Mircera® (methoxy polyethylene glycol-epoetin beta)
(Intravenous/Subcutaneous)

NON-DIALYSIS

Document Number: IC-0244

Last Review Date: 04/01/2020
Date of Origin: 01/06/2015
Dates Reviewed: 01/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 04/2019, 04/2020

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 30 mcg; 50 mcg; 75 mcg; 100 mcg; 120 mcg; 150 mcg: 1 pre-filled syringe every 14 days
- 200 mcg; 250 mcg; 360 mcg: 1 pre-filled syringe every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 360 billable units every 28 days

III. Initial Approval Criteria [1-5]

Coverage is provided in the following condition(s):

- Patient must be 18 years or older; **AND**

Universal Criteria:

- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
- Patient does not have uncontrolled hypertension; **AND**

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

- Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%

Proprietary & Confidential
© 2020 Magellan Health, Inc.
Magellan Rx MANAGEMENT

† FDA approved indications; ‡ Compendium recommended indications

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal criteria indentified in section III; **AND**
- Previous dose was administered within the past 60 days; **AND**
- Anemia response compared to pretreatment baseline; **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**
- Hemoglobin (Hb) <11 g/dL and/or Hematocrit (Hct) <33%; **AND**

* *Intravenous iron supplementation may be taken into account when evaluating iron status*
• Functional iron deficiency (i.e., adequate iron stores with an insufficient supply of available iron) may occur in patients with chronic diseases, cancer, and/or in those currently receiving ESAs. • Iron is not generally recommended in anemic patients with a Ferritin >500 ng/mL • Anemic patients with a Ferritin <500 ng/mL AND TSAT <50% may derive benefit from IV iron therapy in conjunction with ESA

V. Dosage/Administration

Indication	Dose
Adults with CKD – Non-dialysis	Starting dose: 0.6 mcg/kg IV or SC once every 2 weeks Maintenance dose: Once monthly dosing (at twice the every-two-week dose) may occur once Hb has been stabilized. Most commonly the dose ranges from 120 to 360 mcg every 4 weeks.
– 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

HCPCS:

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

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2020, Magellan Rx Management

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. August 2019. Accessed March 2020.
2. Levin NW, Fishbane S, Cañedo FV, Zeig S, Nassar GM, Moran JE, Villa G, Beyer U, Oguey D; MAXIMA study investigators .: Intravenous methoxy polyethylene glycol-epoetin beta for haemoglobin control in patients with chronic kidney disease who are on dialysis: A randomised non-inferiority trial (MAXIMA). Lancet 370: 1415–1421, 2007.
3. Sulowicz W, Locatelli F, Ryckelynck JP, Balla J, Csiky B, Harris K, Ehrhard P, Beyer U; PROTOS Study Investigators .: Once-monthly subcutaneous C.E.R.A. maintains stable hemoglobin control in patients with chronic kidney disease on dialysis and converted directly from epoetin one to three times weekly. Clin J Am Soc Nephrol 2: 637–646, 2007.
4. Fischbach M, Wühl E, Reigner SCM, Morgan Z, Schaefer F. Efficacy and Long-Term Safety of C.E.R.A. Maintenance in Pediatric Hemodialysis Patients with Anemia of CKD [published correction appears in Clin J Am Soc Nephrol. 2019;14(6):907] Clin J Am Soc Nephrol. 2018;13(1):81-90.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO clinical practice guideline for anemia in chronic kidney disease. Kidney Int Suppl. 2012;2(suppl):279-335. https://kdigo.org/guidelines/anemia-in-ckd/. Published August 2012.
6. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L34633). Centers for Medicare & Medicaid Services, Inc. Updated on 12/16/2019 with effective dates 2/9/2020. Accessed March 2020.
7. First Coast Service Options, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L36276). Centers for Medicare & Medicaid Services. Updated on 10/25/2019 with effective dates 10/29/2019. Accessed March 2020.
8. CGS Administrators, LLC. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESA) (L34356). Centers for Medicare & Medicaid Services. Updated on 02/24/2020 with effective dates 10/03/2019. Accessed March 2020.
9. Wisconsin Physicians Service Insurance Corporation. Local Coverage Article (LCA): Billing and Coding: Erythropoiesis Stimulating Agents (ESAs) (A56795). Centers for Medicare &

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2020, Magellan Rx Management

Medicaid Services, Inc. Updated on 12/16/2019 with effective dates 2/9/2020. Accessed March 2020.

10. First Coast Service Options, Inc. Local Coverage Article (LCA): Billing and Coding: Erythropoiesis Stimulating Agents (ESAs) (A57628). Centers for Medicare & Medicaid Services. Updated on 12/16/2019 with effective dates 1/1/2020. Accessed March 2020.
11. CGS Administrators, LLC. Local Coverage Article (LCA): Billing and Coding: Erythropoiesis Stimulating Agents (ESA) (A56462). Centers for Medicare & Medicaid Services. Updated on 02/24/2020 with effective dates 1/23/2020. Accessed March 2020.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D63.1	Anemia in chronic kidney 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
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.9	Chronic kidney disease, unspecified

Dual coding requirements:

- Anemia due to CKD (not on dialysis): must bill D63.1 AND I12.9, I13.0, I13.10, N18.3, N18.4, or N18.9

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), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) 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/LCA):

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==	

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2020, Magellan Rx Management

Jurisdiction(s): 15	NCD/LCD Document (s): L34356
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34356&bc=gAAAAAAAAAAA	

Jurisdiction(s): 5, 8	NCD/LCD Document (s): A56795
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56795&bc=gAAAAAAAAAAA	

Jurisdiction(s): N	NCD/LCD Document (s): A57628
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57628&bc=gAAAAAAAAAAA	

Jurisdiction(s): 15	NCD/LCD Document (s): A56462
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56462&bc=gAAAAAAAAAAA	

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

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2020, Magellan Rx Management