



Updated: 09/2023  
DMMA Approved: 09/2023

**Request for Prior Authorization for Lantidra (donislecel-juju)**  
**Website Form – [www.highmarkhealthoptions.com](http://www.highmarkhealthoptions.com)**  
**Submit request via: Fax - 1-855-476-4158**

All requests for Lantidra (donislecel-juju) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

**Lantidra (donislecel-juju) Prior Authorization Criteria:**

Coverage may be provided with a diagnosis of **Type I Diabetes** and the following criteria is met:

- Documentation the member has had Type I diabetes for more than 5 years accompanied by all the following despite intensive insulin management efforts (including insulin, devices, and education):
  - Unable to reach target HbA1C due to repeated episodes of severe hypoglycemia
  - At least one episode of severe hypoglycemia in the past 3 years defined as an event with symptoms compatible with hypoglycemia in which the member required the assistance of another person, and which was associated with either a blood glucose level < 50 mg/dL (2.8 mmol/L) or prompt recovery after oral carbohydrate, intravenous glucose, or glucagon administration
  - Prescriber attestation that the member reports reduced awareness of hypoglycemia as defined by the absence of adequate autonomic symptoms at capillary glucose levels of < 54 mg/dL (3 mmol/L) AND the member is unable to prevent repeated severe hypoglycemia events using intensive diabetes management (including insulin, devices, and education)
- Prescriber by or in consultation with an endocrinologist
- The member must not have any of the following:
  - Co-existing cardiac disease defined by one of the following:
    - Recent (within past 6 months) myocardial infarction
    - Angiographic evidence of non-correctable coronary artery disease
    - Evidence of ischemia on functional cardiac exam (with a stress echo test recommended for members with a history of ischemic disease).
    - Heart failure > New York Heart Association (NYHA) II
    - History of stroke within the past 6 months
  - Active alcohol or substance abuse-includes cigarette smoking (must be abstinent for six months). Active alcohol abuse should be considered using the current National Institute on Alcohol Abuse and Alcoholism (NIAAA) definitions.
  - Psychiatric disorder making the member not a suitable candidate for transplantation, e.g., schizophrenia, bipolar disorder, or major depression that is unstable or uncontrolled on current medication.
  - History of non-adherence to prescribed regimens
  - Active infection including hepatitis C, hepatitis B, HIV
  - TB (by history or currently infected as evidenced by a positive QuantiFERON® -TB Gold test or under treatment for suspected TB)
  - Any history of malignancies except squamous or basal skin cancer. Any member found to have squamous or basal cancer is required to have it removed prior to transplant.

- Body Mass Index (BMI) > 27 kg/m<sup>2</sup>.
- C-peptide response to glucagon stimulation (1 mg IV) (any C-peptide ≥ 0.3 ng/mL)
- Creatinine clearance < 80 mL/min/1.73 m<sup>2</sup> by 24-hour urine collection. If corrected creatinine clearance is < 80 and serum creatinine is < 1.2 mg/dL, then a nuclear renal scan is required to determine glomerular filtration rate.
- Serum creatinine consistently > 1.5 mg/dL
- Macroalbuminuria (urinary albumin excretion rate > 300 mg/24h)
- Baseline Hb < 12 gm/dL in women or < 13 gm/dL in men
- Baseline liver function tests (LFT) outside of normal range (An initial LFT test panel with any values > 1.5 times normal upper limits will exclude a member without a re-test. A re-test for any values between normal and 1.5 times normal should be made, and if the values remain elevated above normal limits, the member will be excluded.)
- Untreated proliferative retinopathy
- Positive pregnancy test, intent for future pregnancy, or male members' intent to procreate, unwilling to follow effective contraceptive measures, or presently breast-feeding
- Insulin requirement > 0.7 IU/kg/day
- HbA1c > 12%
- Hyperlipidemia (fasting LDL cholesterol > 130 mg/dL, treated or untreated; and/or fasting triglycerides > 200 mg/dL)
- Under treatment for a medical condition requiring chronic use of steroids other than a previous organ transplant
- Use of coumadin or other antiplatelet or anticoagulant therapy, or member with PT INR > 1.5. Low dose aspirin is allowed after transplantation.
- History of Factor V deficiency
- Addison's disease
- Allergy to radiographic contrast material
- Symptomatic cholecystolithiasis
- Acute or chronic pancreatitis
- Symptomatic peptic ulcer disease
- Severe unremitting diarrhea, vomiting, or other gastrointestinal disorders that could interfere with the ability to absorb oral medications
- Received live attenuated vaccine(s) within 2 months
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- Must be used in conjunction with concomitant immunosuppression
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Documentation the member 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
- **Reauthorization Duration of Approval:** 12 months (maximum 3 infusions per lifetime)

