Chemotherapy: T-Cell Hairy Lymphoma Cancer Drugs

Folotyn (pralatrexate inj) J9307, Romidepsin (generic) 9315, Istodax (romidepsin) (non-lyph)J9318 / (lypholized)J9319, Nipent (pentostatin) J9268, Adcetris (brentuximab vedotin) J9042, Lymphir (denileukin diftitox) J9160

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Chemotherapy: Hairy/T-Cell Cancer Meds PA

Drug Name(s):

ISTODAX	**ROMIDEPSIN**
NIPENT	**PENTOSTATIN**
FOLOTYN	**PRALATREXATE**
LYMPHIR	**DENILEUKIN DIFITOX**
ADCETRIS	**BRENTUXIMAB VEDOTIN**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per **NCCN**, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Coverage Duration:

New Start: Approval will be for 6 months
Continuation: Approval will be for 12 months

FDA Indications:

Istodax / Romidepsin

- Primary cutaneous T-cell lymphoma, Following at least one prior systemic therapy

Nipent

- Hairy cell leukemia, Untreated or alpha-interferon-refractory

Folotyn

- Peripheral T-cell lymphoma (clinical), Relapsed or refractory

Adcetris

- Anaplastic large T-cell systemic malignant lymphoma, After failure of at least one multi-agent chemotherapy regimen
- Anaplastic large T-cell systemic malignant lymphoma, Or other CD30-expressing peripheral T cell lymphomas, previously untreated, in combination with cyclophosphamide, DOXOrubicin, and predniSONE
- Hodgkin's disease, Classical, after failure of autologous hematopoietic stem cell transplant (auto-HSCT) or after failure of at least 2 multiagent chemotherapy regimens in patients not eligible for auto-HSCT
- Hodgkin's disease, Classical, consolidation therapy after autologous hematopoietic stem-cell transplantation (auto-HSCT), in patients at high risk of relapse or progression
- Hodgkin's disease, Classical, first-line treatment, stage III or IV disease, in combination with DOXOrubicin, vinBLAStine, and dacarbazine
- Hodgkin's disease, Classical, high risk, first-line treatment, in combination with doxorubicin, vinCRIStine, etoposide, predniSONE, and cyclophosphamide

- Mycosis fungoides, CD30-expressing, in patients who have received prior systemic therapy
- Primary cutaneous lymphoma, Anaplastic large cell, in patients who have received prior systemic therapy

Lymphir

- (in phase trials)

Off-Label Uses:

Nipent

- Chronic lymphoid leukemia, In combination with cyclophosphamide and rituximab
- Graft-versus-host disease, chronic, Corticosteroid-refractory
- Primary cutaneous lymphoma

Age Restrictions:

Safety and effectiveness not established in pediatric patients

Other Clinical Considerations:

Cancer diagnoses: Criteria as per NCCN or other FDA-approved cancer related guidelines.

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/261382/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/DFC899/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=929527&contentSetId=100&title=Romidepsin&servicesTitle=Romidepsin&brandName=Istodax&UserMdxSearchTerm=Istodax&=null#

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