Reference number(s)
1900-A

MEDICAL PRIOR AUTHORIZATION

ALIMTA (pemetrexed)
PEMFEXY (pemetrexed)
PEMRYDI RTU (pemetrexed)
pemetrexed

POLICY

I. 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.

A. FDA-Approved Indications
   1. Non-squamous non-small cell lung cancer (NSCLC)
      a. In combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EFGR or ALK genomic tumor aberrations.
      b. In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC).
      c. As a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
      d. As a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy.

         Limitations of use: Pemetrexed is not indicated for the treatment of patients with squamous cell, non-small cell lung cancer (NSCLC).

   2. Mesothelioma
      In combination with cisplatin, for the initial treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

B. Compendial Uses
   1. Bladder cancer
   2. Pleural mesothelioma
   3. Peritoneal mesothelioma
   4. Pericardial mesothelioma
   5. Tunica vaginalis testis mesothelioma
   6. Nonsquamous non-small cell lung cancer (NSCLC)
   7. Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serious carcinoma/ovarian borderline epithelial tumor (low malignant potential), and mucinous carcinoma of the ovary
   8. Primary central nervous system (CNS) lymphoma
   9. Thymomas and thymic carcinomas
   10. Cervical cancer

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided for members with squamous cell NSCLC.

III. CRITERIA FOR INITIAL APPROVAL

A. Bladder Cancer
Authorization of 6 months may be granted for treatment of locally advanced, metastatic, or relapsed transitional cell urothelium cancer, as second-line treatment.

B. Pleural or Peritoneal Mesothelioma
Authorization of 6 months may be granted for treatment of pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma, when any of the following criteria are met:
1. The requested medication will be used as a single agent or in combination with cisplatin or carboplatin; or
2. The requested medication will be used in combination with bevacizumab or durvalumab (Imfinzi) and either cisplatin or carboplatin.

C. Non-Small Cell Lung Cancer (Non-Squamous Histology)
Authorization of 6 months may be granted for treatment of non-squamous non-small cell lung cancer (including leptomeningeal metastases).

D. Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer
Authorization of 6 months may be granted for treatment of persistent or recurrent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serious carcinoma/ovarian borderline epithelial tumor (low malignant potential), or mucinous carcinoma of the ovary, as single agent therapy.

E. Primary Central Nervous System (CNS) Lymphoma
Authorization of 6 months may be granted for treatment of primary CNS lymphoma, as a single agent.

F. Thymomas and Thymic Carcinomas
Authorization of 6 months may be granted for treatment of thymoma or thymic carcinoma, as a single agent.

G. Cervical Cancer
Authorization of 6 months may be granted for treatment of persistent, recurrent, or metastatic cervical cancer.

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Alimta [package insert]. Indianapolis, IN: Lilly USA, LLC; August 2022.
2. Pemfexy [package insert]. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc.; December 2022.
3. Pemetrexed disodium [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; September 2022.
4. Pemrydi RTU [package insert]. Ahmedabad, India: Zydus Lifesciences Limited; June 2023
5. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed July 13, 2023.
6. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; https://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 13, 2023.
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