

Reference number(s)
1661-A

Specialty Guideline Management levoleucovorin-Fusilev-Khaphzory

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Fusilev	levoleucovorin	powder/solution
Khaphzory	levoleucovorin	powder

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

- Levoleucovorin/Fusilev/Khaphzory is indicated for rescue after high-dose methotrexate therapy in osteosarcoma.
- Levoleucovorin/Fusilev/Khaphzory is indicated for diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination.
- Levoleucovorin/Fusilev/Khaphzory is indicated for the treatment of adults with metastatic colorectal cancer in combination with fluorouracil.

Compendial Uses

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

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

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Coverage Criteria

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:

- Rescue treatment after high-dose methotrexate therapy
- Treatment of a folate antagonist overdose or impaired methotrexate elimination
- Combination therapy with fluorouracil-based chemotherapy regimens

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

References

1. Fusilev [package insert]. East Windsor, NJ: Acrotech Biopharma LLC.; November 2020.
2. Levoleucovorin injection [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2023.
3. Khapzory [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; March 2024.
4. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org> . Accessed July 2, 2024.