Niaspan® (niacin extended-release) — Indication Removal

- On April 27, 2015, the FDA approved revisions for AbbVie's Niaspan (niacin extended-release) tablets to remove the following indication from its package insert and related labeling statements regarding the combined use of Niaspan and statins.
  - Niaspan in combination with simvastatin or lovastatin is indicated for the treatment of primary hyperlipidemia and mixed dyslipidemia when treatment with Niaspan, simvastatin, or lovastatin monotherapy is considered inadequate.
- Niaspan is currently indicated as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate.
  - Niaspan is indicated to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B) and triglyceride levels (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hyperlipidemia and mixed dyslipidemia.
  - In patients with a history of myocardial infarction and hyperlipidemia, niacin is indicated to reduce the risk of recurrent nonfatal myocardial infarction.
  - In patients with a history of coronary artery disease and hyperlipidemia, niacin, in combination with a bile acid binding resin, is indicated to slow progression or promote regression of atherosclerotic disease.
  - Niaspan in combination with a bile acid binding resin is indicated to reduce elevated TC and LDL-C levels in adult patients with primary hyperlipidemia.
  - Niacin is also indicated as adjunctive therapy for treatment of adult patients with severe hypertriglyceridemia who present a risk of pancreatitis and who do not respond adequately to a determined dietary effort to control them.
- Addition of Niaspan did not reduce cardiovascular morbidity or mortality among patients treated with simvastatin in a large, randomized controlled trial.