Reference number(s)
1661-A

SPECIALTY GUIDELINE MANAGEMENT

FUSILEV (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 is indicated for rescue after high-dose methotrexate therapy in osteosarcoma.
2. Levoleucovorin/Fusilev 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.

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, and leptomeningeal metastases
2. Used in combination with fluorouracil based regimens for colorectal cancer, gastric adenocarcinoma, esophageal/esophagogastric junction cancer, pancreatic cancer, thymomas/thymic carcinomas, cervical cancer, anal adenocarcinoma, occult primary, mucinous ovarian carcinomas, and bladder cancer when leucovorin is not an available option

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

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 meet all initial authorization criteria.

IV. REFERENCES

Reference number(s)
1661-A

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2. Levoleucovorin injection [package insert]. Princeton, NJ: Sandoz Inc.; November 2013.
3. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 22, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® Colon Cancer (Version 2.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 22, 2018.
5. The NCCN Clinical Practice Guidelines in Oncology® Gastric Cancer (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 22, 2018.
6. The NCCN Clinical Practice Guidelines in Oncology® Esophageal and Esophagogastric Junction Cancer (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 22, 2018.
7. The NCCN Clinical Practice Guidelines in Oncology® Pancreatic Adenocarcinoma (Version 3.2017). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 22, 2018.
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15. The NCCN Clinical Practice Guidelines in Oncology® Bone Cancer (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 22, 2018.
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19. The NCCN Clinical Practice Guidelines in Oncology® Central Nervous System Cancers (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 22, 2018.