Leqvio® (inclisiran) – Updated indication

- On July 10, 2023, Novartis announced the FDA approval of Leqvio (inclisiran), as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).
    - Leqvio was previously approved as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C.
- In addition to the updated indication, the FDA removed the *Limitations of Use* in the Leqvio label (which stated the effect of Leqvio on cardiovascular morbidity and mortality has not been determined).
- The recommended dose of Leqvio, in combination with statin therapy, is 284 mg administered as a single subcutaneous injection initially, again at 3 months, and then every 6 months.
    - Leqvio should be administered by a healthcare professional.