Reyataz® (atazanavir) – New warning, label updates

- On October 20, 2017, the FDA approved an update to the *Warnings and Precautions* section of the Reyataz (atazanavir) drug label regarding chronic kidney disease.

- Reyataz is indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection for patients 3 months and older weighing at least 5 kg.

    — Reyataz is not recommended for use in pediatric patients below the age of 3 months due to the risk of kernicterus.
    — Use of Reyataz/Norvir® (ritonavir) in treatment-experienced patients should be guided by the number of baseline primary protease inhibitor resistance substitutions.

- Chronic kidney disease in HIV-infected patients treated with Reyataz, with or without Norvir, has been reported during postmarketing surveillance.

    — Reports included biopsy-proven cases of granulomatous interstitial nephritis associated with the deposition of Reyataz drug crystals in the renal parenchyma.
    — Consider alternatives to Reyataz in patients at high risk for renal disease or with preexisting renal disease.
    — Renal laboratory testing (including serum creatinine, estimated creatinine clearance, and urinalysis with microscopic examination) should be conducted in all patients prior to initiating therapy with Reyataz and continued during treatment with Reyataz.
    — Expert consultation is advised for patients who have confirmed renal laboratory abnormalities while taking Reyataz.
    — In patients with progressive kidney disease, discontinuation of Reyataz may be considered.

- In addition, the *Dosage and Administration* section was updated with a subsection regarding testing prior to initiation and during treatment with Reyataz.

    — Renal laboratory testing should be performed in all patients prior to initiation of Reyataz and continued during treatment with Reyataz.
    — Renal laboratory testing should include serum creatinine, estimated creatinine clearance, and urinalysis with microscopic examination.
    — Hepatic laboratory testing should be performed in patients with underlying liver disease prior to initiation of Reyataz and continued during treatment with Reyataz.

- The *Contraindications* section was also updated to include coadministration with Zepatier™ (elbasvir/grazoprevir) because concomitant use may increase the risk of alanine aminotransferase elevations due to a significant increase in grazoprevir plasma concentrations.