GAMUNEX-C COVERAGE AUTHORIZATION LETTERS

This resource is designed to help you and your staff draft coverage authorization letters for GAMUNEX-C when a health plan does not include GAMUNEX-C as part of their plan formulary or when you receive a denial for a GAMUNEX-C prescription for CIDP. A checklist is included below that may be helpful when creating each letter on behalf of your patient based on his/her medical needs. In addition, sample letters (in template format) are attached to this document and include information that plans often require when considering coverage.

Some third-party payers may require that the prescriber document a patient's medical necessity for treatment to obtain insurance coverage for GAMUNEX-C. The following information and template letters are provided for informational purposes only and do not guarantee coverage or reimbursement. Healthcare providers make the ultimate determination as to when to use a specific product based on clinical appropriateness for a patient. The prescriber should refer to the Important Safety Information in the full Prescribing Information when determining whether the product is medically appropriate for a patient. Third-party payment for medical products and services is affected by numerous factors, and Grifols cannot make any representation or guarantee concerning reimbursement or coverage for any service or product.

Health plan requirements may vary, so prescribers should refer to the prior authorization or coverage information specific to their patient's health plan before completing a coverage authorization letter when requesting coverage for GAMUNEX-C.

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

- ☐ Include the full name of the patient, plan identification number, and date of birth
- ☐ Prescriber name, NPI number, specialty, address, phone/fax number, email, and submission date
- ☐ GAMUNEX-C characteristics including indication, IgA content, pH (after reconstitution), and half-life
- ☐ Explain why the plan's preferred formulary agents are not appropriate for this patient and provide a recommendation summary, including professional opinion of the patient's likely prognosis or disease progression without GAMUNEX-C treatment
- ☐ A copy of the patient's records with the following details:
  - Severity of condition at baseline, 3-month follow-up, and 6-month follow-up or longer
  - The patient's clinical history, diagnosis, and ICD-10 code(s)
  - The patient's recent history of other related therapies including Ig dose and frequency and why each treatment was discontinued or is insufficient (if applicable)
  - The patient's current condition and symptoms including quality of life, and list of other key events such as hospitalizations, unplanned physician visits, required medications, side effects, etc
- ☐ If applicable, examination and test results that support a diagnosis of CIDP
- ☐ Provide the clinical rationale for treatment with GAMUNEX-C; information may be found in the Prescribing Information and/or clinical peer-reviewed literature

*The Centers for Medicare & Medicaid Services (CMS) provides specific information of particular importance to beneficiaries receiving Part D drug benefits through a Part D plan and/or benefits through Medicare Part B Durable Medical Equipment (DME). Please visit the following link to download forms and instructions concerning Part D grievances, coverage determinations (including exceptions), and appeals processes. https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev/coveragedeterminationsandexceptions.html. For Medicare Part B please consult the appropriate regional DME Medicare Administrative Contractor or Medicare Advantage plan.

For additional support, contact Gamunex Connexions at 1-844-MYGAMUNEX (1-844-694-2686).
Please see Important Safety Information on the last 2 pages of this letter and refer to full Prescribing Information for complete prescribing details.

Sample Coverage Authorization Appeal Letter

[Date]

[Payer Name]

ATTN: [Medical Director]
[Payer Contact Name, if available]
[Payer Address]

Re: Appeal for Denial of GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified)

Patient: [Patient's First and Last Name]
Date of Birth: [MM/DD/YYYY]
Weight: [kg]
Subscriber Identification Number: [Insurance ID Number]
Subscriber Group Number: [Insurance Group Number]
Case Identification Number: [Case ID Number]
Dates of Service: [Dates]

Dear [Contact Name/Medical Director]:

I am writing to request that you reassess your recent denial of GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) coverage. I understand that the reason for your denial is [insert reason verbatim from the plan's denial letter]. However, I believe that GAMUNEX-C [dose, frequency] is a necessary treatment for my patient. In further support of my recommendation for GAMUNEX-C treatment, I have provided an overview of the relevant information.

Sample Coverage Authorization Appeal Letter (continued)

PATIENT HISTORY	TEST USED AND RESULTS	DATE OF TEST
Severity of condition:		
Baseline measurement:		
3-month measurement:		
6-month measurement:		
Current measurement:		

[In this section, list other key events such as hospitalizations, unplanned HCP visits, required medications, other treatments, and possible side effects that your patient is experiencing.]

OTHER THERAPIES	
Name of therapy:	
Start date:	
Complications and/or side effects:	
Reason(s) for discontinuation or reason(s) why insufficient:	

Clinical Information and Recommendation

[In this section, provide a summary of clinical information and your recommendation, including peer-to-peer discussions and your professional opinion of your patient's likely prognosis or disease progression without GAMUNEX-C treatment.]

Sincerely,

[Prescriber name and signature]
[Prescriber medical specialty]
[National Provider Identifier]
[Practice Name, address, phone/fax and email]

[Patient name and signature]

Enclosure(s)

[List enclosures which may include Prescribing Information, clinical notes/medical records, diagnostic test results, and relevant peer-reviewed articles.]

