



Department of Health

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RETRODUR INTERVENTION NOTICE: Erythropoiesis-Stimulating Agents

June 7, 2016

Dear Prescriber,

The New York State (NYS) Medicaid Drug Utilization Review (DUR) Program retrospectively reviews the prescribing and dispensing of outpatient prescription medications in order to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes. The NYS Medicaid DUR Board has reviewed Erythropoiesis-Stimulating Agents (ESAs) utilization within the NYS Medicaid program. NYS Medicaid pharmacy claims data indicate that you have written prescription(s) for ESAs.

The NYS DUR Board recommended an intervention at the prescriber level highlighting safety issues regarding the utilization of ESAs that include the following boxed warning:

ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence.

- Chronic kidney disease (Aranesp®, Epogen®, Mircera®, Procrit®):
 - In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin (Hb) level of greater than 11 g/dL.
 - No trial has identified an Hb target level, ESA dose, or dosing strategy that does not increase these risks.
 - Use the lowest dose sufficient to reduce the need for red blood cell (RBC) transfusions.
- Cancer (Aranesp®, Epogen®, Procrit® only):
 - 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.
 - Prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense to patients with cancer.
 - Use the lowest dose to avoid RBC transfusions.
 - Use ESAs only for anemia caused by 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.
- Perisurgery (Epogen® and Procrit® only):
 - Due to increased risk of deep venous thrombosis (DVT), DVT prophylaxis is recommended.

In presenting this information to you, the DUR Program recognizes that safe and effective pharmacotherapy depends on the assessment of the patient's entire clinical profile. We ask that you consider the information provided regarding the prescribing of ESAs for your patients.

Thank you for your professional assistance in this matter.

Sincerely,

John F. Naioti, Jr., R.Ph.
Manager, Drug Utilization Review Program