Lemtrada® (alemtuzumab) – New warning

- On October 5, 2017, the FDA approved an update to the *Warnings and Precautions* section of the Lemtrada (alemtuzumab) drug label regarding the risk of acute acalculous cholecystitis.

- Lemtrada is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).

    — Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to ≥ 2 drugs indicated for the treatment of MS.

- Lemtrada may increase the risk of acute acalculous cholecystitis. In controlled clinical studies, 0.2% of Lemtrada-treated MS patients developed acute acalculous cholecystitis, compared to 0% of patients treated with interferon beta-1a (Avonex®, Rebif®).

    — During postmarketing use, additional cases of acute acalculous cholecystitis have been reported in Lemtrada-treated patients. Time to onset of symptoms ranged from less than 24 hours to 2 months after Lemtrada infusion. Typical risk or predisposing factors such as concurrent critical illness were often not reported. Abnormal ultrasound or computed tomography was used to support the diagnosis of acute acalculous cholecystitis in some cases. Some patients were treated conservatively with antibiotics and recovered without surgical intervention, whereas others underwent cholecystectomy.
    — Symptoms of acute acalculous cholecystitis include abdominal pain, abdominal tenderness, fever, nausea, and vomiting. Leukocytosis and abnormal liver enzymes are also commonly observed.
    — Acute acalculous cholecystitis is a condition that is associated with high morbidity and mortality rates if not diagnosed early and treated.
    — If acute acalculous cholecystitis is suspected, evaluate and treat promptly.

- Lemtrada carries a boxed warning regarding the risk of autoimmunity, infusion reactions, and malignancies.