MEDICAL MUTUAL®

# Drug Policy

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| **Policy:** | **082204** | **Initial Effective Date: 08/30/2022** |
| **Code(s):** | **HCPCS J0587** | **Annual Review Date: 12/19/2024** |
| **SUBJECT:** | **Xeomin® (incobotulinumtoxinA)** | **Last Revised Date: 12/19/2024** |

☐Subject to Site of Care

**Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.**

## I. Length of Authorization [20]

- **Coverage will be provided for 12 months and may be renewed.**
- Preoperative use in Ventral Hernia may NOT be renewed.

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

| Indication | Billable Units | Per # days |
|---|---|---|
| **Cervical Dystonia** | 200 | 84 |
| **Blepharospasms** | 100 | 84 |
| **Upper Limb Spasticity** | 400 | 84 |
| **Prophylaxis for Chronic Migraines** | 200 | 84 |
| **Incontinence due to Neurogenic Detrusor Overactivity** | 200 | 84 |
| **Overactive Bladder (OAB)** | 100 | 84 |
| **Severe Primary Axillary Hyperhidrosis** | 100 | 112 |
| **Sialorrhea** | 100 | 112 |
| **Ventral Hernia** | 500 | N/A |

## II. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**

**Universal Criteria [1]**

- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**

- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB, daxibotulinumtoxinA, etc.); **AND**

**Cervical Dystonia † [1,2]**

- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; **AND**
    - Patient has sustained head tilt; **OR**
    - Patient has abnormal posturing with limited range of motion in the neck

**Blepharospasms † [1]**

**Spastic Conditions [1]**

- Patient has one of the following:
    - Upper Limb spasticity in adults (i.e., used post-stroke for spasms) †
    - Pediatric upper limb spasticity in patients aged 2 years to 17 years of age, excluding spasticity caused by cerebral palsy †

**Prophylaxis for Chronic Migraines ‡ [3,8,10,23-25,27]**

- Patient is utilizing prophylactic intervention modalities (i.e., avoiding migraine triggers, pharmacotherapy, behavioral therapy, physical therapy, etc.); **AND**
- Patient has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for > 3 months; **AND**
    - Patient has had at least five attacks with features consistent with migraine (with and/or without aura)**§**; **AND**
    - On at least 8 days per month for > 3 months:
        - Headaches have characteristics and symptoms consistent with migraine**§**; **OR**
        - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
- One of the following apply:
    - Patient has failed at least an 8-week trial of any two oral medications for the prevention of migraines (see list of migraine-prophylactic medications below for examples **±**); **OR**
    - Patient had previous treatment with a CGRP antagonist used for prevention of migraines

**Incontinence due to Neurogenic Detrusor Overactivity ‡** [7,9,19,28]

- Patient has detrusor overactivity associated with a neurologic condition (i.e., spinal cord injury, multiple sclerosis, etc.) that is confirmed by urodynamic testing; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (e.g., mirabegron, vibegron, etc.) classes

**Overactive Bladder (OAB) ‡** [7,9,19,28]

- Patient has symptoms of urge urinary incontinence, urgency, and frequency; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium, etc.) or beta-adrenergic (e.g., mirabegron, vibegron, etc.) classes

**Severe Primary Axillary Hyperhidrosis ‡** [4-6,26]

- Patient has tried and failed ≥ 1 month trial of a topical agent (e.g., 20% aluminum chloride, glycopyrronium, aluminum zirconium trichlorohydrate, etc.); **AND**
    - Patient has a history of medical complications such as skin infections or significant functional impairments; **OR**
    - Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings, etc.)

**Chronic Sialorrhea †** [1,13,22]

- Patient has a history of troublesome sialorrhea for at least a 3 month period; **AND**
    - Patient has Parkinson's disease, atypical Parkinsonism, stroke, or traumatic brain injury †; **OR**
    - Patient has a severe developmental delay ‡; **OR**
    - Patient has cerebral palsy, other genetic or congenital disorders, or traumatic brain injury †; **AND**
        - Patient is at least 2 years of age

**Ventral Hernia ‡** [20,21]

- Patient has a large ventral hernia with loss of domain or contaminated ventral hernia; **AND**
- Used preoperatively in patients scheduled to receive abdominal wall reconstruction (AWR)

† FDA Approved Indication(s); ‡ Literature Supported Indication; **Φ** Orphan Drug

| **± Migraine-Prophylaxis Oral Medications *(list not all-inclusive)*** [11,12,16,27] |
|---|
| • Antidepressants (e.g., amitriptyline, nortriptyline, venlafaxine, duloxetine, etc.)<br>• Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.)<br>• Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g. lisinopril, candesartan, etc.)<br>• Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.) |
| **§ Migraine Features §** [16,23,24] |
| **Migraine without aura**<br>• At least five attacks have the following:<br>o Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)<br>o Headache has at least two of the following characteristics:<br>– Unilateral location<br>– Pulsating quality<br>– Moderate or severe pain intensity<br>– Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); **AND**<br>o During headache at least one of the following:<br>– Nausea and/or vomiting<br>– Photophobia and phonophobia |
| **Migraine with aura**<br>• At least two attacks have the following:<br>o One or more of the following fully reversible aura symptoms:<br>– Visual<br>– Sensory<br>– Speech and/or language<br>– Motor<br>– Brainstem<br>– Retinal; **AND**<br>o At least three of the following characteristics:<br>– At least one aura symptom spreads gradually over ≥5 minutes<br>– Two or more symptoms occur in succession<br>– Each individual aura symptom lasts 5 to 60 minutes<br>– At least one aura symptom is unilateral<br>– At least one aura symptom is positive (e.g., scintillations and pins and needles)<br>– The aura is accompanied, or followed within 60 minutes, by headache |

## III. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific criteria as identified in section III; **AND**
- Duration of authorization has not been exceeded (refer to Section I); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect (e.g., asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, breathing difficulties, etc.), serious hypersensitivity reactions (e.g., anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea, etc.), corneal exposure/ulceration, ectropion in patients treated for blepharospasm, etc.; **AND**
- Disease response as evidenced by the following:

**Blepharospasms** [1]

- Improvement of severity and/or frequency of eyelid spasms

**Cervical Dystonia** [1]

- Improvement in the severity and frequency of pain; **AND**
- Improvement of abnormal head positioning

**Upper Limb Spasticity** [1]

- Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression (CGI), etc.)

**Severe Primary Axillary Hyperhidrosis** [4-6]

- Significant reduction in spontaneous axillary sweat production; **AND**
- Patient has a significant improvement in activities of daily living

**Prophylaxis for Chronic Migraines** [10,16,23]

- Significant decrease in the number, frequency, and/or intensity of headaches; **AND**
- Improvement in function; **AND**
- Patient continues to utilize prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, physical therapy, etc.)

**Incontinence due to Detrusor Overactivity** [9]

- Significant improvements in weekly frequency of incontinence episodes; **AND**
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

**Overactive Bladder (OAB)** [9]

- Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; **AND**
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

**Chronic Sialorrhea** [1,13,22]

- Significant decrease in saliva production

## IV. Dosage/Administration [1-23]

| Indication | Dose |
|---|---|
| Cervical Dystonia | The recommended initial total dose for cervical dystonia is 120 units. Initial dose is divided among the affected muscles every 12 weeks or longer, as necessary. |
| Blepharospasm | The recommended initial dose for treatment naïve patients is 50 units (25 units per eye). Subsequent doses in patients previously treated with Xeomin should not exceed the maximum dose of 100 units per treatment session (50 units per eye), every 12 weeks or longer, as necessary. |
| Upper Limb Spasticity | The dosage, frequency, and number of injection sites should be tailored to the individual patient based on the size, number, and location of muscles to be treated, severity of spasticity, presence of local muscle weakness, patient's response to previous treatment, and adverse event history with Xeomin. Localization of the involved muscles with electromyographic guidance, nerve stimulation, or ultrasound techniques is recommended.<br>Adults<br>Up to 400 units total, repeated no sooner than every 12 weeks<br>Pediatrics<br>8 units/kg, divided among affected muscles, up to a maximum dose of 200 units per single upper limb. If both upper limbs are treated, total Xeomin dosage should not exceed 16 Units/kg, up to a maximum of 400 units, repeated no sooner than every 12 weeks |
| Chronic Migraine | Up to 200 units divided among the affected muscles every 12 weeks |

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|---|---|
| Severe Primary Axillary Hyperhidrosis | 50 units intradermally per axilla every 16 weeks |
| Neurogenic Bladder/ Detrusor Overactivity | Up to 200 units per treatment divided among the affected muscles every 12 weeks. |
| Overactive Bladder (OAB) | Up to 100 units per treatment divided among the affected muscles every 12 weeks |
| Sialorrhea | Adults:<br>30 units per parotid gland and 20 units per submandibular gland (50 units per each side of the face for a total recommended dose of 100 units per treatment session), repeated no sooner than every 16 weeks<br>Pediatrics: Dosing is based on body weight as noted below and is repeated no sooner than every 16 weeks<br>– 12 kg to <15 kg: 6 units per parotid gland and 4 units per submandibular gland (10 units per each side of the face for a total recommended dose of 20 units per treatment session)<br>– 15 kg to <19 kg: 9 units per parotid gland and 6 units per submandibular gland (15 units per each side of the face for a total recommended dose of 30 units per treatment session)<br>– 19 kg to <23 kg: 12 units per parotid gland and 8 units per submandibular gland (20 units per each side of the face for a total recommended dose of 40 units per treatment session)<br>– 23 kg to <27 kg: 15 units per parotid gland and 10 units per submandibular gland (25 units per each side of the face for a total recommended dose of 50 units per treatment session)<br>– 27 kg to <30 kg: 18 units per parotid gland and 12 units per submandibular gland (30 units per each side of the face for a total recommended dose of 60 units per treatment session)<br>– 30 kg or more: 22.5 units per parotid gland and 15 units per submandibular gland (37.5 units per each side of the face for a total recommended dose of 75 units per treatment session) |

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| Ventral Hernia | 500 units divided among abdominal muscles, injected 2-4 weeks prior to AWR surgery. *May not be renewed.* |
| *Note:*<br>*- The recommended maximum cumulative dose for any indication should not exceed 400 Units in a treatment session (unless used for Ventral Hernia).*<br>*- Units of Xeomin are specific to the preparation and assay method utilized and are not interchangeable with other preparations of botulinum toxin products and cannot be compared to or converted into units of any other botulinum toxin products* | |

## V. Billing Code/Availability Information

HCPCS Code:

- J0588 – Injection, incobotulinumtoxinA, 1 unit; 1 billable unit = 1 unit

NDC(s):

- Xeomin 50 unit powder for injection; single-dose vial: 00259-1605-xx
- Xeomin 100 unit powder for injection; single-dose vial: 00259-1610-xx
- Xeomin 200 unit powder for injection; single-dose vial :00259-1620-xx

## VI. References

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**Appendix 1 – Covered Diagnosis Codes**

| ICD-10 | ICD-10 Description |
|---|---|
| G24.3 | Spasmodic torticollis |
| G24.5 | Blepharospasm |
| G25.89 | Other specified extrapyramidal and movement disorders |
| G35 | Multiple sclerosis |
| G37.0 | Diffuse sclerosis of central nervous system |
| G43.709 | Chronic migraine without aura, not intractable, without status migrainosus |
| G43.719 | Chronic migraine without aura, intractable, without status migrainosus |
| G43.701 | Chronic migraine without aura, not intractable, with status migrainosus |
| G43.711 | Chronic migraine without aura, intractable, with status migrainosus |
| G80.0 | Spastic quadriplegic cerebral palsy |
| G80.1 | Spastic diplegic cerebral palsy |
| G80.2 | Spastic hemiplegic cerebral palsy |
| G81.10 | Spastic hemiplegia affecting unspecified side |
| G81.11 | Spastic hemiplegia affecting right dominant side |
| G81.12 | Spastic hemiplegia affecting left dominant side |

