



Stelara® (ustekinumab)

(Intravenous/Subcutaneous)

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I. Length of Authorization

Crohn's Disease and Ulcerative Colitis:

Coverage will be provided for 8 weeks initially and may be renewed in 6 month intervals thereafter.

All other indications:

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Subcutaneous

- Stelara 45 mg vial/prefilled syringe:
 - o Loading: 1 syringe at weeks 0 & 4
 - o Maintenance: 1 syringe every 12 weeks
- Stelara 90 mg prefilled syringe:
 - o Loading: 1 syringe at weeks 0 & 4
 - Maintenance: 1 syringe every 8 weeks

Intravenous

• Stelara 130 mg (5 mg/mL) single-dose vial: 4 vials

B. Max Units (per dose and over time) [HCPCS Unit]:

| Indication | Max Units |
|------------------------------|--|
| Psoriatic Arthritis with co- | Subcutaneous Loading (J3357): • 90 billable units at weeks 0 & 4; maintenance dosing 12 weeks later Subcutaneous Maintenance (J3357): • 90 billable units every 12 weeks |
| Psoriatic Arthritis | Subcutaneous Loading (J3357): • 45 billable units at weeks 0 & 4; maintenance dosing 12 weeks later |

| Indication | Max Units | |
|------------------------------|--|--|
| | Subcutaneous Maintenance (J3357): | |
| | • 45 billable units every 12 weeks | |
| | Intravenous Induction (J3358): | |
| Crohn's Disease & Ulcerative | • 520 billable units | |
| Colitis | Subcutaneous Maintenance (J3357): | |
| | • 90 billable units 8 weeks after induction & every 8 weeks thereafter | |

III. Initial Approval Criteria ¹

Site of care specialty infusion program requirements are met (refer to Moda Site of Care Policy).

• Self-administered injectable medications are not covered when supplied in a provider's office, clinic or facility.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; AND

Universal Criteria ¹

- Patient has been evaluated and screened for the presence of latent (tuberculosis) TB
 infection prior to initiating treatment and will receive ongoing monitoring for presence of TB
 during treatment; AND
- Patient does not have an active infection, including clinically important localized infections;
 AND
- Therapy will not be administered concurrently with live vaccines; AND
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib);

Plaque Psoriasis † 1-5,25,26,30

- Patient is at least 6 years of age; AND
- Patient has moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
 - o Involvement of at least 3% of body surface area (BSA); **OR**
 - o Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
 - Incapacitation or serious emotional consequences due to plaque location (i.e. hands, feet, head and neck, or genitalia) or with intractable pruritis; AND
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or vitamin D analogues);
 AND

- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least one systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); AND
- Patient did not respond adequately (or is not a candidate*) to a 3 month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol)
- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of TWO of the following: Enbrel, Humira and Cosentyx; **OR**
- Patient is continuing treatment

Psoriatic Arthritis (PsA) † 1,6-9,15,16,17,27

- Patient has documented moderate to severe active disease; AND
 - For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; OR
 - o For patients with peripheral arthritis, a trial and failure of at least a 3 month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine
- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of TWO of the following: Enbrel, Humira and Cosentyx; **OR**
- Patient is continuing treatment

Crohn's Disease † 1,10-12,14,18,24

- Documented moderate to severely active disease; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate); **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g. adalimumab, certolizumab, or infliximab)
- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Humira; **OR**
- Patient is continuing treatment

Ulcerative Colitis \dagger 1,13,19-23,29

- Documented moderate to severely active disease; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate); **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g. adalimumab, golimumab, or infliximab)

*Examples of contraindications to phototherapy (PUVA or UVB) include the following: 31,32

- Xeroderma pigmentosum
- Pregnancy or lactation (PUVA only)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, treatment with arsenic or ionizing radiation
 Immunosuppression in an organ transplant patient

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); ♠ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include
 the following: serious infections, malignancy, severe hypersensitivity reactions, reversible
 posterior leukoencephalopathy syndrome (RPLS), non-infectious pneumonia, etc; AND

Plaque Psoriasis 15,16

• Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement ≤1%), and/or an improvement on a disease activity scoring tool [e.g. a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and a four-point reduction in the DLQI from when treatment started].

Psoriatic Arthritis (PsA) 14

• Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria].

Crohn's Disease 13

• Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].

