

Evolut Clinical Guideline 5016.CC for Intravenous Immune Globulins (IVIG) & Subcutaneous Immune Globulins (SCIG)

Guideline Number: EVH_CG_5016.CC	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for all commercially available intravenous immune globulin (IVIG) and subcutaneous immune globulin (SCIG) products.

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

Special Note

Additional uses are included in this policy based on being supported by one or more compendia (e.g., Merative Micromedex[®], UpToDate[®] Lexidrug[™], Elsevier Clinical Pharmacology).

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

General Criteria

- *For FDA-approved indications ONLY:* Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
 - Ideal body weight (IBW) should be used to calculate the dose for members that are not obese
 - Actual body weight should be used if actual body weight is less than ideal body weight (IBW)
 - For obese members (BMI > 30 kg/m²), adjusted Body Weight (ABW) must be used to calculate the dose instead of actual or ideal body weight

- Body weight calculator available at: <https://www.mdcalc.com/ideal-body-weight-adjusted-body-weight>
- **DOSING NOTES** are included below for several indications in which clinical guidelines recommend a specific regimen. For all requests in which the requested dose exceeds recommendations by either guidelines, compendia, or the manufacturer's dosing guidelines – the request will be reviewed using off-label dosing criteria.

Autoimmune Hemolytic Anemia (*off-label supported indication*)

- Must have warm-type diagnosis
- Must have a trial and failure or have a contraindication to corticosteroids

Autoimmune Mucocutaneous Blistering Disease (AMBD) (*off-label supported indication*)

- Must have ONE of the following supported by biopsy:
 - Pemphigus vulgaris,
 - Pemphigus foliaceus,
 - Bullous pemphigoid,
 - Mucous membrane pemphoid (a.k.a., cictrical pemphigoid), OR
 - Epidermolysis bullosa acquisita
- Must have a trial and failure or have contraindications to corticosteroids or immunosuppressive agents
 - **EXCEPTION:** In rapidly progressive, extensive, or debilitating cases, immune globulin may be approved along with corticosteroids or immunosuppressive agents

CAR-T Therapy-Related Toxicity (*off-label supported indication*)

- Must be prescribed by a hematologist, oncologist, or infectious disease specialist
- Must have Hypogammaglobinemia (IgG level <400mg/dL)
- Must have documentation of serious or recurrent infections
- **DOSING NOTE:** Clinical guidelines recommend 400-500mg/kg monthly¹⁵⁵

Chronic B-Cell Lymphocytic Leukemia

- Must be prescribed by a hematologist, oncologist, or infectious disease specialist
- Must have Hypogammaglobulinemia (IgG <500mg/dL)
- Must have previous history of serious infection (requiring antibiotics)

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Must be prescribed by a neurologist

- Must have a diagnosis of CIDP
- Must provide documentation of electrodiagnostic testing (an EMG report)
- Must have moderate-to-severe functional disability
- Must provide a baseline disability score (using a validated disability scale, such as I-RODs, ODSS, ONLS, or INCAT)

Dermatomyositis & Polymyositis (*off-label supported indication*)

- Must have dermatomyositis and polymyositis confirmed by biopsy
- Must have tried and failed or have a contraindication to both of the following:
 - Corticosteroids for 3 months
 - Concomitant adjuvant therapy (azathioprine, methotrexate, cyclosporine)

Guillain-Barre Syndrome (*off-label supported indication*)

- Must start immune globulin within 4 weeks of onset of neuropathic symptoms
- Must be unable to walk independently

Human Immunodeficiency Virus (HIV)

- Must be prescribed by an immunologist or infectious disease specialist
- Must be <13 years old
- Must have CD4 count $\geq 200/\text{mm}^3$
- Must have ONE of the following
 - Recurrent (2 or more) serious infections such as bacteremia, meningitis, or pneumonia during a 1-year period despite administration of highly active antiretroviral therapy (HAART) and prophylactic sulfamethoxazole/trimethoprim (TMP-SMZ) or other antimicrobials
 - Hypogammaglobulinemia with an IgG <400mg/dL
 - Absence of detectable antibodies to common antigens, (measles, pneumococcal, and/or haemophilus influenzae Type B)
 - Bronchiectasis not optimally responsive to antibiotics and pulmonary therapy
 - A need for passive immunization for measles if Intramuscular Immune Globulin (IMIG) is contraindicated. IM injection contraindicated with severe thrombocytopenia or any coagulation disorder

