

# Erythropoietin Stimulating Agent (ESA)

Guideline Number: MPG103.06  
Approval Date: November 11, 2020

[↪ Terms and Conditions](#)

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Related Medicare Advantage Policy Guidelines
<ul style="list-style-type: none"> <li><a href="#">Coverage of Drugs and Biologicals for Label and Off-Label Uses</a></li> <li><a href="#">Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (NCD 110.21)</a></li> </ul>
Related Medicare Advantage Coverage Summary
<ul style="list-style-type: none"> <li><a href="#">Medications/Drugs (Outpatient/Part B)</a></li> </ul>

## Policy Summary

[↪ See Purpose](#)

### Overview

Erythropoietin is a specialized cytokine that is produced by the kidneys and stimulates the proliferation of red blood cells in the bone marrow. Erythropoietin is released into the blood stream in response to hypoxia. In response to the hypoxia, erythropoietin interacts with the progenitor cells to increase the production of red blood cells. An erythropoietin stimulating agent (ESA) is an analog of erythropoietin. ESAs are biologically engineered hormones produced by recombinant DNA technology. Erythropoietin analogs contain the identical amino acid sequence as naturally occurring erythropoietin and have the same biological effect. A number of chronic conditions, especially chronic renal failure, result in decreased production of or relative resistance to erythropoietin often causing anemia. Supplementation by synthetic drugs with structures identical or similar to naturally occurring erythropoietin has been proven safe and effective in correcting anemia in certain groups of patients. Both erythropoietin and ESAs stimulate the bone marrow to form new red blood cells. They are used to treat anemia by elevating or maintaining the red blood cell level (as demonstrated by the hematocrit and/or hemoglobin levels), therefore decreasing anemia and the need for transfusions.

### Indications and Limitations

Please see the FDA drug label for the FDA approved indications and dosages. This can be accessed at: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>. Additionally, coverage indications and limitations vary by LCD. Refer to the appropriate LCDs for specific individual state coverage guidelines.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPSC Code	Description
J0881	Injection, darbepoetin alfa, 1 mcg (non-ESRD use) (refer to the Medicare Advantage Policy Guideline titled- <a href="#">Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (NCD 110.21)</a> )
J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)
J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units (refer to the Medicare Advantage Policy Guideline titled- <a href="#">Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (NCD 110.21)</a> )
J0887	Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)
J0888	Injection, epoetin beta, 1 microgram, (for non-ESRD use)
J0890	Injection, peginesatide, 0.1 mg (for ESRD on dialysis) (FDA recalled 02/23/2013)
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units (refer to the Medicare Advantage Policy Guideline titled- <a href="#">Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (NCD 110.21)</a> )

Modifier	Description
EA	Erythropoetic stimulating agent (ESA) administered to treat anemia due to anticancer chemotherapy
EB	Erythropoetic stimulating agent (ESA) administered to treat anemia due to anticancer radiotherapy
EC	Erythropoetic stimulating agent (ESA) administered to treat anemia not due to anticancer radiotherapy or anticancer chemotherapy
JA	Administered intravenously
JB	Administered subcutaneously
JE	Administered via dialysate

## References

### CMS National Coverage Determinations (NCDs)

[NCD 110.21 Erythropoiesis Stimulating Agents \(ESAs\) in Cancer and Related Neoplastic Conditions](#)

### CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
<a href="#">L34356 Erythropoiesis Stimulating Agents (ESA)</a>	<a href="#">A56462 Billing and Coding: Erythropoiesis Stimulating Agents (ESA)</a>	CGS	KY, OH	KY, OH
<a href="#">L36276 Erythropoiesis Stimulating Agents</a>	<a href="#">A57628 Billing and Coding: Erythropoiesis Stimulating Agents</a>	First Coast	FL, PR, VI	FL, PR, VI

LCD	Article	Contractor	Medicare Part A	Medicare Part B
<a href="#">L34633 Erythropoiesis Stimulating Agents</a>	<a href="#">A56795 Billing and Coding: Erythropoiesis Stimulating Agents (ESAs)</a>	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, KS, MO, NE, IN, MI

## CMS Benefit Policy Manual

[Chapter 1 Inpatient Hospital Services Covered Under Part A](#)

[Chapter 6; § 30 Drugs and Biologicals](#)

[Chapter 11 End Stage Renal Disease \(ESRD\)](#)

[Chapter 15; § 50 Drugs and Biologicals](#)

## CMS Claims Processing Manual

[Chapter 6 SNF Inpatient Part A Billing and SNF Consolidated Billing](#)

[Chapter 8 Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims](#)

[Chapter 17 Drugs and Biologicals](#)

## MLN Matters

[Article MM5818, Erythropoiesis Stimulating Agents \(ESAs\) in Cancer and Related Neoplastic Conditions](#)

[Article MM7064, End Stage Renal Disease \(ESRD\) Prospective Payment System \(PPS\) and Consolidated Billing for Limited Part B Services](#)

