Drug Policy:

Fusilev™/Khapzory™ (levoleucovorin)

POLICY NUMBER UM ONC_1288	**SUBJECT** Fusilev™/Khapzory™ (levoleucovorin)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 04/13/16, 02/06/17, 02/01/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20	**APPROVAL DATE** November 11, 2020	**EFFECTIVE DATE** November 30, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 04/13/16, 02/06/17, 02/01/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Fusilev/Khapzory (levoleucovorin) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Osteosarcoma

1. The member has osteosarcoma or dedifferentiated chondrosarcoma and Fusilev/Khapzory is being used only when Leucovorin is not available at the office and the shortage is reported on FDA drug shortage website[1] AND
2. Fusilev/Khapzory is being used following administration of high-dose methotrexate >500 mg/m^2 over <4 hours OR >1 g/m^2 over >4 hours AND
3. Is administered 24 hours after start of methotrexate infusion so that it does not interfere with the therapeutic effect of methotrexate.

C. Colorectal Cancer

1. The member has colorectal cancer and Fusilev/Khapzory is being used only when Leucovorin is not available at the office and the shortage is reported on FDA drug shortage website[1] AND
2. Fusilev/Khapzory is being used in combination with fluorouracil-based regimens in ONE of the following conditions:
   a. For potentiation of fluorouracil therapy in the treatment of colorectal cancer
   b. For treatment of colorectal cancer in combination regimen consisting of fluorouracil, leucovorin, and either irinotecan and/or oxaliplatin.

D. Overdosages of Folic Acid Antagonists

1. Fusilev/Khapzory is being used only when Leucovorin is not available at the office and the shortage is reported on FDA drug shortage website[1] AND
2. Fusilev/Khapzory is being used to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of methotrexate in ONE of the following conditions:
   a. Used in combination with cerebral spinal fluid (CSF) exchange and dexamethasone for intrathecal methotrexate overdose
   b. Used in combination with forced diuresis and alkalization of urine to prevent potentially toxic blood levels of methotrexate
   c. Used as high dose for methotrexate-induced nephrotoxicity.

III. EXCLUSION CRITERIA

A. Fusilev/Khapzory (levoleucovorin) is being used in member with pernicious or megaloblastic anemia.

B. Dosing exceeds single dose limit of Fusilev/Khapzory (levoleucovorin) 200 mg/m^2.

C. Treatment in colorectal cancer exceeds the maximum 24 weeks duration limit.

D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA:

B. http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

C. Fusilev PI prescribing information. Acrotech Biopharma LLC. Irvine, CA. 2020.

D. Khapzory PI prescribing information. Acrotech Biopharma LLC. Irvine, CA. 2019.

E. Clinical Pharmacology Elsevier Gold Standard. 2020.

F. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.

H. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.

New Century Health