Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medication that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored, as indicated, via individual departmental audit process(es).

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived.

Background Information:

Medication Summary

- Darbepoetin alfa is an erythropoiesis stimulating protein, closely related to erythropoietin, that is produced in Chinese hamster ovary (CHO) cells using recombinant DNA technology. Erythropoietin is produced in the kidneys, and induces erythropoiesis by stimulating the division and differentiation of red blood cells in bone marrow.

- Darbepoetin alfa is indicated for the treatment of anemia associated with Chronic Kidney Disease. Darbepoetin alfa is used to elevate or maintain the red blood cell levels as determined by the hematocrit and hemoglobin levels, and to decrease the need for blood transfusions.
Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Coverage Guidelines

- Member must be eligible and have applicable benefit coverage within the specified date(s) of service.
- For Commercial Members Aranesp will be a:
  - Medical benefit when the diagnosis is anemia secondary to ESRD on home-dialysis;
  - Pharmacy benefit with applicable co-payment, when the diagnosis is anemia secondary to Chronic Kidney Disease (CKD);
- For Medicare Members, will need to determine if Part B versus Part D for each indication.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist to review.

Exclusion Criteria

- Uncontrolled hypertension
- Hypersensitivity to the active substance or mammalian cell-derived products
- Known hypersensitivity to albumin (human)

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
- Requests received for Medicare Members will be reviewed using CMS “LCD for Erythropoiesis.Stimulating.Agents”
Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization

Title: darbepoetin alfa (Aranesp)

Procedure:

1.0 Request for therapy with darbepoetin alfa for anemia due to chemotherapy requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying all of the following:

1.1 Member has had an inadequate response to Epoetin alfa (Procrit) therapy as defined as failure to achieve target Hgb/Hct in the presence of adequate iron stores at a dose of 300 units/kg three times a week SC within four (4) to six (6) months, or failure to maintain target Hgb/Hct subsequently at that dose; AND

1.2 Member is a cancer patient on chemotherapy or received last dose of chemotherapy within past eight (8) weeks; AND

1.3 Hemoglobin (Hgb) levels <10g/dL OR Hematocrit (Hct) levels <30%;

1.4 If criteria are met, Aranesp is approveable for up to 45 days.

2.0 Request for therapy with darbepoetin alfa for myelodysplastic therapy syndrome requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying all of the following:

2.1 Member has had an inadequate response to Epoetin alfa (Procrit) therapy as defined as failure to achieve target Hgb/Hct in the presence of adequate iron stores at a dose of 300 units/kg three (3) times a week SC within four (4) to six (6) months, or failure to maintain target Hgb/Hct subsequently at that dose; AND

2.2 Hemoglobin (Hgb) levels <10g/dL OR Hematocrit (Hct) levels <30%;

2.3 If criteria are met, Aranesp is approveable for up to 45 days.
Procedures, continued:

3.0 Request for therapy with darbepoetin alfa for anemia associated with chronic renal failure (CRF) requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying all of the following:

3.1 Member has had an inadequate response to Epoetin alfa (Procrit) therapy as defined as failure to achieve target Hgb/Hct in the presence of adequate iron stores at a dose of 300 units/kg three (3) times a week SC within four (4) to six (6) months, or failure to maintain target Hgb/Hct subsequently at that dose; **AND**

3.2 Hemoglobin (Hgb) levels <10g/dL **OR** Hematocrit (Hct) levels <30%;

3.3 If criteria are met, Aranesp is approvable for up to 45 days.

4.0 Request for therapy with darbepoetin alfa for anemia in zidovudine-treated, HIV infected Members requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying all of the following:

4.1 Member has had an inadequate response to Epoetin alfa (Procrit) therapy as defined as failure to achieve target Hgb/Hct in the presence of adequate iron stores at a dose of 300 units/kg three (3) times a week SC within four (4) to six (6) months, or failure to maintain target Hgb/Hct subsequently at that dose; **AND**

4.2 Hemoglobin (Hgb) levels <10g/dL **OR** Hematocrit (Hct) levels <30%;

4.3 If criteria are met, Aranesp is approvable for up to 45 days.
Procedure, continued:

5.0 Request for therapy with darbepoetin alfa for anemia associated with treatment of Hepatitis C infection requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying all of the following:

5.1 Member has had an inadequate response to Epoetin alfa (Procrit) therapy as defined as failure to achieve target Hgb/Hct in the presence of adequate iron stores at a dose of 300 units/kg three (3) times a week SC within four (4) to six (6) months, or failure to maintain target Hgb/Hct subsequently at that dose; AND

5.2 Hemoglobin (Hgb) levels <10g/dL OR Hematocrit (Hct) levels <30%;

5.3 If criteria are met, Aranesp is approvable for up to 45 days.

6.0 Request for therapy with darbepoetin alfa for anemia associated with rheumatoid arthritis requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying all of the following:

6.1 Member has had an inadequate response to Epoetin alfa (Procrit) therapy as defined as failure to achieve target Hgb/Hct in the presence of adequate iron stores at a dose of 300 units/kg three times a week SC within four (4) to six (6) months, or failure to maintain target Hgb/Hct subsequently at that dose; AND

6.2 Hemoglobin (Hgb) levels <10g/dL OR Hematocrit (Hct) levels <30%;

6.3 If criteria are met, Aranesp is approvable for up to 45 days.
Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization

Title: darbepoetin alfa (Aranesp)

References: