

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	Lantidra for hepatic portal vein infusion is an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education.						
<b>Exclusion Criteria</b>	None.						
<b>Required Medical Information</b>	<p>The following are required for approval:</p> <ol style="list-style-type: none"> <li>1. Medical records supporting the request</li> <li>2. Diagnosis of type 1 diabetes</li> <li>3. Patient has had intensive insulin management that includes the appropriate use of a CGM (i.e., with insulin pump or with an automated insulin delivery system)</li> <li>4. Patient has been unable to reach target HbA1c despite intensive diabetes education and insulin management due to current, repeated episodes of severe hypoglycemia defined by the ADA as Level 3 hypoglycemia (a severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery, regardless of glucose level)</li> <li>5. Lantidra must be taken with concomitant immunosuppressants</li> <li>6. Approval of the patient's islet cell transplant must be on file prior to determination of Lantidra's use in any patient.</li> </ol>						
<b>Age Restriction</b>	Patient is at least 18 years of age.						
<b>Prescriber Restrictions</b>	None.						
<b>Coverage Duration</b>	<p>Initial: one infusion. Reauthorization: up to two additional infusions.</p> <p>For reauthorization: Patient has not achieved independence from exogenous insulin within one year of infusion - or - within one year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion. There are no data regarding the effectiveness or safety for patients receiving more than three infusions.</p>						
<b>Other Criteria/Information</b>	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1" data-bbox="495 1486 1515 1812"> <thead> <tr> <th data-bbox="495 1486 695 1528">HCPCS</th> <th data-bbox="695 1486 1159 1528">Description</th> <th data-bbox="1159 1486 1515 1528">Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td data-bbox="495 1528 695 1812">J3590*, C9399*</td> <td data-bbox="695 1528 1159 1812">Lantidra (donislecel-jujn)</td> <td data-bbox="1159 1528 1515 1812"> <p>Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.</p> <p>400 mL infusion bag containing not more than 10 cc of estimated packed islet tissue and not more than 1 x 10<sup>6</sup> EIN</p> </td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J3590*, C9399*	Lantidra (donislecel-jujn)	<p>Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.</p> <p>400 mL infusion bag containing not more than 10 cc of estimated packed islet tissue and not more than 1 x 10<sup>6</sup> EIN</p>
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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	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025