FDA Approves Novartis Leqvio® (inclisiran)

On December 22, 2021, the FDA approved Novartis Leqvio® (inclisiran), the first small interfering RNA (siRNA) therapy to lower low-dentistry lipoprotein cholesterol (LDL-C). Leqvio reduces the amount of LDL-C in the bloodstream by improving the liver's natural ability to prevent the production of a protein (PCSK9i) that plays a role in keeping circulating cholesterol levels high.

In the Phase III ORION trials, Leqvio delivered effective and sustained LDL-C reduction up to 52% in comparison to placebo at month 17. This therapy is indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) who require additional lowering of LDL-C. The effects of Leqvio on cardiovascular morbidity and mortality is being explored in clinical trials currently underway.

Leqvio is provided as a 284mg dose administered via subcutaneous injection given by a healthcare provider with an initial dose, then again at three months, and then every six months thereafter. If a dose is missed by less than 3 months from the usual day of administration, it is recommended to administer the dose as soon as possible and resume the original schedule. If a dose is missed greater than 3 months, it is recommended to skip the missed dose and restart with a new dosing schedule as an initial dose, then again in 3 months then every 6 months.

It is recommended to obtain a lipid profile prior to initiation of treatment then recheck in 4 to 12 weeks after starting therapy, and then every 3 to 12 months thereafter. There are no renal or hepatic dose adjustments required by the manufacturer for Leqvio. Additionally, there are no drug-drug interactions or contraindications to use at this time.

Leqvio was well-tolerated with a safety profile shown to be comparable to placebo in the clinical trial. The most common side effects were mild to moderate injection site reaction including pain, redness, rash, joint pain, urinary tract infection, diarrhea, chest cold, pain in legs or arms, and shortness of breath.

Leqvio is available in cartons containing 1 single-dose prefilled syringe offered through a buy-and-bill service through authorized distributors or through participating specialty pharmacies. If your office does not wish to obtain the product through a buy-and-bill process, there may be alternative injection centers (AIC) in your area. Please use the following website to see if there is a center located near you at www. Leqvio-locator.com . Once you have found the AIC and notified your patient, you will need to send a referral to the AIC. Each AIC may have different requirements for a referral so it is important to check with the AIC to make sure you have all the correct information prepared before you send the referral.

Leqvio is considered a medical benefit therefore information regarding exact copays vary based on the patient's insurance plan. Leqvio's service center representatives (Susan Neamon at 716-560-1208) can run benefit investigations for patients and provide a statement of benefits for each specific patient depending on their coverage or secondary plans, as well as provide your office with support on prior authorizations. For those with commercial insurance, Novartis is currently offering a $0 copay savings card. Additionally, patients can sign up for the copay program directly by visiting Leqvio.com or calling 1-833-537-8462.

Below is a table of the medical policies that are available to the public. Plans, such as Independent Health, do not publicly publish their policies therefore please consider referring these patients whose plans are not listed below to the Leqvio service center for additional assistance on coverage. Additionally, Fidelis Care does not currently have a policy for Leqvio however it still may be covered with prior authorization or exception.

Insurance Plan	Leqvio Coverage by Plan
Aetna	Inclisiran (Leqvio) - Medical Clinical Policy Bulletins | Aetna
BlueCross BlueShield – Federal Employee Program	54032 Leqvio inclisiran.pdf (fepblue.org)
BlueCross BlueShield - WNY	leqvio.pdf (bcbswny.com)
Empire Blue	Leqvio.pdf (empireblue.com)
Univera	POLICY: (univerahealthcare.com)
United Healthcare	Leqvio® (Inclisiran) – Commercial Medical Benefit Drug Policy (uhcprovider.com)

More information regarding the distribution and acquisition of Leqvio can be found at Leqvio-access.com.

References:

1. FDA approves Novartis Leqvio® (Inclisiran), first-in-class Sirna to lower cholesterol and keep it low with twodoses a year. Novartis. (n.d.). Retrieved June 6, 2022, from https://www.novartis.com/news/media-releases/fda-approves-novartis-leqvio-inclisiran-first-class-sirnalower-cholesterol-and-keep-it-low-two-doses-year