HIGHMARK HEALTH OPTIONS

Updated: 07/2024
Approved:01/2024

Request for Prior Authorization for Lantidra (donislecel-juju)
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

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/m2.
  - C-peptide response to glucagon stimulation (1 mg IV) (any C-peptide ≥ 0.3 ng/mL)
  - Creatinine clearance < 80 mL/min/1.73 m2 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, 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)

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-

reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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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: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: 1-844-325-6251 Mon – Fri 8 am to 7 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? ☐ Yes ☐ 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? ☐ Yes ☐ No		

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

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 > Ne w 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.

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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/m2.
☐ C-peptide response to glucagon stimulation (1 mg IV) (any C-peptide ≥ 0.3 ng/mL)
☐ Creatinine clearance < 80 mL/min/1.73 m2 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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☐ 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

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

Prescribing Provider Signature	Date