

# STANDARD MEDICARE PART B MANAGEMENT

## FUSILEV (levoleucovorin) powder KHAPZORY (levoleucovorin) powder levoleucovorin solution

### 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. Levoleucovorin/Fusilev/Khazpory is indicated for rescue after high-dose methotrexate therapy in osteosarcoma.
2. Levoleucovorin/Fusilev/Khazpory is indicated for diminishing the toxicity and counteracting the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists.
3. Fusilev is indicated for use in combination chemotherapy with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer.
4. Khazpory is indicated for use in combination chemotherapy with fluorouracil for treatment of metastatic colorectal cancer.

##### B. Compendial Uses

1. Rescue treatment after high-dose methotrexate therapy in osteosarcoma, dedifferentiated chondrosarcoma, high-grade undifferentiated pleomorphic sarcoma, peripheral T-cell lymphomas, adult T-cell leukemia/lymphoma, nasal type extranodal NK/T-cell lymphoma, mantle cell lymphoma, AIDS-related B-cell lymphomas, Burkitt lymphoma, acute lymphoblastic leukemia, primary CNS lymphoma, brain metastases, leptomeningeal metastases, gestational trophoblastic neoplasia, grade 1-2 follicular lymphoma, diffuse large B-cell lymphoma, high-grade B-cell lymphoma, rhabdomyosarcoma, chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), hepatosplenic gamma-delta T-cell lymphoma, and anal carcinoma.
2. Used in combination with fluorouracil based regimens for colorectal cancer, gastric adenocarcinoma, esophageal/esophagogastric junction cancer, pancreatic adenocarcinoma, thymomas/thymic carcinomas, cervical cancer, squamous cell anal carcinoma, occult primary, mucinous ovarian carcinomas, bladder cancer, extrahepatic/intrahepatic cholangiocarcinoma, gallbladder cancer, hepatocellular carcinoma, small bowel adenocarcinoma, and neuroendocrine and adrenal tumors when leucovorin is not an available option.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

<b>Reference number(s)</b>
4212-A

Authorization of 12 months may be granted for any of the indications listed below when leucovorin is not an appropriate/available option at this time:

- A. Rescue treatment after high-dose methotrexate therapy
- B. Treatment of a folate antagonist overdose
- C. Combination therapy with fluorouracil based chemotherapy regimens

### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with levoleucovorin, Fusilev, or Khapzory
- B. Levoleucovorin, Fusilev, or Khapzory is being used to treat an indication enumerated in Section II
- C. Leucovorin is not an appropriate /available option at this time
- D. The member is receiving benefit from therapy.

### IV. REFERENCES

1. Fusilev [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; April 2011.
2. Levoleucovorin injection [package insert]. Princeton, NJ: Sandoz Inc.; September 2016.
3. Khapzory [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; October 2018.
4. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org> . Accessed August 24, 2020.