MASSACHUSETTS

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Pharmacy Medical Policy

Erythropoietin, Recombinant Human

Table of Contents

Policy Number: 262

BCBSA Reference Number: 5.01.04

Related Policies

- Quality Care Dosing guidelines may apply to the following medications and can be found in Medical Policy #621
- Interferential Current Stimulation #509
- Temporomandibular Joint Dysfunction #035
- Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy #172

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PA which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com. Patients must have pharmacy benefits under their subscriber certificates.

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

NOTE: Hemoglobin (Hb) levels must be actual lab values from within the previous seven days, not target levels. For medications dispensed under the retail pharmacy benefit, current hemoglobin levels will be required upon request by the specialty pharmacy prior to each dispense.

Standard Formulary	
Drug	**Formulary Status**
Aranesp®*^ (darbepoetin alfa)	Not Covered
Epogen®*^ (erythropoietin)	Not Covered
Procrit®*^ (erythropoietin)	PA Required

Retacrit™ (epoetin alfa-epbx)	PA Required

***^ - This Drug is part of Medications covered only under the pharmacy benefit only program. This program does not apply when the medication is administered: in the emergency room, as an inpatient, at a surgical day care facility, in an ambulatory surgery-center, or through home infusion therapy or dialysis.**

We may cover **Procrit**® (erythropoietin) or **Retacrit** (epoetin alfa-epbx) for the following indications:
We may also cover **Epogen**® (erythropoietin) with treatment failure of **Procrit**® (erythropoietin) or **Retacrit** (epoetin alfa-epbx) for the following indications also:

- Anemia of chronic renal failure[6] defined as GFR ≤ 60 mL/min/1.73m2 for at least 3 months or patients on dialysis[16]
  - Initiation: Approve x 6 months if Hb ≤ 11.0 g/dL
  - Continuation: Approve x 6 months if Hb ≤ 12.0 g/dL
- Anemia due to AZT treatment in AIDS2[17]
  - Initiation: Approve x 6 months if Hb ≤ 10.0 g/dL or endogenous erythropoietin levels ≤ 500mUnits/mL
  - Continuation: Approve x 6 months if Hb ≤ 12.0g/dL
- Anemia due to Ribavirin therapy in the treatment of Hepatitis C[9,10,11, 25]
  - Initiation: Approve x 6 months if Hb ≤ 10.0 g/dL
  - Continuation: Approve x 6 months is Hb ≤ 12.0g/dL
- Myelodysplastic syndromes1 confirmed by bone marrow biopsy and/or aspirate[23]
  - Initiation: Approve x 6 months if Hb ≤ 12.0 g/dL
  - Continuation: Approve x 6 months if Hb ≤ 12.0 g/dL
- Anemia due to the effects of concurrently-administered chemotherapy in patients with non-myeloid malignancies[2,4,18,19]
  - Initiation: Approve x 6 months if Hb ≤ 10.0 g/dL OR Hb > 10.0 g/dL but ≤12 g/dL and the physician anticipates a Hb decrease OR the patient has comorbidities that require higher Hb levels
  - Continuation: Approve x 6 months if Hb ≤ 12.0 g/dL
- Anemia following allogeneic bone marrow transplant[1,4]
  - Initiation: Approve x 6 months if Hb ≤ 10.0 g/dL
  - Continuation: Approve x 6 months is Hb ≤ 12.0g/dL
- Anemic surgical patients who meet **ALL** the following:[2]
  - The surgery is elective, non-cardiac, and non-vascular
  - Hemoglobin levels are between 10 and 13 g/dL
  - Not willing to donate blood
  - Approve x 1 month of therapy

We may cover **Aranesp**® (Darbepoetin alpha) with treatment failure of **Procrit**® (erythropoietin) or **Retacrit** (epoetin alfa-epbx) and for the following anemias only:

- Anemia associated with chronic renal failure[7,15] defined as GFR ≤ 60 mL/min/1.73m2 for at least 3 months or patients on dialysis
  - Initiation: Approve x 6 months if Hb ≤ 11.0 g/dL
  - Continuation: Approve x 6 months if Hb ≤ 12.0 g/dL
- Anemia due to the effects of concurrently-administered chemotherapy in patients with non-myeloid malignancies:[8,18,19]
  - Initiation: Approve x 6 months if Hb ≤ 10.0 g/dL OR Hb > 10.0 g/dL but ≤12 g/dL and the physician anticipates a Hb decrease OR the patient has comorbidities that require higher Hb levels
  - Continuation: Approve x 6 months if Hb ≤ 12.0 g/dL

We may cover Peginesatide with treatment failure of **Procrit**® (erythropoietin) or **Retacrit** (epoetin alfa-epbx) and to treat the following anemias only[26]:

- Anemia associated with chronic kidney disease (CKD) in adult patients (18 years or older) receiving Dialysis
  - Initiation: Approve x 6 months if Hb ≤ 10.0 g/dL
  - Continuation: Approve x 6 months if Hb < 11.0 g/dL

We do not cover Epoetin alpha or Darbepoetin alpha to treat other anemias, including the following, because there is inadequate published evidence to show that health outcomes (such as decreased need for transfusions) are improved:

- Anemia due to hemolysis, nutritional deficiencies, GI bleeds, and other problems[2]
- Iron deficiency anemia: It is known that patients with iron deficiency do not respond as well to epoetin alpha or darepoetin alpha, therefore these drugs are not covered for patients whose transferrin saturation is less than 20%.[2]
- Anemia due to cancer in patients not receiving cancer chemotherapy

Other Information

Blue Cross Blue Shield of Massachusetts (BCBSMA*) members (other than Medex®; Blue MedicareRx, Medicare Advantage plans that include prescription drug coverage) will be required to fill their prescriptions for the above medications at one of the providers in our retail specialty pharmacy network, as listed below:

Retail Specialty Pharmacy Contact Information:
AcariaHealth. Phone:1-866-892-1202 Fax: 1-866-892-3223 Website: www.acariahealth.com
Accredo Health Group Phone: 1-877-988-0058 Fax: 1-866-489-1907 Website: www.accredo.com
AllCare Plus Pharmacy Phone: 1-855-880-1091 Fax: 1-844-265-0265 Website: www.allcarepluspharmacy.com
Caremark, Inc. Phone: 1-866-846-3096 Fax: 1-800-323-2445 Website: www.caremark.com
Onco360, the Oncology Pharmacy Phone: 1-877-662-6633 Fax: 1-877-662-6355 Website: www.onco360.com
AllianceRx Walgreens Prime Phone: 1-800-649-2872 Fax: 1-866-935-0719 Website: https://alliancerxwp.com

Clinical trials for Cancer Mandate

As required by law, we provide coverage for services and supplies received as part of a qualified clinical trial (for treatment of cancer) when the member is enrolled in that trial. This coverage is provided for services and supplies that are consistent with the study protocol and with the standard of care for someone with the patients' diagnosis, and that would be covered if the patient did not participate in the trials. This coverage may also be provided for investigational drugs and devices that have been approved for use as part of the trial. Coverage for services and supplies that are received as part of a qualified clinical trial is provided to the same extent as it would have been provided if the patient did not participate in the trial.

However, no coverage is provided for:

- Investigational drugs and devices that have not been approved for use in the trial.
- Investigational drugs and devices that are paid for by the manufacturer, distributor or provider of the drug or device, whether or not the drug or device has been approved for use in the trial.
- Non-covered services under the member's contract.
- Costs associated with managing the research for the trial.
- Items, services or costs that are reimbursed or otherwise furnished by the sponsor of the trial.
- Costs of services that are inconsistent with widely accepted and established national and regional standards of care.
- Costs of clinical trials that are not "qualified trials."

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Managed Care Authorization Instructions

- Prior authorization is required for all out patient sites of service
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
  Pharmacy Operations: (800)366-7778
- For all outpatient sites of service requesting retail pharmacy exceptions, physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- For all outpatient sites of service requesting retail pharmacy exceptions, physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com

PPO and Indemnity Authorization Instructions

- Prior authorization **is** required when these medications are processed under the retail pharmacy benefit and home infusion therapy benefit.
- Prior authorization **is not** required when drugs are not part of Pharmacy benefits only program and are purchased by the physician and administered in the office in accordance with this medical policy.
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
  Pharmacy Operations: (800)366-7778

- Physicians may also fax or mail the attached form for retail pharmacy exceptions to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patient.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com

CPT Codes / HCPCS Codes / ICD Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

HCPCS Codes

HCPCS codes:	Code Description
J0881	Injection, darbepoetin alfa, 1 mcg (non-ESRD use) [Arenesp]
J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis) [Arenesp]
J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units [Epogen, Procrit]
J0886	Injection, epoetin alfa, 1000 units (for ESRD on dialysis) [Epogen, Procrit]
J0890	Injection, peginesatide, 0.1 mg (for ESRD on dialysis) [Omontys]
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis) [Epogen, Procrit]

Effective 7/1/08:
One of the following modifier codes must accompany the drug HCPCS code on the CMS 1500 form in order for the claim to adjudicate.
ED - 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.
EE – Hematocrit level has not exceeded 39% (or hemoglobin level has not exceeded 13.0 g/dL) for 3 or more consecutive billing cycle immediately prior to and including the current cycle.
**PLEASE NOTE: These coding modifiers do not apply to the Federal Employee Program (FEP), the BlueCard® Program (BCBSBMA members), or to plans in which Medicare is the primary insurer (e.g. Medicare Advantage, Medex®, or Managed Blue for Seniors™).

For end stage renal disease (ESRD) patients only:

- The initial claim **must** contain the fo**l**lowing information:
  - patient's diagnosis
  - most recent creatinine prior to starting on erythropoietin
  - most recent hematocrit prior to starting on erythropoietin
  - most recent transferrin saturation
  - dosage in units/kilograms
  - patients weight in kilograms
  - number of units of erythropoietin administered
  - Subsequent claims **must** contain:
    - patient's diagnosis
    - hematocrit
    - number of units administered

- We do not separately reimburse the administration of the drug () when done in conjunction with an office visit.

ICD-10 Diagnosis Codes

ICD-10-CM diagnosis codes:	Code Description
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.Z	Other myelodysplastic syndromes
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D61.9	Aplastic anemia, unspecified
D63.0	Anemia in neoplastic disease
D63.1	Anemia in chronic kidney disease
D63.8	Anemia in other chronic diseases classified elsewhere
D64.4	Congenital dyserythropoietic anemia
D64.81	Anemia due to antineoplastic chemotherapy
D64.89	Other specified anemias
D64.9	Anemia, unspecified
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
N18.6	End stage renal disease
N18.9	Chronic kidney disease, unspecified

Policy History

Date	Action
11/2018	BCBSA National medical policy review. No changes to policy statements. New references added.
11/2018	Updated to co-prefer Retacrit & Procrit.
7/2018	Updated to include new to market Retacrit.
10/2017	Updated to change Walgreens Specialty Name.
7/2017	Updated to add AllCare to Pharmacy Specialty list.
6/2017	Updated address for Pharmacy Operations.
5/2017	Updated to clarify Epoetin alpha criteria.
1/2016	Updated to add NC designation to Epogen & Aranesp.
8/2015	Updated to add Pharmacy Benefit only Program designation.
7/2015	Updated to add Walgreens Specialty.

7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
2/2014	Updated Onco360 name and removed Curascript in Specialty Pharmacy section.
1/2014	Updated ExpressPAth Language and removed Blue Value.
1/2013	Updated 1/2013 to include coverage criteria for new FDA approved medication Omontys®.
4/2012	Updated with specialty pharmacy contact information.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
1/2011	Updated to define diagnosis criteria, authorization timeframes and hemoglobin level requirements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
9/2010	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
4/2010	Updated to include updated Specialty Retail Pharmacy contact and 4/1/2010 transition information.
11/2009	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
9/2009	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
10/2009	Updated to remove Medicare Part D criteria and update UM requirements.
8/7/2009	Updated to add Q code for epoetin alpha on dialysis as requested, formatting updated.
11/2008	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
11/2008	Updated to clarify claim submission requirements and update of ICD-9 code.
10/2008	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
7/2008	Updated to include applicable ICD-9 diagnosis codes, addition of specialty pharmacy vendor OTN Specialty Services and to include modifier codes for physician billing submission.
9/2007	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
6/2007	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
6/2007	Updated to include retail pharmacy specialty network information, addition of criteria for target hemoglobin ≤ 12 g/dL and removal of “anemia due to cancer” as a covered diagnosis based upon.
10/1989	New policy, issued 10/1989, describing covered and non-covered indications.

References

1. Food and Drug Administration (FDA) ODAC. FDA Briefing Document: Continuing reassessment of the risks of erythropoiesis-stimulating agents (ESAs) administered for the treatment of anemia associated with cancer chemotherapy. 2007; https://wayback.archive-it.org/7993/20170405053529/https://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4301b2-02-FDA.pdf. Accessed September 29, 2018.

2. Food and Drug Administration (FDA). Postmarket Drug Safety Information for Patients and Providers: Information on Erythropoiesis-Stimulating Agents (ESA) Epoetin alfa (marketed as Procrit, Epogen), Darbepoetin alfa (marketed as Aranesp). 2017; https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm109375.htm. Accessed September 29, 2018.
3. Hoffmann-LaRoche. Highlights of Prescribing Information: Mircera® (methoxy polyethylene glycol-epoetin beta). 2014; https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125164s062lbledt.pdf. Accessed September 29, 2018.
4. Amgen. Highlights of Prescribing Information: Aranesp® (darbepoetin alfa). 2018; https://pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/aranesp/ckd/aranesp_pi_hcp_english.ashx. Accessed September 29, 2018.
5. Amgen. Highlights of Prescribing Information: Epogen® (epoetin alfa). 2018; https://pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/epogen/epogen_pi_hcp_english.ashx. Accessed September 29, 2018.
6. Janssen. Highlights of Prescribing Information: Procrit® (epoetin alfa). 2018; http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PROCRIT-pi.pdf. Accessed September 29, 2018.
7. Seidenfeld J, Piper M, Bohlius J, et al. *Comparative Effectiveness of Epoetin and Darbepoetin for Managing Anemia in Patients Undergoing Cancer Treatment (Comparative Effectiveness Review No. 3).* Rockville, MD: Agency for Healthcare Research and Quality; 2006.
8. Bohlius J, Wilson J, Seidenfeld J, et al. Recombinant human erythropoietins and cancer patients: updated meta-analysis of 57 studies including 9353 patients. *J Natl Cancer Inst.* May 17 2006;98(10):708-714. PMID 16705125
9. Grant MD, Piper M, Bohlius J, et al. *Epoetin and Darbepoetin for Managing Anemia in Patients Undergoing Cancer Treatment: Comparative Effectiveness Update (Comparative Effectiveness Review No. 113).* Rockville, MD: Agency for Healthcare Research and Quality; 2013.
10. Bohlius J, Schmidlin K, Brillant C, et al. Erythropoietin or Darbepoetin for patients with cancer--meta-analysis based on individual patient data. *Cochrane Database Syst Rev.* Jul 08 2009(3):CD007303. PMID 19588423
11. Bohlius J, Schmidlin K, Brillant C, et al. Recombinant human erythropoiesis-stimulating agents and mortality in patients with cancer: a meta-analysis of randomised trials. *Lancet.* May 2 2009;373(9674):1532-1542. PMID 19410717
12. Tonia T, Mettler A, Robert N, et al. Erythropoietin or darbepoetin for patients with cancer. *Cochrane Database Syst Rev.* Dec 12 2012;12:CD003407. PMID 23235597
13. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Clinical Oncology/American Society of Hematology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. *J Clin Oncol.* Nov 20 2010;28(33):4996-5010. PMID 20975064
14. Centers for Medicare & Medicaid Services (CMS). Decision Memo for Erythropoiesis Stimulating Agents (ESAs) for non-renal disease indications (CAG-00383N). 2007; https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=203&ver=12&NcaName=Erythropoiesis+Stimulating+Agents+&bc=BEAAAAAIAAA. Accessed September 29, 2018.
15. Food and Drug Administration (FDA). FDA Advisory Committee Briefing Document: Joint meeting of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Committee. Reassessment of the risks of erythropoiesis-stimulating agents (ESAs) administered for the treatment of anemia associated with chronic renal failure. 2007; https://wayback.archive-it.org/7993/20170405051117/https://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4315b1-01-FDA.pdf. Accessed September 29, 2018.
16. Strippoli GF, Craig JC, Manno C, et al. Hemoglobin targets for the anemia of chronic kidney disease: a meta-analysis of randomized, controlled trials. *J Am Soc Nephrol.* Dec 2004;15(12):3154-3165. PMID 15579519
17. KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for anemia in chronic kidney disease: 2007 update of hemoglobin target. *Am J Kidney Dis.* Sep 2007;50(3):471-530. PMID 17720528

18. Besarab A, Bolton WK, Browne JK, et al. The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin. *N Engl J Med.* Aug 27 1998;339(9):584-590. PMID 9718377
19. Fishbane S, Besarab A. Mechanism of increased mortality risk with erythropoietin treatment to higher hemoglobin targets. *Clin J Am Soc Nephrol.* Nov 2007;2(6):1274-1282. PMID 17942772
20. Singh AK, Szczech L, Tang KL, et al. Correction of anemia with epoetin alfa in chronic kidney disease. *N Engl J Med.* Nov 16 2006;355(20):2085-2098. PMID 17108343
21. Inrig JK, Barnhart HX, Reddan D, et al. Effect of hemoglobin target on progression of kidney disease: a secondary analysis of the CHOIR (Correction of Hemoglobin and Outcomes in Renal Insufficiency) trial. *Am J Kidney Dis.* Sep 2012;60(3):390-401. PMID 22537421
22. Drueke TB, Locatelli F, Clyne N, et al. Normalization of hemoglobin level in patients with chronic kidney disease and anemia. *N Engl J Med.* Nov 16 2006;355(20):2071-2084. PMID 17108342
23. Pfeffer MA, Burdmann EA, Chen CY, et al. A trial of darbepoetin alfa in type 2 diabetes and chronic kidney disease. *N Engl J Med.* Nov 19 2009;361(21):2019-2032. PMID 19880844
24. Skali H, Parving HH, Parfrey PS, et al. Stroke in patients with type 2 diabetes mellitus, chronic kidney disease, and anemia treated with Darbepoetin Alfa: the trial to reduce cardiovascular events with Aranesp therapy (TREAT) experience. *Circulation.* Dec 20 2011;124(25):2903-2908. PMID 22104547
25. Amato L, Addis A, Saulle R, et al. Comparative efficacy and safety in ESA biosimilars vs. originators in adults with chronic kidney disease: a systematic review and meta-analysis. *J Nephrol.* Jun 2018;31(3):321-332. PMID 28646375
26. Roger SD, Tio M, Park HC, et al. Intravenous iron and erythropoiesis-stimulating agents in haemodialysis: A systematic review and meta-analysis. *Nephrology (Carlton).* Dec 2017;22(12):969-976. PMID 27699922
27. Cody JD, Hodson EM. Recombinant human erythropoietin versus placebo or no treatment for the anaemia of chronic kidney disease in people not requiring dialysis. *Cochrane Database Syst Rev.* Jan 20 2016(1):CD003266. PMID 26790135
28. Collister D, Komenda P, Hiebert B, et al. The effect of erythropoietin-stimulating agents on health-related quality of life in anemia of chronic kidney disease: a systematic review and meta-analysis. *Ann Intern Med.* Apr 05 2016;164(7):472-478. PMID 26881842
29. Palmer SC, Saglimbene V, Craig JC, et al. Darbepoetin for the anaemia of chronic kidney disease. *Cochrane Database Syst Rev.* Mar 31 2014;3(3):CD009297. PMID 24683046
30. Vinhas J, Barreto C, Assuncao J, et al. Treatment of anaemia with erythropoiesis-stimulating agents in patients with chronic kidney disease does not lower mortality and may increase cardiovascular risk: a meta-analysis. *Nephron Clin Pract.* Nov 2012;121(3-4):c95-101. PMID 23182871
31. Saglimbene V, Palmer SC, Craig JC, et al. Low versus high dose erythropoiesis-stimulating agents in hemodialysis patients with anemia: A randomized clinical trial. *PLoS One.* Mar 1 2017;12(3):e0172735. PMID 28249030
32. Walker RG, Strippoli GF. A pegylated epoetin in anaemia of renal disease: non-inferiority for an unvalidated surrogate. *Lancet.* Oct 20 2007;370(9596):1395-1396. PMID 17950848
33. Macdougall IC, Walker R, Provenzano R, et al. C.E.R.A. corrects anemia in patients with chronic kidney disease not on dialysis: results of a randomized clinical trial. *Clin J Am Soc Nephrol.* Mar 2008;3(2):337-347. PMID 18287255
34. Klinger M, Arias M, Vargemezis V, et al. Efficacy of intravenous methoxy polyethylene glycol-epoetin beta administered every 2 weeks compared with epoetin administered 3 times weekly in patients treated by hemodialysis or peritoneal dialysis: a randomized trial. *Am J Kidney Dis.* Dec 2007;50(6):989-1000. PMID 18037099
35. Canaud B, Mingardi G, Braun J, et al. Intravenous C.E.R.A. maintains stable haemoglobin levels in patients on dialysis previously treated with darbepoetin alfa: results from STRIATA, a randomized phase III study. *Nephrol Dial Transplant.* Nov 2008;23(11):3654-3661. PMID 18586762
36. Spinowitz B, Coyne DW, Lok CE, et al. C.E.R.A. maintains stable control of hemoglobin in patients with chronic kidney disease on dialysis when administered once every two weeks. *Am J Nephrol.* 2008;28(2):280-289. PMID 18004064
37. Levin NW, Fishbane S, Canedo FV, et al. 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.* Oct 20 2007;370(9596):1415-1421. PMID 17950856

38. Sulowicz W, Locatelli F, Ryckelynck JP, et al. 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.* Jul 2007;2(4):637-646. PMID 17699476
39. Oh J, Joo KW, Chin HJ, et al. Correction of anemia with continuous erythropoietin receptor activator in Korean patients on long-term hemodialysis. *J Korean Med Sci.* Jan 2014;29(1):76-83. PMID 24431909
40. Vankar SG, Dutta P, Kohli HS, et al. Efficacy & safety of continuous erythropoietin receptor activator (CERA) in treating renal anaemia in diabetic patients with chronic kidney disease not on dialysis. *Indian J Med Res.* Jan 2014;139(1):112-116. PMID 24604046
41. Roger SD, Locatelli F, Woitas RP, et al. C.E.R.A. once every 4 weeks corrects anaemia and maintains haemoglobin in patients with chronic kidney disease not on dialysis. *Nephrol Dial Transplant.* Dec 2011;26(12):3980-3986. PMID 21505096
42. Al-Ali FS, El-Sayed Abdelfattah M, Fawzy AA, et al. Erythropoietin-stimulating agents in the management of anemia of end-stage renal disease patients on regular hemodialysis: a prospective randomized comparative study from Qatar. *Hemodial Int.* Jan 2015;19(1):33-43. PMID 24894344
43. Hirai T, Nishizawa Y, Nakazono H, et al. Hemoglobin maintenance and dosing strategies using intravenous continuous erythropoietin receptor activator in Japanese hemodialysis patients. *Ther Apher Dial.* Oct 2013;17(5):498-503. PMID 24107278
44. Kessler M, Martinez-Castelao A, Siamopoulos KC, et al. C.E.R.A. once every 4 weeks in patients with chronic kidney disease not on dialysis: The ARCTOS extension study. *Hemodial Int.* Apr 2010;14(2):233-239. PMID 19888948
45. Hahn D, Cody JD, Hodson EM. Frequency of administration of erythropoiesis-stimulating agents for the anaemia of end-stage kidney disease in dialysis patients. *Cochrane Database Syst Rev.* May 28 2014;5(5):CD003895. PMID 24872328
46. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). *TEC Specialty Pharmacy Reports: Peginesatide: #6-2012.* Chicago, IL: Blue Cross and Blue Shield Association; 2012.
47. Wilhelm-Leen ER, Winkelmayer WC. Mortality risk of darbepoetin alfa versus epoetin alfa in patients with CKD: systematic review and meta-analysis. *Am J Kidney Dis.* Jul 2015;66(1):69-74. PMID 25636816
48. Palmer SC, Saglimbene V, Mavridis D, et al. Erythropoiesis-stimulating agents for anaemia in adults with chronic kidney disease: a network meta-analysis. *Cochrane Database Syst Rev.* Dec 08 2014;12(12):CD010590. PMID 25486075
49. Alsalimy N, Awaisu A. Methoxy polyethylene glycol-epoetin beta versus darbepoetin alfa for anemia in non-dialysis-dependent CKD: a systematic review. *Int J Clin Pharm.* Dec 2014;36(6):1115-1125. PMID 25288147
50. Mhaskar R, Wao H, Miladinovic B, et al. The role of iron in the management of chemotherapy-induced anemia in cancer patients receiving erythropoiesis-stimulating agents. *Cochrane Database Syst Rev.* Feb 04 2016;2:CD009624. PMID 26845108
51. Marchetti C, De Felice F, Palaia I, et al. Erythropoiesis-stimulating agents in gynecological malignancies: A study-level meta-analysis. *Crit Rev Oncol Hematol.* Mar 2016;99:123-128. PMID 26748593
52. Gao S, Ma JJ, Lu C. Venous thromboembolism risk and erythropoiesis-stimulating agents for the treatment of cancer-associated anemia: a meta-analysis. *Tumour Biol.* Jan 2014;35(1):603-613. PMID 23959477
53. Leyland-Jones B, Bondarenko I, Nemsadze G, et al. A randomized, open-label, multicenter, phase III study of epoetin alfa versus best standard of care in anemic patients with metastatic breast cancer receiving standard chemotherapy. *J Clin Oncol.* Apr 10 2016;34(11):1197-1207. PMID 26858335
54. Boccia RV, Henry DH, Belton L, et al. Efficacy and safety of darbepoetin alfa initiated at hemoglobin </=10 g/dL in patients with stage IV cancer and chemotherapy-induced anemia. *Cancer Med.* Dec 2016;5(12):3445-3453. PMID 27882724
55. Pirker R, Hedenus M, Vansteenkiste J, et al. ffectiveness of darbepoetin alfa for chemotherapy-induced anemia when initiated at hemoglobin </=10 g/dL. *Clin Ther.* Jan 01 2016;38(1):122-135.e126. PMID 26730453

