Praluent® (alirocumab) – Expanded indication

- On March 11, 2024, Regeneron announced the FDA approval of Praluent (alirocumab), as an adjunct to diet and other low density lipoprotein cholesterol (LDL-C)-lowering therapies in pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH) to reduce LDL-C.

- Praluent is also approved:

    - To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease
    - As an adjunct to diet, alone or in combination with other LDL-C-lowering therapies, in adults with primary hyperlipidemia, including HeFH, to reduce LDL-C
    - As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

- The approval of Praluent for the expanded indication was based on a randomized, placebo controlled, double blind study in 153 pediatric patients aged 8 to 17 years with HeFH. Patients were randomized to receive Praluent or placebo.

    - At week 24 in the group receiving treatment every 4 weeks, the treatment difference between the Praluent and placebo groups in least squares (LS) mean LDL-C percent change from baseline was -31.4% (97.5% CI: -45.0, -17.9; $p < 0.0001$).

- The recommended dose of Praluent for the treatment of pediatric patients with HeFH and with a body weight less than 50 kg is 150 mg once every 4 weeks administered subcutaneously (SC). If the LDL-C lowering response is inadequate, the dosage may be adjusted to 75 mg SC once every 2 weeks.

- The recommended dose of Praluent for the treatment of pediatric patients with HeFH and with a body weight of 50 kg or more is 300 mg once every 4 weeks administered SC. If the LDL-C lowering response is inadequate, the dosage may be adjusted to 150 mg SC once every 2 weeks.

- Refer to the Praluent drug label for dosing for its adult indications.