Praluent® (alirocumab) – New dosing regimen

- On April 25, 2017, Sanofi and Regeneron announced the FDA approval of a once-monthly starting dose regimen of 300 mg for Praluent (alirocumab).
    - The 300 mg dose is administered via two 150 mg subcutaneous (SC) injections given consecutively at two different injection sites.
    - Previously, the only recommended starting dose regimen for Praluent was 75 mg injected SC once every 2 weeks.
    - For both regimens, the dosage may be adjusted to 150 mg every 2 weeks if low density lipoprotein-cholesterol (LDL-C) reduction is inadequate.

- Praluent, a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor, is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C.
    - The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

- The FDA approval of the alternative Praluent dosing regimen was based on a clinical study of 547 patients on statin therapy randomized to Praluent 300 mg every 4 weeks, Praluent 75 mg every 2 weeks, or placebo. Both Praluent treatment arms demonstrated greater reductions in mean LDL-C from baseline over placebo at week 24 (300 mg: -56% [97.5% CI: -62%, -49%]; 75 mg: -48% [97.5% CI: -57%, -39%]). Approximately 20% of patients required dose adjustments to 150 mg every 2 weeks at week 12 for additional LDL-C lowering.