Immune Thrombocytopenia [Idiopathic Thrombocytopenic Purpura (ITP)]

- Must be prescribed by a hematologist or oncologist

- For children with ITP:
 - Must have ONE of the following (platelet counts expressed per mm³):
 - Active bleeding AND platelet count <30,000
 - Upcoming invasive surgery AND either platelet level below threshold designated for procedure (threshold must be provided with request) OR blood loss is expected
 - Non-life-threatening mucosal bleeding and/or diminished quality of life AND documented previous inadequate response or intolerance to corticosteroids
- For adults with ITP:
 - Must have ONE of the following:
 - Active bleeding AND platelet count <30,000
 - Upcoming invasive surgery AND platelet level below threshold designated for procedure (threshold must be provided with request)
 - Platelet count <30,000 AND documented previous inadequate response or intolerance to corticosteroids
- For pregnant women with ITP:
 - Must be pregnant and have ONE of the following:
 - Platelet count <50,000
 - Upcoming invasive surgery/procedure
 - History of splenectomy
 - Previously delivered infants with autoimmune thrombocytopenia
- **DOSING NOTE:** Clinical guidelines recommend up to 1,000mg/kg/dose as a 1-time dose; dosage may be repeated if necessary¹⁵¹

Kawasaki Disease

- Must be receiving aspirin concomitantly
- Must be requesting treatment within the first 10 days of illness
 - If greater than 10 days after illness onset, must have persistent signs of inflammation (e.g., persistent fever without explanation, elevated ESR or CRP, coronary artery aneurysms)
- **DOSING NOTE:** Clinical guidelines recommend 2 grams/kg¹⁵²

Multifocal Motor Neuropathy (MMN)

- Must be prescribed by a neurologist
- Must provide chart note documentation supporting a clinical examination of the member and BOTH of the following:

- Progressive, asymmetric limb weakness over a course of at least 1 month
- No objective sensory abnormalities except for minor vibration sense abnormalities in the lower limbs
- Must provide documentation of electrophysiologic findings that support the diagnosis of MMN (such as nerve conduction studies showing conduction blocks and EMG report)
- **DOSING NOTE:** Clinical guidelines recommend up to 2g/kg given over 2-5 days¹⁵⁴

Multiple Sclerosis (MS) (*off-label supported indication*)

- Must be prescribed by a neurologist
- For acute exacerbations of MS:
 - Must have a trial and failure or have contraindications to corticosteroids or plasma exchange
- For chronic maintenance treatment of MS:
 - Must have relapsing, remitting type of MS
 - Must have a trial and failure (duration of at least 3 months) or have contraindications to ALL the following:
 - At least one interferon [interferon beta-1a (Rebif[®]) or interferon beta-1b (Betaseron[®])]
 - Glatiramer (Copaxone[®])
 - Fingolimod (Gilenya[®])
 - No previous trials are required if:
 - Member is pregnant
 - Member is immunosuppressed or is having recurrent infections

Myasthenia Gravis (MG) (*off-label supported indication*)

- Must be prescribed by a neurologist
- For acute use:
 - Must have chart documentation showing an acute exacerbation and associated impaired function (e.g., respiratory insufficiency, inability to swallow)
- For temporary use as a bridge to immunotherapy:
 - Must have a history of myasthenia gravis exacerbation
 - Must be recently started (within 3 months) on immunosuppressant therapy (e.g., azathioprine, mycophenolate, cyclosporine, or tacrolimus)
 - Chart documentation of use as bridge therapy is required
- For stabilization prior to surgery:
 - Must have a history of myasthenia gravis with current or previous difficulty with

- swallowing, speech, or respiratory involvement (e.g., shortness of breath or reduced force vital capacity on pre-op pulmonary function test). Chart documentation of symptoms is required.
- IVIG infusion must be scheduled within 14 days of anticipated surgery date
 - For chronic use in refractory disease:
 - Must have an adequate trial with inadequate response, significant side effects/toxicity, or have a contraindication to BOTH of the following:
 - Cholinesterase inhibitors (pyridostigmine or neostigmine)
 - Corticosteroids
 - Must have an adequate trial (of at least 3 months each) with inadequate response, significant side effects/toxicity, or have a contraindication to TWO of the following:
 - Azathioprine
 - Mycophenolate mofetil
 - Cyclosporine
 - Tacrolimus

Parvovirus B19 Infection (*off-label supported indication*)

- Must have documentation (e.g., Polymerase Chain Reaction test result) confirming presence of HPV-B19 infection
- Must have severe anemia defined as hemoglobin level <8ng/dL
- Must have low reticulocyte count defined as <8x10⁹/L
- Must have history of immunodeficiency due to suppressive medications or HIV
- **DOSING NOTE:** Clinical guidelines recommend 400-500mg for 5 days¹⁵⁴

Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS) (*off-label supported indication*)

- Documented diagnosis of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS) made by or in consultation with a pediatric psychiatrist or pediatric neurologist
- Must meet the following criteria consistent with PANDAS:
 - Obsessive-compulsive disorder (OCD) and/or tic disorder (such as Tourette disorder, chronic motor or vocal tic disorder)
 - Pediatric onset (between three years and onset of puberty)
 - Abrupt onset and episodic course of symptoms
 - Temporal relation between group A streptococcal (GAS) infection and onset and/or

exacerbation

- Neurologic abnormalities, such as motoric hyperactivity, choreiform movements, or tics during exacerbations

Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) *(off-label supported indication)*

- Documented diagnosis of pediatric acute-onset neuropsychiatric syndrome (PANS) made by or in consultation with a pediatric psychiatrist or pediatric neurologist
- Must meet the following criteria consistent with PANS:
 - Abrupt, dramatic onset of obsessive-compulsive disorder or severely restricted food intake
 - Concurrent presence of additional neuropsychiatric symptoms, (with similarly severe and acute onset), from at least two of the following seven categories
 - Anxiety
 - Emotional lability and/or depression
 - Irritability, aggression, and/or severely oppositional behaviors
 - Behavioral (developmental) regression
 - Deterioration in school performance (related to attention deficit/hyperactivity disorder [ADHD]-like symptoms, memory deficits, cognitive changes)
 - Sensory or motor abnormalities
 - Somatic signs and symptoms, including sleep disturbances, enuresis, or urinary frequency
 - Symptoms are not better explained by a known neurologic or medical disorder, such as Sydenham chorea (SC)

Primary Immunodeficiency

Syndromes may include Common Variable Immunodeficiency (CVID), Congenital Agammaglobulinemia, Bruton's or X-linked Agammaglobulinemia, Severe Combined Immunodeficiency (SCID), X-linked Hyper-IgM Syndrome, Wiskott-Aldrich Syndrome, or Hypergammaglobulinemia Types.

- Must be prescribed by or in consultation with an immunologist or hematologist
- Must have deficient antibody production, as evidenced through a documented IgG level ≤ 500 mg/dL
 - Requests with IgG levels >500 mg/dL require chart documentation that provides clinical rationale for the use of IVIG or SCIG (NOTE: Several primary immunodeficiencies do have normal levels of IgG with documented specific antibody deficiency)¹⁴⁹
- Must have history of at least 1 infection directly attributable to this deficiency

Systemic Lupus Erythematosus (*off-label supported indication*)

- Must have severe active SLE
- Must have tried and failed or have contraindications to ALL the following:
 - Corticosteroids
 - Antimalarials
 - 1 additional immunosuppressant (e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate)

Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN) (*off-label supported indication*)

- Must have chart note documentation supporting a diagnosis of Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TENS)
- **DOSING NOTE:** Package insert/clinical guidelines recommend 1 g/kg/day in divided doses for 3-4 days¹⁵⁵

Stiff Person Syndrome (*off-label supported indication*)

- Must have a diagnosis of Stiff-Person Syndrome confirmed by electromyography (EMG) or elevated levels of glutamic acid decarboxylase (GAD)
- Must be prescribed by a neurologist
- Must have an adequate trial with inadequate responses, significant side effects/toxicity, or have contraindications to THREE of the following:
 - Corticosteroids
 - Antiepileptics
 - Benzodiazepines
 - Muscle relaxants
 - Gabapentin

Transplant Desensitization – Pancreatic and/or Renal (*off-label supported indication*)

- Must be prescribed by a transplant specialist
- Must be age 18 or older *if being used in combination with rituximab*
- Must be awaiting kidney and/or pancreas transplant requiring desensitization as defined by the following criteria:
 - For deceased donor transplants:
 - Panel reactive antibody (PRA) level >30% **OR**
 - PRA <30% with previous kidney and/or pancreas transplant

- For living donor transplants:
 - Positive crossmatch **OR**
 - Positive donor-specific antibody using Luminex® assay
- Must be using in combination with rituximab *only if awaiting pancreatic transplant* (renal transplant does not require use with rituximab)

Transplant – Post-Stem Cell (Allogenic or Hematopoietic) or Post-Bone Marrow (*off-label supported indication*)

- Must have severe hypogammaglobulinemia (IgG <400 mg/dL)
- Must have history of recurrent infections

Transplant Rejection – Renal (*off-label supported indication*)

- Must have received a renal transplant from a living donor with post-transplant rejection

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on a case-by-case basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

General Criteria

- *For FDA-approved indications ONLY:* Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
 - Ideal body weight (IBW) should be used to calculate the dose for members that are not obese
 - Actual body weight should be used if actual body weight is less than ideal body weight (IBW)
 - For obese members (BMI > 30 kg/m²), adjusted Body Weight (ABW) must be used to calculate the dose instead of actual or ideal body weight
 - Body weight calculator available at: <https://www.mdcalc.com/ideal-body-weight-adjusted-body-weight>

Autoimmune Hemolytic Anemia (*off-label supported indication*)

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
- Must have chart documentation describing the previous response and clinical rationale for re-treatment

Autoimmune Mucocutaneous Blistering Disease (AMBD) (*off-label supported indication*)

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
- Must have chart documentation describing the previous response and clinical rationale for re-treatment

CAR-T Therapy-Related Toxicity (*off-label supported indication*)

- Must have chart note documentation from the prescriber indicating that the member's condition has improved as a result of treatment

Chronic B-Cell Lymphocytic Leukemia

- Must have chart note documentation from the prescriber indicating that the member's condition has improved as a result of treatment

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Must have documentation showing the member's condition has improved as a result of treatment, as evidenced by improvement or stability in the member's baseline disability score (using a validated disability scale, such as I-RODS, ODSS, ONLS, or INCAT)

Dermatomyositis & Polymyositis (*off-label supported indication*)

- Must have chart note documentation from the prescriber indicating that the member's condition has improved as a result of treatment

Guillain-Barre Syndrome (*off-label supported indication*)

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
- Must have chart documentation describing the previous response and clinical rationale for re-treatment

Human Immunodeficiency Virus (HIV)

- Must have chart note documentation from the prescriber indicating that the member's condition has improved as a result of treatment

Immune Thrombocytopenia [Idiopathic Thrombocytopenic Purpura (ITP)]

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
- Must have chart documentation describing the previous response and clinical rationale

for re-treatment

Kawasaki Disease

- **First Reauthorization:** Must submit documentation showing the member failed to respond to therapy
- **Subsequent Reauthorizations:** Must meet initial criteria again under INITIAL CRITERIA indication-specific section AND must have chart documentation describing the previous response and clinical rationale for re-treatment

Multifocal Motor Neuropathy (MMN)

- Must have chart note documentation from the prescriber indicating that the member's condition has improved as a result of treatment

Multiple Sclerosis (MS) (off-label supported indication)

- For acute exacerbations of MS:
 - Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
 - Must have chart documentation describing the previous response and clinical rationale for re-treatment if immune globulin did not provide a sufficient response
- For chronic maintenance treatment of MS:
 - Must have chart note documentation from the prescriber indicating that the member's condition has improved as a result of treatment

Myasthenia Gravis (MG) (off-label supported indication)

- For acute use:
 - Must have chart documentation describing the previous response and clinical rationale for re-treatment if immune globulin did not provide a sufficient response
- For temporary use as a bridge to immunotherapy:
 - Must have chart documentation describing the previous response and clinical rationale for re-treatment if immune globulin did not provide a sufficient response
- For stabilization prior to surgery:
 - Must have chart documentation describing the previous response and clinical rationale for re-treatment if immune globulin did not provide a sufficient response
- For chronic use in refractory disease:
 - Must have chart note documentation describing the member's previous response to treatment, including improvement in symptoms that limit daily functioning

Parvovirus B19 Infection (off-label supported indication)

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section

AND

- Must have chart documentation describing the previous response and clinical rationale for re-treatment

Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS) (*off-label supported indication*)

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
- Must have chart documentation describing the previous response and clinical rationale for re-treatment

Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) (*off-label supported indication*)

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
- Must have chart documentation describing the previous response and clinical rationale for re-treatment

Primary Immunodeficiency

- Must have chart note documentation that the member's condition has improved as a result of treatment
- Must have documentation of an updated IgG level

Systemic Lupus Erythematosus (*off-label supported indication*)

- Must have chart note documentation from the prescriber indicating that the member's condition has improved as a result of treatment

Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis (TEN) (*off-label supported indication*)

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
- Must have chart documentation describing the previous response and clinical rationale for re-treatment

Stiff Person Syndrome (*off-label supported indication*)

- May only be approved for an additional 2 MONTHS if the below is met:
 - Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND

- Must have chart documentation describing the previous response and clinical rationale for re-treatment
- Continued use beyond a total of 6 months of therapy is not covered.

Transplant Desensitization – Pancreatic and/or Renal (*off-label supported indication*)

- For pancreatic and/or renal transplant desensitization *in combination with rituximab*:
 - Must meet initial criteria again under the INITIAL CRITERIA indication-specific section
 - Reauthorizations are not granted until at least 6 months have passed since the initial treatment
- For renal transplant desensitization *NOT in combination with rituximab*:
 - Must meet initial criteria again under the INITIAL CRITERIA indication-specific section
 - Reauthorizations are not granted until at least 12 months have passed since the initial treatment

Transplant – Post-Stem Cell (Allogenic or Hematopoietic) or Post-Bone Marrow (*off-label supported indication*)

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
- Must have chart documentation describing the previous response and clinical rationale for re-treatment

Transplant Rejection – Renal (*off-label supported indication*)

- Must meet initial criteria again under the INITIAL CRITERIA indication-specific section AND
- Must have chart documentation describing the previous response and clinical rationale for re-treatment

APPROVAL DURATIONS

If the above criteria are met, the request will be approved for up to the duration of time dictated below:

<p>Initial Authorization</p>	<ul style="list-style-type: none"> ● AMBD: 4 months ● CAR-T: 1 year ● Chronic B-Cell Lymphocytic Leukemia: 1 year ● CIDP: 1 year ● Dermatomyositis/Polymyositis: 1 year ● Guillain-Barre: 2 months ● HIV: 1 year ● ITP: 1 month ● Kawasaki Disease: 1 month ● MMN: 1 year ● MG (Acute): 1 month ● MG (Bridge): 6 months ● MG (Surgery): 1 month ● MG (Chronic): 1 year ● MS (Acute): 1 month ● MS (Maintenance): 1 year ● PANDAS: 1 month ● PANS: 1 month ● Parvovirus B19: 1 month ● Primary Immunodeficiency: 1 year ● SLE: 1 year ● SJS/TENS: 1 month ● Transplant (Desensitization): 4 months ● Transplant (Rejection): 1 month ● Transplant (HSCT/Bone Marrow): 6 months
<p>Reauthorization</p>	<ul style="list-style-type: none"> ● The following are NOT eligible for reauthorization: Beyond 6 months of therapy for Stiff-Person Syndrome

	<ul style="list-style-type: none"> • All other indications: Same as initial
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CODING AND STANDARDS

Codes

Code	Brand	Description
J1459	PRIVIGEN	INJECTION, IMMUNE GLOBULIN IV, NON-LYOPHILIZED, 500MG
J1460	GAMASTAN	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, 1 CC
J1551	CUTAQUIG	INJECTION, IMMUNE GLOBULIN (CUTAQUIG), 100 MG
J1552	ALYGLO	INJECTION, IMMUNE GLOBULIN (ALYGLO), 500MG
J1554	ASCENIV	INJECTION, IMMUNE GLOBULIN (ASCENIV), 500 MG
J1555	CUVITRU	INJECTION, IMMUNE GLOBULIN, 100 MG
J1556	BIVIGAM	INJECTION, IMMUNE GLOBULIN (BIVIGAM), 500 MG
J1557	GAMMAPLEX	INJECTION, IMMUNE GLOBULIN, IV, NONLYOPHILIZED, 500 MG
J1558	XEMBIFY	INJECTION, IMMUNE GLOBULIN, 100 MG
J1559	HIZENTRA	INJECTION, IMMUNE GLOBULIN (HIZENTRA), 100 MG
J1560	GAMASTAN S-D	INJECTION, GAMMA GLOBULIN, INTRAMUSCULAR, OVER 10 CC
J1561	GAMUNEX-C, GAMMAKED	INJECTION, IMMUNE GLOBULIN, NONLYOPHILIZED, 500 MG
J1566	GAMMAGARD S/D,	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, LYOPHILIZED, NOT OTHERWISE SPECIFIED, 500 MG
J1568	CARIMUNE NF	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, NON-LYOPHILIZED, 500 MG
J1569	OCTAGAM	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, NON-LYOPHILIZED, 500 MG

J1572	GAMMAGARD	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, NON-LYOPHILIZED, 500 MG
J1575	FLEBOGAMMA, FLEBOGAMMA DIF	INJECTION, IMMUNE GLOBULIN/HYALURONIDASE 100 MG
J1576	HYQVIA	INJECTION, IMMUNE GLOBULIN (PANZYGA), INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1459	PANZYGA	INJECTION, IMMUNE GLOBULIN IV, NON-LYOPHILIZED, 500MG

Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input type="checkbox"/>	Commercial
<input type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

INCAT (Inflammatory Neuropathy Cause and Treatment Scale) – is used to assess functional disability of both upper and lower extremities in chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)

Grade	Arm Disability
0	No upper limb problems
1	Symptoms, in one or both arms, not affecting the ability to perform any of the following functions: doing all zips and buttons; washing or brushing hair; using a knife and fork together; and handling small coins
2	Symptoms, in one arm or both arms, affecting but not preventing any of the above-mentioned functions

3	Symptoms, in one arm or both arms, preventing one or two of the above-mentioned functions
4	Symptoms, in one arm or both arms, preventing three or all of the functions listed, but some purposeful movements still possible
5	Inability to use either arm for any purposeful movement
Grade	Leg Disability
0	Walking not affected
1	Walking affected, but walks independently outdoors
2	Usually uses unilateral support (stick, single crutch, one arm) to walk outdoors
3	Usually uses bilateral support (stick, crutches, frame, two arms) to walk outdoors
4	Usually uses wheelchair to travel outdoors, but able to stand and walk a few steps with help
5	Restricted to wheelchair, unable to stand and walk a few steps with help

Inflammatory Rasch-built Overall Disability Scale (I-RODS) – intended to specifically assess activity and social participation limitations in patients with inflammatory neuropathies

Overall Disability Sum Score (ODSS) / Overall Neuropathy Limitations Scale (ONLS) – focuses on upper and lower limb functions and consists of a checklist for interviewing patients. The ODSS was the first scale designed to assess the limitations of patients with immune-mediated peripheral neuropathies. To reduce a possible ceiling effect, the ODSS was modified to include climbing stairs and running. The new measure is called the ONLS.

Grade	Arm Disability
0	Normal
1	Minor symptoms in one or both arms but not affecting any of the functions listed
2	Disability in one or both arms affecting but not preventing any of the functions listed
3	Disability in one or both arms preventing at least one but not all functions listed

4	Disability in both arms preventing all functions listed but purposeful movement still possible
5	Disability in both arms preventing all purposeful movements
Grade	Leg Disability
0	Walking/climbing stairs/running not affected
1	Walking/climbing stairs/running is affected, but gait does not look abnormal
2	Walks independently but gait looks abnormal
3	Requires unilateral support to walk 10 metres (stick, single crutch, one arm)
4	Requires bilateral support to walk 10 metres (sticks, crutches, crutch and arm, frame)
5	Requires wheelchair to travel 10 metres but able to stand and walk 1 metre with the help of one person
6	Restricted to wheelchair, unable to stand and walk 1 metre with the help of one person, but able to make some purposeful leg movements
7	Restricted to wheelchair or bed most of the day, unable to make any purposeful movements of the legs

Refractory Myasthenia Gravis Disease – unchanged or worse disease after corticosteroids and at least 2 other immunosuppressants, used in adequate doses for an adequate duration, with persistent symptoms or side effects that limit functioning, as defined by patient and physician

POLICY HISTORY

Date	Summary
March 2025	<ul style="list-style-type: none"> Added Alyglo
January 2024	<ul style="list-style-type: none"> Added Panzyga
February 2023	<ul style="list-style-type: none"> Added Cutaquig Extended authorization durations for various indications to 1 year

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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