Composing a Letter of Medical Necessity (LMN)

gamunex®-C
immune globulin injection (human), 10%
caprylate/chromatography purified

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it.

Providers are encouraged to contact third-party payers for specific information on their coverage policies. For more information, please call Gamunex Connexions at 1-888-694-2686.

Many health plans require that an LMN accompany a Coverage Authorization Appeals Letter. (See accompanying pages for details.) The purpose of an LMN is to explain the prescribing healthcare provider's (HCP's) rationale and clinical decision-making when choosing a treatment. LMNs are often required by plans when submitting a Coverage Authorization Appeals Letter and Formulary Exception Request Letter. (See accompanying pages for details.)

This resource is designed to help you and your staff fast-track the process of crafting and composing an LMN. A checklist is included below that can be followed when creating an LMN. In addition, **a sample letter in template format is attached** to this document and includes information that plans often require.

Follow the patient's plan requirements when requesting GAMUNEX-C. Otherwise treatment may be delayed.

LMN Considerations

- Include the patient's full name, plan identification number, date of birth, and case identification number if a decision has already been rendered
- Provide a copy of the patient's records with the following details
  - The patient's history, diagnosis with specific ICD code, and present-day condition and symptoms
  - The patient's recent history of neuromuscular issues and other existing conditions, comorbidities (allergies, diabetes, cardiovascular disease, autoimmune diseases, etc.)
- Note the severity of the patient's condition, using the plan's preferred scoring system
- Document prior treatments and the duration of each. It may be beneficial to include ICD codes and J codes to define prior services/treatments, so that the health plan can conduct research and make a timely determination request
- Describe the rationale for why each treatment was discontinued
- Attach clinical documentation that supports your recommendation; this information may be found in the prescribing information for GAMUNEX-C and/or clinical peer-reviewed literature
- Note onset of weakness, distributions (shoulders, hips, hands, feet) and pace, as well as daily functions compromised. Include how long weakness has been progressing and if patient has missed work/school/duties because of illness
- Note any proximal weakness of shoulders, hips, or trunk, as well as any hand/ankle weakness
- Note deep tendon reflexes in all 4 limbs, particularly those that are depressed/absent compared to others. Note any problems that might exist with balance/walking

Sample Letter of Medical Necessity

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[Date]	[Patient's name]
[Medical director]	[Coverage plan]
[National Provider Identifier]	[Identification/Group number]
[Specialty]	[Date of birth]
[Mailing address]	

I am writing to provide additional information to support my claim for [insert patient's name]'s treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) with GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified). In short, treatment with GAMUNEX-C is medically appropriate and necessary for the patient. This letter outlines the patient's history of neuromuscular issues, diagnosis, current conditions and symptoms, previous treatments, and existing conditions that support my recommendation for treatment with GAMUNEX-C.

[In this section, give details on the severity of CIDP symptoms at the time when the patient was first treated with GAMUNEX-C. In addition, include a summary of the patient's clinical response to GAMUNEX-C and list improvements in symptoms since treatment began.]

Please detail all symptoms and add additional information you deem necessary.

Patient history—provide records and ICD code(s):

Neuromuscular issues:	Current condition:
Diagnosis:	Current symptoms:

Other existing conditions/comorbidities—provide ICD code(s) where applicable:

Allergies:	Diabetes:
Cardiovascular disease:	Other:
Autoimmune diseases:	

Findings from physical exam

Grip strength:	Proximal and distal weakness:
INCAT/RODS/CAPRI/TUGS:	Shoulder weakness Right ☐ Left ☐ Both ☐ Arm weakness Right ☐ Left ☐ Both ☐ Hand weakness Right ☐ Left ☐ Both ☐ Hip weakness Right ☐ Left ☐ Both ☐ Leg weakness Right ☐ Left ☐ Both ☐ Trunk or neck weakness Right ☐ Left ☐ Both ☐
MRC Score:	Reflexes, all 4 limbs:
	Brisk
	Present
	Trace
	Absent
	Other:

Please see page 4 for Important Safety Information, and refer to accompanying full Prescribing Information for complete prescribing details.

Sample Letter of Medical Necessity *cont.*

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Confirmation of diagnosis	**Date of confirmation: ___ /___ /_____**
Electrodiagnostic exam:	Ultrasound:
Nerve conduction study (NCS) (at least 1 demyelination finding)	MRI:
Cerebrospinal fluid: white count and protein	Nerve biopsy:

List therapeutic/treatment trials

Treatment start date:	Rationale for discontinuation:
Prior treatment(s) and the duration:	Other therapies used:

Baseline measurement scores if done

CAPRI: _____	RODS: _____
INCAT: _____	Gait assessment (timed up and go): _____

Guidelines for diagnosis and treatment considerations

Include measurement at 3-month initiation and 6-month follow-up *(prepare to reauthorize every 6 months).*

3-month measurement:	6-month follow-up:
Post 6 months' changes after tapering of dosage:	
[In this section, document soft lifestyle improvements (eg, return to work), list outcome measures used at reauthorization, and provide details on where to access.]	

Please feel free to contact me, [insert HCP name], at [office phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

To learn more about GAMUNEX-C and the landmark ICE trial, the longest IVIG study for CIDP, visit GAMUNEX-C.com.

Sincerely,

[Physician name and signature]

[Physician medical specialty]

[National Provider Identifier]

[Practice name]

[Office number]

[Fax number]

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Important Safety Information

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GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) is indicated for the treatment of primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older, idiopathic thrombocytopenic purpura (ITP) in adults and children, and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

Thrombosis may occur with immune globulin products, including GAMUNEX-C. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. For patients at risk of thrombosis, administer GAMUNEX-C at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IVIG) products in predisposed patients. Patients predisposed to renal dysfunction include those with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IVIG products containing sucrose. GAMUNEX-C does not contain sucrose. For patients at risk of renal dysfunction or failure, administer GAMUNEX-C at the minimum concentration available and the minimum infusion rate practicable.

GAMUNEX-C is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. It is contraindicated in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

Severe hypersensitivity reactions may occur with IVIG products, including GAMUNEX-C. In case of hypersensitivity, discontinue GAMUNEX-C infusion immediately and institute appropriate treatment.

Monitor renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output in patients at risk of developing acute renal failure.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IVIG treatment, including GAMUNEX-C.

There have been reports of aseptic meningitis, hemolytic anemia, and noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) in patients administered with IVIG, including GAMUNEX-C.

The high-dose regimen (1g/kg x 1-2 days) is not recommended for individuals with expanded fluid volumes or where fluid volume may be a concern.

Because GAMUNEX-C is made from human blood, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Do not administer GAMUNEX-C subcutaneously in patients with ITP because of the risk of hematoma formation.

Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of GAMUNEX-C and at appropriate intervals thereafter.

Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies, because of the potentially increased risk of thrombosis.

If signs and/or symptoms of hemolysis are present after an infusion of GAMUNEX-C, perform appropriate laboratory testing for confirmation.

If TRALI is suspected, perform appropriate tests for the presence of antineutrophil antibodies and anti-HLA antibodies in both the product and patient's serum.

After infusion of IgG, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation.

In clinical studies, the most common adverse reactions with GAMUNEX-C were headache, pyrexia, hypertension, chills, rash, nausea, arthralgia, and asthenia (in CIDP); cough, rhinitis, pharyngitis, headache, asthma, nausea, fever, diarrhea, and sinusitis with intravenous use (in PIDD) and local infusion-site reactions, fatigue, headache, upper respiratory tract infection, arthralgia, diarrhea, nausea, sinusitis, bronchitis, depression, allergic dermatitis, migraine, myalgia, viral infection, and pyrexia with subcutaneous use (in PIDD); and headache, ecchymosis, vomiting, fever, nausea, rash, abdominal pain, back pain, and dyspepsia (in ITP).

The most serious adverse reactions in clinical studies were pulmonary embolism (PE) in 1 subject with a history of PE (in CIDP), an exacerbation of autoimmune pure red cell aplasia in 1 subject (in PIDD), and myocarditis in 1 subject that occurred 50 days post-study drug infusion and was not considered drug related (in ITP).

Please see accompanying full Prescribing Information for GAMUNEX-C.

GRIFOLS