Gleevec® (imatinib) – New warning

- On September 6, 2017, the FDA approved an update to the *Warnings and Precautions* section of the Gleevec (imatinib) drug label regarding the risk of renal toxicity.

- Gleevec is approved for multiple oncology indications, including newly diagnosed Philadelphia (Ph)-positive chronic myeloid leukemia (CML); Ph-positive CML in blast crisis, accelerated phase, or chronic phase after interferon-alpha therapy; adult patients with Ph-positive acute lymphoblastic leukemia (ALL); pediatric patients with Ph-positive ALL; myelodysplastic/myeloproliferative diseases; aggressive systemic mastocytosis; hypereosinophilic syndrome and/or chronic eosinophilic leukemia; dermatofibrosarcoma protuberans; KIT-positive gastrointestinal stromal tumors (GIST); and adjuvant treatment of GIST.

- A decline in renal function may occur in patients receiving Gleevec.

    — The median estimated glomerular filtration rate values in patients on Gleevec 400 mg daily for newly-diagnosed CML (four randomized trials) and malignant GIST (one single-arm trial) declined from a baseline value of 85 ml/min/1.73m^2 (n = 1190) to 75 ml/min/1.73m^2 at 12 months (n = 1082) and 69 ml/min/1.73m^2 at 60 months (n = 549).
    — Healthcare providers should evaluate renal function prior to initiating Gleevec and monitor during therapy, with attention to risk factors for renal dysfunction such as pre-existing renal impairment, diabetes mellitus, hypertension, and congestive heart failure.