Ulcerative Colitis 19-23

• Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, normalization of C-reactive protein (CRP) or fecal

calprotectin (FC), and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

V. Dosage/Administration

| Indication | Dose | | |
|--|--|--|--|
| Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis | Adult Subcutaneous Loading Dose: <100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Adult Subcutaneous Maintenance Dose: <100 kg: 45 mg every 12 weeks >100 kg: 90 mg every 12 weeks Pediatric Subcutaneous Loading Dose: <60 kg: 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later 60 - 100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Pediatric Subcutaneous Maintenance Dose: <60 kg: 0.75 mg/kg every 12 weeks 60 - 100 kg: 45 mg every 12 weeks 90 mg every 12 weeks physical subcutaneous Maintenance Dose: <60 kg: 90 mg every 12 weeks >100 kg: 90 mg every 12 weeks 90 mg every 12 weeks | | |
| | Subcutaneous Loading Dose: | | |
| Psoriatic Arthritis | 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Subcutaneous Maintenance Dose: 45 mg every 12 weeks | | |
| Crohn's Disease & Ulcerative Colitis | Intravenous Induction Dose (one-time only): • ≤ 55 kg: 260 mg • > 55 kg to 85 kg: 390 mg • > 85 kg: 520 mg Subcutaneous Maintenance Dose: • 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter | | |

VI. Billing Code/Availability Information

HCPCS Code:

- J3357 Ustekinumab, for subcutaneous injection, 1 mg; 1 billable unit = 1 mg
- J3358 Ustekinumab, for intravenous injection, 1 mg; 1 billable unit = 1 mg

NDC:

- Subcutaneous
 - Stelara 45 mg single-dose vial (SDV) and prefilled (PF) syringe: 57894-0060-xx
 - Stelara 90 mg prefilled (PF) syringe: 57894-0061-xx
- Intravenous
 - Stelara 130 mg (5 mg/mL) single-dose vial (SDV): 57894-0054-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

Subcutaneous (J3357)

| ICD-10 | ICD-10 Description | |
|---------|--|--|
| K50.00 | Crohn's disease of small intestine without complications | |
| K50.011 | Crohn's disease of small intestine with rectal bleeding | |
| K50.012 | Crohn's disease of small intestine with intestinal obstruction | |
| K50.013 | Crohn's disease of small intestine with fistula | |

| ICD-10 | ICD-10 Description | |
|---------|--|--|
| K50.014 | Crohn's disease of small intestine with abscess | |
| K50.018 | Crohn's disease of small intestine with other complication | |
| K50.019 | Crohn's disease of small intestine with unspecified complications | |
| K50.10 | Crohn's disease of large intestine without complications | |
| K50.111 | Crohn's disease of large intestine with rectal bleeding | |
| K50.112 | Crohn's disease of large intestine with intestinal obstruction | |
| K50.113 | Crohn's disease of large intestine with fistula | |
| K50.114 | Crohn's disease of large intestine with abscess | |
| K50.118 | Crohn's disease of large intestine with other complication | |
| K50.119 | Crohn's disease of large intestine with unspecified complications | |
| K50.80 | Crohn's disease of both small and large intestine without complications | |
| K50.811 | Crohn's disease of both small and large intestine with rectal bleeding | |
| K50.812 | Crohn's disease of both small and large intestine with intestinal obstruction | |
| K50.813 | Crohn's disease of both small and large intestine with fistula | |
| K50.814 | Crohn's disease of both small and large intestine with abscess | |
| K50.818 | Crohn's disease of both small and large intestine with other complication | |
| K50.819 | Crohn's disease of both small and large intestine with unspecified complications | |
| K50.90 | Crohn's disease, unspecified, without complications | |
| K50.911 | Crohn's disease, unspecified, with rectal bleeding | |
| K50.912 | Crohn's disease, unspecified, with intestinal obstruction | |
| K50.913 | Crohn's disease, unspecified, with fistula | |
| K50.914 | Crohn's disease, unspecified, with abscess | |
| K50.918 | Crohn's disease, unspecified, with other complication | |
| K50.919 | Crohn's disease, unspecified, with unspecified complications | |
| K51.00 | Ulcerative (chronic) pancolitis without complications | |
| K51.011 | Ulcerative (chronic) pancolitis with rectal bleeding | |
| K51.012 | Ulcerative (chronic) pancolitis with intestinal obstruction | |
| K51.013 | Ulcerative (chronic) pancolitis with fistula | |
| K51.014 | Ulcerative (chronic) pancolitis with abscess | |
| K51.018 | Ulcerative (chronic) pancolitis with other complication | |
| K51.019 | Ulcerative (chronic) pancolitis with unspecified complications | |
| K51.20 | Ulcerative (chronic) proctitis without complications | |
| K51.211 | Ulcerative (chronic) proctitis with rectal bleeding | |
| K51.212 | Ulcerative (chronic) proctitis with intestinal obstruction | |
| K51.213 | Ulcerative (chronic) proctitis with fistula | |

