

Operations Bulletin 01-07



Date: May 2007

To: Participating Providers

Re: Erythropoietin Stimulating Agents

In response to recently published peer-reviewed medical literature regarding safety concerns associated with the use of erythropoietin stimulating agents (ESA's) and the revised guidelines by the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services, the Health Plan¹ will be implementing a prior authorization requirement for the use of these agents effective June 15, 2007.

The FDA has issued a public health advisory to healthcare professionals regarding the significantly increased risk for serious and life-threatening cardiovascular complications associated with the use of ESA's. Amgen and Ortho-Biotec (Johnson & Johnson), the manufacturers of these agents, have also revised the product labeling to reflect the updated warnings and a change to the dosage and administration sections for all ESA's.

Steps for Authorizing Erythropoietin Stimulating Agents

The prior authorization requirement includes the following medications:

- Epoetin alfa (Epoen/Procrit), and/or
- Darbepoetin alfa (Aranesp)

Prior authorization is required for outpatient prescription and medical services occurring on or after June 15, 2007 for all lines of business.

Step 1: Complete the ESA Request Form (attached) in its entirety and fax to (570) 214-1516 for authorization review.

Step 2: Upon receipt of the completed ESA Request form, the Health Plan will review and approve or deny within applicable regulatory timeframes. The prescribing physician will receive written and verbal communication of the decision.

Step 3: Recertification; authorizations expire three (3) months from the authorization approval date. If continued treatment is required beyond the three-month authorization period, submit a new ESA Request form as outlined in Step 1.

A medical policy outlining the criteria for initial and continued coverage for FDA approved indications can be found at www.thehealthplan.com or by contacting your Provider Relations Representative.

Additionally, due to new FDA guidelines, **Xolair must be monitored by a physician after administration.** Effective immediately, Xolair is no longer available as an outpatient prescription drug benefit.

Information contained in this Bulletin and its attachments amend the Participating Provider Guide (Dev 08/05), effective June 15, 2007.

If you have any questions regarding the information in this Bulletin, please contact the Health Plan Pharmacy Department at (800) 988-4861 or (570) 271-5673.

¹Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance shall be collectively referred to herein as "Health Plan"



GEISINGER HEALTH PLAN® Erythropoietin Stimulating Agents (ESA) Request Form

Instructions: All areas **MUST BE COMPLETED** in order to process the request. This form must be submitted to obtain a prior authorization for an Erythropoietin Stimulating Agent (Epogen, Procrit or Aranesp). If approved, all authorizations will be valid for a time period of 3 months. If more doses are needed, repeat prior authorizations are required. Applicable copay or coinsurance will still apply.

Please fax form to 570-214-1516.

Patient Information (*print legibly*)

Patient Name _____ D.O.B. _____

Address _____ City _____ State _____ Zip _____

Home Phone _____ Daytime Phone _____

Diagnosis _____ ICD-9 code _____ Health Plan Member ID # _____

Physician Information (*print legibly*)

Physician Name _____

Office Address _____ City _____ State _____ Zip _____

Office Contact _____

Office Phone# _____ Office Fax # _____

Physician signature and Date: _____

Requested Medication	Dose	Directions

Is this patient being newly initiated on ESA therapy? Yes No

How will ESA be administered? from provider stock at office visit patient will self administer with Rx dispensed

Where will ESA be administered? home provider's office nursing home/personal care facility

Chemotherapeutic or other relevant drug therapy including doses and most recent dates received: _____

If diagnosis is anemia of chronic disease, please state the chronic disease: _____

If the diagnosis is end stage renal disease, is the patient receiving dialysis? Yes No

Does the patient have symptomatic anemia? Yes No If yes, describe _____

Required labs

Hemoglobin	g/dL	Date:	Baseline endogenous erythropoietin level	MU/mL	Date:
Note: Only required for MDS and HIV patients treated with zidovudine					
Ferritin	ng/mL	Date:	Transferrin level saturation	%	Date:

Is this patient currently on iron therapy? Yes No

Additional information: _____

Note: Possession of a Health Plan insurance card does not guarantee coverage.

Geisinger Health Plan Pharmacy Department
Phone: (800) 988-4861 or Fax: (570) 214-1516