Gilenya® (fingolimod) – New warning

- On December 15, 2017, the FDA approved an update to the *Warnings and Precautions* section of the Gilenya (fingolimod) drug label regarding cutaneous malignancies.

- Gilenya is indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

- The risk of basal cell carcinoma (BCC) and melanoma is increased in patients treated with Gilenya. In two-year placebo-controlled trials, the incidence of BCC was 2% in patients on Gilenya 0.5 mg and 1% in patients on placebo. Melanoma has been reported with Gilenya in the postmarketing setting.

    — Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.
    — Providers and patients are advised to monitor for suspicious skin lesions. If a suspicious skin lesion is observed, it should be promptly evaluated.
    — As usual for patients with increased risk for skin cancer, exposure to sunlight and ultraviolet light should be limited by wearing protective clothing and using a sunscreen with a high protection factor.
- Revisions were also made to the subsection of the *Warning and Precautions* section regarding progressive multifocal leukoencephalopathy.

- Due to the *Warnings and Precautions* section updates, similar changes were made to the *Patient Counseling* section and the Medication Guide of the Gilenya drug label.