

Coding Medical Necessity

Erythropoiesis Stimulating Agents (ESAs) B2006.106 R12

This article contains instructions for coding medical necessity in accordance with both the national coverage determination (NCD) and local coverage determination (LCD) and other CMS instructions on darbepoetin alfa (Aranesp®, DPA) and epoetin alfa (Epogen®, Procrit®, EPO). *These coding guidelines are not intended to replace any found in the ICD-9-CM Official Guidelines for Coding and Reporting, nor are they intended to provide guidance on when a condition should be coded. Rather, this article should be used in conjunction with the UB-04 Data Specifications Manual and the ICD-9-CM Official Guidelines for Coding and Reporting.* This article supersedes all previous articles on this subject. Providers should refer to CMS manuals and updates issued in Change Requests for additional claim form-specific billing instructions, including, but not limited to modifiers, necessary for payment.

General Information for all claims for ESAs:

These coding guidelines specifically address the *documentation of medical necessity* on the claim, i.e., the coding in this guidance must be used to indicate the conditions that convey medical necessity of the drug treatment.

Providers may not code a claim with more than one drug code (J or Q) for DPA or EPO, i.e., only one of the DPA or EPO codes may appear on a claim.

The administration of this class of drugs should NOT be billed using any of the chemotherapy administration codes. Providers should use the appropriate therapeutic, prophylactic, and diagnostic injections and infusions code.

No payment can be made for drugs when self-administered or administered by a caregiver (except for drugs administered under the auspices of the ESRD program).

Diagnosis codes are based on the current ICD-9-CM codes that are effective at the time of LCD publication. Any updates to ICD-9-CM codes will be reviewed by NAS, and coverage should not be presumed until the results of such review have been published on the website.

Required Coding for Nationally Non-Covered Indications under the CMS National Coverage Determination for ESAs (NCD 110.21). (Each of the following conditions will cause the claim to deny as not reasonable and necessary under Medicare's ESA NCD.)

Providers must code the presence of any of the following conditions: Anemia in cancer or cancer treatment patients due to folate deficiency (diagnosis 281.2), B₁₂ deficiency (281.1 or 281.3), iron deficiency (280.0-280.9), hemolysis (282.0, 282.2, 282.9, 283.0, 283.10, 283.19, 283.2, or 283.9), or bleeding (280.0 or 285.1).

For any of the following conditions, use the code listed immediately below this list:

- Anemia of cancer not related to cancer treatment;

- Prophylactic use to prevent chemotherapy-induced anemia;
- Prophylactic use to reduce tumor hypoxia;
- Erythropoietin-type resistance due to neutralizing antibodies;
- Anemia due to cancer treatment in a patient with uncontrolled hypertension.

Use code:

ICD-9-CM CODE	DESCRIPTION
V49.89	OTHER SPECIFIED CONDITIONS INFLUENCING HEALTH STATUS

Because the NCD AND ITS ASSOCIATED EDIT excludes ESA treatment where there is a **current** anemia resulting from one of these conditions, coding any of these anemia will result in a NCD denial of reimbursement for the ESA. The ICD-9-CM codes 281.0-281.9 should not appear on a claim for a patient receiving ESA therapy when these conditions do not underlie and/or not responsible for the **current** anemia.

In those patients who have a history of one of the above conditions but where the condition has been corrected and no longer the cause of the anemia, the following codes should be used if and when ongoing replacement therapy is required concurrently with ESA therapy.

- Iron deficiency due to ESA therapy alone. V58.69: Long-term (current) use of other medications may be used to describe a previous iron deficiency that developed in response to ESA therapy *alone* and remains corrected with ongoing iron replacement provided in addition to the ESA.

ICD-9-CM CODE	DESCRIPTION
V58.69	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS (OTHER HIGH- RISK MEDICATIONS)

- Other conditions requiring long-term replacement *after resolution* of initial anemia. When it is necessary to administer continuing supplements (e.g. folate or B₁₂), do **not** code this administration to an anemia diagnosis (281.0-281.9, which causes the ESA claim to deny); rather, code the underlying absorptive, bowel or other disorder or diagnosis that necessitates supplementation.

