Aranesp® (darbepoetin alfa) – New warning

- On October 31, 2017, the FDA approved an update to the *Warnings and Precautions* section of the Aranesp (darbepoetin alfa) drug label regarding severe cutaneous reactions.

- Aranesp is approved for the treatment of anemia due to chronic kidney disease in patients on dialysis and patients not on dialysis; and in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

- Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use:

    - In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
    - In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
    - In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.
    - As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.

- Information regarding severe cutaneous reactions was also added to the *Warnings and Precautions* section of the Epogen®/Procrit® (epoetin alfa) drug labels and reported in a previous Clinical News Summary.

- Information regarding severe cutaneous reactions was added to the *Warnings and Precautions* section of the Aranesp drug label.

    - Blistering and skin exfoliation reactions including erythema multiforme and Stevens-Johnson Syndrome (SJS)/toxic epidermal necrolysis (TEN), have been reported in patients treated with erythropoiesis-stimulating agents (ESAs) (including Aranesp) in the postmarketing setting.
    - Discontinue Aranesp therapy immediately if a severe cutaneous reaction, such as SJS/TEN, is suspected.

- Information regarding laboratory monitoring was removed from the *Warnings and Precautions* section.

- Aranesp carries a boxed warning stating that ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence.