Folotyn (pralatrexate)

**Line(s) of Business:**
- HMO; PPO; QUEST Integration
- Medicare Advantage

**Original Effective Date:**
10/01/2015

**Current Effective Date:**
01/01/2018

**POLICY**

**A. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

**FDA-Approved Indication**

Folotyn is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated.

**Compendial Uses**

- **Mycosis fungoides/Sézary syndrome (MF/SS)**
  - First-line therapy for
    - Stage IB-IIA MF with histologic evidence of folliculotropic or large cell transformation
    - Stage IIB with generalized tumor lesions
    - Stage IV non-Sézary or visceral disease
    - Stage III MF or SS which has progressed or is refractory to multiple previous therapies
  - Single-agent therapy for tumors with histologic evidence of large cell transformation and aggressive growth rate for
    - Stage IB-IIA MF with histologic evidence of folliculotropic or large cell transformation
    - Stage IIB with generalized tumor lesions
    - Stage IV non-Sézary or visceral disease

- **Adult T-cell leukemia/lymphoma (ATLL)**
  - Second-line therapy as a single agent for nonresponders to first-line therapy for acute disease or lymphoma
  - Subsequent therapy after high dose therapy/autologous stem cell rescue (HDT/ASCR)

- **Primary cutaneous CD30+ T-cell lymphoproliferative disorders (LPDs), single-agent therapy as primary treatment or therapy for relapsed or refractory disease:**
  - Primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions
  - Cutaneous ALCL with regional nodes

- **Peripheral T-cell lymphoma (PTCL), second-line or subsequent therapy for relapsed or refractory:**
  - Angioimmunoblastic T-cell lymphoma (AITL)
  - PTCL, not otherwise specified
o ALCL
o Enteropathy-associated T-cell lymphoma (EATL)
o Monomorphic epitheliotropic intestinal T-cell lymphoma

B. REQUIRED DOCUMENTATION
The following documentation from the medical record is necessary to initiate the prior authorization review:

- Initial therapy:
  o Current oncology notes
  o Clinical notes that include the history of previous treatments
  o Pertinent pathology reports and/or imaging studies
- Continuation of therapy: documentation (including clinical notes and objective findings such as imaging studies) that demonstrate lack of disease progression on therapy

C. INITIAL CRITERIA FOR APPROVAL

1. Adult T-cell leukemia/lymphoma (ATLL)
Authorization of 6 months may be granted when Folotyn is used for second-line therapy as a single agent and either of the following criteria is met:
   a. The member is a nonresponder to first-line therapy for acute disease or lymphoma, or
   b. Folotyn will be used as subsequent therapy after high-dose therapy/autologous stem cell rescue

2. Peripheral T-cell lymphoma (PTCL)
Authorization of 6 months may be granted to members who are prescribed Folotyn when ALL of the following criteria are met:
   a. The member has one of the following subtypes of PTCL:
      i. Angioimmunoblastic T-cell lymphoma (AITL)
      ii. PTCL, not otherwise specified
      iii. ALCL
      iv. Enteropathy-associated T-cell lymphoma (EATL)
      v. Monomorphic epitheliotropic intestinal T-cell lymphoma
   b. Folotyn will be used as second-line or subsequent therapy for relapsed or refractory disease

3. Primary cutaneous CD30+ T-cell lymphoproliferative disorder (LDP)
Authorization of 6 months may be granted to members who are prescribed Folotyn when ALL of the following criteria are met:
   a. Member has one of the following disease subtypes:
      i. Primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions
      ii. Cutaneous ALCL with regional nodes
      iii. CD30+ transformed mycosis fungoides (Refer to criteria for approval in Section 4)
   b. Folotyn will be used as primary treatment OR as therapy for relapsed or refractory disease
   c. Folotyn will be used as a single agent (as monotherapy)

4. Mycosis fungoides (MF)/Sézary syndrome (SS)
Authorization of 6 months may be granted to members who are prescribed Folotyn for when ALL of the criteria pertaining to the MF/SS disease stage are met (Sections 4.1 to 4.4 below)
4.1 Stage IB and IIA MF:
Members with Stage IB or IIA disease must meet the criteria below:
   a. Histologic evidence of folliculotropic or large cell transformation is present
   b. Folotyn is used either in low doses as first-line therapy or in standard doses as a single agent (monotherapy) for tumors with histologic evidence of large cell transformation and aggressive growth rate

4.2 Stage IIB MF:
Members with Stage IIB disease must meet the criteria below:
   a. Member has generalized tumor lesions
   b. Folotyn is used either in low doses as first-line therapy or in standard doses as a single agent (monotherapy) for tumors with histologic evidence of large cell transformation and aggressive growth rate

4.3 Stage III MF:
Members with either Stage III disease must meet the criteria below:
   a. Member must have progressive disease or disease refractory to multiple previous therapies
   b. Folotyn is used in low doses as first-line therapy

4.4 Stage IV, non-Sézary or visceral (solid organ) disease
Members with Stage IV non-Sézary or visceral (solid organ) disease must meet the following criterion:
   Folotyn is used either in low doses as first-line therapy or in standard doses as a single agent (monotherapy) for tumors with histologic evidence of large cell transformation and aggressive growth rate

D. CONTINUATION OF THERAPY
1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.
2. Reauthorization:
   Authorization of 6 months may be granted to members requesting authorization for continuation of therapy if Folotyn was previously authorized by HMSA/CVS and there is evidence of a lack of disease progression on therapy.

E. DOSAGE AND ADMINISTRATION
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES
   Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

G. IMPORTANT REMINDER
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.
Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. REFERENCES

Document History

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