Department:	Pharmacy Management	**Original Approval:**	01/09/2017
Policy #:	PM140	**Last Approval:**	03/08/2019
Title:	Darbepoetin alfa (Aranesp®) injection		
Approved By:	UM Pharmacy Subcommittee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Darbepoetin alfa: History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Labs/Diagnostics -Medication list (current and past) -Dosing and duration requested -Weight -Initial/Extended approval -Age -Prescribed by or in consultation with a hematologist, oncologist or specialist, when indicated.

BACKGROUND

Aranesp is an erythroid stimulating agent (ESA) that is approved for the following indications:[1]

1) Treatment of anemia with chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.
2) Treatment of anemia due to the effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Aranesp is available as single-dose vials and as single-dose prefilled syringes (SingleJect®) in various strengths and package sizes.

Limitations of Use
Aranesp has not been shown to improve quality of life, fatigue, or patient well-being.[1]

Aranesp is not indicated for use[1]:

- 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.
- As a substitute for RBC transfusions in patients who require immediate correction of anemia.

INDICATIONS/CRITERIA

Medicaid Members	Aranesp is the preferred Darbepoetin alfa on the WA HCA Single Preferred Drug list. Other products are not considered for approval unless member has tried and failed the preferred product (Aranesp). ***Continue to criteria for approval below.***
Medicare Members	***Step-utilization of Part D drugs not required.***

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Aranesp is recommended in those who meet one of the following criteria.

Food and Drug Administration (FDA)-Approved Indications

1. **Anemia in Patients with Chronic Kidney Disease (CKD) who are on Dialysis.**
   Criteria. *The patient must meet the following criteria (A AND B)*:
   - **A)** For initial therapy, hemoglobin (Hb) is < 10.0 g/dL for adults and ≤ 11.0 g/dL for children; OR For patients currently receiving Aranesp, epoetin alfa, or Mircera (methoxy polyethylene glycol-epoetin beta injection for intravenous or subcutaneous use), Hb is ≤ 11.5 g/dL for adults and ≤ 12.0 g/dL for children; AND
   - **B)** The patient is currently receiving iron therapy or iron stores are adequate (e.g., Aranesp prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%).

Aranesp is indicated for the treatment of anemia associated with CKD, including patients on dialysis.[1] The prescribing information for Aranesp recommends that therapy should be initiated for adult patients with CKD on dialysis when the Hb is < 10.0 g/dL and if the Hb level approaches or exceeds 11.0 g/dL, reduce or interrupt the Aranesp dose. For pediatric patients with CKD, initiate Aranesp when the Hb < 10.0 g/dL and if the Hb level approaches 12.0 g/dL, reduce or interrupt the dose of Aranesp.[1] Additional longer-term data in children using Aranesp for CKD are available.[2] The Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines for anemia in CKD, published in 2012, state that for adults with CKD on dialysis ESA therapy should be used to avoid having the Hb concentration fall below 9.0 g/dL by initiating ESA therapy when the Hb is between 9.0 to 10.0 g/dL.[3] In general, ESAs should not be used to maintain Hb concentrations above 11.5 g/dL in adult patients with CKD. For pediatric patients with CKD, the Hb concentration in which ESAs should be initiated in the individual patient should be considered with awareness of the potential benefits and potential harms. In all pediatric patients with CKD receiving ESA therapy the selected Hb concentration should be in the range of 11.0 to 12.0 g/dL. For adult patients with CKD on ESA therapy who are not receiving iron supplementation, a trial of intravenous iron (or oral iron therapy in patients with CKD not on dialysis) is recommended when transferrin saturation is < 30% and ferritin is ≤ 500 mcg/L. For all pediatric patients with CKD receiving ESA therapy who are not receiving iron supplementation, oral iron (or intravenous iron in patients with CKD who are on dialysis) should be administered to maintain transferrin saturation > 20% and ferritin > 100 mcg/L. During the initiation of ESA therapy, KDIGO guidelines recommend to measure Hb concentrations at least monthly. During the maintenance phase of ESA therapy for patients with CKD on dialysis, measure Hb concentrations at least monthly. KDIGO recommends to evaluate iron status

(transferrin saturation and ferritin) at least every 3 months during ESA therapy, including the decision to start or continue iron therapy. [3]

Dosing in Patients with CKD who are on Dialysis. *Dosing must meet the following (A OR B):*

A) For adults or children, initiate therapy at 0.45 mcg/kg subcutaneously (SC) or intravenously (IV) as a single injection once weekly; OR

B) For adults, initiate therapy at 0.75 mcg/kg SC or IV once every 2 weeks.

