

| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|-------------------------------------|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

Fusilev (levoleucovorin calcium)

CG-DRUG-63

| Override(s) | Approval Duration |
|---------------------|-------------------|
| Prior Authorization | 1 year |

| Medications |
|---|
| Fusilev (levoleucovorin calcium) 50mg, 175 mg/17.5mL, 250 mg/ 25mL intravenous solution |

APPROVAL CRITERIA

Requests for Fusilev (levoleucovorin calcium) may be approved when the following criteria are met:

- I. As a component of high-dose methotrexate therapy in osteosarcoma; **OR**
- II. As a treatment of impaired methotrexate elimination; **OR**
- III. As a treatment of inadvertent over-dosage of folic acid antagonists; **OR**
- IV. In combination chemotherapy with fluorouracil-based regimens to treat colorectal adenocarcinoma.

Use of levoleucovorin calcium may not be approved when the criteria above are not met and for all other indications.

| State Specific Mandates | | |
|-------------------------|----------------|---|
| State name | Date effective | Mandate details (including specific bill if applicable) |
| N/A | N/A | N/A |

Key References:

1. Fusilev [Product Information]. Spectrum Pharmaceuticals, Inc.; April 2011. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020140s002lbl.pdf. Accessed on September 12, 2016.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

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2. Levoleucovorin. In: DrugPoints System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated August 3, 2016. Available at: <http://www.micromedexsolutions.com>. Accessed on September 12, 2016.
3. Levoleucovorin Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised December 13, 2012. Accessed on September 12, 2016.
4. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (electronic version). For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on September 12, 2016.
5. NCCN Clinical Practice Guidelines in Oncology®. 2016 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website at: <http://www.nccn.org/index.asp>. Accessed on September 12, 2016.
 - Colon Cancer (V.2.2016). Revised November 24, 2015.
 - Esophageal and Esophagogastric Junction Cancers (V.2.2016). Revised July 7, 2016.
 - Gastric Cancer (V.3.2016) Revised August 3, 2016.
 - Pancreatic Adenocarcinoma (V.2.2016). Revised August 16, 2016.
 - Rectal Cancer (V.2.2016). Revised April 6, 2016.

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