| Policy and Procedure | |
|---|---|
| **PHARMACY PRIOR AUTHORIZATION AND STEP THERAPY POLICY AND CRITERIA ORPTCBIO019.0824** | **BIOLOGICAL PRODUCTS**<br>**IMMUNE GAMMA GLOBULIN (IgG)**<br>See Table 2 for Specific Products |
| **Effective Date: 10/1/2024** | **Review/Revised Date**: 05/24, 08/24 |
| **Original Effective Date: 08/23** | **P&T Committee Meeting Date**: 06/23, 06/24, 08/24 |
| **Approved by: Oregon Region Pharmacy and Therapeutics Committee** | |

**SCOPE:**
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

**APPLIES TO:**
Medicare Part B

## POLICY CRITERIA:

**COVERED USES:**
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit. Off-label uses may be approved according to the clinical criteria outlined in the below policy.

**REQUIRED MEDICAL INFORMATION:**
**Initial Authorization for ALL indications:**
1. The medical diagnosis is an FDA approved indication or is listed as a covered medical condition below and any indication specific criteria in the policy is met

**AND**
2. Requested dosage, frequency and length of therapy are supported by FDA-approved labeling, accepted compendia and/ or evidence-based practice guidelines (See Table 1). If request is for a non-standard dose, frequency or length, medical rational should be provided and exceptions will be considered on a case by cases basis. *Dosing is subject to audit.*

**Re-Authorization for ALL indications:**
1. Documentation of response to therapy and any indication specific re-authorization criteria listed below is met

**Indication-Specific Requirements:**
**Primary immune deficiency disorders** such as agammaglobulinemia, hypogammaglobulinemia (common variable immunodeficiency), Hyper-IgM (X-linked or autosomal recessive hypogammaglobulinemia), Wiskott-Aldrich syndrome
1. The patient has one of the following:

a. The patient has a total IgG less than 200 mg/dL at baseline prior to immune globulin therapy
b. The patient has abnormal Bruton tyrosine kinase (BTK) gene or absence of BTK protein
c. The patient has an absence of B lymphocytes
d. The patient meets all of the following:
    i. One of the following:
        1) The patient has selective IgG subclass deficiency [Defined as deficiency of one or more IgG subclasses (e.g., IgG1, IgG2, IgG3, or IgG4) more than two standard deviations (SD) below age-specific mean, assessed on two separate occasions during infection free period
        2) The patient has specific antibody deficiency (SAD) with normal levels of both immunoglobulin and total IgG subclasses
        3) The patient has hypogammaglobulinemia (defined as total IgG less than 700 mg/dL OR more than two SDs below mean for the patient's age at baseline prior to immune globulin therapy)
    ii. The patient has a lack of response or inability to mount an adequate response to protein and/or polysaccharide antigens (such as inability to make IgG antibody against either diphtheria and tetanus toxoids, or pneumococcal polysaccharide vaccine, or both)
    iii. The patient has evidence of recurrent, persistent, severe, difficult-to-treat infections (such as recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics)

**Reauthorization:**

1. Documentation that treatment has been effective in reducing the number or severity of clinical infections

**Prevention of infections in patients with B-cell chronic lymphocytic leukemia (CLL):**

1. Documented pre-treatment endogenous IgG less than 700 mg/dL OR more than two standard deviations below mean for the patient's age

**OR**

2. History of recurrent, severe bacterial infections requiring antibiotics and/or hospitalization

**Kawasaki Disease:**

1. Documentation that use is for acute treatment given in conjunction with aspirin and within 10 days of the onset of symptoms

**Idiopathic or Immune Thrombocytopenic Purpura (ITP):**
(Platelet counts expressed per microliter and should be obtained within the past 30 days)

**For children with ITP:**
1. Documentation of one of the following:
    a. Platelet count less than 20,000 and significant mucous membrane bleeding
    b. Platelet count less than 10,000 and minor purpura
    c. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss

**Pregnant Women with ITP:**
1. Documentation of one of the following:
    a. Platelet count is less than 100,000
    b. Past history of splenectomy
    c. Past history of delivered infant with autoimmune thrombocytopenia