Note: The IV route is recommended for patients on hemodialysis. For adult and pediatric patients receiving epoetin alfa ≥ 1,500 units once weekly, doses for conversion from epoetin alfa to Aranesp are available in the prescribing information. If the Hb approaches or exceeds 11.5 g/dL for adults or 12.0 g/dL for children, reduce or interrupt the Aranesp dose. Refer to the prescribing information insert regarding titration of Aranesp.[1] Use the lowest dose that will maintain a Hb level sufficient to reduce the need for red blood cell (RBC) transfusions.[1]

Initial Approval/Extended Approval.

A) *Initial Approval*. Initial approval is for 6 months if Hb is < 10.0 g/dL for adults and ≤ 11.0 g/dL for children.

B) *Extended Approval*. Extended approval is at 6-month intervals if the Hb is ≤ 11.5 g/dL for adults and ≤ 12.0 g/dL for children and the patient responds to therapy. Response is defined as Hb has increased, Hb has stayed the same and not decreased further, RBC transfusions are not required, and/or the number of RBC transfusions has decreased. For patients not responding discontinue Aranesp and evaluate and treat for other causes of anemia.

Duration of Therapy in Patients with CKD who are on Dialysis. Indefinite as long as the patient has CKD and is receiving dialysis.

Labs/Diagnostics. *Patient must meet the following criteria (A AND B)*:

A) Monitor Hb at therapy initiation and at 6-month intervals; AND

B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, percent transferrin saturation [TSAT], bone marrow biopsy) must be evaluated at therapy initiation and at 6-month intervals, unless the patient is currently receiving iron therapy.

2. Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis.

Criteria. *The patient must meet the following criteria (A AND B)*:

A) For initial therapy Hb is **<** 10.0 g/dL for adults and ≤ 11.0 g/dL for children; OR
For patients currently receiving Aranesp or epoetin alfa, Hb is ≤ 11.5 g/dL for adults and ≤ 12.0 g/dL for children OR for patients currently receiving Mircera, Hb is ≤ 11.5 g/dL for adults; AND

B) The patient is currently receiving iron therapy or iron stores are adequate (e.g., Aranesp prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%).

Aranesp is indicated for the treatment of anemia due to CKD in patients not on dialysis.[1] The Aranesp prescribing information recommends that for adult patients with CKD not on dialysis, Aranesp should be initiated when Hb is < 10.0 g/dL and other considerations apply (e.g., patient is likely to need transfusions). If the Hb levels exceeds 10.0 g/dL, reduce or interrupt the Aranesp dose and use the lowest dose sufficient to reduce the need for RBC transfusions. For pediatric patients with CKD, initiate Aranesp when the Hb is < 10.0 g/dL and if the Hb level approaches or exceeds 12.0 g/dL, reduce or interrupt the Aranesp dose.[1] Additional longer-term data in children using Aranesp for CKD is available.[2] Clinical practice guidelines for anemia in CKD from KDIGO recommend against ESA therapy initiation for adult patients with CKD who are not on dialysis when Hb levels are ≥ 10.0 g/dL.[3] For adult patients with CKD who are not on dialysis with Hb levels < 10.0 g/dL, the decision whether to initiate ESA therapy should be individualized based on many factors (e.g., prior response to iron therapy, the risk of needing a transfusion, presence of symptoms). In general, ESAs should not be used to maintain Hb concentrations above 11.5 g/dL in adult patients with CKD. For pediatric patients with CKD, the Hb concentration in which ESAs should be initiated in the individual patient should be considered with awareness of the potential benefits and potential harms. In all pediatric patients with CKD receiving ESA therapy the selected Hb concentration should be in the range of 11.0 to 12.0 g/dL. For adult patients with CKD on ESA therapy who are not receiving iron supplementation, a trial of IV iron (or oral iron therapy in patients with CKD not on dialysis) is suggested when transferrin saturation is < 30% and ferritin is ≤ 500 mcg/L. For all pediatric patients with CKD receiving ESA therapy who are not receiving iron supplementation, oral iron (or IV iron in patients with CKD who are on dialysis) should be administered to maintain transferrin saturation > 20% and ferritin > 100 mcg/L. KDIGO guidelines recommend during the initiation of ESA therapy to measure the Hb concentration at least monthly. For patients with CKD not on dialysis during the maintenance phase of ESA therapy, measure Hb concentration at least every 3 months. KDIGO recommends to evaluate iron status (transferrin saturation and ferritin) at least every 3 months during ESA therapy, including the decision to start or continue iron therapy. [3]

