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. **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 is in compliance will all initial criteria

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.
11/18/2021	Removed iron status requirement, supplemental iron therapy requirement, and hemoglobin labs. Revised reauthorization criteria.

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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