**Adult Patients with ITP:**
1. Documentation of one of the following:
    a. Platelet count of less than 30,000
    b. Platelet count less than 50,000 with acute bleeding or high-risk of bleeding
    c. To defer or avoid splenectomy
    d. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss (platelet count goal is generally greater than 50,000)
2. Documentation that IGG product will be used in combination with corticosteroid therapy or corticosteroid therapy is contraindicated

**Dermatomyositis and polymyositis:**
1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (such as prednisone or methylprednisolone)

**AND**

2. Documented trial, failure, intolerance or contraindication to immunosuppressant therapy (e.g., methotrexate, azathioprine, cyclosporine, 6-mercaptopurine, chlorambucil, cyclophosphamide)

**AND**

3. Documentation of severe symptoms/disability despite previous therapy with above agents

**Reauthorization**: Documented response to therapy

**Chronic inflammatory demyelinating polyneuropathy (CIDP):**
1. Documentation of severe disability

**AND**

2. One of the following:
    a. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (such as prednisone or methylprednisolone)
    b. Documentation of pure motor CIDP

**Autoimmune Hemolytic Anemia:**
1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (such as prednisone or methylprednisolone)

**AND**

2. Documented trial, failure, intolerance or contraindication to another conventional therapy for autoimmune hemolytic anemia (e.g., splenectomy, cyclophosphamide, azathioprine, cyclosporine)

**Guillain-Barre Syndrome:**
1. Documentation that symptom onset is within two weeks or symptoms are severe (such as being unable to ambulate independently)

**AND**

2. Documented trial, failure, intolerance or contraindication to plasma exchange

**Multifocal motor neuropathy:**
1. Confirmed diagnosis: motor involvement of at least two nerves (for more than one month) without symptoms of sensory abnormalities

**AND**

2. Documentation of severe disease/disability

**Multiple Sclerosis:**
1. Documentation of relapsing/remitting disease

**AND**

2. Documented trial, failure, intolerance or contraindication to at least two conventional therapies (such as glatiramer, interferon beta, dimethyl fumarate)

**Myasthenia Gravis:**
**Myasthenic exacerbation:**
1. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month:
    a. Difficulty swallowing
    b. Acute respiratory failure

c. Major functional disability responsible for the discontinuation of physical activity

**Refractory disease:**

1. Documentation that patient has severely impaired function due to myasthenia gravis

**AND**

2. Documented trial, failure, intolerance or contraindication to at least two of the following conventional therapies:
    a. Acetylcholinesterase inhibitors (such as pyridostigmine)
    b. Corticosteroids (such as prednisone, methylprednisolone)
    c. Immunosuppressive agents (such as azathioprine, cyclosporine, mycophenolate)
    d. Plasma exchange

**Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients:**

1. Documentation of one of the following:
    a. Therapy is requested for use within 100 days after transplantation (transplantation date must be documented)

    **OR**

    b. Documentation that patient has an IgG less than 400 mg/dL with a history of recurrent infections

**Autoimmune mucocutaneous blistering disease:** pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis

1. Documentation of biopsy proven disease

**AND**

2. One of the following:
    a. Documented trial, failure or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment (such as azathioprine, cyclophosphamide, mycophenolate mofetil).

    **OR**

    b. Patient has rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. In such situations documentation that IgG therapy will be given with conventional treatment(s) and only used until the conventional therapy can take effect is required.

**Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute-onset neuropsychiatric syndrome (PANS):**

1. Clinical documentation must be provided detailing patient's primary symptom complex along with baseline clinical testing(s) using validated instrument(s)

**AND**

2. A clinically appropriate trial of two or more less-intensive treatments was either not effective, not tolerated, or did not result in sustained improvement in symptoms, as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient's primary symptom complex. For example, treatments may include appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, or short-course antibiotic therapy). These trials may be done concurrently.

**Reauthorization in PANDAS/PANS:**

1. Documentation that a reevaluation at three months post treatment have been performed by an appropriate specialist

**AND**

2. Documentation of objective clinically meaningful improvement posttreatment as defined by an improvement in the clinical testing with a validated instrument

**Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD)**

1. Documentation of severe residual deficits following an initial attack, to prevent further disability (for example, to preserve vision in patients with residual monocular blindless after an initial attack)

**OR**

2. As maintenance treatment for patients who have experienced at least one relapse following an initial attack

**Reauthorization for MOGAD**: Documented positive response to therapy as demonstrated by recovery of function from previous attack or reduction in frequency or severity of attacks.

**EXCLUSION CRITERIA:** N/A

**AGE RESTRICTIONS:** N/A

**PRESCRIBER RESTRICTIONS:**
Must be prescribed by or in consultation with an appropriate specialist (such as a neurologist for multiple sclerosis; immunologist, hematologist or infections disease

expert for primary immunodeficiency; neurologist, psychiatrist, or rheumatologist for PANDAS/PANS)

**COVERAGE DURATION:**
Generally, initial authorization is up to six months subject to criteria and reauthorization is up to one year subject to criteria. See Table 1 for indication specific coverage duration

**TABLE 1**

| Indication | Coverage Duration | Recommended Dose for Adult Patients* |
| --- | --- | --- |
| Primary or secondary Immunodeficiency | Initial authorization: up to six months<br>Reauthorization: up to one year | Initial dosing: 400-600 mg/kg IV every three to four weeks or equivalent scIG weekly |
| ITP | Initial authorization: up to six months<br>Reauthorization: up to one year | For acute ITP: Up to 1,000 mg/kg/day IV for one to two days.<br>For chronic ITP: 2000 mg/kg IV per month given over two to five days<br>May be repeated monthly as needed to prevent exacerbation |
| Kawasaki disease | two weeks (IVIG is typically not effective after 10 days post diagnosis) | 400 mg/kg IV for five days or a single dose of 2000 mg/kg IV |
| Prevention infection in B-cell CLL | Initial authorization: up to six months<br>Reauthorization: up to one year | 400 mg/kg IV every three to four weeks |
| Dermatomyositis and Polymyositis | Initial authorization: up to six months<br>Reauthorization: up one year | Initial: 2,000 mg/kg IV per month given over two to five days.<br>Maintenance dose: Up to 2000 mg/kg IV per month adjusted to maintain clinical response (general 500-1000 mg/kg IV every three to four weeks) |
| CIPD | Initial authorization: up to six months<br>Reauthorization: up to one year | 2000 mg/kg IV per month given over two to five days. Dosing interval may need to be adjusted in patients with severe comorbidities |
| Guillain-Barre Syndrome | Initial authorization: one month | 400 mg/kg IV once daily for two to five days. |

| | | |
| --- | --- | --- |
| | Reauthorization: up to three months | May be repeated in up to three monthly infusions. |
| Autoimmune Hemolytic Anemia | Initial authorization and reauthorization: one month | 1000 mg/kg IV per day for five days<br>May require retreatment |
| Multifocal motor neuropathy | Initial authorization: up to six months<br>Reauthorization: up to one year | 2,400 mg/kg IV per month given over two to five days, may be repeated monthly to prevent exacerbation |
| Multiple Sclerosis | Initial authorization: up to six months<br>Reauthorization: up to one year | No standard dose has been determined |
| Myasthenia Gravis | For Myasthenic Crisis:<br>Initial and reauthorization approved for one month<br>For Refractory disease:<br>Initial authorization: up to six months<br>Reauthorization: up to one year | Myasthenic Crisis: Single treatment 2000 mg/kg IV divided over two to five days<br>Refractory disease: 2000 mg/kg IV every three to eight weeks adjusted to maintain clinical response |
| Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients | Initial authorization: up to 100 days post-transplant | 500 mg/kg IV once weekly for the first 90 days post-transplant |
| Autoimmune mucocutaneous blistering disease | Initial authorization: up to six months<br>Reauthorization: up to one year | 2000 mg/kg IV divided over two to five days then monthly |
| PANDAS/PANS | Initial authorization: up to three months<br>Reauthorization: up to one year | No standard dose has been determined |
| MOGAD | Initial authorization: up to six months<br>Reauthorization: up to one year | Loading dose of 0.4 g/Kg/day for five consecutive days, followed by treatment every four weeks with a dose of 0.4 g/kg to 2 g/kg |

* Dosing may vary between products, please refer to FDA approved label. The following recommendations are not all inclusive. For SCIG products please refer to FDA-label and conversion guidelines. **Dosing for intravenously infused medications may be subject to audit.**

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*Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy*

*document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.*

*Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.*

*Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.*

## INTRODUCTION:

Immunoglobulins (IgG) are major effector protein molecules of the immune system. Intravenous immune globulin (IVIG) and subcutaneous immune globulin (SCIG) are purified preparations of IgG derived from pooled human serum. The broad range of antibodies contained in these products have specific action against bacterial and viral antigens. In many circumstances, the specificity of a given Immunoglobulin antibody is unknown. IVIG products have 100% bioavailability, but the rate of degradation is dependent upon the serum IgG level (the higher the serum level, the faster the degradation). SCIG formulations typically have 2/3 the bioavailability of the IVIG products, and therefore may require higher monthly doses to achieve the same response. Product selection will vary depending on the characteristics of the patient and it is generally recommended to stay with the same product unless there is a compelling reason to switch.

**Table 2**: Immune gamma globulin product availability

| HCPCS Code | Product Name | Administration | Indications |
| --- | --- | --- | --- |
| J1568 | Octagam® | IV | PID, D/P (10% strength) |
| J1566 | Gammagard S/D® | IV | PID, B-cell CLL, ITP, Kawasaki disease (peds) |
| J1561 | Gamunex-C® | IV or SC | PID, ITP, CIDP |
| J1561 | Gammaked® | IV or SC | PID, ITP, CIDP |
| J1459 | Privigen® | IV | PID, ITP, CIDP |
| J1556 | Bivigam® | IV | PID |
| J1557 | Gammaplex® | IV | PID, ITP |
| J1572 | Flebogamma Dif® | IV | PID |
| J1569 | Gammagard Liquid® | IV or SC | PID, MMN |
| J1559 | Hizentra® | SC infusion only (via pump) | PID, CIDP |
| J1575 | HyQvia® | IV or SC | PID |

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|---|---|---|---|
| J1460/J1560 | Gamastan S-D® | IM injection | Post-exposure to varicella, measles, rubella<br>Hepatitis A prevention |
| J1555 | Cuvitru® | SC infusion only (via pump) | PID |
| J1558 | Xembify® (Immune Globulin-klhw) | SC infusion only (via pump) | PID |
| J1554 | Asceniv® (Immune Globulin-slra) | IV | PID |
| J1576 | Panzyga® (Immune Globulin-ifas) | IV | ITP, CIDP, PID |
| J1551<br><br>J3590 | Cutaquig® (Immune Globulin-hipp)<br>Alyglo® | SC infusion only (via pump)<br>IV | PID<br><br>PID |

PID: primary immunodeficiency; B-cell CLL: prevention of bacterial infections associated with CLL; ITP: immune thrombocytopenic purpura; CIDP: chronic Inflammatory demyelinating polyradiculoneuropathy; MMN: multifocal motor neuropathy; D/P: Dermatomyositis/polymyositis

**FDA INDICATIONS:**

- Prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with chronic B cell lymphocytic leukemia
- Immune thrombocytopenic purpura (ITP)
- Kawaskai Syndrome
- Primary humoral immunodeficiency diseases **(Medicare Part B always)**. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Multifocal motor neuropathy (MMN)
- Hepatitis A prevention
- Post-exposure to varicella, measles and rubella
- Dermatomyositis

**POSITION STATEMENT:**

- IVIG preparations with low IgA content are used to minimize reactions in patients with hypogammaglobulinemia and concurrent IgA deficiency or when anti-IgA antibodies are present in a recipient.
- Renal dysfunction and acute renal failure have been associated with many of the licensed IVIG products. Sucrose containing IVIG products have had a higher incidence of renal dysfunction when infused at a rate greater than the FDA

maximum infusion rate recommendation. Non-sucrose containing IVIG products may be indicated in high-risk patients.

- Dosing adjustments are based on clinical response and IgG levels. Target IgG trough levels maintained above 500 gm/dL has been considered sufficient to prevent most system infections in patients with hypogammaglobulinemia
    - IgG trough levels > 800 mg/dL may have the potential to improve pulmonary outcomes
- In patients with severe hypogammaglobulinemia or agammaglobinemia, IgG levels (trough) should be checked every 3-6 months in growing children and every 6 – 12 months in adults.
- Subcutaneous (SC) administration of immune globulin is considered an alternative to intravenous administration of immune globulin when used for one of the covered indications. In some patients, the SC administration can reduce the occurrence of adverse events.
- There are no randomized, controlled comparative trials that show any differences between the currently available agents. The available products differ in the methods used for preparation and viral inactivation, storage requirement, and dosage form (lyophilized versus liquid) although these differences are not clinically significant. Various pharmaceutical characteristics may alter the potential for adverse effectives in select, specific patient populations, such as sodium content, osmolality, IgA content, sugar content and latex content. Consideration for the patient's age, medical history, and concurrent disease states must be taken when selecting a product.
- Immune globulin therapy is used for many different conditions. For specific indications FDA label, compendia and/ or evidence-based practice guidelines should be consulted.
- The off-label use of IVIG in pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute onset neuropsychiatric syndrome (PANS) is based on expert opinion and low-quality observational studies showing some patients may benefit from therapy. However, due to the severe impact of symptoms associated with PANDAS/PANS on child health, growth and development, and the lack of known effective treatments, coverage of IVIG is recommended by the Health Evidence Review Commission (HERC) when recommended by the patient's primary care provider (PCP) and a pediatric subspecialist and after less-intensive therapies were not effective, were not tolerated or did not result in sustained improvement in symptoms.[21]
- Please refer to HERC guidance on recommended symptom specific validated instruments for clinical assessment. [21]
- While the efficacy for using IVIG in MOGAD is extremely limited, two retrospective studies have shown a potential for lowering the rate of relapse[22,23]. The National Multiple Sclerosis Society makes recommendations for the use of

IVIG in MOGAD[25]. For initial attacks, IVIG is typically used in cases of very severe or refractory cases, after treatment with high-dose corticosteroids. Plasma exchange may also be used. While 40-50% of patients only have one attack with good recovery following, some patients may experience residual deficits following their initial attack or may relapse. For these patients, long-term maintenance treatment may include maintenance IVIG, rituximab, azathioprine, or IL-6 targeting treatments. There is limited data available on the use of any of these therapies in MOGAD, and none have been approved by the FDA for use in this condition.

**For Medicare, in addition, see further criteria for determination of Medicare B vs Medicare D coverage determination for a Medicare PA request.**

**REFERENCE/RESOURCES**:

1. Individual product prescribing information accessed May 2022
2. Hays WS, Inc. Intravenous Immunoglobulin for Multiple Sclerosis October 14, 2005
3. HaysWS, Inc. Intravenous Immunoglobulin for Neurological Diseases. February 2, 2006
4. Zulay JP et al. Long-term follow up of multifocal motor neuropathy with conduction block under treatment. *J. Neurol 1997*; 62(4): 391-4.
5. Azulay JP et al. intravenous immunoglobulin treatment in patients with Motor neuron syndromes associated with anti-GM1 antibodies. *Neurology 1994;* 44: 429-32.
6. Conley ME et al. Diagnostic criteria for primary immunodeficiencies. Representing PAGID (Pan-American Group for Immuodeficiency) and ESDI (European Society for Immunodeficiencies). *Clin Immunol* 1999; 93: 190-7.
7. Bonilla, FA et al. Practice Parameters for Diagnosis and Management of Primary Immunodeficiencies. *Ann Allergy Asthma Immunol.* 2005 May; 94(5 Supp 1): S1-63.
8. Immune Globulin. DrugPoint Summary. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed March 12, 2014
9. Orange JS, Hossny EM, Weiler CR et al. Use of intravenous immunoglobulin in human disease: A review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. *J Allergy Clin Immunol* 2006; 117:S525-53.
10. DynaMed [database online]. Ipswich (MA): EBSCO Information Services. http://www.ebscohost.com.liboff.ohsu.edu/DynaMed/. Accessed November 20, 2014.Provan D, Stasi R, Newland AC, et al. International consensus report on the investigation and management of primary immune thrombocytopenia. Blood. 2010 Jan 14; 115(2):168-86.

11. Immune Globulin. In: AHFS Drug Information STAT!Ref Online Electronic Medical Library. Bethesda, MD: American Society of Health-System Pharmacists. Updated periodically; Accessed January 22, 2105].
12. Patwa HS, Chaudry V, Katzberg H, et al. Evidenced-based guidelines: intravenous immunoglobulin in the treatment of neuromuscular disorders: reports of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2012; 78(13);1009-1015.
13. Perez EE, Orange JS, Bonilla F, et all. Update on the use of immunoglobulin in human disease: a review of evidence. J allergy Clin Immunol, 2017: 139:21-46
14. UpToDate Online. Subcutaneous and intramuscular immune globulin therapy. Accessed 11/2017.
15. Ahmed AR, Dahl MV. Consensus statement on the use of intravenous immunoglobulin therapy in the treatment of autoimmune mucocutaneous blistering diseases. Arch Dermatol. 2003;139:1051-1059.
16. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis-Executive Summary. Neurology. 2016 Jul 26; 87(4): 419-25.
17. Oaklander AL, Lunn MP, Hughes RA, van Schaik IN, Frost C, Chalk CH. Treatments for chronic inflammatory demyelinating polyradiculoneuropathy (CIDP): an overview of systematic reviews. Cochrane Database Syst Rev. 2017;1 CD010369.
18. Sriaroon P, Ballow M. Immunoglobulin replacement therapy for primary immunodeficiency. Immunol Allergy Clin North Am. 2015; 35: 713–730.
19. Mahdi-Rogers M, Brassington R, Gunn AA, van Doorn PA, Hughes RA. Immunomodulatory treatment other than corticosteroids, immunoglobulin and plasma exchange for chronic inflammatory demyelinating polyradiculoneuropathy. Cochrane Database Syst Rev. 2017;5 CD003280.
20. Hacohen Y, Banwell B. Treatment Approaches for MOG-Ab-Associated Demyelination in Children. Current Treatment Options in Neurology. January 2019. 21(1):2. DOI: 10.1007/s11940-019-0541-x. Accessed on October 7, 2021.
21. Health Evidence Review Commission (HERC). Coverage Guidance: Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS). Approved 5/19/2022. Available at: https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/PANDAS-PANS_Coverage-Guidance_FINALapproved_5-19-2022.pdf (Accessed September 20, 2022)
22. Chen JJ, Flanagan EP, Bhatti MT, et al. Steroid-sparing maintenance immunotherapy for MOG-IgG associated disorder. Neurology. (2020) 95:e111–e20. doi: 10.1212/WNL.0000000000009758

23. Chen JJ, Huda S, Hacohen Y, et al. Association of maintenance intravenous immunoglobulin with prevention of relapse in adult myelin oligodendrocyte glycoprotein antibody-associated disease. JAMA Neurol. (2022). doi: 10.1001/jamaneurol.2022.0489
24. Sechi E, Cacciaguerra L, Chen JJ, et al. Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD): A Review of Clinical and MRI Features, Diagnosis, and Management. Frontiers in Neurology. June 2022; 13. https://doi.org/10.3389/fneur.2022.885218
25. "Myelin Oligodendrocyte Glycoprotein Antibody Disease (MOGAD)." National Multiple Sclerosis Society, Aug 2022. Accessed May 7, 2022. Available at: https://www.nationalmssociety.org/What-is-MS/Related-Conditions/MOGAD#:~:text=Treatment%20for%20MOGAD,-There%20are%20several&text=Intravenous%20(infusion%20through%20the%20vein,liquid%20part%20of%20the%20blood
26. *Billing and Coding: Immune Globulin Intravenous (IVIg) A57194*. CMS.gov Centers for Medicare & Medicaid Services. Retrieved May 10, 2023, from https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57194
27. *Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases.* CMS.gov Centers for Medicare & Medicaid Services. Retrieved May 10, 2023, from https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=158
28. *Billing and Coding: Intravenous Immune Globulin (IVIg)-NCD 250.3 A54643.* CMS.gov Centers for Medicare & Medicaid Services. Retrieved May 10, 2023, from https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=54643&ver=9&=