To describe the presence of any anemia of cancer or in cancer treatment patients that is due to bone marrow fibrosis, use one or more of the following three codes:

ICD-9-CM CODE	DESCRIPTION
238.76	MYELOFIBROSIS WITH MYELOID METAPLASIA (IDOPATHIC, PRIMARY)
289.83	MYELOFIBROSIS

To describe the presence of an anemia associated *with the treatment* of any of the following conditions:

- Acute myelogenous leukemias (AML)

- Chronic myelogenous leukemias (CML)
- Erythroid cancers

Use any one or more of the following codes:

ICD-9-CM CODE	DESCRIPTION
205.00- 205.22 205.80- 205.92	MYELOID LEUKEMIAS
207.00- 207.82	ERYTHREMIA AND ERYTHROLEUKEMIA

To describe the presence of an anemia related to the administration of radiotherapy,
Use code:

ICD-9-CM CODE	DESCRIPTION
V58.0	RADIOTHERAPY
V67.1	FOLLOW-UP EXAMINATION, FOLLOWING RADIOTHERAPY

Required Coding for Nationally and Locally-Covered Indications under the CMS National Coverage Determination (NCD 110.21) and NAS Local Coverage Determination for ESAs:

The claim must document the correct drug code and both an anemia code and the code for the condition that underlies the anemia (or the qualifier V code).

For Both DPA (J0882) and EPO (Q4081, J0886*) (List I only)

List I. Covered ICD-9-CM codes for patients in the ESRD Program *and* on dialysis: For **J0882** (DPA) and **Q4081, J0886** (EPO) for anemia associated with chronic renal failure for the patient who is **in the ESRD program and on dialysis** (List I only):

ICD-9-CM CODE	DESCRIPTION
285.21	ANEMIA IN CHRONIC KIDNEY DISEASE (ANEMIA IN END-STAGE RENAL DISEASE)

plus

ICD-9-CM CODE	DESCRIPTION
585.6	END STAGE RENAL DISEASE

For Both DPA (J0881) and EPO (J0885), Lists II, III, IV & V

For **J0881** (DPA) or **J0885** (EPO) for anemia for either the patient who is **not in the ESRD program** or for the patient who is **in the ESRD program but not currently on dialysis**: [NOTE: The HCPCS codes J0881 (DPA) and J0885 (EPO) have text in

parenthesis saying “for non ESRD use”. Nonetheless, these ARE the codes CMS intends be used for a patient in the ESRD program but not on dialysis.]

List II. Covered ICD-9-CM codes for chronic renal failure patients not in the ESRD Program OR in the ESRD program but not currently on dialysis:

ICD-9-CM CODE	DESCRIPTION
285.21	ANEMIA IN CHRONIC KIDNEY DISEASE (ANEMIA IN END-STAGE RENAL DISEASE)

plus one of the following codes that indicate the presence of chronic renal failure:

ICD-9-CM CODE	DESCRIPTION
403.01	HYPERTENSIVE CHRONIC KIDNEY DISEASE, MALIGNANT, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
403.11	HYPERTENSIVE CHRONIC KIDNEY DISEASE, BENIGN, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
403.91	HYPERTENSIVE CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.02	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, MALIGNANT, WITHOUT HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.03	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, MALIGNANT, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.12	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITHOUT HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.13	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITH HEART FAILURE AND CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.92	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITHOUT HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.93	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH HEART FAILURE AND CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
585.3	CHRONIC KIDNEY DISEASE, STAGE III (MODERATE)
585.4	CHRONIC KIDNEY DISEASE, STAGE IV (SEVERE)
585.5	CHRONIC KIDNEY DISEASE, STAGE V
585.6	END STAGE RENAL DISEASE
585.9*	CHRONIC KIDNEY DISEASE, UNSPECIFIED
V42.0	ORGAN OR TISSUE REPLACED BY TRANSPLANT, KIDNEY

* The use of the ICD-9-CM code 585.9 is permitted *only* where the chronic “renal failure” is sufficient to meet the criteria of one of the codes: 585.3, 585.4, 585.5 or 585.6. This code is *not* to be used if the “renal failure” is not chronic and/or only meets criteria for 585.1 or 585.2.

