ERYTHROPOIETIN STIMULATING AGENT (ESA)

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Policy Summary

Overview
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. Primarily, the kidneys produce erythropoietin in response to hypoxia. 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.

Anemia of Chronic Renal Failure (CRF) as well as certain other anemias may respond to supplemental erythropoietin administration despite adequate erythropoietin levels. Following the establishment (e.g., correction of any iron deficiency, vitamin deficiency, occult or other blood loss, etc.) and documentation of an erythropoietin-associated anemia, supplementation with synthetic drugs with structures identical to or similar to naturally occurring erythropoietin has been accepted as safe and effective in correcting anemia in certain groups of patients.

Synthetic supplemental erythropoietin is a biologically engineered protein that stimulates bone marrow to make new red blood cells. The FDA has approved two distinct drugs for use as synthetic erythropoietin substitutes:
- **Epoetin alfa** is structurally identical to naturally occurring erythropoietin.
- **Darbepoetin alfa** is a supersialated protein that binds to the erythropoietin receptor and stimulates erythropoiesis by the same mechanism as endogenous erythropoietin. It has a half-life approximately two to three times longer than Epoetin alfa and therefore needs to be administered less often.

Guidelines
The following causes of anemia should be considered, documented, and corrected (when possible) before starting therapy:
- Iron deficiency
- Underlying infection or inflammatory process
- Underlying hematological disease
- Hemolysis
- Vitamin deficiencies (e.g. Folic acid or b 12)
- Blood loss
- Aluminum intoxication
- Drug exposure history

In addition, prior to therapy, the physician makes a comprehensive assessment of the patient, which would include:
- Hematocrit or hemoglobin
• Serum iron
• Transferrin saturation; or serum ferritin and/or documentation of iron stores in bone marrow
• Creatinine
• Bone Marrow Biopsy (for myelodysplastic disease or where otherwise indicated)
• Erythropoietin level (for myelodysplastic disease; AZT therapy, anemia of chronic disease)

Section 153b of the Medicare Improvements for Patients and Providers Act (MIPPA) requires that all ESRD-related drugs and biologicals be billed by the renal dialysis facility. When a drug or biological is billed by providers other than the ESRD facility and the drug or biological furnished is designated as a drug or biological that is included in the ESRD PPS (ESRD-related), the claim will be rejected or denied. In the event that an ESRD-related drug or biological was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the provider may submit a claim for separate payment using modifier AY.

With the implementation of the ESRD PPS, ESRD-related EPO is included in ESRD PPS payment amount and is not separately payable on Part B claims with dates of service on or after January 1, 2011 for other providers with the exception of a hospital billing for an emergency or unscheduled dialysis session.

**Indications**
Erythropoietin analogues are covered to treat patients who have one of the FDA-approved or “accepted” conditions, and have either symptomatic anemia or are transfusion dependent.

Epoetin alpha (EPO) and darbepoetin alfa (DPA) may be a covered service for treatment of anemia when other treatable causes of anemia are identified and treated and when the anemia is associated with the following conditions:

- **Anemia and ESRD**
  Patients with End Stage Renal Disease (ESRD) on dialysis and those with CRF not on dialysis.

  The likelihood of anemia associated with EPO deficiency increases as renal failure progresses, because the diseased kidneys are unable to produce sufficient quantities of erythropoietin. The anemia of Chronic Renal Failure should not be confused with the anemia of chronic disease. In the latter, inflammatory cytokines suppress the endogenous production of EPO and erythropoiesis directly. Measurable levels of circulating cytokines may be found in stable dialysis patients, but, in the absence of inflammation, do not adversely affect the action of ESAs. In patients with impaired renal function and a normochromic, normocytic anemia, it is rare for the serum EPO level to be elevated. Therefore, measurement of EPO levels in such patients is not likely to guide clinical decision-making or ESA therapy. Anemia can develop relatively early in the course of CRF and has been associated with a serum creatinine as low as 2.0 mg/dL.

A CKD staging system has been developed by the National Kidney Foundation through KDOQI and has classified CKD into five distinct stages, based on the level of kidney function using Glomerular Filtration Rate (GFR).

