CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Aranesp (darbepoetin alfa)
BILLING CODE	For Medical - J0881 (non-ESRD) For Pharmacy - Must use valid NDC code
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Office/Home/Freestanding facility or clinic
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— vary per diagnosis
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Aranesp (darbepoetin alfa) is a **preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANEMIA

For **initial** authorization:

1. Medication must be prescribed by an oncologist, a nephrologist, an immunologist or infectious disease specialist; AND
2. Member has documented diagnosis of anemia due to **one** of the following:
   a) Myelodysplastic syndrome;
   b) Chronic Kidney Disease (GFR below 60 mL/min/1.73 m^2);
   c) The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy; AND
3. Member's individual iron status reveals **both** of the following:
   a) Transferrin saturation is at least 20%;
   b) Ferritin is at least 100 mcg/L; AND
4. Member is on supplemental iron therapy (unless serum ferritin level > 800 mcg/L); AND
5. Member's labs show hemoglobin ≤ 10 g/dL for adults (≤ 11 g/dL for children) within the last 14 days for initial therapy OR ≤ 10.5 g/dL for adults (≤ 11.5 g/dL for children) currently receiving therapy.
6. **Dosage allowed:** Recommended starting dose for adult members with CKD on dialysis - 0.45 mcg/kg IV or SQ weekly, or 0.75 mcg/kg IV or SQ every 2 weeks. IV route is recommended for patients on hemodialysis. Recommended starting dose for members with CKD not on dialysis - 0.45 mcg/kg IV or SQ at 4 week intervals. Recommended starting dose for pediatric members with CKD: 0.45 mcg/kg IV or SQ weekly, members with CKD not on dialysis may also be initiated at 0.75 mcg/kg every 2 weeks. Recommended starting dose for members with cancer on chemotherapy: 2.25 mcg/kg subcutaneously weekly, or 500 mcg subcutaneously every 3 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member's hemoglobin increased, stayed the same and not decreased further (baseline labs and current labs required); AND
2. Red blood cells transfusions are not required or the number of the transfusions has decreased.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Aranesp (darbepoetin alfa) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- In members with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy
- In members with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure
- In members with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion
- In members scheduled for surgery who are willing to donate autologous blood
- As a substitute for RBC transfusions in patients who require immediate correction of anemia

DATE	ACTION/DESCRIPTION
10/04/2018	New policy for Aransep created. Hemoglobin requirement expanded. Endogenous serum erythropoietin level requirement removed.

References:

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5. New risk management program for erythropoiesis-stimulating agents. Aranesp, Procrit, and Epogen Article; Pharmacist's Letter; April 2010; Vol: 26 Hematology / Oncology.
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12. Definition and management of anemia in patients infected with hepatitis C virus. McHutchison JG, Manns MP, Longo DL Liver Int. 2006;26(4):389 MCG 20th edition, 2016.

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