Sample Letter of Formulary Exception Request

[Date]

[Payer Name]

ATTN: [Medical Director]
[Payer Contact Name, if available]
[Payer Address]

Re: Formulary Exception Request Letter for GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified)

Patient: [Patient's First and Last Name]
Date of Birth: [MM/DD/YYYY]
Weight: [kg]
Subscriber Identification Number: [Insurance ID Number]
Subscriber Group Number: [Insurance Group Number]
Case Identification Number: [Case ID Number]
Dates of Service: [Dates]

Dear [Contact Name/Medical Director]:

My name is [Name], and I am [board certification and/or relationship to patient]. I am writing to request a formulary exception on behalf of [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). Treatment with GAMUNEX-C [dose and frequency] is medically appropriate and necessary for this patient who has been diagnosed with chronic inflammatory demyelinating polyneuropathy, [ICD-10 code]. However, GAMUNEX-C is not included on your plan's formulary list. I am requesting that the plan allow a formulary exception and remove any relevant NDC* blocks so that GAMUNEX-C can be made available to my patient as a preferred treatment

Previous Treatments
[In this section, explain why the plan's preferred formulary agents are not appropriate for this patient. Include any previous treatments, start/stop dates, and reasons for discontinuation where applicable including any unplanned physician, urgent care, emergency department visits, or inpatient hospitalizations.]

Clinical Rationale for GAMUNEX-C
[In this section, provide clinical rationale for GAMUNEX-C including patient's medical history and diagnosis, condition supporting the use of GAMUNEX-C, and a statement summarizing the recommended treatment plan.]

*GAMUNEX-C NDCs include: 13533-800-12; 13533-800-15; 13533-800-20; 13533-800-71; 13533-800-24; 13533-800-40

For additional support, contact Gamunex Connexions at 1-844-MYGAMUNEX (1-844-694-2686).
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Sample Letter of Formulary Exception Request (continued)

GAMUNEX-C Characteristics

Indication	CIDP
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 sample lots

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

Clinical Information and Recommendation

[In this section, provide a summary of clinical information and your recommendation 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.]

Attach letter of medical necessity.

If it would be helpful, please contact me, [HCP's name], at [HCP's telephone number, email, and/or fax] 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] treatment of chronic inflammatory demyelinating polyneuropathy.

Sincerely,

[Prescriber name and signature]
[Prescriber medical specialty]
[National Provider Identifier]
[Practice Name, address, phone/fax and email]

[Patient name and signature]

Enclosure(s)
[List enclosures which may include Prescribing Information, clinical notes/medical records, diagnostic test results, and relevant peer-reviewed articles.]

For additional support, contact Gamunex Connexions at 1-844-MYGAMUNEX (1-844-694-2686).
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Sample Letter of Medical Necessity

[Date]

[Payer Name]

ATTN: [Medical Director]
[Payer Contact Name, if available]
[Payer Address]

Re: Letter of Medical Necessity for GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified)

Patient: [Patient's First and Last Name]
Date of Birth: [MM/DD/YYYY]
Weight: [kg]
Subscriber Identification Number: [Insurance ID Number]
Subscriber Group Number: [Insurance Group Number]
Case Identification Number: [Case ID Number]
Dates of Service: [Dates]

Dear [Contact Name/Medical Director]:
I am writing on behalf of my patient, [Patient's name], to [request prior authorization of/document medical necessity for] treatment with GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified). This letter provides information about my patient's medical history, diagnosis, and treatment plan. On behalf of my patient, I am requesting approval for use and payment for treatment.

Patient's Clinical History
[Patient's name] is a [age] year old [male/female] who was diagnosed with [chronic inflammatory demyelinating neuropathy (CIDP)]. [Patient's name] underwent [describe treatments to date to include other immune globulin replacement therapies].

- [Include diagnosis along with relevant ICD-10 code and dates]
- [Past treatments and results]
- [If applicable, test results that would support patient diagnosis. For patients with CIDP test results may include;]

  - ✓ Grip strength
  - ✓ Muscle strength testing (MRC) including testing of proximal and distal muscles
  - ✓ INCAT/RODS/CAPRI/TUGS
  - ✓ NCS/EMG
  - ✓ Diagnostic imaging (MRI, Ultrasound)
  - ✓ CSF
  - ✓ Nerve Biopsy

Sample Letter of Medical Necessity (continued)

Treatment Plan
GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) is indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. The recommended dose for [identify disease state treated, dose and frequency prescribed, and recommended duration of treatment.]

Clinical Information and Recommendation
In summary, please consider coverage of GAMUNEX-C on behalf of [Patient name], and approve use and subsequent payment for GAMUNEX-C.

If you have any further questions regarding this matter, please do not hesitate to contact me, [Prescriber name] at [phone number, email, and/or fax]. Thank you for your prompt attention to this matter.

Sincerely,

[Prescriber name and signature]
[Prescriber medical specialty]
[National Provider Identifier]
[Practice Name, address, phone/fax and email]

Enclosure(s)
[List enclosures which may include Prescribing Information, clinical notes/medical records, diagnostic test results, and relevant peer-reviewed articles.]

Important Safety Information

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.

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.

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.

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

 March 2023 US-GXC-2300034