

Specialty Guideline Management

levoleucovorin-Khapzory

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
Khapzory	levoleucovorin
levoleucovorin (all other brands)	levoleucovorin

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^{1,2}

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

Compendial Uses³

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

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

Reference number(s)
1661-A

Coverage Criteria¹⁻³

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. Levoleucovorin injection [package insert]. Chicago, IL; Meitheal Pharmaceuticals; December 2020.
2. Khapzory [package insert]. East Windsor, NJ: Acrotech Biopharma Inc.; December 2024.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org> . Accessed July 21, 2025.