Drafting a Formulary Exception Request Letter

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.

A formulary exception is a type of coverage determination. It is used when a drug is not included on a health plan's formulary or is subject to a National Drug Code (NDC) block.

Plans frequently provide specific formulary exception request templates that must be used when making the request. These forms may be downloaded from each plan's website.

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

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

- Include the patient's full name, plan identification number, and date of birth
- Add the prescribing HCP's name, relationship to the requestor, National Provider Identifier (NPI) number, specialty, address, telephone number/fax number, and date of submission
- Explain why the plan's preferred formulary agents are not appropriate for this patient
  - -Include the patient's current diagnosis
  - -Describe other therapies that have been tried, and any allergies and existing comorbidities
- Provide GAMUNEX-C characteristics including indication, IgA content, pH (after reconstitution), plasma source, half-life, and pathogen inactivation/removal
- Explain and attest to why the plan's preferred formulary agents are not appropriate for the patient and a recommendation summary, including professional opinion of the patient's likely prognosis or disease progression without GAMUNEX-C treatment
- Include a Letter of Medical Necessity (See accompanying pages for details)

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For support and assistance, contact Gamunex Connexions at 1-888-MYGAMUNEX (1-888-694-2686).

Please see page 5 for Important Safety Information, and refer to accompanying full Prescribing Information for complete prescribing details.

Sample Letter of Formulary Exception Request

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[Date]	[Patient's name]
[Formulary director]	[Plan identification number]
[Name of health plan]	[Date of birth]
[Mailing address]	[Case identification]

To whom it may concern:

My name is [HCP's name], and I am a [board-certified medical specialty] [(NPI)]. I am writing to request a formulary exception for my patient, [patient's name], who is currently a member of [name of health plan]. The request is for GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified). The patient was receiving treatment with GAMUNEX-C [dose, frequency], which is medically appropriate and necessary for this patient, who has been diagnosed with chronic inflammatory demyelinating polyneuropathy, [ICD code]. However, GAMUNEX-C is no longer included on your plan's formulary list. Therefore, I am requesting that the plan remove any relevant NDC blocks, so that GAMUNEX-C can be made available to my patient as a preferred treatment.

If this appeal has been previously denied, add the following here: This is our [add level of request] coverage authorization appeal. A copy of the most recent denial letter is attached for reference. The patient's medical records are also included in response to the denial.

[In this section, explain why the plan's preferred formulary agents are not appropriate for this patient.]

Please detail all reasons why and add additional information you deem necessary.

Clinical rationale for GAMUNEX-C

[In this section, provide clinical rationale for GAMUNEX-C; refer to information that may be found in the prescribing information for GAMUNEX-C, peer-reviewed clinical literature, and ICE trial details for indication and dosing.]

GAMUNEX-C characteristics[1]

Indication	CIDP, ITP, PIDD
IgA content	51±1.4 mcg/mL*
pH (after reconstitution)	4.0-4.5*
Plasma source	US source IQPP-certified plasma from FDA-registered sites
Formulation	No sugar, trace amounts of sodium, no stabilizer, close to physiologic osmolality
Half-life	35 days
Pathogen inactivation/removal	Caprylate precipitation/depth filtration, caprylate incubation, depth filtration, column chromatography, low pH incubation, TSE removal

*Average of sample lots.
1. Data on file, Grifols.

Sample Letter of Formulary Exception Request *cont'd*

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Tolerability considerations:
Comorbidities considerations:
Allergies:
Cardiovascular disease:
Autoimmune diseases:
Diabetes:
Other:
Why continuation is required:

Adverse events sometimes associated with IVIG

Common Adverse Events		
☐ Headache	☐ Nausea	☐ Influenza-like illness
☐ Asthenia	☐ Rash	☐ Leukopenia
☐ Hypertension	☐ Pain in extremity	☐ Other
Serious Adverse Events		
☐ Hemolysis	☐ Migraine	☐ Pulmonary embolism
☐ Exacerbation of CIDP	☐ Increased diastolic blood pressure	☐ Respiratory failure
☐ Acute rash	☐ Other	

Make sure to check all that apply.

Summary of recommendation

[In this section, provide your recommendation summary, including peer-to-peer discussions and your professional opinion of the patient's likely prognosis or disease progression without GAMUNEX-C treatment.]
Request peer-to-peer discussion if initial rejection occurs.

Include all the Adverse Events when explaining rationale for change of treatment request.

Sample Letter of Formulary Exception Request *cont'd*

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Attach letter of medical necessity.

Please contact me, [HCP's name], at [HCP's telephone number] for a peer-to-peer review. I would be pleased to speak to why a GAMUNEX-C formulary exception is necessary for [patient's name]'s treatment of chronic inflammatory demyelinating polyneuropathy.

Sincerely,

[Physician name and signature]

[Physician medical specialty]

[National Provider Identifier]

[Practice name]

[Office number]

[Fax number]

[Patient's name and signature]

Please see page 5 for Important Safety Information, and refer to accompanying full Prescribing Information for complete prescribing details.

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.

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