Clinical Policy: Epoetin Alfa (Epogen, Procrit), Epoetin Alfa-epbx (Retacrit)

Reference Number: MDN.CP.PHAR.237
Effective Date: 04.01.22
Last Review Date: 10.23.26 Coding Implications
Line of Business: Meridian IL Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Epoetin alfa (Epogen®, Procrit®) and its biosimilar, epoetin alfa-epbx (Retacrit™), are erythropoiesis-stimulating agents (ESAs).

FDA Approved Indication(s)

Epogen, Procrit, and Retacrit are indicated for:

- Treatment of anemia due to:
  - Chronic kidney disease (CKD) in patients on dialysis and not on dialysis.
  - Zidovudine in patients with HIV-infection.
  - The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
- Reduction of allogeneic red blood cell (RBC) transfusions in patients undergoing elective, noncardiac, nonvascular surgery.

Limitation(s) of use:

- Epogen, Procrit, and Retacrit have not been shown to improve quality of life, fatigue, or patient well-being.
- Epogen, Procrit, and Retacrit are not indicated for use:
  - In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
  - In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.
  - In patients scheduled for surgery who are willing to donate autologous blood.
  - In patients undergoing cardiac or vascular surgery.
  - As a substitute for RBC transfusions in patients who require immediate correction of anemia.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Epogen, Procrit, and Retacrit are **medically necessary** when the following criteria are met:

Initial Approval Criteria

A. Anemia due to Chronic Kidney Disease (must meet all)**:**

1. Diagnosis of anemia of CKD (dialysis and non-dialysis members);
2. Prescribed by or in consultation with a hematologist or nephrologist;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
4. Pretreatment hemoglobin level < 10 g/dL;
5. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

B. Anemia due to Zidovudine in HIV-infected Patients (must meet all)**:**

1. Diagnosis of zidovudine induced anemia;
2. Prescribed by or in consultation with a hematologist or HIV specialist;
3. Member is HIV-positive;
4. Dose of zidovudine is < 4,200 mg/week;
5. Endogenous serum erythropoietin levels < 500 mUnits/mL;
6. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
7. Pretreatment hemoglobin level < 10 g/dL;
8. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

C. Anemia due to Chemotherapy in Patients with Cancer (must meet all)**:**

1. Request is for use in solid or non-myeloid malignancies;
2. Member is receiving myelosuppressive chemotherapy without curative intent;
3. Prescribed by or in consultation with a hematologist or oncologist;
4. Age ≥ 5 years;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
6. Pretreatment hemoglobin < 10 g/dL;
7. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

D. Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery (must meet all)**:**

1. Member is at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery;
2. Perioperative hemoglobin > 10 to < 13 g/dL;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
4. Member is unwilling or unable to donate autologous blood pre-operatively;
5. Dose does not exceed one of the following (a or b):
   a. 300 Units/kg administered daily for a total of 15 doses (*see Appendix D for dose rounding guidelines*);

b. 600 Units/kg for a total of 4 doses (*see Appendix D for dose rounding guidelines*).

6. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 15 days (for 300 Units/kg daily) OR 21 days (for 600 Units/kg in 4 doses)

E. Anemia Associated with Myelodysplastic Syndromes (off-label) (must meet all)**:**

1. Diagnosis of anemia from myelodysplastic syndrome (MDS);
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Current (within the last 3 months) serum erythropoietin (EPO) ≤ 500 mU/mL;
   b. Member has lower risk (IPSS low/intermediate-1) disease associated with symptomatic anemia with del(5q);
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
6. Pretreatment hemoglobin < 10 g/dL;
7. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

F. Myelofibrosis-Associated Anemia (off-label) (must meet all)**:**

1. Diagnosis of anemia associated with myelofibrosis;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Current (within the last 3 months) serum EPO < 500 mU/mL;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
6. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

G. Other diagnoses/indications

1. Member meets one of the following (a, b, or c):
   a. Request is for Epogen or Procrit;
   b. If Retacrit, one of the following (i or ii):
      i. Member must use Epogen and Procrit, unless contraindicated or clinically significant adverse effects are experienced;
      ii. If Epogen and Procrit are unavailable due to shortage, member must use Retacrit, unless contraindicated or clinically significant adverse effects are experienced;
   c. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
2. Must meet one of the following (a or b):
   a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
      i. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
      ii. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
   b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Anemia due to Chronic Kidney Disease (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Current hemoglobin ≤ 12 g/dL;
4. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%.
5. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration: 6 months

B. Anemia due to Zidovudine in HIV-infected Patients (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member continues to receive zidovudine therapy
3. Current hemoglobin level is < 12 g/dL;
4. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin
5. level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%.

6. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

C. Anemia due to Chemotherapy in Patients with Cancer (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Continuation of ESA therapy is concurrent with myelosuppressive chemotherapy;
3. If member has received ≥ 8 weeks of ESA therapy, member meets both of the following (a and b):
   a. Documented response to therapy as evidenced by a rise in hemoglobin levels > 1 g/dL;
   b. No RBC transfusions are required;
4. Current hemoglobin < 10 g/dL;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%.
6. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

D. Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery
1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

E. Anemia Associated with Myelodysplastic Syndrome (off-label) (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. If member has received ≥ 8 weeks of ESA therapy, member meets one of the following (a or b):
   a. Documented response to therapy as evidenced by a rise in hemoglobin levels > 1.5 g/dL;
   b. Decrease of RBC transfusions requirement;
4. Current hemoglobin ≤ 12 g/dL;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%.
6. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

F. Myelofibrosis-Associated Anemia (off-label) (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. receiving medication via Centene benefit or member has previously met initial approval criteria;
3. Member is responding positively to therapy (examples may include, but are not limited to: for transfusion-independent members with a baseline hemoglobin < 10 g/dL, a ≥ 2 g/dL increase in hemoglobin; or for previously transfusion-dependent members, transitioning to become transfusion-independent);

4. Pretreatment hemoglobin < 12 g/dL;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%.
6. If Retacrit is requested, failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

G. Other diagnoses/indications (must meet 1 or 2)**:**

1. Member meets one of the following (a, b, or c):
   a. Request is for Epogen or Procrit;
   b. If Retacrit is requested, one of the following (i or ii):
      i. Member must use Epogen and Procrit, unless contraindicated or clinically significant adverse effects are experienced;
      ii. If Epogen and Procrit are unavailable due to shortage, member must use Epogen, unless contraindicated or clinically significant adverse effects are experienced;
   c. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
2. Member meets one of the following (a or b):
   a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
      i. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
      ii. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
   b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
ESA: erythropoiesis-stimulating agent
FDA: Food and Drug Administration
HIV: human immunodeficiency virus
RBC: red blood cell

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Uncontrolled hypertension
  - Pure red cell aplasia (PRCA) that begins after treatment with erythropoietin protein drugs
  - Allergic reactions
  - Use of the multiple-dose vials containing benzyl alcohol in neonates, infants, pregnant women, and lactating women
- Boxed warning(s): ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence

- *Appendix D: Dose Rounding Guidelines*

Weight-based Dose Range	Vial Quantity Recommendation
≤ 2,099.99 units	1 vial of 2,000 units
2,100 units-3,149.99 units	1 vial of 3,000 units
3,150 units-4,199.99 units	1 vial of 4,000 units
4,200 units-6,299.99 units	1 vial of 4,000 units and 1 vial of 2,000 units
6,300 units-7,349.99 units	1 vial of 4,000 units and 1 vial of 3,000 units
7,350 units-8,399.99 units	2 vials of 4,000 units
8,400 units-10,499 units	1 vial of 10,000 units
10,500 units-12,599.99 units	1 vial of 2,000 units and 1 vial of 10,000 units
12,600 units-13,649.99 units	1 vial of 3,000 units and 1 vial of 10,000 units
13,650 units-14,699.99 units	1 vial of 4,000 units and 1 vial of 10,000 units
14,700 units-16,799.99 units	1 vial of 2,000 units, 1 vial of 4,000 units and 1 vial of 10,000 units
16,800 units-17,849.99 units	1 vial of 3,000 units, 1 vial of 4,000 units and 1 vial of 10,000 units
17,849 units-18,899.99 units	2 vials of 4,000 units and 1 vial of 10,000 units
18,900 units-20,999 units	2 vials of 10,000 units

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose

Anemia due to CKD	Initial dose: 50 to 100 Units/kg 3 times weekly (adults) IV or SC and 50 Units/kg 3 times weekly (children on dialysis) IV or SC. Individualize maintenance dose. IV route recommended for patients on hemodialysis	Varies depending on indication and frequency of administration
Anemia due to zidovudine in HIV-infected patients	100 Units/kg IV or SC 3 times weekly	
Anemia due to chemotherapy	40,000 Units SC weekly *or* 150 Units/kg SC 3 times weekly (adults) until completion of a chemotherapy course; 600 Units/kg IV weekly (children ≥ 5 years) until completion of a chemotherapy course	
Reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery	300 Units/kg per day SC daily for 15 days total: administered daily for 10 days before surgery, on the day of surgery, and for 4 days after surgery or 600 Units/kg SC weekly in 4 doses administered 21, 14, and 7 days before surgery and on the day of surgery	
Anemia associated with MDS†	40,000-60,000 units SC one to two times weekly	
Anemia associated with myelofibrosis†	In a clinical trial, patients initially received erythropoietin 10,000 units SC 3 days per week. Erythropoietin was increased to 20,000 units 3 days per week if a response was not obtained after 2 months and erythropoietin	

Indication	Dosing Regimen	Maximum Dose
	was discontinued in patients who did not experience a response at 3 months.	