  - Stage 1 - Kidney damage with normal or increased GFR > 90
  - Stage 2 - Kidney damage with mild or decreased GFR 60-89
  - Stage 3 - Moderate decline in GFR 30-59
  - Stage 4 - Severe Decline in GFR 15-29
  - Stage 5 - Kidney failure <15 (for dialysis)

Refer to the Medicare Benefit Policy Manual, Chapter 15, section 50.5.2, Erythropoietin (EPO) which discusses ESAs for end-stage renal disease related anemia.

Below are several charts illustrating the diagnosis criteria as well as the resultant claim actions under all possible reporting scenarios for ESRD related treatment.

- **Anemia in Chronic Renal Failure**
  By definition, chronic kidney disease (CKD) is kidney damage for 3 months or longer, regardless of the cause of kidney damage. CKD typically evolves over a long period of time and patients may not have symptoms until significant, possibly irreversible, damage has been done. Complications can develop from kidneys that do not function properly, such as high blood pressure, anemia, and weak bones. When chronic kidney disease progresses, it may lead to kidney failure, which requires artificial means to perform kidney functions (dialysis) or a kidney transplant to maintain life.

- **Anemia and Cancer Chemotherapy and for a non-cancer diagnosis or following stem cell transplantation and associated immunosuppression**
Erythropoietin Stimulating Agent (ESA) may be a covered service for treatment of anemia when other treatable causes of anemia are identified and treated and one of the following clinical situations applies:

- The patient must have, within the past 30 days, hct 30 or below or hgb 10 or below, before coverage by UnitedHealthcare will begin. Where the patient has required a blood or red cell transfusion within the past month, you may use the most recent hct or hgb before the transfusion.
- For patients with anemia associated with cancer chemotherapy, see NCD 110.21.

**Anemia related to therapy with Zidovudine (AZT) in acquired immunodeficiency syndrome (AIDS) or AIDS-related complex (ARC)**

HIV infected patients taking AZT develop anemia. It has been observed that this anemia responds to exogenous erythropoietin therapy in the individuals who were receiving AZT doses of 4200 mg or less/week, and whose endogenous levels of erythropoietin are 500 MU/ml or less. Patients with AZT induced anemia whose endogenous serum erythropoietin levels are more than 500 MU/ml do not appear to respond to this therapy. It would be expected that the drug would be discontinued when there is lack of response following no more than 3 months of treatment or 3 months following the discontinuation of Zidovudine therapy. The patient must have, within the past 30 days, hct 30 or below or hgb 10 or below, before coverage by UnitedHealthcare will begin.

**Anemia and MDS**

Myelodysplastic syndromes are a heterogeneous group of hematological malignancies characterized by dysplastic (abnormal) and ineffective hematopoiesis (blood cell production) and a variable risk of transformation to acute leukemia.

Anemia is observed in 90 percent of individuals with MDS. Those MDS patients with an endogenous EPO level of less than 500 mU/mL are more likely to respond to erythropoiesis-stimulating agent ESA therapy. ESA therapy is indicated for patients with a confirmed diagnosis of MDS, when the anemia is symptomatic, there is a reasonable expectancy of longer survival and therapy is provided in order to end or reduce the need for transfusions.

**Anemia of Chronic Disease**

In anemia of Inflammatory disease, inflammatory cytokines suppress the endogenous production of erythropoietin and erythropoiesis directly. This anemia usually results from a combination of slightly shortened red blood cell survival, the sequestration of iron in the reticuloendothelial systems, and epo levels that are less than expected for the degree of anemia.

The diagnosis is usually exclusionary; meaning other causes of the anemia have been ruled out.

**Common Features:**

- Low or normal serum iron
- Low or normal iron-binding capacity levels
- Elevated iron in reticuloendothelial cell in bone marrow

**Note:** There may be variances in the above.

To respond appropriately to exogenous erythropoietin administration, patients must have adequate available iron stores (i.e., normal or elevated ferritin levels and/or normal bone marrow iron stain). Further, their endogenous erythropoietin level must indicate poor responsiveness to the anemic process.

The severity of these anemias is usually moderate and they are rarely symptomatic or in need of therapy with EPO or DPA. The anemia usually resolves when the inflammatory process is successfully treated.