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| G81.13 | Spastic hemiplegia affecting right nondominant side |
| G81.14 | Spastic hemiplegia affecting left nondominant side |
| G82.53 | Quadriplegia, C5-C7, complete |
| G82.54 | Quadriplegia, C5-C7, incomplete |
| G83.0 | Diplegia of upper limbs, Diplegia (Upper), Paralysis of both upper limbs |
| G83.20 | Monoplegia of upper limb affecting unspecified side |
| G83.21 | Monoplegia of upper limb affecting right dominant side |
| G83.22 | Monoplegia of upper limb affecting left dominant side |
| G83.23 | Monoplegia of upper limb affecting right nondominant side |
| G83.24 | Monoplegia of upper limb affecting left nondominant side |
| I69.031 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side |
| I69.032 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side |
| I69.033 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side |
| I69.034 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side |
| I69.039 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting unspecified side |
| I69.051 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side |
| I69.052 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side |
| I69.053 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side |
| I69.054 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side |
| I69.059 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting unspecified side |
| I69.131 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side |
| I69.132 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side |
| I69.133 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side |
| I69.134 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side |

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| I69.139 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting unspecified site |
| I69.151 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side |
| I69.152 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side |
| I69.153 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side |
| I69.154 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side |
| I69.159 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting unspecified side |
| I69.231 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side |
| I69.232 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side |
| I69.233 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side |
| I69.234 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side |
| I69.239 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting unspecified site |
| I69.251 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side |
| I69.252 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side |
| I69.253 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side |
| I69.254 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side |
| I69.259 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side |
| I69.331 | Monoplegia of upper limb following cerebral infarction affecting right dominant side |
| I69.332 | Monoplegia of upper limb following cerebral infarction affecting left dominant side |
| I69.333 | Monoplegia of upper limb following cerebral infarction affecting right non-dominant side |
| I69.334 | Monoplegia of upper limb following cerebral infarction affecting left non-dominant side |
| I69.339 | Monoplegia of upper limb following cerebral infarction affecting unspecified site |
| I69.351 | Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side |
| I69.352 | Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side |

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| I69.353 | Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side |
| I69.354 | Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side |
| I69.359 | Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side |
| I69.831 | Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side |
| I69.832 | Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side |
| I69.833 | Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side |
| I69.834 | Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side |
| I69.839 | Monoplegia of upper limb following other cerebrovascular disease affecting unspecified site |
| I69.851 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side |
| I69.852 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side |
| I69.853 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side |
| I69.854 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side |
| I69.859 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side |
| I69.931 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side |
| I69.932 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side |
| I69.933 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting right non-dominant side |
| I69.934 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side |
| I69.939 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side |
| I69.951 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side |
| I69.952 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side |
| I69.953 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side |
| I69.954 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side |
| I69.959 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting unspecified side |
| K11.7 | Disturbances of salivary secretion |

| | |
|---|---|
| K43.6 | Other and unspecified ventral hernia with obstruction, without gangrene |
| K43.7 | Other and unspecified ventral hernia with gangrene |
| K43.9 | Ventral hernia without obstruction or gangrene |
| M43.6 | Torticollis |
| N31.0 | Uninhibited neuropathic bladder, not elsewhere classified |
| N31.1 | Reflex neuropathic bladder, not elsewhere classified |
| N31.8 | Other neuromuscular dysfunction of bladder |
| N31.9 | Neuromuscular dysfunction of bladder, unspecified |
| N32.81 | Overactive bladder |
| L74.510 | Primary focal hyperhidrosis, axilla |

**Dual coding requirements:**

- Primary G and M codes require a secondary G or I code in order to be payable

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

| Medicare Part B Covered Diagnosis Codes | | |
|---|---|---|
| **Jurisdiction** | **NCD/LCA/LCD Document (s)** | **Contractor** |
| 6 & K | A52848 | National Government Services, Inc. (NGS) |
| F | A57186 | Noridian Healthcare Solutions, LLC |
| E | A57185 | Noridian Healthcare Solutions, LLC |
| 5 & 8 | A57474 | Wisconsin Physicians Service Insurance Corp |
| 15 | A56472 | CGS Administrators, LLC |
| J & M | A56646 | Palmetto GBA |
| N | A57715 | First Coast Service Options, Inc. |

| | | |
|---|---|---|
| H & L | A58423 | Novitas Solutions, Inc. |

| 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, | 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 |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

**FOR MEDICAL BENEFIT COVERAGE REQUESTS:**

**Prior approval is required for HCPCS Codes J0588.**

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# Drug Policy