## LANTIDRA (DONISLECEL-JUJU) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE: (844) 325-6251 Mon – Fri 8:00 am to 7:00 pm**

### PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

### MEMBER INFORMATION

Member Name:	DOB:
Member ID:	Member weight: Height:

### REQUESTED DRUG INFORMATION

Medication:	Strength:
Directions:	Quantity: Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	

### Billing Information

This medication will be billed: <input type="checkbox"/> at a pharmacy <b>OR</b> <input type="checkbox"/> medically, JCODE:
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other

### Place of Service Information

Name:	NPI:
Address:	Phone:

### MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:
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How long has the member been diagnosed with Type I diabetes? \_\_\_\_\_

Does the member have any of the following (please check all that apply):

- ☐ the inability to reach target HbA1C due to repeated episodes of severe hypoglycemia
- ☐ History of at least one episode of severe hypoglycemia in the past 3 years defined as an event with symptoms compatible with hypoglycemia in which the member required the assistance of another person, and which was associated with either a blood glucose level < 50 mg/dL (2.8 mmol/L) or prompt recovery after oral carbohydrate, intravenous glucose, or glucagon administration
- ☐ reduced awareness of hypoglycemia as defined by the absence of adequate autonomic symptoms at capillary glucose levels of < 54 mg/dL (3 mmol/L) AND the member is unable to prevent repeated severe hypoglycemia events using intensive diabetes management (including insulin, devices, and education)
- ☐ Recent (within past 6 months) myocardial infarction
- ☐ Angiographic evidence of non-correctable coronary artery disease
- ☐ Evidence of ischemia on functional cardiac exam (with a stress echo test recommended for members with a history of ischemic disease).
- ☐ Heart failure > New York Heart Association (NYHA) II
- ☐ History of stroke within the past 6 months
- ☐ Active alcohol or substance abuse-includes cigarette smoking (must be abstinent for six months). Active alcohol abuse should be considered using the current National Institute on Alcohol Abuse and Alcoholism (NIAAA) definitions.
- ☐ Psychiatric disorder making the member not a suitable candidate for transplantation, e.g., schizophrenia, bipolar disorder, or major depression that is unstable or uncontrolled on current medication.
- ☐ History of non-adherence to prescribed regimens
- ☐ Active infection including hepatitis C, hepatitis B, HIV
- ☐ TB (by history or currently infected as evidenced by a positive QuantiFERON® -TB Gold test or under treatment for suspected TB)
- ☐ Any history of malignancies except squamous or basal skin cancer. Any member found to have squamous or basal cancer is required to have it removed prior to transplant.

**LANTIDRA (DONISLECEL-JUJU)  
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2**

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**MEMBER INFORMATION**

Member Name:	DOB:	
Member ID:	Member weight:	Height:

**MEDICAL HISTORY (Complete for ALL requests)**

- ☐ Body Mass Index (BMI) > 27 kg/m<sup>2</sup>.
- ☐ C-peptide response to glucagon stimulation (1 mg IV) (any C-peptide ≥ 0.3 ng/mL)
- ☐ Creatinine clearance < 80 mL/min/1.73 m<sup>2</sup> by 24-hour urine collection. If corrected creatinine clearance is < 80 and serum creatinine is < 1.2 mg/dL, then a nuclear renal scan is required to determine glomerular filtration rate.
- ☐ Serum creatinine consistently > 1.5 mg/dL
- ☐ Macroalbuminuria (urinary albumin excretion rate > 300 mg/24h)
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- ☐ Untreated proliferative retinopathy
- ☐ Positive pregnancy test, intent for future pregnancy, or male members' intent to procreate, unwilling to follow effective contraceptive measures, or presently breast-feeding
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- ☐ Symptomatic cholecystolithiasis
- ☐ Acute or chronic pancreatitis
- ☐ Symptomatic peptic ulcer disease
- ☐ Severe unremitting diarrhea, vomiting, or other gastrointestinal disorders that could interfere with the ability to absorb oral medications
- ☐ Received live attenuated vaccine(s) within 2 months

Will the therapy be used conjunction with concomitant immunosuppression? ☐ Yes ☐ No

**REAUTHORIZATION**

Has the member achieved independence from exogenous insulin? ☐ Yes ☐ No

Date of last infusion: \_\_\_\_\_

Date member lost independence from exogenous insulin: \_\_\_\_\_

How many infusions has the member had? \_\_\_\_\_

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No

**SUPPORTING INFORMATION or CLINICAL RATIONALE**

<b>Prescribing Provider Signature</b>	<b>Date</b>