

Reference number(s)
1661-A

## SPECIALTY GUIDELINE MANAGEMENT

### FUSILEV (levoleucovorin) powder/solution 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.

##### 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 associated with overdosage of folic acid antagonists or impaired methotrexate elimination.
3. Levoleucovorin/Fusilev/Khazpory is indicated for use in combination chemotherapy with fluorouracil for treatment of metastatic colorectal cancer.

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

##### II. CRITERIA FOR INITIAL APPROVAL

Authorization of 3 months may be granted for any of the settings 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. REFERENCES

1. Fusilev [package insert]. East Windsor, NJ: Acrotech Biopharma LLC.; November 2020.
2. Levoleucovorin injection [package insert]. Princeton, NJ: Sandoz Inc.; December 2020.
3. Khazpory [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; March 2020.
4. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org> . Accessed March 1, 2021.