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NCCN Guidelines Panel: Cancer- and Chemotherapy-induced Anemia

On behalf of Amgen, I respectfully request the *NCCN* Cancer- and Chemotherapy-induced Anemia Guidelines panel review the enclosed information for revision of the darbepoetin alfa and epoetin alfa guidelines.

Specific Changes: Recommend modifying existing guidelines to remove reference to the Erythropoiesis Stimulating Agents (ESAs) Risk Evaluation and Mitigation Strategy (REMS) and ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program.

FDA notified Amgen and Janssen on April 13, 2017 that the ESA REMS requirement (which includes the ESA APPRISE Oncology Program) has been removed for Aranesp® (darbepoetin alfa), EPOGEN® (epoetin alfa) and PROCRIT® (epoetin alfa). ESA REMS assessments have indicated that healthcare providers demonstrate acceptable knowledge of the product risks of decreased survival and/or the increased risk of tumor progression or recurrence and that the products' risks can be conveyed adequately via the product labeling, which includes the medication guide.

In addition to the removal of reference to APPRISE from the ESA USPIs the following statement, which pertains to the aforementioned indication, has been added to the Limitations of Use section of the ESA USPIs:

[ESAs are] not indicated for use in patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.

NCCN action request:

- **We request that you update relevant materials and inform your members about the removal of ESAs from the ESA REMS and ESA APPRISE Oncology Program.**
 - Healthcare Providers are no longer required to adhere to the ESA APPRISE Oncology Program requirements. No further action regarding the ESA REMS is required.
 - All Program materials (e.g. enrollment-related documents, Acknowledgment Forms, site policies and procedures, etc.) no longer need to be retained.
- **We request that you update relevant materials and inform your members about the addition of a Limitation of Use Statement to the USPIs.**
 - Prior to treatment, Healthcare Providers should inform patients of the risks and benefits of ESAs as described in Section 17 Patient Counselling Information of the USPI.

Sincerely,

Cisio De Brandao, MD
Global Development Lead, Aranesp Oncology