Dosing in Patients with CKD who are not on Dialysis. *Dosing must meet the following (A or B):*

- **A)** For adults, initiate therapy at 0.45 mcg/kg subcutaneously (SC) or intravenously (IV) once every 4 weeks; OR
- **B)** For children, the starting dose is 0.45 mcg/kg body weight given as a single SC or IV injection once weekly OR 0.75 mcg/kg SC or IV once every 2 weeks.

Note: If Hb exceeds 11.5 g/dL for adults or 12.0 g/dL in children, reduce or interrupt the Aranesp dose, and use the lowest dose sufficient to reduce the need for RBC transfusions. Refer to the prescribing information regarding titration of Aranesp.[1]

Initial Approval/Extended Approval.

- **A)** *Initial Approval*. Initial approval is for 6 months if Hb is < 10.0 g/dL for adults and ≤ 11.0 g/dL for children.
- **B)** *Extended Approval*. Extended approval is at 6-month intervals if the Hb is ≤ 11.5 g/dL for adults and ≤ 12.0 g/dL for children and the patient responds to therapy. Response is defined as Hb has increased, Hb has stayed the same and not decreased further, RBC transfusions are not

required, and/or the number of RBC transfusions has decreased. For patients not responding, discontinue Aranesp and evaluate and treat for other causes of anemia.

Duration of Therapy in Patients with CKD who are not on Dialysis: Indefinite as long as the patient has CKD.

Labs/Diagnostics. *Patients must meet the following criteria (A AND B)*:

A) Monitor Hb at therapy initiation and at 6-month intervals; AND

B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, TSAT, bone marrow biopsy) must be evaluated at therapy initiation and at 6-month intervals, unless the patient is currently receiving iron therapy.

3. Anemia in Patients with Cancer due to Cancer Chemotherapy.

Criteria. *The patient must meet the following criteria (A, B, AND C)*:

A) Hb is < 10.0 g/dL for initial therapy; OR
Hb is ≤ 12.0 g/dL for patients currently receiving Aranesp or epoetin alfa; AND

B) The patient is currently receiving myelosuppressive chemotherapy; AND

C) The patient is currently receiving iron therapy or iron stores are adequate (e.g., Aranesp prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum tranferrin saturation is < 20%).

Aranesp is indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of 2 additional months of planned chemotherapy.[1] Discontinue Aranesp following the completion of a chemotherapy course. Initiate Aranesp for patients on cancer chemotherapy only if the Hb is < 10.0 g/dL. Use the lowest dose of Aranesp to avoid RBC transfusions.[1] Hb can be increased to (or near) a concentration of 12.0 g/dL, at which time the dose of Aranesp should be titrated to maintain that level.[4] Iron studies should accompany ESA therapy to monitor the development of iron deficiency. Iron supplementation can improve response to ESA therapy.[4-5] Baseline and periodic monitoring of iron, total iron-binding capacity, transferrin saturation, or ferritin levels and instituting iron replacement when needed may be useful in limiting the need for ESAs, maximizing symptomatic improvement for patients, and determining the reason for failure to adequately respond to ESAs.[4] Iron deficiency can occur following continued ESA use and, therefore, iron supplementation is required in most patients to maintain optimal response.[5] Of note, data in children with chemotherapy-induced anemia with Aranesp are limited.[6]

Dosing in Anemia due to Cancer Chemotherapy. *Dosing for adults must meet ONE of the following (A, B, C, D, OR E)*:

A) 2.25 mcg/kg weekly by SC injection (increase up to 4.5 mcg/kg weekly SC) until completion of a chemotherapy course[1]; OR

B) 500 mcg every 3 weeks by SC injection until completion of a chemotherapy course[1]; OR

C) 100 mcg fixed dose once every week by SC injection (increase up to 150 to 200 mcg fixed dose every week by SC injection) until completion of a chemotherapy course[5]; OR

D) 200 mcg fixed dose once every 2 weeks by SC injection (increase up to 300 mcg fixed dose every 2 weeks by SC injection) until completion of a chemotherapy course[5]; OR

E) 300 mcg fixed dose once every 3 weeks by SC injection (increase up to 500 mcg fixed dose once every 3 weeks by SC injection) until completion of a chemotherapy course[5].

Note: Doses are not established in children. Aranesp 2.25 mcg/kg SC (given at a 2-week interval, followed by 2.25 mcg/kg SC once weekly) has been used.[6] Different doses and intervals between doses have been used for initiating therapy and for adjusting the dose to maintain a response. Examples of some initial and maximum doses of Aranesp are listed above for adults. Use the lowest dose necessary to avoid RBC transfusions. Dosing modifications are determined by the prescribing physician.[1]

Initial Approval/Extended Approval,

a) *Initial Approval*. Initial approval is for 4 months if Hb is < 10 g/dL.

b) *Extended Approval*. Approval can be given at 4-month intervals if the Hb is ≤ 12.0 g/dL and the patient responds to therapy. Response is defined as Hb has increased, Hb has stayed the same and not decreased further, RBC transfusions are not required, and/or the number of RBC transfusions has decreased. If the patient does not have a response, discontinue Aranesp. Discontinue Aranesp following completion of a cancer chemotherapy course.[4-5]

Duration of Therapy in Anemia due to Cancer Chemotherapy. Indefinite as long as the patient is receiving myelosuppressive chemotherapy.

Labs/Diagnostics. *Patient must meet the following criteria (A AND B)*:

A) Monitor Hb at therapy initiation and at 4-month intervals; AND

B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, TSAT, bone marrow biopsy) must be evaluated at therapy initiation and at 4-month intervals, unless the patient is currently receiving iron therapy.

Other Uses with Supportive Evidence

4. Anemia Associated with Myelodysplastic Syndrome (MDS).

Criteria. *The patient must meet the following criteria (A, B, C, AND D)*:

A) Patient is ≥ 18 years of age; AND

B) Hb is ≤ 10 g/dL for initial therapy; OR
serum erythropoietin level is ≤ 500 mU/mL for initial therapy; OR
Hb is ≤ 12.0 g/dL for patients currently receiving Aranesp or Epoetin alfa; AND

C) Aranesp is prescribed by, or in consultation with, a hematologist or oncologist; AND

D) The patient is currently receiving iron therapy or iron stores are adequate (e.g., Aranesp prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum tranferrin saturation is < 20%).

Clinical practice guidelines from the National Comprehensive Cancer Network (NCCN)[7] for MDS (version 2.2018) list Aranesp as having a role in anemic, symptomatic patients with MDS if serum

erythropoietin levels are ≤ 500 mU/mL. Iron stores should be adequate. Due to safety issues, the guidelines suggest that ESAs be used in the management of symptomatic anemia in patients with MDS and to aim for a target Hb ≤ 12.0 g/dL.[7] Other data suggest Aranesp may provide some benefits in MDS.[8-12,15]

Dosing in MDS. *Dosing must meet ONE of the following (A OR B)*:

A) 150 to 300 mcg SC once every other week[7]; OR

B) 500 mcg SC once every other week or once every 3 weeks.[7,11, 15]

Initial Approval/Extended Approval.

A) *Initial Approval*. Initial approval is for 6 months if Hb is ≤ 10 g/dL OR the serum erythropoietin level is ≤ 500 mU/mL.

B) *Extended Approval*. Approve at additional 6-month intervals if a response is achieved (increase in Hb or a decrease in transfusions) and Hb is ≤ 12.0 g/dL. For patients not responding, despite dose titrations and/or concomitant use of granulocyte colony stimulating factor (G-CSF) (e.g., Neupogen® [filgrastim injection]) during the first 6 months, discontinue Aranesp and evaluate and treat for other causes of anemia.

Duration of therapy in MDS. Indefinite as long as the patient has MDS.

Labs/Diagnostics. *Patient must meet the following criteria (A AND B)*:

A) Monitor Hb or serum erythropoietin levels at therapy initiation and monitor Hb at 6-month intervals; AND

B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, TSAT, bone marrow biopsy) must be evaluated at therapy initiation and at 4-month intervals, unless the patient is currently receiving iron therapy.

