Reference number(s)
4212-A

STANDARD MEDICARE PART B 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

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

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 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. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with levoleucovorin, Fusilev, or Khapzory.
B. Levoleucovorin, Fusilev, or Khapzory is being used to treat an indication enumerated in Section II.
C. Leucovorin is not an appropriate /available option at this time.
D. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen and

2. No evidence of disease progression while on the current regimen

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. Khapzory [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 17, 2021.