

volanesorsen sodium solution for injection in pre-filled syringe (Waylivra®)

Akcea Therapeutics UK Ltd

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ADVICE: in the absence of a submission for reassessment through the ultra-orphan framework from the holder of the marketing authorisation

volanesorsen (Waylivra®) is not recommended for use within NHSScotland.

Indication under review: as an adjunct to diet in adult patients with genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate.

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result, we cannot recommend its use within NHSScotland.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Chair
Scottish Medicines Consortium