| ICD-10 | ICD-10 Description | |
|---------|--|--|
| K51.214 | Ulcerative (chronic) proctitis with abscess | |
| K51.218 | Ulcerative (chronic) proctitis with other complication | |
| K51.219 | Ulcerative (chronic) proctitis with unspecified complications | |
| K51.30 | Ulcerative (chronic) rectosigmoiditis without complications | |
| K51.311 | Ulcerative (chronic) rectosigmoiditis with rectal bleeding | |
| K51.312 | Ulcerative (chronic) rectosigmoiditis with intestinal obstruction | |
| K51.313 | Ulcerative (chronic) rectosigmoiditis with fistula | |
| K51.314 | Ulcerative (chronic) rectosigmoiditis with abscess | |
| K51.318 | Ulcerative (chronic) rectosigmoiditis with other complication | |
| K51.319 | Ulcerative (chronic) rectosigmoiditis with unspecified complications | |
| K51.50 | Left sided colitis without complications | |
| K51.511 | Left sided colitis with rectal bleeding | |
| K51.512 | Left sided colitis with intestinal obstruction | |
| K51.513 | Left sided colitis with fistula | |
| K51.514 | Left sided colitis with abscess | |
| K51.518 | Left sided colitis with other complication | |
| K51.519 | Left sided colitis with unspecified complications | |
| K51.80 | Other ulcerative colitis without complications | |
| K51.811 | Other ulcerative colitis with rectal bleeding | |
| K51.812 | Other ulcerative colitis with intestinal obstruction | |
| K51.813 | Other ulcerative colitis with fistula | |
| K51.814 | Other ulcerative colitis with abscess | |
| K51.818 | Other ulcerative colitis with other complication | |
| K51.819 | Other ulcerative colitis with unspecified complications | |
| K51.90 | Ulcerative colitis, unspecified, without complications | |
| K51.911 | Ulcerative colitis, unspecified with rectal bleeding | |
| K51.912 | Ulcerative colitis, unspecified with intestinal obstruction | |
| K51.913 | Ulcerative colitis, unspecified with fistula | |
| K51.914 | Ulcerative colitis, unspecified with abscess | |
| K51.918 | Ulcerative colitis, unspecified with other complication | |
| K51.919 | Ulcerative colitis, unspecified with unspecified complications | |
| K52.1 | Toxic gastroenteritis and colitis | |
| L40.0 | Psoriasis vulgaris | |
| L40.50 | Arthropathic psoriasis, unspecified | |
| L40.51 | Distal interphalangeal psoriatic arthropathy | |

| ICD-10 | ICD-10 Description | |
|--------|------------------------------|--|
| L40.52 | Psoriatic arthritis mutilans | |
| L40.53 | Psoriatic spondylitis | |
| L40.59 | Other psoriatic arthropathy | |
| R19.7 | Diarrhea, unspecified | |

Intravenous (J3358)

| ICD-10 | ICD-10 Description | |
|---------|--|--|
| K50.00 | Crohn's disease of small intestine without complications | |
| K50.011 | Crohn's disease of small intestine with rectal bleeding | |
| K50.012 | Crohn's disease of small intestine with intestinal obstruction | |
| K50.013 | Crohn's disease of small intestine with fistula | |
| K50.014 | Crohn's disease of small intestine with abscess | |
| K50.018 | Crohn's disease of small intestine with other complication | |
| K50.019 | Crohn's disease of small intestine with unspecified complications | |
| K50.10 | Crohn's disease of large intestine without complications | |
| K50.111 | Crohn's disease of large intestine with rectal bleeding | |
| K50.112 | Crohn's disease of large intestine with intestinal obstruction | |
| K50.113 | Crohn's disease of large intestine with fistula | |
| K50.114 | Crohn's disease of large intestine with abscess | |
| K50.118 | Crohn's disease of large intestine with other complication | |
| K50.119 | Crohn's disease of large intestine with unspecified complications | |
| K50.80 | Crohn's disease of both small and large intestine without complications | |
| K50.811 | Crohn's disease of both small and large intestine with rectal bleeding | |
| K50.812 | Crohn's disease of both small and large intestine with intestinal obstruction | |
| K50.813 | Crohn's disease of both small and large intestine with fistula | |
| K50.814 | Crohn's disease of both small and large intestine with abscess | |
| K50.818 | Crohn's disease of both small and large intestine with other complication | |
| K50.819 | Crohn's disease of both small and large intestine with unspecified complications | |
| K50.90 | Crohn's disease, unspecified, without complications | |
| K50.911 | Crohn's disease, unspecified, with rectal bleeding | |
| K50.912 | Crohn's disease, unspecified, with intestinal obstruction | |
| K50.913 | Crohn's disease, unspecified, with fistula | |
| K50.914 | Crohn's disease, unspecified, with abscess | |
| K50.918 | Crohn's disease, unspecified, with other complication | |

