59353-0405-xx
- Mircera 250 mcg/0.3 mL single-dose prefilled syringe: 59353-0406-xx
- Mircera 360 mcg/0.6 mL single-dose prefilled syringe: 59353-0408-xx

VII. References

1. Mircera [package insert]. St. Gallen, Switzerland; Vifor (International) Inc: April 2016. Accessed March 2018.
2. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (L34633). Centers for Medicare & Medicaid Services, Inc. Updated on 09/20/2017 with effective date 10/01/2017. Accessed March 2018.
3. First Coast Service Options, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L36276). Centers for Medicare & Medicaid Services. Updated on 02/22/2018 with effective dates 02/08/2018. Accessed March 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D63.1	Anemia in chronic kidney disease
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5

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N18.6	End stage renal disease
N18.9	Chronic kidney disease, unspecified

Dual coding requirements:

- J0888 must be billed in conjunction with D63.1 AND a code from the I or N series of codes for ESRD not on dialysis.

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s): L34633
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34633&bc=gAAAAAAAAAAAAA ==	

Jurisdiction(s): N	NCD/LCD Document (s): L36276
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L36276&bc=gAAAAAAAAAAAAA ==	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC