

Medical Policy:

Fusilev® (levoleucovorin) injection for intravenous use

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.83	March 1, 2024	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Length of Authorization

Coverage will be provided for 90 days and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [Medical Benefit]:

In combination with methotrexate or for inadvertent overdosage

1,200 billable units every 28 days

In combination with fluorouracil

2,500 billable units every 28 days

Guideline

I. Initial Approval Criteria

Coverage is provided in the following conditions:

- 1. Patient is at least 6 years old; AND
- 2. Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; AND
- 3. Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA Drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; AND

Bone Cancer (Osteosarcoma †, Dedifferentiated Chondrosarcoma ‡, High-Grade Undifferentiated Pleomorphic Sarcoma (UPS) ‡)

- 1. Patient is undergoing high-dose methotrexate chemotherapy treatment; AND
- 2. Must be used as rescue therapy in combination with chemotherapy regimen containing high dose methotrexate

Reduction of toxicity due to impaired elimination or inadvertent overdose with folic acid antagonists †

- 1. Patient is undergoing treatment with a folic acid antagonist, such as methotrexate; AND
- 2. Patient has developed toxicity due to impaired elimination or inadvertent overdosage of the folic acid antagonist (i.e., methotrexate)

Colorectal cancer † ‡

1. Must be used in combination with fluorouracil-based regimens

Used in combination with high-dose methotrexate for the following ‡

- 1. Acute Lymphoblastic Leukemia/Pediatric Acute Lymphoblastic Leukemia
- 2. Adult T-cell Leukemia/Lymphoma
- 3. AIDS-related B-cell Lymphoma
- 4. Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)
- 5. Burkitt Lymphoma
- 6. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
- 7. Mantle Cell Lymphoma
- 8. CNS Cancer (Primary CNS Lymphoma, Brain Metastases, & Leptomeningeal Metastases)
- 9. Diffuse Large B-Cell Lymphoma
- 10. Hepatosplenic T-Cell Lymphoma
- 11. High Grade B-Cell Lymphomas
- 12. Pediatric Aggressive Mature B-Cell Lymphomas
- 13. Peripheral T-cell Lymphoma
- 14. Post-Transplant Lymphoproliferative Disorders (PTLD)
- 15. Extranodal NK/T-cell Lymphoma (nasal type)

16. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma (Used for the management of symptomatic Bing-Neel syndrome)

Used in combination with fluorouracil-based regimens for the following ‡

- 1. Ampullary Adenocarcinoma
- 2. Anal Carcinoma
- 3. Bladder Cancer (non-urothelial and urothelial with variant histology)
- 4. Cervical Cancer
- 5. Esophageal, Esophagogastric Junction, & Gastric Cancer
- 6. Gallbladder Cancer, Extrahepatic Cholangiocarcinoma, and Intrahepatic Cholangiocarcinoma
- 7. Neuroendocrine and Adrenal Tumors
- 8. Occult Primary
- 9. Ovarian/Fallopian Tube/Primary Peritoneal Mucinous Carcinomas
- 10. Pancreatic Adenocarcinoma
- 11. Small Bowel Adenocarcinoma
- 12. Thymoma and Thymic Carcinoma
- † FDA labeled indication(s); ‡ Compendia recommended indication(s)

Limitations/Exclusions

Fusilev is considered investigational when used for any indication not listed above.

II. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- 1. Patient continues to meet the criteria in INITIAL APPROVAL CRITERIA; AND
- 2. Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA Drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; AND
- 3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hypersensitivity reactions, seizures, and severe gastrointestinal disorders such as stomatitis, severe diarrhea, and severe nausea and vomiting

Dosing and AdministrationPlease see Package Insert

Applicable Procedure Codes

Code Description

J0641	Injection, levoleucovorin calcium, 0.5 mg = 1 billable unit
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Applicable NDCs

Code	Description
68152-0101-xx	Fusilev 50 mg single-use vial powder for injection
68152-0102-xx	Fusilev 10 mg/mL single-use vial (175 mg/17.5 mL; 250 mg/25 mL) injection
72893-0009-01	Fusilev 50 mg single-use vial powder for injection

ICD-10 Diagnoses

Code	Description		
C15.3	Malignant neoplasm of upper third of esophagus		
C15.4	Malignant neoplasm of middle third of esophagus		
C15.5	Malignant neoplasm of the lower third of esophagus		
C15.8	Malignant neoplasm of overlapping sites of esophagus		
C15.9	Malignant neoplasm of esophagus, unspecified		
C16.0	Malignant neoplasm of cardia		
C16.1	Malignant neoplasm of fundus of stomach		
C16.2	Malignant neoplasm of body of stomach		
C16.3	Malignant neoplasm of pyloric antrum		
C16.4	Malignant neoplasm of pylorus		
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified		
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified		
C16.8	Malignant neoplasm of overlapping sites of stomach		
C16.9	Malignant neoplasm of stomach, unspecified		
C17.0	Malignant neoplasm of duodenum		
C17.1	Malignant neoplasm of jejunum		
C17.2	Malignant neoplasm of ileum		
C17.8	Malignant neoplasm of overlapping sites of small intestine		
C17.9	Malignant neoplasm of small intestine, unspecified		
C18.0	Malignant neoplasm of cecum		
C18.1	Malignant neoplasm of appendix		
C18.2	Malignant neoplasm of ascending colon		
C18.3	Malignant neoplasm of hepatic flexure		
C18.4	Malignant neoplasm of transverse colon		
C18.5	Malignant neoplasm of splenic flexure		
C18.6	Malignant neoplasm of descending colon		
C18.7	Malignant neoplasm of sigmoid colon		
C18.8	Malignant neoplasm of overlapping sites of colon		
C18.9	Malignant neoplasm of colon, unspecified		
C19	Malignant neoplasm of rectosigmoid junction		
C20	Malignant neoplasm of rectum		
C21.0	Malignant neoplasm of anus, unspecified		
C21.1	Malignant neoplasm of anal canal		
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal		

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C25.0	Malignant neoplasm of head of pancreas		
C25.1	Malignant neoplasm of body of pancreas		
C25.2	Malignant neoplasm of tail of pancreas		
C25.3	Malignant neoplasm of pancreatic duct		
C25.7	Malignant neoplasm of other parts of pancreas		
C25.8	Malignant neoplasm of overlapping sites of pancreas		
C25.9	Malignant neoplasm of pancreas, unspecified		
C37	Malignant neoplasm of thymus		
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb		
C40.01	Malignant neoplasm of scapula and long bones of right upper limb		
C40.02	Malignant neoplasm of scapula and long bones of left upper limb		
C40.10	Malignant neoplasm of short bones of unspecified upper limb		
C40.11	Malignant neoplasm of short bones of right upper limb		
C40.12	Malignant neoplasm of short bones of left upper limb		
C40.20	Malignant neoplasm of long bones of unspecified lower limb		
C40.21	Malignant neoplasm of long bones of right lower limb		
C40.22	Malignant neoplasm of long bones of left lower limb		
C40.30	Malignant neoplasm of short bones of unspecified lower limb		
C40.31	Malignant neoplasm of short bones of right lower limb		
C40.32	Malignant neoplasm of short bones of left lower limb		
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb		
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb		
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb		
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb		
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb		
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb		
C41.0	Malignant neoplasm of bones of skull and face		
C41.1	Malignant neoplasm of mandible		
C41.2	Malignant neoplasm of vertebral column		
C41.3	Malignant neoplasm of ribs, sternum and clavicle		
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx		
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified		
C48.1	Malignant neoplasm of specified parts of peritoneum		
C48.2	Malignant neoplasm of peritoneum, unspecified		
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum		
C53.0	Malignant neoplasm of endocervix		
C53.1	Malignant neoplasm of exocervix		
C53.8	Malignant neoplasm of overlapping sites of cervix uteri		
C53.9	Malignant neoplasm of cervix uteri, unspecified		
C56.1	Malignant neoplasm of right ovary		
C56.2	Malignant neoplasm of left ovary		
C56.9	Malignant neoplasm of unspecified ovary		
C57.00	Malignant neoplasm of unspecified fallopian tube		
C57.01	Malignant neoplasm of right fallopian tube		
C57.02	Malignant neoplasm of left fallopian tube		
C57.10	Malignant neoplasm of unspecified broad ligament		