Anemia of cancer is not considered a chronic disease for this purpose and should not be billed as such.

UnitedHealthcare will cover the use of EPO or DPA for the refractory anemia of chronic disease for patients with Rheumatoid Arthritis, Systemic Lupus Erythematosus, Chronic Hepatitis C, Regional Enteritis (or Crohn's Disease) and Ulcerative Colitis when all of the following conditions are met:

- At least one of the conditions below:
  - Low or normal serum iron
  - Low or normal iron binding capacity
  - Normal or elevated serum ferritin
  - Adequate iron stores in bone marrow.
- The pretreatment hct level is 30 percent or less and/or if the patient has been transfusion dependent.
- The pretreatment erythropoietin level is 100 MU/ml or less

**Anemia and Pre-Operative Indications**
Prophylactic pre-operative use for reduction of allogenic blood transfusions prior to elective hip and knee replacement surgery.

Patients receiving ESAs pre-operatively for reduction of allogeneic red blood cell transfusions: A higher incidence of deep venous thrombosis was documented in patients receiving ESAs who were not receiving prophylactic anticoagulation.

Note: Lab results can be skewed if the patient has had transfusions or has been given iron supplements prior to determining the need for EPO or DPA. In instances such as this there must be written acknowledgement of this and the reasoning behind the need for these agents.

**Initiation of Therapy**
Initiation of therapy may begin with a hct of 30% or hgb of 10 or less. If the transferrin saturation is less than 20% and/or the serum ferritin is less than 100mg/ml, appropriate iron supplementation should be administered.

**Maintenance Therapy**
Effective 04/16/2008, the maintenance hematocrit (hct) level should be maintained at 30-36 or the Hemoglobin (hgb) level should be maintained at 10-12.

Use the lowest dose of ESA that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion.

**Contraindications**
ESAs are contraindicated in patients with:
- Uncontrolled hypertension
- Known hypersensitivity to mammalian cell-derived products
- Known hypersensitivity to Albumin (Human)

**Lack or Loss of Response**
Because of the length of time required for erythropoiesis (several days for erythroid progenitors to mature and be released into the circulation) a clinically significant increase in hematocrit is usually not observed in less than 2 weeks and may require up to six weeks in some patients.

If the patient fails to respond or to maintain a response to doses within the recommended dosing range, the following etiologies should be considered and evaluated:
- Iron deficiency: Virtually all patients will eventually require supplemental iron therapy.
- Underlying infectious, inflammatory, or malignant processes
- Occult blood loss
- Underlying hematologic diseases (i.e., thalassemia, refractory anemia, or other myelodysplastic disorders)
- Vitamin deficiencies: Folic acid or vitamin B12
- Hemolysis
- Aluminum intoxication
- Osteitis fibrosa cystica

Pure Red Cell Aplasia (PRCA) or anti-erythropoietin antibody-associated anemia: In the absence of another etiology, the patient should be evaluated for evidence of PRCA and sera should be tested for the presence of antibodies to erythropoietin.

**Documentation Requirements**
- Document the reason for the use of the drug, the type of the underlying disease and the type of anemia in the patient chart. This information should be available upon request.
- Documentation supporting the medical necessity of this item, such as ICD-10-CM codes, must be submitted with each claim. Claims submitted without such evidence will be denied as not being medically necessary.

**Utilization Guidelines**
- Refer to the Indications and limitations of coverage for each condition to determine the information required in the medical record.
- When ESAs are given for ESRD/CRD patients, the following information must be in the patients record and available upon request:
  - The current hematocrit or hemoglobin level and the date obtained.
Serum creatinine, with the date obtained. If a creatinine clearance was done, include that information, with the date obtained.

- Patient's weight in kilograms.
- Dose per kilogram.

For ESRD patients, the maximum number of administrations of epoetin alfa for a billing cycle is 13 times in 30 days and 14 times in 31 days (CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 8, Section 60.4.1)

Darbepoetin alfa is given not more than once per week according to its Food and Drug Administration-approved labeling. For this reason, we will allow it to be billed a maximum of five times during any calendar month (CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 8, Section 60.7.1).

### APPLICABLE CODES

The following list(s) of 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.

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<th>HCPCS Code</th>
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<tr>
<td>J0881</td>
<td>Injection, darbepoetin alfa, 1 mcg (non-ESRD use) (see--Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (NCD 110.21))</td>
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<td>Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)</td>
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<td>Injection, epoetin alfa, (for non-ESRD use), 1000 units (see-Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (NCD 110.21))</td>
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<td>AY</td>
<td>Item or service furnished to an ESRD patient that is not for the treatment of ESRD</td>
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<td>EA</td>
<td>Erythropoietic stimulating agent (ESA) administered to treat anemia due to anticancer chemotherapy</td>
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<td>EB</td>
<td>Erythropoietic stimulating agent (ESA) administered to treat anemia due to anticancer radiotherapy</td>
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<td>ED</td>
<td>Hematocrit level has exceeded 39% (or hemoglobin level has exceeded 13.0 G/dl) for 3 or more consecutive billing cycles immediately prior to and including the current cycle</td>
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<td>EE</td>
<td>Hematocrit level has not exceeded 39% (or hemoglobin level has not exceeded 13.0 G/dl) for 3 or more consecutive billing cycles immediately prior to and including the current cycle</td>
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<td>GS</td>
<td>Dosage of erythropoietin stimulating agent has been reduced and maintained in response to hematocrit or hemoglobin level</td>
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<td>JA</td>
<td>Administered intravenously</td>
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<td>JB</td>
<td>Administered subcutaneously</td>
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<td>0635</td>
<td>Pharmacy - Erythropoietin (EPO)&gt;=10,000 Units</td>
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DEFINITIONS

**Autologous**: Originating within an individual.

**Bone Marrow**: The soft tissue in the marrow cavities of long bones (yellow marrow) and in the spaces between trabeculae of spongy bone in the sternum and other flat and irregular bones (red marrow). Yellow marrow is mostly fat, stored energy. Red marrow produces all the types of blood cells.

**CRF**: Chronic renal failure.

**Dialysis**: The process of diffusing blood across a semi-permeable membrane to remove toxic materials and to maintain fluid, electrolyte, and acid-base balance in cases of impaired kidney function or absence of the kidneys.

**DNA**: DNA is a nucleic acid that contains the genetic instructions used in the development and functioning of all known living organisms (with the exception of RNA viruses). The DNA segments that carry this genetic information are called genes, but other DNA sequences have structural purposes, or are involved in regulating the use of this genetic information. Along with RNA and proteins, DNA is one of the three major macromolecules that are essential for all known forms of life.

**Erythrocyte**: A mature red blood cell.

**ESRD (End Stage Renal Disease)**: The stage of chronic renal failure in which the clearance of creatinine has fallen to about 5ml/min. Renal replacement therapies are required to prevent fatal fluid overload, hyperkalemia, and other uremic complications.

**Hematocrit (hct)**: The volume of erythrocytes packed by centrifugation in a given volume of blood. The hematocrit is expressed as the percentage of total blood volume that consists of erythrocytes or as the volume in cubic centimeters of erythrocytes packed by centrifugation of blood. Approximate normal values at sea level: men, average 47%, range 40% to 54%; women, average 42%, range 37% to 47%; children, varies with age from 35% to 49%; newborn, 49% to 54%.

**Hemoglobin (hgb)**: The iron-containing pigment of red blood cells that carries oxygen from the lungs to the tissues. The amount of hemoglobin in the blood averages 12 to 16 g/100ml in women, 14 to 18 g/100ml in men, and somewhat less in children. Hemoglobin is a crystallizable, conjugated protein consisting of heme, an iron-containing pigment, and globin, a simple protein.

**Hemolysis**: The destruction of red blood cells because of red blood cell diseases or because of their exposure to drugs, toxins, artificial heart valves, antibodies, some infections, or snake venoms.

**Hypoxia**: An oxygen deficiency in body tissues.

**Red Blood Cells**: Erythrocyte.

**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 LCDs, NCDs, 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.
REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 110.21 Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions

CMS Local Coverage Determinations (LCDs)

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CMS Articles

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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.

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<td>04/01/2019</td>
<td>Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
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<tr>
<td>11/14/2018</td>
<td>Annual review</td>
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<td>Updated HCPCS coding;</td>
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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.

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*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.