

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.

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

B. Compendial Uses

1. Rescue treatment after high-dose methotrexate therapy
2. Combination with fluorouracil-based chemotherapy regimens

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:

1. Rescue treatment after high-dose methotrexate therapy
2. Treatment of a folate antagonist overdose or impaired methotrexate elimination
3. 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

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.

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4. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc.
Available at: <https://www.nccn.org> . Accessed July 6, 2023.