Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 0422 – February 2022

Inclisiran (Leqvio®) 284 mg solution for injection in pre-filled syringe

Full submission by Novartis Pharmaceuticals UK Ltd

Recommendation of AWMSG

Inclisiran (Leqvio®) is recommended as an option for restricted use within NHS Wales.

Inclisiran (Leqvio®) is licensed for the treatment of adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- **in combination with a statin or statin with other lipid lowering therapies in patients who are unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin, or**
- **alone or in combination with other lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated.**

Inclisiran (Leqvio®) is restricted for use in a subpopulation of the licensed indication who are at high risk of further cardiovascular (CV) events:

- **patients with high risk due to previous CV events and LDL-C ≥4.0 mmol/L, or**
- **patients with recurrent/polyvascular disease and LDL-C ≥3.5 mmol/L, or**
- **patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥3.5 mmol/L, for secondary prevention of CV events, or**
- **patients with HeFH and LDL-C ≥5.0 mmol/L, for primary prevention of CV events.**

Inclisiran (Leqvio®) is not recommended for use within NHS Wales outside of this subpopulation.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent to or lower than the WPAS price.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3746), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.