C57.11	Malignant neoplasm of right broad ligament		
C57.12	Malignant neoplasm of left broad ligament		
C57.20	Malignant neoplasm of unspecified round ligament		
C57.21	Malignant neoplasm of right round ligament		
C57.22	Malignant neoplasm of left round ligament		
C57.3	Malignant neoplasm of parametrium		
C57.4	Malignant neoplasm of uterine adnexa, unspecified		
C57.7	Malignant neoplasm of other specified female genital organs		
C57.8	Malignant neoplasm of overlapping sites of female genital organs		
C57.9	Malignant neoplasm of female genital organ, unspecified		
C67.0	Malignant neoplasm of trigone of bladder		
C67.1	Malignant neoplasm of dome of bladder		
C67.2	Malignant neoplasm of lateral wall of bladder		
C67.3	Malignant neoplasm of anterior wall of bladder		
C67.4	Malignant neoplasm of posterior wall of bladder		
C67.5	Malignant neoplasm of bladder neck		
C67.6	Malignant neoplasm of ureteric orifice		
C67.7	Malignant neoplasm of urachus		
C67.8	Malignant neoplasm of overlapping sites of bladder		
C67.9	Malignant neoplasm of bladder, unspecified		
C78.00	Secondary malignant neoplasm of unspecified lung		
C78.01	Secondary malignant neoplasm of right lung		
C78.02	Secondary malignant neoplasm of left lung		
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum		
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct		
C79.31	Secondary malignant neoplasm of brain		
C79.32	Secondary malignant neoplasm of cerebral meninges		
C79.89	Secondary malignant neoplasm of other specified sites		
C79.9	Secondary malignant neoplasm of unspecified site		
C80.0	Disseminated malignant neoplasm, unspecified		
C80.1	Malignant (primary) neoplasm, unspecified		
C7A.1	Malignant poorly differentiated neuroendocrine tumors		
C7A.8	Other malignant neuroendocrine tumors		
C7B.8	Other secondary neuroendocrine tumors		
C83.10	Mantle cell lymphoma, unspecified site		
C83.11	Mantle cell lymphoma, lymph nodes of head, face and neck		
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes		
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes		
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb		
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb		
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes		
C83.17	Mantle cell lymphoma, spleen		
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites		
C83.19	Mantle cell lymphoma, extranodal and solid organ sites		
C83.30	Diffuse large B-cell lymphoma unspecified site		
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck		

C83.32	Diffuse large B-cell lymphoma intrathoracic lymph nodes		
C83.33	Diffuse large B-cell lymphoma intra-abdominal lymph nodes		
C83.34	Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb		
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb		
C83.36	Diffuse large B-cell lymphoma intrapelvic lymph nodes		
C83.37	Diffuse large B-cell lymphoma, spleen		
C83.38	Diffuse large B-cell lymphoma lymph nodes of multiple sites		
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites		
C83.70	Burkitt lymphoma, unspecified site		
C83.71	Burkitt lymphoma, lymph nodes of head, face, and neck		
C83.72	Burkitt lymphoma, intrathoracic lymph nodes		
C83.73	Burkitt lymphoma, intra-abdominal lymph nodes		
C83.74	Burkitt lymphoma, lymph nodes of axilla and upper limb		
C83.75	Burkitt lymphoma, lymph nodes of inguinal region and lower limb		
C83.76	Burkitt lymphoma, intrapelvic lymph nodes		
C83.77	Burkitt lymphoma, spleen		
C83.78	Burkitt lymphoma, lymph nodes of multiple sites		
C83.79	Burkitt lymphoma, extranodal and solid organ sites		
C83.80	Other non-follicular lymphoma, unspecified site		
C83.81	Other non-follicular lymphoma, lymph nodes of head, face and neck		
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes		
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes		
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb		
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb		
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes		
C83.87	Other non-follicular lymphoma, spleen		
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites		
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites		
C84.40	Peripheral T-cell lymphoma, not classified, unspecified site		
C84.41	Peripheral T-cell lymphoma, not classified, lymph nodes of head, face, and neck		
C84.42	Peripheral T-cell lymphoma, not classified, intrathoracic lymph nodes		
C84.43	Peripheral T-cell lymphoma, not classified, intra-abdominal lymph nodes		
C84.44	Peripheral T-cell lymphoma, not classified, lymph nodes of axilla and upper limb		
C84.45	Peripheral T-cell lymphoma, not classified, lymph nodes of inguinal region and lower limb		
C84.46	Peripheral T-cell lymphoma, not classified, intrapelvic lymph nodes		
C84.47	Peripheral T-cell lymphoma, not classified, spleen		
C84.48	Peripheral T-cell lymphoma, not classified, lymph nodes of multiple sites		
C84.49	Peripheral T-cell lymphoma, not classified, extranodal and solid organ sites		
C84.60	Anaplastic large cell lymphoma, ALK-positive, unspecified site		
C84.61	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of head, face, and neck		
C84.62	Anaplastic large cell lymphoma, ALK-positive, intrathoracic lymph nodes		
C84.63	Anaplastic large cell lymphoma, ALK-positive, intra-abdominal lymph nodes		
C84.64	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of axilla and upper limb		
C84.65	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of inguinal region and lower limb		
C84.66	Anaplastic large cell lymphoma, ALK-positive, intrapelvic lymph nodes		
C84.67	Anaplastic large cell lymphoma, ALK-positive, spleen		