[Article MM7460 Revised, Implementation of the Medicare Improvements for Patients and Providers Act of 2008 \(MIPPA\) 153c End Stage Renal Disease \(ESRD\) Quality Incentive Program \(QIP\) and Other Requirements for ESRD Claims](#)

[Article MM8050, New Erythropoietin Stimulating Agent \(ESA\) Peginesatide Requirements for End-Stage Renal Disease \(ESRD\)](#)

[Article MM10624, Quarterly Healthcare Common Procedure Coding System \(HCPCS\) Drug/Biological Code Changes – July 2018 Update](#)

[Article MM11134, International Classification of Diseases, 10th Revision \(ICD10\) and Other Coding Revisions to National Coverage Determination \(NCDs\), July 1, 2019](#)

[Article MM12027, International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)–April 2021](#)

## UnitedHealthcare Commercial Policy

[Erythropoiesis-Stimulating Agents](#)

## Other(s)

[CMS Medicare Part B ASP Drug Pricing Files](#)

[End Stage Renal Disease \(ESRD\) Prospective Payment System \(PPS\)](#)

[ESRD PPS Consolidated Billing](#)

[FDA label for Retacrit \(epoetin alfa-epbx\) injection](#)

[Federal Register: Takeda Pharmaceuticals U.S.A., Inc.; Withdrawal of Approval of a New Drug Application for Omontys \(peginesatide\) Injection](#)

[Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues](#)

[Proposed Decision Memo for Erythropoiesis Stimulating Agents \(ESAs\) for non-renal disease indications \(CAG-00383N\)](#)

[UnitedHealthcare Medicare Advantage Medical Benefit Injectable Policy: Medicare Part B Step Therapy Programs](#)

## Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>Reformatted policy; transferred content to new template</li> </ul>
11/11/2020	<p><b>Related Policies</b></p> <ul style="list-style-type: none"> <li>Added reference link to the Medicare Advantage Policy Guideline titled <i>Coverage of Drugs and Biologicals for Label and Off-Label Uses</i></li> </ul> <p><b>Policy Summary</b></p> <p><b>Overview</b></p> <ul style="list-style-type: none"> <li>Revised language to indicate:           <ul style="list-style-type: none"> <li>Erythropoietin is a specialized cytokine that is produced by the kidneys and stimulates the proliferation of red blood cells in the bone marrow</li> <li>Erythropoietin is released into the blood stream in response to hypoxia; erythropoietin interacts with the progenitor cells to increase the production of red blood cells</li> <li>An erythropoietin stimulating agent (ESA) is an analog of erythropoietin; ESAs are biologically engineered hormones produced by recombinant DNA technology</li> <li>Erythropoietin analogs contain the identical amino acid sequence as naturally occurring erythropoietin-and have the same biological effect</li> <li>A number of chronic conditions, especially chronic renal failure, result in decreased production of or relative resistance to erythropoietin often causing anemia</li> <li>Supplementation by synthetic drugs with structures identical or similar to naturally occurring erythropoietin has been proven safe and effective in correcting anemia in certain groups of patients</li> <li>Both erythropoietin and ESAs stimulate the bone marrow to form new red blood cells; they are used to treat anemia by elevating or maintaining the red blood cell level (as demonstrated by the hematocrit and/or hemoglobin levels), therefore decreasing anemia and the need for transfusions</li> </ul> </li> <li>Removed content/language pertaining to appropriate billing of End Stage Renal Disease (ESRD)-related drugs and biologicals</li> </ul> <p><b>Indications and Limitations (previously listed as <i>Indications</i>)</b></p> <ul style="list-style-type: none"> <li>Revised language to indicate:           <ul style="list-style-type: none"> <li>See the FDA drug label for the FDA approved indications and dosages; this can be accessed at <a href="https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm">https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm</a></li> <li>Additionally, coverage indications and limitations vary by Local Coverage Determination (LCD); refer to the appropriate LCDs for specific individual state coverage guidelines</li> </ul> </li> <li>Removed content/language pertaining to:           <ul style="list-style-type: none"> <li>Documentation requirements</li> <li>Utilization guidelines</li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <p><b>HCPCS Codes</b></p> <ul style="list-style-type: none"> <li>Added reference link to the Medicare Advantage Policy Guideline titled <i>Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (NCD 110.21)</i> for HCPCS code Q5106</li> </ul> <p><b>Modifiers</b></p> <ul style="list-style-type: none"> <li>Removed Modifier codes AY, ED, EE, and GS</li> </ul> <p><b>Revenue Codes</b></p> <ul style="list-style-type: none"> <li>Removed Revenue codes 0634, 0635, and 0636</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>References</i> section to reflect the most current information</li> </ul>

Date	Summary of Changes
	<ul style="list-style-type: none"><li>Archived previous policy version MPG103.05</li></ul>

## Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

## Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document\* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

\*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).