Waste Management for All Indications.

Single-dose vials and syringes are available in many different strengths. The dose should be calculated and the number of vials/syringes needed assessed. Refer to the Aranesp prescribing information for more information. http://www.aranesp.com

Conditions Not Recommended for Approval

Aranesp has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Anemia Associated with Cancer in Patients not Receiving Myelosuppressive Cancer Chemotherapy.** Aranesp is not indicated in patients with cancer who are not receiving cancer chemotherapy.[1] The American Society of Clinical Oncology (ASCO)/American Society of Hematology (ASH) guidelines for the use of epoetin alfa and Aranesp in adult patients with cancer recommend that ESAs not be used in treatment of anemia associated with malignancy in those who are not receiving concurrent myelosuppressive chemotherapy.[4]

2. **Anemia Associated with Acute Myelogenous Leukemia (AML), Chronic Myelogenous Leukemia (CML), or other Myeloid Cancers.** Aranesp is indicated for use in non-myeloid cancers. AML and CML are examples of myeloid cancers.[1]

3. **Anemia Associated with Radiotherapy in Cancer.** Aranesp is not indicated for use in cancer patients who are given only radiation therapy.[1]

4. **To Enhance Athletic Performance.** Aranesp is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.

5. **Anemia in Patients due to Acute Blood Loss.** Use of Aranesp is not appropriate in these types of situations.

6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SPECIAL CONSIDERATIONS

BOXED WARNING: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE. See full prescribing information for complete boxed warning.[1]

Contraindications include[1]:

1. Uncontrolled hypertension
2. Pure red cell aplasia (PRCA) that begins after treatment with Aranesp or other erythropoietin protein drugs
3. Serious allergic reactions to Aranesp

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

References

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2. Schaefer F, Hoppe B, Jungraithmayr T, et al. Safety and usage of darbepoetin alfa in children with chronic kidney disease: prospective registry study. *Pediatr Nephrol*. 2016;31:443-453.
3. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Inter*. 2012;2(Suppl):279-335. Available at: http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf. Accessed on June 22, 2018.
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6. Blumer J, Berg S, Adamson PC, et al. Pharmacokinetic evaluation of darbepoetin alfa for the treatment of pediatric patients with chemotherapy-induced anemia. *Pediatr Blood Cancer*. 2007;49:687-693.
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2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/clinical.asp. Accessed on June 18, 2018.
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9. Stasi R, Abruzzese E, Lanzetta G, et al. Darbepoetin alfa for the treatment of anemic patients with low- and intermediate-risk myelodysplastic syndromes. *Ann Oncol*. 2005;16:1921-1927.
10. Mannone L, Gardin C, Quarre MC, et al. High-dose darbepoetin alpha in the treatment of anemia of lower risk myelodysplastic syndrome: results of a phase II study. *Br J Haematol*. 2006;133(5):513-519.
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12. Oliva EN, Nobile F, Alimena G, et al. Darbepoetin alfa for the treatment of anemia associated with myelodysplastic syndromes: efficacy and quality of life. *Leuk Lymphoma*. 2010;51(6):1007-1014.
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15. Platzbecker U, Symeonidis A, Oliva EN, et al. A phase 3 randomized placebo-controlled trial of darbepoetin alfa in patients with anemia and lower-risk myelodysplastic syndromes. *Leukemia*. 2017;31(9):1944-1950.

OTHER REFERENCES UTILIZED

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CFR		
WAC	WAC 284-43-2050	
RCW		
Contract Citation	☒ WAH	http://chpw.org/our-plans/apple-health/
	☐ IMC	

	☒ MA	https://healthfirst.chpw.org/our-plans/2018-medicare-plans/
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
01/09/2017	NEW	Sophia Yun, PharmD
01/10/2017	Approval	MMLT
03/06/2017	Medication name formatting revision	Sophia Yun, PharmD
03/06/2017	Approval	MMLT
02/12/2018	Updated review	Catherine Vu, PharmD
03/01/2018	Approval	MMLT
03/09/2018	Reassigned from UM to Pharmacy	Cindy Bush
07/16/2018	Minor revisions	Jennifer Farley, PharmD
03/08/2019	Approval	UM Pharmacy Subcommittee