Preparing a Coverage Authorization Appeals 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.

If the Coverage Authorization Request Letter form is denied by the patient's health plan, the payer may require a Coverage Authorization Appeals Letter. (See accompanying pages for details.) Depending on the plan, there may be varying levels of appeals. If you are uncertain about a plan's appeal levels or specific procedures, always refer to the plan's appeal guidelines.

A Coverage Authorization Appeals Letter originates from the patient and the prescribing HCP. It should be submitted with 2 additional items: the patient's medical records and a Letter of Medical Necessity. The LMN is outlined on accompanying pages.

This resource is designed to help you and your staff fast-track the process of crafting and composing a Coverage Authorization Appeals 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.

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

Coverage Authorization: Appeals Considerations

- Include the patient's full name, plan identification number, and date of birth
- Add the prescribing HCP's National Provider Identifier (NPI) number and specialty
- Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with case identification number from the initial denial letter
- Provide a copy of the patient's records with the following details
  - Severity of condition at baseline, 3-month follow-up, 6-month follow-up
  - The patient's history, diagnosis, and ICD code(s)
  - The patient's recent history of other therapies that have been tried, and list any allergies and existing comorbidities
  - The patient's current condition and symptoms including QOL, and list other key events such as hospitalizations, unplanned HCP visits, required medications, side effects, etc.
- Document prior treatments and the duration of each
- Describe the rationale for why each treatment was discontinued
- Provide the clinical rationale for treatment; this information may be found in the prescribing information for GAMUNEX-C and/or clinical peer-reviewed literature
- Include LMN and explain options if coverage for GAMUNEX-C is not approved

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

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

Sample Letter of Appeal

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[Date]	[Patient's name]
[Prior authorization]	[Plan identification number]
[Name of health plan]	[Date of birth]
[Mailing address]	

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) coverage. We understand that the reason for your denial is [insert reason verbatim from the plan's denial letter]. However, we believe that GAMUNEX-C [dose, frequency] is the appropriate treatment for the patient. In support of our recommendation for GAMUNEX-C treatment, we have provided an overview of the patient's relevant clinical history below.

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.

Patient history	Test used	Date of test
Severity of condition:		
Baseline measurement:		
3-month measurement:		
6-month measurement:		
Current measurement:		
QOL measurement:		
[In this section, list other key events such as hospitalizations, unplanned HCP visits, required medications, other treatments, and possible side effects that the patient is experiencing.]		

Please detail all that applies and add additional information you deem necessary.

Other therapies

Start date:
Complications:
Side effects:
Reason for discontinuation:

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Sample Letter of Appeal *cont'd*

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Attach initial letter and interim determination letter.

[In this section, provide clinical rationale for this treatment; refer to information that may be found in the prescribing information for GAMUNEX-C and/or peer-reviewed clinical literature.]
[In this section, provide your recommendation summary, including your professional opinion of the patient's likely prognosis or disease progression without GAMUNEX-C treatment.]

Attach letter of medical necessity.

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

Sincerely,

[Physician name and signature]

[Physician medical specialty]

[National Provider Identifier]

[Practice name]

[Office number]

[Fax number]

[Patient's name and signature]

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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.

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