SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Lantidra™ (donislecel) **IV (J3590) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage and Administration:

- Lantidra is supplied as two (2) infusion bags connected to each other via sterile connector. One bag contains Lantidra up to a maximum of $1x10^6$ equivalent islet number (EIN) in 400ml of transplant media and the second bag (Rinse Bag) contains transplant media used to rinse the Lantidra bag and infusion line. **Must be administered for infusion into the hepatic portal vein only.**
- Administered by interventional radiologists and surgeons with expertise in islet cell infusion in an interventional radiology suite or operating suite under controlled aseptic conditions.
- The recommended minimum dose is 5000 equivalent islet number (EIN) per kg patient body weight for initial infusion (transplant) and 4,500 EIN/kg for subsequent infusions.
- **Maximum Dose – 1 infusion up to a maximum of $1x10^6$ EIN per bag per year: 1 infusion bag yearly x 3 infusions only.**

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months (1 infusion bag yearly)

- ❑ Prescribed by or in consultation with an endocrinologist
- ❑ Member must be 18 years of age or older
- ❑ Member has a confirmed diagnosis of Type I diabetes mellitus for more than 5 years complicated by **ALL** of the following despite intensive insulin management **(must submit chart note documentation and labs)**:
  - ❑ Intensive insulin management that includes coordination of diet and activity with physiologic insulin replacement (i.e., multiple daily injections of prandial and basal insulin or continuous subcutaneous insulin infusion)
  - ❑ Intensive monitoring of blood glucose with either use of a continuous glucose monitor (CGM) or insulin pump
  - ❑ One or more episodes of severe hypoglycemia in the past 3 years which necessitated assistance from another person and was associated with either a blood glucose level less than 50 mg/dL or prompt recovery after oral carbohydrate, intravenous glucose, or glucagon administration
  - ❑ Reduced awareness of hypoglycemia, defined by the absence of adequate autonomic symptoms (e.g., palpitations, anxiety, sweating, confusion, sensation of warmth, weakness, or fatigue, severe cognitive failure) at a plasma glucose levels of less than 54 mg/dL
- ❑ Lantidra will be prescribed in combination with immunosuppressive therapy (e.g., anakinra, daclizumab, basiliximab, mycophenolate mofetil, etanercept, everolimus, sirolimus, tacrolimus, cyclosporine, anti-thymocyte immunoglobulin) **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Member is T- and B- cell crossmatch assay negative (**Provider please note:** patients with a positive T- and B-cell crossmatch between recipient serum and donor lymphocytes may be at increased risk for graft infections)
- ❑ Member has **NOT** received a previous transplant or evidence of sensitization on Panel Reactive Antibody (PRA) that indicates high-risk for transplant rejection. (Product administration may elevate PRA and negatively impact candidacy for renal transplant).
- ❑ Member does **NOT** have concomitant disease or condition (including pregnancy) that contraindicates the procedure for infusion or immunosuppression
- ❑ Member does **NOT** have a history of a history of prior portal vein thrombosis (excludes thrombosis limited to second or third order portal vein branches)
- ❑ Member does **NOT** have a history of liver disease or renal failure
- ❑ Member does **NOT** have an active infection, including clinically important localized infections
- ❑ Member will **NOT** receive live vaccines during treatment with immunosuppression
- ❑ Member will be clinically monitored for increased risk of severe infections including opportunistic infections, severe anemia and malignancy including skin cancer during treatment.

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Reauthorization: 12 months. (1 infusion bag yearly; maximum of 3 infusions). Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has received authorization/reauthorization for the requested agent previously approved by another health plan in the past 2 years **(must submit documentation of a health plan paid claim during the last 2 years and clinical chart notes before authorization request is submitted)**
- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., severe infections, portal vein thrombosis, portal hypertension, islet graft rejection)
- ❑ Member has not achieved independence from exogenous insulin, is not at the target HbA1c goal, and continues to experience severe hypoglycemia episodes requiring intervention (e.g., oral carbohydrate, intravenous glucose, or glucagon administration) and hospitalization **(must submit chart notes and labs)**
- ❑ Member is adherent to the prescribed immunosuppressive therapy
- ❑ Provider is requesting a second infusion which may be performed due to failure to achieve independence from exogenous insulin within one year of infusion (or within one year after losing independence exogenous insulin within one year of infusion
- ❑ Provider is requesting a third infusion which may be performed using the same criteria as stated above for the second infusion. (There is no evidence to support the effectiveness or safety for patients receiving more than three infusions)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR
- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****