

Fusilev[®] (levoleucovorin)

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Fusilev 50 mg powder for injection: 25 vials per 28 days
- Fusilev 175 mg/17.5 mL injection: 8 vials per 28 days
- Fusilev 250 mg/25 mL injection: 5 vials per 28 days

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

In combination with methotrexate or for inadvertent overdose

- 1,200 billable units every 28 days

In combination with fluorouracil

- 2,500 billable units every 28 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 6 years old; **AND**
- Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
- Racemic *d*,Fleucovorin 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) ‡)

- Patient is undergoing high-dose methotrexate chemotherapy treatment; **AND**
- 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 †

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

Colorectal cancer † ‡

- Must be used in combination with fluorouracil-based regimens

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

- Acute Lymphoblastic Leukemia
- AIDS-related B-cell Lymphoma
- Burkitt Lymphoma
- Mantle Cell Lymphoma
- CNS Cancer (Primary CNS Lymphoma, Brain Metastases, & Leptomeningeal Metastases)
- Peripheral T-cell Lymphoma
- Adult T-cell Leukemia/Lymphoma
- Extranodal NK/T-cell Lymphoma (nasal type)

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

- Anal Carcinoma
- Bladder Cancer (non-urothelial and urothelial with variant histology)
- Cervical Cancer
- Esophageal, Esophagogastric Junction, & Gastric Cancer
- Neuroendocrine and Adrenal Tumors
- Occult Primary
- Ovarian/Fallopian Tube/Primary Peritoneal Mucinous Carcinomas
- Pancreatic Adenocarcinoma
- Thymoma and Thymic Carcinoma

† FDA labeled indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria in section III; **AND**
- 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**
- 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.

V. Dosage/Administration

Fusilev is dosed at **one-half** the usual dose of racemic *d, l*-leucovorin

Indication	Dose
In combination with high-dose methotrexate	7.5 mg (approximately 5 mg/m ²) IV every 6 hours for 10 doses starting 24 hours after beginning of methotrexate infusion. Dosing is based on a methotrexate dose of 12 grams/m ² administered by intravenous infusion over 4 hours. Continue until methotrexate levels are less than 5 x 10 ⁻⁸ M (0.05 micromolar)
Reduction of toxicity due to impaired elimination or inadvertent overdose with folic acid antagonists	Methotrexate over dosage: 7.5 mg (approximately 5 mg/m ²) IV every 6 hours until methotrexate levels are less than 10 ⁻⁸ M (0.01 micromolar)
In combination with 5-FU	100 mg/m ² administered by slow intravenous injection over a minimum of 3 minutes, followed by 5-FU at 370 mg/m ² by intravenous injection. OR 10 mg/m ² administered by intravenous injection followed by 5-FU at 425 mg/m ² by intravenous injection. Treatment is repeated daily for five days. This five-day treatment course may be repeated at 4-week (28-day) intervals, for 2 courses and then repeated at 4 to 5 week (28 to 35 day) intervals provided that the patient has completely recovered from the toxic effects of the prior treatment course. <u>Alternate Dosing Regimen</u> 200 mg/m ² administered by intravenous injection DAY 1 followed by 5-FU 400 mg/m ² bolus on DAY 1, then 5-FU 1200 mg/m ² /day x 2 days IV continuous infusion; repeat every 14 days.

VI. Billing Code/Availability Information

Jcode:

- J0641 – Injection, levoleucovorin calcium, 0.5 mg = 1 billable unit

NDC:

- Fusilev 50 mg single-use vial powder for injection: 68152-0101-xx
- Fusilev 10 mg/mL single-use vial (175 mg/17.5 mL; 250 mg/25 mL) injection: 68152-0102-xx
**generics available through various manufacturers*

VII. References

1. Fusilev [package insert]. Irvine, CA; Spectrum Pharmaceuticals, Inc; April 2011. Accessed April 2018.
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.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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

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ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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
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 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

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ICD-10	ICD-10 Description
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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC