

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	Leqvio is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).						
<b>Exclusion Criteria</b>	Must not be used in combination with a PCSK9 inhibitor (e.g., Repatha), Nexletol, or Nexlizet.						
<b>Required Medical Information</b>	Must submit most recent LDL-C level. Medical records supporting the request must be provided.						
<b>Age Restriction</b>	None.						
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board- certified lipidologist.						
<b>Coverage Duration</b>	Initial Coverage: one year. Reauthorization: two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.						
<b>Other Criteria/Information</b>	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. <table border="1" data-bbox="496 961 1511 1108"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J1306</td> <td>Leqvio (inclisiran)</td> <td><b>Billing unit: 1 mg</b>  284 mg/1.5 mL prefilled syringe</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J1306	Leqvio (inclisiran)	<b>Billing unit: 1 mg</b>  284 mg/1.5 mL prefilled syringe
HCPCS	Description	Billing Units/How Supplied					
J1306	Leqvio (inclisiran)	<b>Billing unit: 1 mg</b>  284 mg/1.5 mL prefilled syringe					

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025