

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	Qalsody is an antisense oligonucleotide indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene.						
Exclusion Criteria	None.						
Required Medical Information	Medical records supporting the request must be provided including the following: <ol style="list-style-type: none"> 1. Documentation confirming the diagnosis; 2. Documentation confirming the superoxide dismutase 1 (SOD1) gene mutation; 3. Documentation of the patient's baseline neurofilament light chain (NfL) level 						
Age Restriction	Must be 18 years of age or older.						
Prescriber Restrictions	Must be prescribed by a neurologist.						
Coverage Duration	<p>Initial and reauthorization: one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</p> <p>For initial approval: Must have weakness associated with ALS, and Must have a vital capacity $\geq 50\%$ (or $\geq 45\%$ if the vital capacity has been stable defined as not declining more than 5% in the previous six months).</p> <p>For reauthorization: Must have documentation of a decrease in plasma neurofilament light chains from baseline.</p>						
Other Criteria/Information	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J1304</td> <td>Qalsody (tofersen)</td> <td>Billing unit: 1 mg 100 mg/15 mL (6.7 mg/mL) solution SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J1304	Qalsody (tofersen)	Billing unit: 1 mg 100 mg/15 mL (6.7 mg/mL) solution SDV
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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