SAMPLE Letter of Appeal
For Aranesp® (darbepoetin alfa) injection, for intravenous and subcutaneous use
Nephrology

Date

Payor Name
Payor Representative
Payor Address
City, State, ZIP Code
Payor Fax Number

Attention: Payor Representative
Attention: Claims Department

Re: Coverage of Aranesp® (darbepoetin alfa)
Subscriber's First and Last Name
Patient's First and Last Name
Policy Number / Patient's ID
Group Number
Patient Date of Birth
Treatment Date and Claim Number
Amount of Claim

Dear Director of Claims:

I am writing to request a review of a denied claim for ***{Patient's name}***. Your company has denied this claim for the following reason(s), listed on the attached Explanation of Benefits (EOB):

{Fill in reason(s) from EOB}

Mr/Mrs/Ms ***{Patient's name}*** was provided with Aranesp® (darbepoetin alfa) therapy for the treatment of anemia due to chronic kidney disease (CKD).

Aranesp® is indicated for the treatment of anemia due to CKD, including patients on dialysis and patients not on dialysis.

Limitations of Use:
- Aranesp® has not been shown to improve quality of life, fatigue, or patient well-being.
- Aranesp® is not indicated for use as a substitute for red blood cell transfusions in patients who require immediate correction of anemia.

Aranesp® is contraindicated in patients with uncontrolled hypertension, pure red cell aplasia (PRCA) that begins after treatment with Aranesp®, or other erythropoietin protein drugs, or serious allergic reactions to Aranesp®.

Please refer to the Aranesp® full prescribing information, including **Boxed WARNINGS** and Medication Guide, available at http://pi.amgen.com/united_states/aranesp/ckd/aranesp_pi_hcp_english.pdf.

(Provide diagnoses, dates of service, outcomes [eg, Hb levels], and rationale for treatment with Aranesp®) ***NOTE: Physicians should exercise medical judgment and discretion in regard to making an appropriate diagnosis and characterization of an individual patient's medical condition. In addition, physicians are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.***

Treatment with Aranesp® has been a necessary therapy for this patient's medical condition, and it is my clinical opinion and assessment that ***{Patient's name}*** has benefited from Aranesp®. I trust that the enclosed information, along with my medical recommendations, will establish the medical necessity for payment of this claim.

Sincerely,

{Physician Name}

Please see Important Safety Information, including ***Boxed WARNINGS about INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE****, on next page.*

Aranesp® (darbepoetin alfa) Indication and Important Safety Information, including **Boxed WARNINGS**

Indication

Aranesp® (darbepoetin alfa) is indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.

Limitations of Use:
- Aranesp® has not been shown to improve quality of life, fatigue, or patient well-being.
- Aranesp® is not indicated for use as a substitute for red blood cell transfusions in patients who require immediate correction of anemia.

Important Safety Information, including **Boxed WARNINGS**

WARNING: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE

Chronic Kidney Disease:

- **In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL.**
- **No trial has identified a hemoglobin target level, Aranesp® dose, or dosing strategy that does not increase these risks.**
- **Use the lowest Aranesp® dose sufficient to reduce the need for red blood cell (RBC) transfusions.**

Cancer:

- **ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.**
- **Because of these risks, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense Aranesp® to patients with cancer. To enroll in the ESA APPRISE Oncology Program, visit www.esa-apprise.com or call 1-866-284-8089 for further assistance.**
- **To decrease these risks, as well as the risk of serious cardiovascular and thromboembolic reactions, use the lowest dose needed to avoid RBC transfusions.**
- **Use ESAs only for anemia from myelosuppressive chemotherapy.**
- **ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure.**
- **Discontinue following the completion of a chemotherapy course.**

- Aranesp® is contraindicated in patients with:
  - Uncontrolled hypertension
  - Pure red cell aplasia (PRCA) that begins after treatment with Aranesp® or other erythropoietin protein drugs
  - Serious allergic reactions to Aranesp®
- Use caution in patients with coexistent cardiovascular disease and stroke.
- Patients with CKD and an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular reactions and mortality than other patients. A rate of hemoglobin rise of > 1 g/dL over 2 weeks may contribute to these risks.
- In controlled clinical trials, ESAs increased the risk of death in patients undergoing coronary artery bypass graft surgery (CABG) and the risk of deep venous thrombosis (DVT) in patients undergoing orthopedic procedures.
- Control hypertension prior to initiating and during treatment with Aranesp®.
- Aranesp® increases the risk of seizures in patients with CKD. Monitor patients closely for new-onset seizures, premonitory symptoms, or change in seizure frequency.
- For lack or loss of hemoglobin response to Aranesp®, initiate a search for causative factors. If typical causes of lack or loss of hemoglobin response are excluded, evaluate for PRCA.
- Cases of PRCA and of severe anemia, with or without other cytopenias that arise following the development of neutralizing antibodies to erythropoietin have been reported in patients treated with Aranesp®.
  - This has been reported predominantly in patients with CKD receiving ESAs by subcutaneous administration.
  - PRCA has also been reported in patients receiving ESAs for anemia related to hepatitis C treatment (an indication for which Aranesp® is not approved).
  - If severe anemia and low reticulocyte count develop during treatment with Aranesp®, withhold Aranesp® and evaluate patients for neutralizing antibodies to erythropoietin.
  - Permanently discontinue Aranesp® in patients who develop PRCA following treatment with Aranesp® or other erythropoietin protein drugs. Do not switch patients to other ESAs.
- Serious allergic reactions, including anaphylactic reactions, angioedema, bronchospasm, skin rash, and urticaria may occur with Aranesp®. Immediately and permanently discontinue Aranesp® if a serious allergic reaction occurs.
- Adverse reactions (≥ 10%) in Aranesp® clinical studies in patients with CKD were hypertension, dyspnea, peripheral edema, cough, and procedural hypotension.

Please refer to the Aranesp® full prescribing information, including **Boxed WARNINGS** and Medication Guide, available at http://pi.amgen.com/united_states/aranesp/ckd/aranesp_pi_hcp_english.pdf.

66486-R1-V2