

This clinical tool is intended for specialist physicians who prescribe IVIg or SCIg for the treatment of various diseases and conditions. It is provided for guidance only and does not replace the clinical judgment of physicians performing the activities reserved to them under applicable laws or regulations. The recommendations were developed using a systematic methodology; they are supported by the scientific literature and by the knowledge and expertise of Quebec-based clinicians and experts. The list of conditions evaluated in this tool is not exhaustive. For additional details, visit inesss.qc.ca.

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SUMMARY

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GENERAL INFORMATION

- ▶ Intravenous (IVIg) or subcutaneous (SCIg) formulations of non-specific human immunoglobulin (Ig) are stable blood products derived from pooled human plasma.
- ▶ The volume of Ig use in Quebec has grown steadily in recent years. Judicious use is important given their high cost and the risk of shortages.

▶ Cost for a 70 kg adult

- **Single immunomodulatory treatment of 2 g/kg ≈ \$14,000**
- **Replacement therapy of 0.4 g/kg every 4 weeks ≈ \$36,400 / year**

1 g IVIg ≈ \$100¹

1. Price may vary according to the the volume of fractionated plasma collected by Héma-Québec.

- ▶ The definitions for classifying the use of IVIg – recommended, a possible treatment option, insufficient data, and not recommended – are presented in the appendix.

INITIATION, MONITORING AND DISCONTINUATION IVIg/SCIg TREATMENT

Before initiation	• History of IVIg and SCIg treatment (efficacy and safety). • Free and informed consent on file (Form AH-113). • Calculation of ideal weight. • Requests for serological tests², if required.
Initiation	• Complete forms AH-211, AH-212, AH-213, AH-214, AH-215, AH-240, or AH-242. • If concomitant plasma exchange is performed, administer IVIg after completion of the plasma exchange cycle. • Consider SCIg if administration is feasible. • Choice between IVIg and SCIg based on: • transfusion reactions, contraindications and precautions (Appendix); • indication, clinical situation and patient preferences; • availability of nursing staff for administrative training; • availability of a caregiver or nursing staff for administration if unable to self-administer; • travel constraints related to receiving IVIg. • Doses and frequencies of administration (Appendix).

2. Serological test results may be affected by IVIg (e.g., anti-HBc). Their interpretation should be undertaken by a clinician with appropriate expertise, based on the clinical situation.

INITIATION, MONITORING AND DISCONTINUATION IVIg/SCIg TREATMENT

Monitoring

- Assessment of tolerability and efficacy:
 - Monitor for transfusion reactions ([Appendix](#));
 - Use validated scales, when available, to assess functional capacity and clinical response.
- Frequency according to clinical status:
 - At 3 to 6 months after treatment initiation, then every 6 to 12 months;
 - At each pregnancy follow-up visit, where applicable.

Discontinuation

-  If no objective clinical benefit is observed after dose adjustment, treatment should be stopped, and alternative therapy considered.
- The need to continue treatment with IVIg or SCIg should be reassessed periodically based on the clinical presentation.

CARDIOLOGY

IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Myocarditis³	• Adults: fulminant myocarditis. • Children: severe acute myocarditis AND reduced ejection fraction OR significant cardiac dysfunction.

3. Consultation with a cardiologist or paediatric cardiologist is required to assess the appropriateness of prescribing IVIg treatment.

IVIg NOT RECOMMENDED

• Dilated cardiomyopathy	• Peripartum cardiomyopathy	• Non-fulminant myocarditis in adults
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DERMATOLOGY

IVIg RECOMMENDED

INDICATIONS	CONDITIONS OF USE
Inflammatory myopathies⁴ (excluding inclusion body myositis) <i>See following table for all clinical situations.</i>	• Initial treatment, in combination with immunomodulatory therapies, if severe muscle weakness OR oropharyngeal dysphagia OR severe necrotizing myositis OR anti-MDA5 syndrome OR scleroderma OR gastrointestinal vasculitis and skin ulcers.

4. This indication includes dermatomyositis, including the juvenile form, polymyositis, and immune-mediated necrotizing myopathies.

DERMATOLOGY (CONTINUED)

! IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Linear IgA bullous dermatosis	- Severe disease, in case of failure, contraindication or intolerance to other treatment options (when available). ⌚ Duration: generally 3 to 6 months, followed by reassessment.
Epidermolysis bullosa acquisita	
Pemphigoid group⁵	
Pemphigus	
Inflammatory myopathies⁶ (excluding inclusion body myositis)	- Always in combination with immunomodulatory therapies. - Initial treatment: failure, contraindication or intolerance to other treatment options OR to reduce chronic high corticosteroid doses OR juvenile dermatomyositis with active cutaneous involvement OR dermatomyositis with severe cutaneous involvement OR paraneoplastic syndrome. ⌚ Duration: until the effectiveness of another treatment option is confirmed. - Maintenance therapy, on a case-by-case basis, to maintain remission. 👤 Discontinuation: Attempt periodically when the patient's clinical status is stable.
Pyoderma gangrenosum	- Severe form, in case of failure, contraindication or intolerance to other treatment options (when available). ⌚ Duration: generally 3 to 6 months, followed by reassessment.
Scleromyxedema	
Livedoid vasculopathy	

5. Includes mucous membrane pemphigoid, bullous pemphigoid, gestational pemphigoid, paraneoplastic pemphigus and immune checkpoint inhibitor-induced pemphigoid.

6. This indication includes dermatomyositis, including the juvenile form, polymyositis, and immune-mediated necrotizing myopathies.

✗ IVIg NOT RECOMMENDED

- Atopic dermatitis/eczema
- Dermatitis herpetiformis
- Urticaria

For dermatitis herpetiformis and urticaria: consider IVIg, on a case-by-case basis, if there is failure, contraindication, or intolerance to all other therapeutic options.

? INSUFFICIENT DATA

- Pretibial myxedema
- Scleredema
- Stevens-Johnson syndrome / Toxic epidermal necrolysis
- Necrobiotic xanthogranuloma

For all these indications: consider IVIg, on a case-by-case basis, if severe form AND failure, contraindication, or intolerance to all other therapeutic options (when available).

FERTILITY

! IVIg OR SCIg A POSSIBLE TREATMENT OPTIONS

INDICATIONS	CONDITIONS OF USE
Repeated unexplained implantation failures	After consultation with a specialist in reproductive immunology - On a case-by-case basis if at least 2 unexplained implantation failures⁷ with day 5 embryos of good quality AND: 3rd implantation failure with another treatment option; OR - contraindication or intolerance to other therapeutic options.
Repeated unexplained miscarriages	After consultation with a specialist in reproductive immunology - On a case-by-case basis if at least 3 unexplained miscarriages⁷ AND : 4th miscarriage with another treatment option; OR - contraindication or intolerance to other treatment options. <i>In the presence of demonstrated euploidy, Ig treatment may be considered after a 3rd miscarriage with another treatment option or after a 2nd miscarriage for individuals who have a contraindication or intolerance to other treatment options.</i>

7. The main causes of miscarriage or implantation failure should be ruled out, including age (less than 41 years of age when women use their own eggs or less than 45 years of age with egg donation).

✗ IVIg NOT RECOMMENDED

- Obstetric antiphospholipid syndrome

HEMATOLOGY

✓ IVIg RECOMMENDED

INDICATIONS	CONDITIONS OF USE
Allogeneic hematopoietic stem cell transplantation⁸ <i>See the next three tables for all clinical situations.</i>	- Continuation of IVIg or SCIg prophylactic treatment initiated prior to transplantation due to primary or secondary immunodeficiency. ⌚ Duration: until immune reconstitution is confirmed, depending on the clinical situation (usually 6 to 24 months). ✋ Discontinuation: consider annually if the clinical condition allows.
Neonatal hemochromatosis	Pregnant women: history of pregnancy affected by the condition. Newborns: confirmed diagnosis.

HEMATOLOGY (CONTINUED)

✓ IVIg RECOMMENDED

INDICATIONS	CONDITIONS OF USE
Fetal or neonatal alloimmune thrombocytopenia	Feto-maternal incompatibility: - From the 12th to the 16th week of gestation if there is a history of fetal or neonatal intracranial hemorrhage associated with alloimmune thrombocytopenia⁹; OR - From the 20th to the 22nd week of gestation if there is a history of fetal or neonatal alloimmune thrombocytopenia⁹ without intracranial hemorrhage. Newborn: - Clinically significant bleeding; OR - Platelet count < 30 x 10⁹/L AND when platelet transfusion is not feasible, regardless of whether the platelets are matched for human platelet antigens [HPA].
Immune thrombocytopenia ^{8,10} <i>See the next table in this specialty for all clinical situations.</i>	- Bleeding or risk of clinically significant bleeding. - Need for rapid platelet count increase prior to urgent surgery or invasive procedures. - Failure, contraindication, or intolerance to other treatment options. ⚠ <i>Platelet count alone is not a treatment criterion.</i>
Immune thrombocytopenia during pregnancy ⁸	- Potentially life-threatening bleeding. - Platelet count < 30 x 10⁹/L. - Preparation for delivery, to achieve a platelet count of at least 50 x 10⁹/L.

8. Indication approved by Health Canada.

9. Presence of maternal antiplatelet alloantibodies known or suspected to cause fetal or neonatal alloimmune thrombocytopenia (usually anti-HPA-1a or anti-HPA-5b).

10. Includes immune thrombocytopenia induced by viral infection.

⚠ IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Allogeneic hematopoietic stem cell transplantation ¹¹ <i>See the other three tables in this specialty for all clinical situations..</i>	- Secondary prophylaxis if all 3 of the following criteria are met: - IgG < 4 g/L OR on a case-by-case basis if IgG ≥ 4 g/L and < 6 g/L; AND severe, unusual or recurrent infection; AND when antibiotic prophylaxis is indicated, treatment failure OR serious adverse effects from antibiotics. ⌚ <i>Duration: until immune reconstitution is confirmed, depending on the clinical situation (generally 6-24 months).</i> 👤 <i>Discontinuation: consider annually if the clinical condition allows.</i>
Autoimmune hemolytic anemia	Temporary measure in urgent situations AND in cases of failure, contraindication or intolerance to other treatment options in the context of warm autoantibodies.

HEMATOLOGY (CONTINUED)

! IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Hemolytic disease of the newborn or fetus¹²	• Pregnant women: maternal antibodies directed against the fetus are detected AND the fetus is affected by a severe form OR a history of a previous pregnancy with a severely and early affected fetus (intrauterine transfusion before 24 weeks of gestation) AND there is a high risk of <i>hydrops fetalis</i> or premature death. • Newborns: in combination with intensive phototherapy if serum bilirubin increases at a rapid rate (e.g. > 8.5 µmol/L/h) AND it is not possible to perform a rapid exchange transfusion AND the serum bilirubin level reaches the pre-exchange transfusion threshold.
Post-transfusion purpura	• Moderate to severe bleeding. • Planned surgery OR invasive procedure associated with a moderate to high risk of bleeding.
Catastrophic antiphospholipid syndrome	• In combination with other treatment options if rapidly progressive thrombosis affecting at least two organs AND diagnosis supported by laboratory results.
Evans syndrome	• See conditions of use for immune thrombocytopenia or autoimmune hemolytic anemia, depending on the clinical presentation.
Hyperhemolysis syndrome associated with sickle cell disease	• In combination with steroids in cases of severe hemolytic reaction (rapid decrease in hemoglobin to levels below the pre-transfusion values).
Immune thrombocytopenia¹¹ <i>See the previous table in this specialty for all clinical situations.</i>	• Bridge therapy: when there is a need to maintain platelet counts at a clinically appropriate level during adjustment of a first- or second-line treatment option. ⌚ <i>Duration: until the effectiveness of the chosen therapeutic option is confirmed.</i>
Heparin-induced thrombocytopenia	• In recurrent OR refractory cases OR spontaneous heparin-induced thrombocytopenia OR severe cases with bleeding AND failure, contraindication, or intolerance to other treatment options.

11. Indication approved by Health Canada.

12. There is insufficient data to determine the role of IVIg in reducing the need for exchange transfusion, both for Rh and ABO-related hemolytic disease of the newborn. For hemolytic disease of the newborn caused by ABO incompatibility, the low probability of significant jaundice attributable to ABO (versus Rh) incompatibility should be weighed against the increased risk of hemolysis from anti-A and/or anti-B in IVIg preparations.

HEMATOLOGY (CONTINUED)

✗ IVIg NOT RECOMMENDED

- Allogeneic hematopoietic stem cell transplant:
 - Prevention or treatment of graft-versus-host disease

See the other three tables in this specialty for all clinical situations.
- Aplastic anemia
- Pure red cell aplasia
- Thrombotic thrombocytopenic purpura
- Hemolytic uremic syndrome (HUS)¹⁵
 - *Consider, on a case-by-case basis, if anti-factor H antibodies AND there is failure, contraindication, or intolerance to other treatment options*
- Atypical hemolytic uremic syndrome [aHUS] or complement-mediated HUS (complement-mediated thrombotic microangiopathy (TMA))

? INSUFFICIENT DATA

- Allogeneic hematopoietic stem cell transplant:

See the other three tables in this specialty for all clinical situations.
- Primary prophylaxis for secondary hypogammaglobulinemia due to allograft
 - *Consider, on a case-by-case basis, if IgG < 4 g/L in children OR if IgG ≥ 4 g/L and < 6 g/L.*
- Treatment of RSV-induced respiratory infection
 - *Consider in combination with antiviral therapy, on a case-by-case basis, if IgG < 6 g/L or drug-induced immunosuppression AND upper respiratory tract infection with high-risk of progression or lower respiratory tract infection.*
- Treatment of CMV-induced pneumonia
 - *Consider in combination with antiviral therapy, on a case-by-case basis, if IgG < 6 g/L.*
- Parvovirus B19-associated red cell aplasia
 - *Consider, on a case-by-case basis, if there is failure, contraindication or intolerance to other treatment options in immunosuppressed individuals with chronic parvovirus B19 infection (anaemia type).*
- Acquired hemophilia¹³
- Coagulation factor inhibitors (including von Willebrand disease)¹³
- Autoimmune neutropenia
- Hemolytic transfusion reaction without hyperhemolysis
 - *Consider, on a case-by-case basis, if sickle cell disease with an urgent need for transfusion AND a high risk of acute transfusion hemolytic reaction OR a history of multiple or life-threatening delayed hemolytic transfusion reactions*

13. Contact an inhibitor centre.

CLINICAL IMMUNOLOGY

✓ IVIg or SCIg RECOMMENDED

INDICATIONS ¹⁴	CONDITIONS OF USE	TERMS OF USE
Primary hypogammaglobulinemia due to impaired antibody production¹⁵	- Confirmed diagnosis. - Pending confirmation of a suspected diagnosis (generally 3-6 months).	Treatment: replacement SCIg: equivalent to IVIg ⌚ Duration: long-term if diagnosis confirmed 🛑 Discontinuation: not indicated, except if diagnosis is reassessed
Secondary hypogammaglobulinemia due to hematological malignancy or its treatment <i>See the next three tables in this specialty for all clinical situations.</i>	- Secondary prophylaxis if all 3 of the following criteria are met: - IgG < 4 g/L OR on a case-by-case basis if Ig is ≥ 4 g/L and < 6 g/L; - biologically active cancer treatment OR incomplete immune reconstitution; - severe, unusual or recurrent infections.	Treatment: replacement SCIg: equivalent to IVIg ⌚ Duration: until remission OR immune reconstitution based on clinical situation. 🛑 Discontinuation: yes, after remission OR immune reconstitution, based on clinical situation.

14. Indications approved by Health Canada.

15. Includes agammaglobulinemia, combined immunodeficiency, and common variable immunodeficiency.

⚠️ IVIg or SCIg A POSSIBLE TREATMENT OPTIONS

INDICATIONS ¹⁶	CONDITIONS OF USE	TERMS OF USE
Primary hypogammaglobulinemia with normal or near-normal antibody production¹⁷	- On a case-by-case basis, if all 3 of the following criteria are met: - absence or near absence of IgG₁, IgG₂ or IgG₃ AND inadequate vaccine response; - severe, unusual or recurrent infections; - failure of antibiotic prophylaxis administered for 6 months OR serious adverse effects caused by antibiotic prophylaxis.	Treatment: replacement SCIg: equivalent to IVIg ⌚ Duration: on a case-by-case basis 🛑 Discontinuation: consider annually if clinical condition allows
Transient hypogammaglobulinemia of early childhood	- On a case-by-case basis, in children under 4 years AND if all 3 of the following criteria are met: - marked reduction in IgG relative to age-specific normal range; - severe, unusual or recurrent infections; - failure of antibiotic prophylaxis OR serious adverse effects caused by antibiotic prophylaxis.	Treatment: replacement SCIg : equivalent to IVIg ⌚ Duration : on a case-by-case basis 🛑 Discontinuation: consider at least annually if the clinical condition allows
Secondary hypogammaglobulinemia other than those caused by hematological malignancy or its treatment <i>See the other tables in this specialty for all clinical situations.</i>	- As secondary prophylaxis, if all 4 of the following criteria are met: - IgG < 4 g/L OR on a case-by-case basis if IgG ≥ 4 g/L and < 6 g/L; - severe, unusual or recurrent infections; - failure of antibiotic prophylaxis for 6 months OR serious adverse reactions to antibiotic prophylaxis OR inadequate vaccine response; - inability to address the underlying cause of hypogammaglobulinemia (non-reversible cause or contraindication to reversal).	Treatment: replacement SCIg : equivalent to IVIg ⌚ Duration : on a case-by-case basis 🛑 Discontinuation: yes, once the cause of hypogammaglobulinemia is resolved and the clinical condition allows

CLINICAL IMMUNOLOGY (CONTINUED)

! IVIg or SCIg A POSSIBLE TREATMENT OPTIONS

INDICATIONS ¹⁶	CONDITIONS OF USE	TERMS OF USE
Hemophagocytic lymphohistiocytosis/macrophage activation syndrome	In the presence of clinical instability or deterioration despite optimal treatment of the underlying cause.	Treatment: immunomodulation SCIg: no ⌚ Duration: one treatment cycle 👉 Discontinuation: not applicable

16. Indications approved by Health Canada.

17. Includes isolated or combined IgG₁₋₃ subclass deficiency and specific antibody deficiency but excludes isolated IgG₄ subclass deficiency.

✗ IVIg NOT RECOMMENDED

- Complement abnormalities
- Phagocytic defects
- Intrinsic and innate immunity defects
- Confirmed isolated Kappa light chain deficiency
- Confirmed isolated IgA deficiency
- Confirmed isolated IgM deficiency
- Isolated IgG₄ subclass deficiency
- Immaturity of the immune system in preterm newborns – primary prophylaxis
See the table on the right for all clinical situations.
- Autoinflammatory syndromes (except ADA2 and CECR1)

? INSUFFICIENT DATA

- Secondary hypogammaglobulinemia, including those caused by hematological malignancy or its treatment – primary prophylaxis
See the three previous tables in this specialty for all clinical situations.
- Immaturity of the immune system in preterm newborns – infection treatment setting
See the table on the left for all clinical situations.
- Drug reaction with eosinophilia and systemic symptoms (DRESS)

INFECTIOLOGY

! IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Viral cardiomyopathy in children	Severe acute viral myocarditis AND presence of reduced ejection fraction or significant cardiac dysfunction – after consultation with a pediatric cardiologist..
Toxic shock syndrome	- Confirmed diagnosis. - Always in combination with appropriate antibiotic treatment.
Multisystem inflammatory syndrome temporally related to COVID-19 in children	Confirmed diagnosis.

INFECTIOLOGY (CONTINUED)

✗ IVIg NOT RECOMMENDED

- Viral cardiomyopathy in adults
 - *Considered, on a case-by-case basis and after consultation with a cardiologist, if fulminant myocarditis OR acute heart failure combined with significant lymphocyte infiltration confirmed by endomyocardial biopsy.*
- COVID-19 (without multisystem inflammatory syndrome)
- *Clostridioides difficile* enterocolitis
- *Mycoplasma pneumoniae*-induced rash and mucositis
 - *Considered, on a case-by-case basis, in severe forms of the disease AND in cases of failure, contraindication, or intolerance to all other treatment options.*
- Necrotizing fasciitis in adults (without shock criteria)
- Infection prevention following trauma or surgery
- Sepsis (excluding neonatal enterovirus sepsis)

? INSUFFICIENT DATA

- Necrotizing fasciitis in children
 - *Considered, on a case-by-case basis, in severe infection.*
- Neonatal enterovirus sepsis
 - *Considered, on a case-by-case basis, in severe forms of neonatal enterovirus sepsis.*
- Multisystem inflammatory syndrome temporally related to COVID-19 in adults

NEUROLOGY

✓ IVIg RECOMMENDED

INDICATIONS	CONDITIONS OF USE
Myasthenia gravis (including Lambert-Eaton myasthenic syndrome) <i>See the next table in this specialty for all clinical situations.</i>	• In cases of severe exacerbation, myasthenic crisis, or preparation for surgery in individuals whose disease is poorly controlled..
Inflammatory myopathies¹⁸ (excluding inclusion body myositis) <i>See following table for all clinical situations..</i>	• Initial treatment, in combination with immunomodulatory therapies, if severe muscle weakness OR oropharyngeal dysphagia OR severe necrotizing myositis OR anti-MDA5 syndrome OR scleroderma OR gastrointestinal vasculitis and skin ulcers.
Multifocal motor neuropathy¹⁹	• First-line treatment.
Chronic inflammatory demyelinating polyneuropathy (CIDP)¹⁹	• Initial treatment: first-line treatment for patients with moderate to severe disability. • Maintenance treatment: Ig can be used as monotherapy or in combination with immunosuppressive agents if initial IVIg treatment is effective.
Guillain-Barré syndrome (or variants, such as Miller-Fischer syndrome) ¹⁹	• Preferably within 2 weeks of symptom onset for moderate to severe disability, or in the event of disease progression. • A second course of treatment is not generally recommended, but may be considered in case of treatment-related fluctuations if improvement was observed following the first course of treatment.
Opsoclonus-myoelonus syndrome in children	• Initial and maintenance treatment in combination with antitumor therapies, as appropriate.

18. This indication includes dermatomyositis, including the juvenile form, polymyositis, and immune-mediated necrotizing myopathies.

19. Indication approved by Health Canada.

NEUROLOGY (CONTINUED)

! IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Sydenham chorea	Failure, intolerance, or contraindication to other treatment options in individuals with significant disability.
Neurological complications secondary to immune checkpoint inhibitors (ICIs)	- Guillain-Barré syndrome secondary to ICI: first-line treatment. - Other severe or very severe neurological complications secondary to ICIs: failure, intolerance or contraindication to corticosteroids.
Autoimmune encephalitis	- In combination with corticosteroids for children and for severely ill individuals. - Failure, intolerance, or contraindication to other treatment options.
Rasmussen encephalitis	- In combination with corticosteroids. - Failure, intolerance, or contraindication to other treatment options.
Acute disseminated encephalomyelitis (ADEM)	- Failure, intolerance or contraindication to corticosteroids. - Failure to wean off corticosteroids.
Acute refractory epilepsy (including NORSE and FIRES)	In case of acute crisis: failure, intolerance or contraindication to other therapeutic options.
MOG Antibody disease (MOGAD)	- Initial treatment: in case of acute crisis. - Maintenance treatment: relapse prevention in recurrent disease with severe relapses.
Myasthenia gravis (including Lambert-Eaton myasthenic syndrome) <i>See the previous table in this specialty for all clinical situations.</i>	Maintenance treatment: failure, intolerance or contraindication to first-line treatments.
Inflammatory myopathies²⁰ (excluding inclusion body myositis) <i>See previous table for all clinical situations.</i>	- Always in combination with immunomodulatory therapies. - Initial treatment: failure, contraindication or intolerance to other treatment options OR to reduce chronic high corticosteroid doses OR juvenile dermatomyositis with active cutaneous involvement OR dermatomyositis with severe cutaneous involvement OR paraneoplastic syndrome. ⌚ Duration: until the effectiveness of another treatment option is confirmed. • Maintenance therapy, on a case-by-case basis, to maintain remission 👤 Discontinuation: Attempt periodically when the patient's clinical status is stable.
Distal acquired demyelinating symmetric (DADS) neuropathy with or without anti-MAG antibodies	Rescue treatment: in cases of significant disability or rapid symptom progression.
Vasculitic neuropathy	Acute treatment of significant disability: failure, intolerance, or contraindication to other treatment options.
Relapsing-remitting multiple sclerosis <i>See the NON RECOMMENDED IVIg table in this specialty for all clinical situations.</i>	Exceptional use for a severe relapse or exacerbation: failure, intolerance or contraindication to established therapies (e.g., corticosteroids or plasma exchange).

NEUROLOGY (CONTINUED)

! IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Neuropsychiatric syndrome PANS/PANDAS <i>See the NON RECOMMENDED IVIg table in this specialty for all clinical situations.</i>	Children – Acute treatment for significant disability: failure, intolerance or contraindication to other treatment options.
Opsoclonus-myoclonus syndrome in adults	For rapid symptom control while determining the cause of the syndrome or while awaiting initiation or therapeutic effect of antitumor treatments.
Stiff person syndrome (or variants, including progressive encephalomyelitis with rigidity and myoclonus)	Significant disability despite treatment with GABAergic medications or when such medications are contraindicated.
Neuromyelitis optica spectrum disorder	Exceptional use during an acute crisis: failure, intolerance, or contraindication to other treatment options (e.g., corticosteroids or plasma exchange).

20. This indication includes dermatomyositis, including the juvenile form, polymyositis, and immune-mediated necrotizing myopathies.

✗ IVIg NOT RECOMMENDED

- Myalgic encephalomyelitis / chronic fatigue syndrome
- Alzheimer disease
- Inclusion body myositis
- Narcolepsy/Cataplexy
- Axonal neuropathy combined with paraproteinemia
- Small fiber neuropathy
- Critical illness polyneuropathy
- Amyotrophic lateral sclerosis
- Neuropsychiatric syndrome PANS/PANDAS – initial treatment in adults or maintenance (including children)
See the table of POSSIBLE IVIg TREATMENT OPTION in this specialty for all clinical situations.
- Primary progressive or secondary progressive multiple sclerosis
- Relapsing-remitting multiple sclerosis in maintenance treatment
See the table of possible IVIg treatment options in this specialty for all clinical situations..
- POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein and skin abnormalities)
- Postpoliomyelitis syndrome
- Postural orthostatic tachycardia syndrome
- Autism spectrum disorder

? INSUFFICIENT DATA

- Diabetic amyotrophy
- Other paraneoplastic neurological syndromes²¹
 - Consider, on a case-by-case basis, for rapid symptom control while determining the underlying cause of the syndrome or pending the initiation or therapeutic effect of antitumor treatments*
- Chronic refractory epilepsy
 - Consider, on a case-by-case basis, when an autoimmune etiology is suspected*
- Paraneoplastic neuropathy
 - Consider, on a case-by-case basis, as an adjunct to other therapeutic agents for certain forms of paraneoplastic neuropathy (in particular subacute pure sensory neuropathies)*
- Sensory ganglionopathy secondary to Sjögren syndrome
- Neuromyotonia (Isaacs syndrome)
- Brachial plexopathy (or Parsonage-Turner syndrome)

21. This condition refers to paraneoplastic neurological syndromes other than those already addressed or which are not defined.

RHEUMATOLOGY

✓ IVIg RECOMMENDED

INDICATIONS	CONDITIONS OF USE
Kawasaki disease in children	- Complete or incomplete. - Repeat possible (1 time) if the initial IVIg treatment fails.
Inflammatory myopathies²² (excluding inclusion body myositis) <i>See following table for all clinical situations.</i>	Initial treatment, in combination with immunomodulatory therapies, if severe muscle weakness OR oropharyngeal dysphagia OR severe necrotizing myositis OR anti-MDA5 syndrome OR scleroderma OR gastrointestinal vasculitis and skin ulcers.

22. This indication includes dermatomyositis, including the juvenile form, polymyositis, and immune-mediated necrotizing myopathies.

⚠ IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Juvenile idiopathic arthritis	- Severe systemic form with or without associated hemophagocytic lymphohistiocytosis. - Maintenance therapy, on a case-by-case basis, to maintain remission: severe systemic form without hemophagocytic lymphohistiocytosis AND failure, contraindication or intolerance to other treatment options. 👤 Discontinuation: Attempt periodically when the patient's clinical status is stable.
Adult-onset Still disease	
Inflammatory myopathies²³ (excluding inclusion body myositis) <i>See previous table for all clinical situations</i>	- Always in combination with immunomodulatory therapies. - Initial treatment: failure, contraindication or intolerance to other treatment options OR to reduce chronic high corticosteroid doses OR juvenile dermatomyositis with active cutaneous involvement OR dermatomyositis with severe cutaneous involvement OR paraneoplastic syndrome. ⌚ Duration: until the effectiveness of another treatment option is confirmed. - Maintenance therapy, on a case-by-case basis, to maintain 👤 Discontinuation: Attempt periodically when the patient's clinical status is stable.
Granulomatosis with polyangiitis	- Severe form. - Failure, contraindication, or intolerance to other treatment options. - Maintenance therapy, on a case-by-case basis, to maintain remission. 👤 Discontinuation: Attempt periodically when the patient's clinical status is stable.
Eosinophilic granulomatosis with polyangiitis	
Microscopic polyangiitis	
Systemic lupus erythematosus	
Neonatal lupus²⁴	- Pregnant women with anti-Ro/SSA antibodies if: - Fetus with an incomplete atrioventricular block²⁵ OR showing signs of myocarditis or endocardial fibroelastosis. - Newborn of a mother with anti-Ro/SSA antibodies if: - Incomplete atrioventricular block²⁵ OR complete atrioventricular block <i>in utero</i> that has shown signs of improvement (i.e., that has reverted to a 1st- or 2nd-degree block or to normal sinus rhythm); OR sign of myocarditis or endocardial fibroelastosis. - Consider, on a case-by-case basis, if severe thrombocytopenia, severe hemolytic anemia or severe liver damage due to neonatal lupus.
Diffuse or limited systemic sclerosis	- Initial treatment, in combination with immunomodulatory therapies, if myositis with a high risk of scleroderma renal crisis OR severe cutaneous involvement. - Severe form AND concurrent myositis if failure, contraindication or intolerance to other treatment options. - Maintenance therapy, on a case-by-case basis, to maintain remission 👤 Discontinuation: Attempt periodically when the patient's clinical status is stable.

RHEUMATOLOGY (CONTINUED)

! IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Catastrophic antiphospholipid syndrome	In combination with other treatment options if rapidly progressive thrombosis affecting at least two organs AND diagnosis supported by laboratory results.
Sjögren syndrome	- Severe neurological form. - Maintenance therapy, on a case-by-case basis, to maintain remission. 👉 Discontinuation: Attempt periodically when the patient's clinical status is stable.

23. This indication includes dermatomyositis, including the juvenile form, polymyositis, and immune-mediated necrotizing myopathies.

24. Consultation with a neonatologist or obstetrician experienced in monitoring this indication may be necessary to assess the appropriateness of prescribing IVIg treatment.

25. Includes a 2nd-degree atrioventricular block or a 1st-degree atrioventricular block with pronounced PR interval prolongation, especially if the mother previously gave birth to a child with neonatal lupus.

✗ IVIg NOT RECOMMENDED

- Temporal arteritis
- Cryopyrinopathies²⁶
- Cutaneous lupus
 - Consider, on a case-by-case basis, if failure, contraindication or intolerance to other treatment options.
- Behçet disease
- Inclusion body myositis
- Rheumatoid arthritis
- Localized scleroderma (morphea)
 - Consider, on a case-by-case basis, if generalized or pansclerotic morphea **AND** failure, contraindication or intolerance to other treatment options.
- Antiphospholipid syndrome (non-catastrophic)²⁷
 - Consider, on a case-by-case basis, if microangiopathic forms
- IgA Vasculitis
 - Consider, on a case-by-case basis, if failure, contraindication or intolerance to other treatment options.
- Leukocytoclastic vasculitis
- Lymphocytic vasculitis

26. Includes familial cold autoinflammatory syndrome, Muckle-Wells syndrome, and neonatal multisystem autoinflammatory disease.

27. See also obstetric antiphospholipid syndrome in the [Fertility section](#).

? INSUFFICIENT DATA

- Takayasu arteritis
- Eosinophilic fasciitis
 - Consider, on a case-by-case basis, if severe or refractory.
- Neonatal lupus – prevention of congenital atrioventricular block during pregnancy
- Kawasaki disease in adults
- Polyarteritis nodosa
 - Consider, on a case-by-case basis, to treat juvenile-onset disease if severe involvement is present **OR** in cases of failure, contraindication or intolerance to other treatment options.
- Autoimmune retinopathy
 - Consider, on a case-by-case basis, if severe and threatening vision **AND** failure, contraindication or intolerance to other treatment options.
- Overlap syndromes
 - Consider, on a case-by-case basis, if severe and threatening vision **AND** failure, contraindication or intolerance to other treatment options.
- Cogan syndrome
- Sneddon syndrome
- Hypocomplementemic urticarial vasculitis syndrome
- Susac syndrome
- Immune-mediated uveitis
 - Consider, on a case-by-case basis, if severe and threatening vision **AND** failure, contraindication or intolerance to other treatment options.
- Primary central nervous system vasculitis
- Levamisole-induced vasculopathy

SOLID ORGAN TRANSPLANTATION

! IVIg A POSSIBLE TREATMENT OPTION

INDICATIONS	CONDITIONS OF USE
Prevention of graft rejection <i>See all tables in this specialty for all clinical situations.</i>	- Hyperimmunization (except liver transplantation). - HLA- or ABO-incompatible transplantation.
Treatment of graft rejection <i>See all tables in this specialty for all clinical situations.</i>	Acute humoral rejection
Treatment of parvovirus B19²⁸ infection <i>See all tables in this specialty for all infection treatments.</i>	Confirmed infection.
Treatment of BK polyomavirus infection	Virus-induced nephropathy, particularly in kidney transplant recipients AND graft rejection concomitant with the suspected infection.

28. IVIg may be considered to treat parvovirus B19-associated red cell aplasia [hematology section](#).

✗ IVIg NOT RECOMMENDED

- Prevention of the following infections:
 - Adenovirus
 - Norovirus
 - Parvovirus B19
 - BK polyomavirus
 - Epstein-Barr virus
 - West Nile virus
 - Human herpesvirus 6 (HHV-6)
- Treatment of the following infections:
 - Epstein-Barr virus
 - Human herpesvirus 6 (HHV-6)
 - Norovirus

? INSUFFICIENT DATA

- Prevention of graft rejection
 - Liver transplantation AND hyperimmunization.
- Prevention of respiratory syncytial virus infection
- Treatment of chronic humoral graft rejection
- Treatment of an infection²⁹:
 - Adenovirus
 - West Nile virus
 - Respiratory syncytial virus

29. In cases of secondary hypogammaglobulinemia, see [Clinical Immunology section](#).

OTHER INDICATIONS

✓ IVIg or SCIg RECOMMENDED

INDICATIONS	CONDITIONS OF USE
Systemic capillary leak syndrome³⁰ – prevention of life-threatening recurrent crisis <i>See the next table in this section for all clinical situations.</i>	Confirmed diagnosis.

30. Consultation with an immunologist is required to confirm the appropriateness of prescribing Ig.

ⓘ INSUFFICIENT DATA

- Systemic capillary leak syndrome – treatment of an acute crisis
See the previous table in this section for all clinical situations.

MAIN REFERENCES

To review the rationale behind this tool and access all supporting references, see the [reports](#) associated with the tool.

ABBREVIATIONS

ADEM:	Acute disseminated encephalomyelitis	Ig:	Immunoglobulins
Anti-HBc:	Antibody against hepatitis B core antigen	IVIg:	Intravenous immunoglobulins
COVID-19:	Coronavirus disease 2019	MOGAD:	Myelin oligodendrocyte glycoprotein antibody-associated disease
DADS:	Distal acquired demyelinating symmetric neuropathy	NORSE:	New-onset refractory status epilepticus
DRESS:	Drug reaction with eosinophilia and systemic symptoms	PANDAS:	Pediatric acute-onset neuropsychiatric disorders associated with Streptococcus
FIRES:	Febrile infection-related epilepsy syndrome	PANS:	Pediatric acute-onset neuropsychiatric syndrome
HHV-6:	Human herpesvirus 6	SCIg:	Subcutaneous immunoglobulins
HLH / MAS:	Hemophagocytic lymphohistiocytosis / macrophage activation syndrome	TACO:	Transfusion-associated circulatory overload
ICI:	Immune checkpoint inhibitors	TRALI:	Transfusion-related acute lung injury



CLASSIFICATION OF IVIg AND SCIg USE

CATEGORY	DEFINITION
IVIg/SCIg recommended	Indications for which the efficacy of Ig has been demonstrated with a high, moderate, or low level of evidence, and for which the data analysis and synthesis have led to a recommendation for its use as first-line therapy.
IVIg/SCIg possible treatment options	Indications for which the efficacy of Ig is supported by a low or insufficient level of evidence, and for which the data analysis and synthesis have led to considering its use as second-line treatment option (failure, intolerance or contraindications to first-line treatments) or in special situations.
IVIg/SCIg not recommended	Indications for which the scientific data and clinicians' experience indicate a lack of efficacy of Ig or even a potential harmful effect, or for which the pathophysiological rationale is insufficient.
INSUFFICIENT DATA	Indications for which the data analysis does not permit any conclusions to be drawn regarding the efficacy of Ig.

TRANSFUSION REACTIONS

- Serious and non-serious transfusion reactions (particularly those resulting in a change in dose, frequency, or type of IVIg administered or that warrant discontinuation of treatment) must be reported to the blood bank using Form [AH-520](#).

NON-SERIOUS TRANSFUSION REACTIONS (MOST FREQUENT – non-exhaustive list)	 SERIOUS TRANSFUSION REACTIONS (USUALLY RARE – non-exhaustive list)
• Asthenia • Atypical pain • Chills • Flu-like symptoms • Nausea • Non-hemolytic febrile reaction • Post-IVIg headache • Post-transfusion hypertension or hypotension • Urticaria • Vomiting	• Acute renal failure • Aseptic meningitis • Immediate anaphylactic-type reaction • Immediate or delayed hemolytic reaction • Thromboembolic reaction • Transfusion-associated circulatory overload (TACO) • Transfusion-related acute lung injury (TRALI)

RELATIVE CONTRAINDICATIONS

- Known allergy to any component of the product.
- History of severe immediate or delayed allergic reaction to Ig, including anaphylaxis.

 Facilitated SCIg may be administered in children aged ≥ 2 years with primary or secondary immunodeficiency.

PRECAUTIONS

Hemolysis	- Primarily observed in blood groups A, B or AB at IVIg doses ≥ 2 g/kg. - Monitor hemolysis signs and symptoms (e.g., fever, chills, hemoglobinuria, dyspnea). - If signs and symptoms appear, perform appropriate laboratory investigations.
Thrombosis	- May occur: - with or without predisposing risk factors; - with any immunoglobulin product (IVIg or SCIg), regardless of dose or route of administration.
Renal function	- Assess kidney function in patients at risk for acute kidney injury. - Consider discontinuing IVIg if renal function deteriorates.



Facilitated SCIg administration should be performed with caution during pregnancy and lactation.



DOSAGE

IMMUNOMODULATORY TREATMENT

- Use the **dose calculator** to determine IVIg and SCIg doses for adults and children over 1.52 m (5 ft) in height and whose weight is at or above ideal body weight.
- See also the pregnancy section when applicable.

TREATMENTS	DOSES & FREQUENCY	NOTES
IVIg		Dose: • The dose and frequency of administration should be chosen to achieve the minimum effective dosage. • The dose may be adjusted or repeated according to individual clinical response. • Maximum daily dose: 1 g/kg, except for certain rheumatological conditions in children. Initial treatment: • The dose can be repeated every 3 to 4 weeks, depending on the individual's clinical response. • Induction therapy every 2 weeks may sometimes be necessary for a few cycles in rheumatology. Traitement d'entretien : • The treatment may be used for certain neurological and rheumatological indications, and for systemic capillary leak syndrome. • IVIg are usually given every 3 to 4 weeks³³. • SCIg may be administered daily, weekly, or every 2 weeks with an adjusted dose corresponding to a weekly dose of 0.1 to 0.4 g/kg. • Facilitated SCIg are generally administered every 3 to 4 weeks Neonates: doses mainly for haematology, infectious disease and rheumatology. Haematology: doses apply to all conditions, except for post-allograft infection prophylaxis. Clinical immunology: doses apply only to HLH/MAS.
Initial	Adults: 1 - 2 g/kg over 2 - 5 days Children: 1 - 2 g/kg over 1 - 5 days ³¹ Neonates: 1 - 2 g/kg over 1 - 2 days ³¹	
IVIg AND facilitated SCI ³²		
Maintenance	Adults and children: 0.1 - 0.4 g/kg	

HLH/MAS: Hemophagocytic lymphohistiocytosis / macrophage activation syndrome.

31. The dose of 2 g/kg may be given as a single administration if no haemodynamic intolerance is anticipated.

32. In adults, depending on tolerance and availability.

33. In neurology and rheumatology, the frequency may be up to every 6 weeks.

REPLACEMENT THERAPY

- The **dose calculator** can be used to calculate the initial dose of IVIg and SCIg to be administered.

TREATMENTS	DOSES IN ADULTS AND CHILDREN	NOTES
IVIg AND facilitated SCIg ³⁴		Dose: • The dose and frequency of administration should be chosen to achieve the minimum effective dosage. Frequency: • IVIg are usually given every 3 to 4 weeks. • Conventional SCIg may be administered daily, weekly, or every 2 weeks with an adjusted dose corresponding to the weekly dose. • Facilitated SCIg is generally administered every 3 to 4 weeks. It may initially be administered weekly with an adjusted dose equal to the weekly dose. Hematology: doses apply only to the prevention of post-allograft infections. Clinical immunology: doses apply to all conditions except HLH/MAS.
Initial	0.4 to 0.6 g/kg ³⁵	
Maintenance	Adjust to obtain a residual IgG level at least equal to the lower limit of the reference range according to age or clinical effectiveness.	
SCIg		
Initial	0.1 to 0.2 g/kg ³⁵	
Maintenance	Adjust to obtain a residual IgG level at least equal to the lower limit of the reference range according to age or clinical effectiveness.	

HLH/MAS: Hemophagocytic lymphohistiocytosis / macrophage activation syndrome.

34. In adults, depending on tolerance and availability.

35. In the case of severe or life-threatening infection, the starting dose may be higher.



TREATMENT OF PREGNANT WOMEN OR WOMEN PLANNING TO BECOME PREGNANT

► The **dose calculator** should always be used with **pre-pregnancy weight** when adjusting the dose.

TREATMENTS	DOSES AND FREQUENCIES	NOTES
IVIg		
Treatment cycle	Repeated unexplained implantation failures: 0.4 - 0.6 g/kg once, 3 - 5 days before embryo transfer ³⁶	Dose: - The dose and frequency of administration should be chosen to achieve the minimum effective dosage. - The dose may be adjusted or repeated according to individual clinical response. - Maximum daily dose: 1 g/kg. Fetal or neonatal alloimmune thrombocytopenia: Adjust the timing of treatment initiation according to history (see condition of use). Neonates: See the immunomodulatory treatment table for the applicable dose. SCIg: May be administered daily, weekly, or every 2 weeks with an adjusted dose corresponding to the indicated weekly treatment dose.
	Repeated unexplained miscarriages: - Pre-pregnancy: 0.4 - 0.6 g/kg every 3 months for up to 6 months - During pregnancy: 0.4 - 0.6 g/kg per month until the 20th week of gestation	
	Neonatal hemochromatosis – prevention: 1 g/kg at the 14 th and 16 th weeks of gestation, then weekly from the 18 th week until the end of pregnancy	
	Neonatal lupus: 1 g/kg every 2 - 3 weeks until delivery	
	Hemolytic disease of the newborn or fetus: 1 g/kg weekly until delivery	
	Fetal or neonatal alloimmune thrombocytopenia – prevention: 1 - 2 g/kg weekly until delivery	
	Immune thrombocytopenia during pregnancy: 1 - 2 g/kg, as needed until delivery	
SCIg		
Treatment cycle	Repeated unexplained miscarriages: - Pre-pregnancy: 0.1 - 0.2 g/kg³⁷ weekly for up to 6 months - During pregnancy: 0.1 - 0.2 g/kg³⁷ weekly until the 20th week of gestation	

36. If implantation failure is combined with repeated miscarriages, treatment for the miscarriages may be considered.

37. The SCIg dose should be adjusted to approximately 10% higher than the equivalent IVIg dose.

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[Adult-onset Still disease](#)

[Allogeneic hematopoietic stem cell transplantation](#)

[Alzheimer disease](#)

[Amyotrophic lateral sclerosis](#)

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