| ICD-10 | ICD-10 Description | | |
|---------|--|--|--|
| K50.919 | Crohn's disease, unspecified, with unspecified complications | | |
| K51.00 | Ulcerative (chronic) pancolitis without complications | | |
| K51.011 | Ulcerative (chronic) pancolitis with rectal bleeding | | |
| K51.012 | Ulcerative (chronic) pancolitis with intestinal obstruction | | |
| K51.013 | Ulcerative (chronic) pancolitis with fistula | | |
| K51.014 | Ulcerative (chronic) pancolitis with abscess | | |
| K51.018 | Ulcerative (chronic) pancolitis with other complication | | |
| K51.019 | Ulcerative (chronic) pancolitis with unspecified complications | | |
| K51.20 | Ulcerative (chronic) proctitis without complications | | |
| K51.211 | Ulcerative (chronic) proctitis with rectal bleeding | | |
| K51.212 | Ulcerative (chronic) proctitis with intestinal obstruction | | |
| K51.213 | Ulcerative (chronic) proctitis with fistula | | |
| K51.214 | Ulcerative (chronic) proctitis with abscess | | |
| K51.218 | Ulcerative (chronic) proctitis with other complication | | |
| K51.219 | Ulcerative (chronic) proctitis with unspecified complications | | |
| K51.30 | Ulcerative (chronic) rectosigmoiditis without complications | | |
| K51.311 | Ulcerative (chronic) rectosigmoiditis with rectal bleeding | | |
| K51.312 | Ulcerative (chronic) rectosigmoiditis with intestinal obstruction | | |
| K51.313 | Ulcerative (chronic) rectosigmoiditis with fistula | | |
| K51.314 | Ulcerative (chronic) rectosigmoiditis with abscess | | |
| K51.318 | Ulcerative (chronic) rectosigmoiditis with other complication | | |
| K51.319 | Ulcerative (chronic) rectosigmoiditis with unspecified complications | | |
| K51.50 | Left sided colitis without complications | | |
| K51.511 | Left sided colitis with rectal bleeding | | |
| K51.512 | Left sided colitis with intestinal obstruction | | |
| K51.513 | Left sided colitis with fistula | | |
| K51.514 | Left sided colitis with abscess | | |
| K51.518 | Left sided colitis with other complication | | |
| K51.519 | Left sided colitis with unspecified complications | | |
| K51.80 | Other ulcerative colitis without complications | | |
| K51.811 | Other ulcerative colitis with rectal bleeding | | |
| K51.812 | Other ulcerative colitis with intestinal obstruction | | |
| K51.813 | Other ulcerative colitis with fistula | | |
| K51.814 | Other ulcerative colitis with abscess | | |
| K51.818 | Other ulcerative colitis with other complication | | |

| ICD-10 | ICD-10 Description | |
|---------|--|--|
| K51.819 | Other ulcerative colitis with unspecified complications | |
| K51.90 | Ulcerative colitis, unspecified, without complications | |
| K51.911 | Ulcerative colitis, unspecified with rectal bleeding | |
| K51.912 | Ulcerative colitis, unspecified with intestinal obstruction | |
| K51.913 | Ulcerative colitis, unspecified with fistula | |
| K51.914 | Ulcerative colitis, unspecified with abscess | |
| K51.918 | Ulcerative colitis, unspecified with other complication | |
| K51.919 | Ulcerative colitis, unspecified with unspecified complications | |
| K52.1 | Toxic gastroenteritis and colitis | |
| R19.7 | Diarrhea, unspecified | |

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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCA):

J3358

| Jurisdiction(s): E | NCD/LCD/LCA Document (s): A52953 | |
|--|----------------------------------|--|
| https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52953&bc=gAAAAAAAAAA | | |
| Jurisdiction(s): F NCD/LCD/LCA Document (s): A52991 | | |
| https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52991&bc=gAAAAAAAAA | | |

| 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. | |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|--|
| Jurisdiction | Applicable State/US Territory | Contractor |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| | 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 | КҮ, ОН | CGS Administrators, LLC |