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C84.68	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites
C84.69	Anaplastic large cell lymphoma, ALK-positive, extranodal and solid organ sites
C84.70	Anaplastic large cell lymphoma, ALK-negative, unspecified site
C84.71	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of head, face, and neck
C84.72	Anaplastic large cell lymphoma, ALK-negative, intrathoracic lymph nodes
C84.73	Anaplastic large cell lymphoma, ALK-negative, intra-abdominal lymph nodes
C84.74	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of axilla and upper limb
C84.75	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of inguinal region and lower limb
C84.76	Anaplastic large cell lymphoma, ALK-negative, intrapelvic lymph nodes
C84.77	Anaplastic large cell lymphoma, ALK-negative, spleen
C84.78	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of multiple sites
C84.79	Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites
C84.90	Mature T/NK-cell lymphomas, unspecified site
C84.91	Mature T/NK-cell lymphomas, unspecified lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, unspecified intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, unspecified intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, unspecified lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, unspecified lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, unspecified intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, unspecified spleen
C84.98	Mature T/NK-cell lymphomas, unspecified lymph nodes of multiple sites
C84.99	Mature T/NK-cell lymphomas, unspecified extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas unspecified site
C84.Z1	Other mature T/NK-cell lymphomas lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas spleen
C84.Z8	Other mature T/NK-cell lymphomas lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas extranodal and solid organ sites
C86.0	Extranodal NK/T-cell lymphoma, nasal type
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.51	Adult T-cell lymphoma/leukemia (HTLV-1-associated) in remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated) in relapse
D09.0	Carcinoma in situ of bladder
D15.0	Benign neoplasm of thymus
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified

T39.4X5A	Adverse effect of antirheumatics, not elsewhere classified, initial encounter	
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter	
T45.8X5A	Adverse effect of other primarily systemic and hematological agents, initial encounter	
T45.95XA	Adverse effect of unspecified primarily systemic and hematological agent, initial encounter	
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter	
Z80.49	Family history of malignant neoplasm of other genital organs	
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ	
Z85.01	Personal history of malignant neoplasm of esophagus	
Z85.028	Personal history of other malignant neoplasm of stomach	
Z85.038	Personal history of other malignant neoplasm of large intestine	
Z85.068	Personal history of other malignant neoplasm of small intestine	
Z85.07	Personal history of malignant neoplasm of pancreas	
Z85.51	Personal history of malignant neoplasm of bladder	
Z85.72	Personal history of non-Hodgkin lymphomas	
Z85.830	Personal history of malignant neoplasm of bone	
Z85.858	Personal history of malignant neoplasm of other endocrine glands	

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/1/2024	Annual Review: added NDC: 72893-0009-01 Initial Criteria:Used in combination with high-dose methotrexate for the following ‡Removed: Follicular Lymphoma, and added: Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma (Used for the management of symptomatic Bing-Neel syndrome) Used in combination with fluorouracil-based regimens for the following ‡: Added: "Ampullary Adenocarcinoma and Cervical Cancer"
EmblemHealth & ConnectiCare	6/29/2023	Annual Review: Length of Authorization updated from 6 months to 90 days Colorectal Cancer: Initial Criteria: Added the following indications under "Used in combination with high-dose methotrexate for the following ‡ 1. Pediatric Acute Lymphoblastic Leukemia 2. Adult T-cell Leukemia/Lymphoma 3. Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) 4. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) 5. Diffuse Large B-Cell Lymphoma 6. Follicular Lymphoma 7. Hepatosplenic T-Cell Lymphoma 8. High Grade B-Cell Lymphomas 9. Pediatric Aggressive Mature B-Cell Lymphomas 10. Post-Transplant Lymphoproliferative Disorders (PTLD)" and Removed "Adult T-cell Leukemia/Lymphoma" Colorectal Initial Criteria: Added the following indications under "Used in combination with fluorouracil-based regimens for the following ‡ 1. Gallbladder Cancer, Extrahepatic Cholangiocarcinoma, and Intrahepatic Cholangiocarcinoma" And Removed "Cervical Cancer"
EmblemHealth & ConnectiCare	6/16/2022	Transferred policy to new template

EmblemHealth & ConnectiCare	1/1/2020	Annual Review
EmblemHealth & ConnectiCare	3/27/2019	Added New C-Code C9043

References

- 1. Fusilev [package insert]. Irvine, CA; Spectrum Pharmaceuticals, Inc; April 2011. Accessed December 2019.
- 2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) levoleucovorin. National Comprehensive Cancer Network, 2018. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2018.
- 3. Goorin A, Strother D, Poplack D, et al. Safety and efficacy of l-leucovorin rescue following high-dose methotrexate for osteosarcoma. Med Pediatr Oncol. 1995 Jun; 24(6):362-7.