List III. Covered ICD-9-CM codes for anemia associated with chemotherapeutic medications when used to treat a cancer diagnoses:

ICD-9-CM CODE	DESCRIPTION
285.3	ANTI-NEOPLASTIC CHEMOTHERAPY-INDUCED ANEMIA

plus one of the following:

ICD-9-CM CODE	DESCRIPTION
V67.2	FOLLOW-UP EXAMINATION, FOLLOWING CHEMOTHERAPY
V58.11	ENCOUNTER FOR ANTINEOPLASTIC CHEMOTHERAPY

List IV. Covered ICD-9-CM codes for anemia associated with chemotherapeutic medications when used to treat a *non*-cancer diagnosis OR temporary erythropoietin-suppression related to stem cell transplantation preparation:

ICD-9-CM CODE	DESCRIPTION
285.3	ANTI-NEOPLASTIC CHEMOTHERAPY-INDUCED ANEMIA

plus

ICD-9-CM CODE	DESCRIPTION
V58.69*	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS (OTHER HIGH- RISK MEDICATIONS)

* The *only* circumstance in which ICD-9-CM code V58.69 is to be billed for either J0881 or J0885 are: a) "Long-term (current) use" is either of an immunosuppressant following stem cell transplantation or of a medication otherwise usable as and recognized as a "chemotherapy" but used in this circumstance for a diagnosis other than a malignancy and b) Iron deficiency solely due to ESA therapy.

Chemotherapeutic Drugs that May Cause a “Chemotherapy-Induced Anemia”

The National Coverage Determination (NCD) on Erythropoiesis Stimulating Agents (ESAs) describes the conditions for which ESAs may be covered for “chemotherapy-induced anemia”. Whenever payment is sought for ESA treatment chemotherapy-induced anemia, the medical record must document the physician’s rationale for the determining that the anemia is “chemotherapy-induced”.

“Chemotherapy drugs” **include** those listed in the Healthcare Common Procedure Coding System (HCPCS, Medicare’s National Level II Codes) in the section “Chemotherapy Drugs J9000-J9999”- when used as anti-neoplastics.

Additionally, *for the purposes of the NCD on Erythropoiesis Stimulating Agents*, when used as anti-neoplastics the following drugs may be considered a “chemotherapeutic” that may cause a “chemotherapy-induced anemia”, including those used orally:

- capecitabine (Xeloda®)
- chlorambucil (Leukeran®)
- * cyclophosphamide (Cytosan®)
- decitabine (Dacogen®)
- erlotinib (Tarceva®)
- hydroxyurea (Hydrea®)
- imatinib mesylate (Gleevec®)
- lenalidomide (Revlimid®)
- lomustine (CeeNu®)
- * melphalan (Alkeran®)
- * methotrexate (several)
- sorafenib (Nexavar®)
- sunitinib malate (Sutent®)
- temozolomide (Temodar®)
- thalidomide (Thalomid®)

*Chemotherapy administration codes may be used with these drugs if, and only when, administered parenterally as an antineoplastic agent.

Any and all other drugs, not listed in the HCPCS Manual Chemotherapy section or in the list above, are **not** considered to be “chemotherapy” potentially able to cause a “chemotherapy-induced anemia”.

List V: Covered ICD-9-CM codes for anemia associated with myelodysplastic syndrome (MDS): Note this is a covered indication for DPA **only** in patients **whose medical records clearly document a clinical need to administer DPA rather than EPO.**

ICD-9-CM CODE	DESCRIPTION
285.29	ANEMIA OF OTHER CHRONIC ILLNESS

plus one of the following:

ICD-9-CM CODE	DESCRIPTION
238.72	LOW GRADE MYELODYSPLASTIC SYNDROME LESIONS (MDS)
238.74	MYLODYSPLASTIC SYNDROME (MDS) WITH 5Q DELETION
238.75	MYLODYSPLASTIC SYNDROME (MDS), UNSPECIFIED

For EPO ONLY (Lists VI, VII, VIII):

Additional covered indications for J0885 (EPO) alone, i.e., **not** covered indications for DPA):

List VI: Covered ICD-9-CM codes for anemic patients with HIV on zidovudine (AZT), EPO only:

ICD-9-CM CODE	DESCRIPTION
285.9	ANEMIA UNSPECIFIED (SECONDARY)

plus

ICD-9-CM CODE	DESCRIPTION
042	HUMAN IMMUNODEFICIENCY VIRUS [HIV] DISEASE

List VII: Covered ICD-9-CM codes for chronically anemic preoperative patients undergoing elective hip or knee surgery, EPO only:

One of the following anemia codes:

ICD-9-CM CODE	DESCRIPTION
284.81	RED CELL APLASTIC ANEMIA (ACQUIRED) (ADULT) (WITH THYMOMA)
284.89	OTHER SPECIFIED APLASTIC ANEMIAS
284.9	APLASTIC ANEMIAS, UNSPECIFIED
285.21	ANEMIA IN CHRONIC KIDNEY DISEASE
285.22	ANEMIA IN NEOPLASTIC DISEASE
285.29	ANEMIA OF OTHER CHRONIC DISEASE
285.3	ANTINEOPLASTIC CHEMOTHERAPY INDUCED ANEMIA
285.8	OTHER SPECIFIED ANEMIA
285.9	UNSPECIFIED ANEMIA (SECONDARY)

Plus

ICD-9-CM CODE	DESCRIPTION
V07.8*	OTHER SPECIFIED PROPHYLACTIC OR TREATMENT MEASURE

*The only circumstance in which ICD-9-CM code V07.8 is to be billed for J0885 occurs when all seven criteria for this indication are met. Refer to LCD.

List VIII. Covered ICD-9-CM codes for the severe anemia due to specific chronic diseases:

ICD-9-CM CODE	DESCRIPTION
285.29	ANEMIA OF OTHER CHRONIC DISEASE

plus any of the following ICD-9-CM codes:

ICD-9-CM CODE	DESCRIPTION
070.41	ACUTE HEPATITIS C WITH HEPATIC COMA

070.44	CHRONIC HEPATITIS C WITH HEPATIC COMA
070.51	ACUTE HEPATITIS C WITHOUT MENTION OF HEPATIC COMA
070.54	CHRONIC HEPATITIS C WITHOUT MENTION OF HEPATIC COMA
070.70	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
070.71	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA
555.0	REGIONAL ENTERITIS OF THE SMALL INTESTINE
555.1	REGIONAL ENTERITIS OF THE LARGE INTESTINE
555.2	REGIONAL ENTERITIS OF THE SMALL INTESTINE WITH LARGE INTESTINE
555.9	REGIONAL ENTERITIS OF UNSPECIFIED SITE
556.0	ULCERATIVE (CHRONIC) ENTEROCOLITIS
556.1	ULCERATIVE (CHRONIC) ILEOCOLITIS
556.2	ULCERATIVE (CHRONIC) PROCTITIS
556.3	ULCERATIVE (CHRONIC) PROCTOSIGMOIDITIS
556.4	PSEUDOPOLYPOSIS OF COLON
556.5	LEFT-SIDED ULCERATIVE (CHRONIC) COLITIS
556.6	UNIVERSAL ULCERATIVE (CHRONIC) COLITIS
556.8	OTHER ULCERATIVE COLITIS
556.9	ULCERATIVE COLITIS, UNSPECIFIED
695.4	LUPUS ERYTHEMATOSUS
710.0	SYSTEMIC LUPUS ERYTHEMATOSUS
714.0	RHEUMATOID ARTHRITIS
714.1	FELTY'S SYNDROME
714.2	OTHER RHEUMATOID ARTHRITIS WITH VISCERAL OR SYSTEMIC INVOLVEMENT
714.4	CHRONIC POSTRHEUMATIC ARTHROPATHY
714.81	RHEUMATOID LUNG
714.89	OTHER SPECIFIED INFLAMMATORY POLYARTHROPATHIES
714.9	UNSPECIFIED INFLAMMATORY POLYARTHROPATHY

**Reference: Medicare National Coverage Manual, chapt. 1 Parts 2 § 110.21
CR5699, Transmittal 1412, released January 11, 2008
CR5818, Transmittals R80NCD and R1413CP, released January 14, 2008**