56. Gascon P, Pirker R, Del Mastro L, et al. Effects of CERA (continuous erythropoietin receptor activator) in patients with advanced non-small-cell lung cancer (NSCLC) receiving chemotherapy: results of a phase II study. *Ann Oncol.* Oct 2010;21(10):2029-2039. PMID 20335369
57. Shiffman ML, Salvatore J, Hubbard S, et al. Treatment of chronic hepatitis C virus genotype 1 with peginterferon, ribavirin, and epoetin alpha. *Hepatology.* Aug 2007;46(2):371-379. PMID 17559152
58. Afdhal NH, Dieterich DT, Pockros PJ, et al. Epoetin alfa maintains ribavirin dose in HCV-infected patients: a prospective, double-blind, randomized controlled study. *Gastroenterology.* May 2004;126(5):1302-1311. PMID 15131791
59. Dieterich DT, Wasserman R, Brau N, et al. Once-weekly epoetin alfa improves anemia and facilitates maintenance of ribavirin dosing in hepatitis C virus-infected patients receiving ribavirin plus interferon alfa. *Am J Gastroenterol.* Nov 2003;98(11):2491-2499. PMID 14638354
60. Kliger AS, Foley RN, Goldfarb DS, et al. KDOQI US commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. *Am J Kidney Dis.* Nov 2013;62(5):849-859. PMID 23891356
61. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology: Cancer- and chemotherapy-induced anemia. Version 3.2018. https://www.nccn.org/professionals/physician_gls/pdf/anemia.pdf Accessed September 29, 2018.
62. Williams AW, Dwyer AC, Eddy AA, et al. Critical and honest conversations: the evidence behind the "Choosing Wisely" campaign recommendations by the American Society of Nephrology. *Clin J Am Soc Nephrol.* Oct 2012;7(10):1664-1672. PMID 22977214
63. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). 2007; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=322&ncdver=1&bc=AAAAgAAAAAAAAA%3d%3d&. Accessed September 29, 2018.

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