†*Off-label indication*

VI. Product Availability

Drug Name	Availability
Epoetin alfa (Epogen)	• Single-dose vial: 2,000 units/mL, 3,000 units/mL, 4,000 units/mL, and 10,000 units/mL • Multiple-dose vial containing benzyl alcohol: 20,000 units/2 mL and 20,000 units/mL
Epoetin alfa (Procrit)	• Single-dose vial: 2,000 units/mL, 3,000 units/mL, 4,000 units/mL, 10,000 units/mL, and 40,000 units/mL • Multiple-dose vial containing benzyl alcohol: 20,000 units/2 • mL and 20,000 units/mL
Epoetin alfa-epbx (Retacrit)	Single-dose vial: 2,000 units/mL, 3,000 units/mL, 4,000 units/mL, 10,000 units/mL, 40,000 units/mL • Multiple-dose vial containing benzyl alcohol: 20,000 units/2 mL and 20,000 units/mL

VII. References

1. Epogen Prescribing Information. Thousand Oaks, CA: Amgen Inc.; December 2024. Available at http://www.epogen.com/. Accessed January 9, 2025 .
2. Procrit Prescribing Information. Thousand Oaks, CA: Amgen Inc.; July April 2024. Available at http://www.procrit.com/. Accessed January 9, 2025.
3. Bohlius J, Bohlke K, Castelli R, et al. American Society of Hematology/American Society of Clinical Oncology clinical practice guideline update: Management of Cancer-Associated Anemia With Erythropoiesis-Stimulating Agents. J Clin Oncol 37:1336-1351. Available at: https://ascopubs.org/doi/pdf/10.1200/JCO.18.02142. Accessed January 9, 2024.
4. Mancino P, Falasca K, Ucciferri C, Pizzigallo E, Vecchiet J. Use of Hematopoietic Growth Factor in the Management of Hematological Side Effects Associated to Antiviral Treatment for Hcv Hepatitis. Mediterranean Journal of Hematology and Infectious Diseases. 2010;2(1):e2010003. doi:10.4084/MJHID.2010.003.
5. Afdhal NH, Dieterich DT, et al. Epoetin alfa maintains ribavirin dose in HCV-infected patients: a prospective, double-blind, randomized controlled study. Gastroenterology. 2004 May;126(5):1302-11.
6. Epoetin alfa. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 23, 2024.
7. Myelodysplastic Syndromes (Version 3.2023). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed January 23, 2024.
8. Myeloproliferative Neoplasms (Version 1.2024). In National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed January 23, 2024.
9. Hematopoietic Growth Factors (Version 1.2024). In National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed January 23, 2024.
10. Epoetin Alfa Drug Monograph. Clinical Pharmacology. Accessed January 23, 2024. http://www.clinicalpharmacology-ip.com.

11. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 23, 2024.
12. Retacrit Prescribing Information. Lake Forest, IL: Hospira, Inc., June 2020. Available at https://www.pfizerpro.com/product/retacrit/hcp. Accessed January 23, 2024.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)
J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted from CP.PHAR.237	04.01.22	04.22
2Q 2023 annual review: per NCCN for MDS continuation of therapy modified treatment response assessment to occur after at least 8 weeks of therapy (previously this was 12 weeks); per NCCN Compendium for MDS added approval pathway for lower risk (IPSS low/intermediate-1) disease associated with symptomatic anemia with del(5q); for cancer indications and other indications sections clarified redirection requirements to include an option for Retacrit requests where no redirection is required; for zidovudine induced anemia continuation of therapy added requirement to confirm member continues to receive zidovudine therapy; references reviewed and updated.	4.20.23	
2Q 2024 annual review: for anemia associated with myelofibrosis, added requirement that pretreatment hemoglobin < 10 g/dL for initial requests and current hemoglobin ≤ 12 g/dL for continuation requests; for anemia due to CKD, added requirement for continuation requests that current hemoglobin ≤ 12 g/dL; references reviewed and updated.	5.14.24	
2Q2025 Annual Review: no significant changes; references reviewed and updated.	4.24.25	
October 2026 Ad Hoc review: no changes.	10.23.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please

refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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