gamunex connexions®

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

COPAY ASSISTANCE PROGRAM ENROLLMENT GUIDE

The GAMUNEX-C Copay Assistance Program provides financial support for eligible patients whose claims are billed under either pharmacy or medical benefit. The program is administered through Medmonk. It offers providers a streamlined process to register, submit claims, and assist patients with their copay needs.

FOR PHARMACY BILLING

If your patient's claim is being billed under the pharmacy benefit, submit a claim to the primary payer first. If your patient requires copay assistance, submit a secondary claim to Medmonk through your NCPDP system using the following processing information:

BIN: 016664
PCN: MEDMONK
Cardholder ID: MEDMONK

Claims must be submitted within 60 days of the dispense date.

FOR MEDICAL BILLING

If your patient's claim is being billed through the medical benefit, your facility needs to be registered with Medmonk.

If your facility has not previously registered with Medmonk for any product, complete a one-time provider registration by visiting **gamunex-c.medmonk.com**. Enter the required details including facility name, NPI number, contact person for financial reimbursement, location tax ID, and facility contact details.

To submit a patient's claim for copay assistance:

1. Submit a request in the Medmonk portal with an estimated financial responsibility within 60 days of the dispense date.
2. After the primary insurance processes the claim, upload the EOB in the portal within 180 days of the date the request was submitted.

For more information or assistance, contact:

Medmonk Support: 1-866-234-3732 (Option 1) | **Gamunex Connexions®:** 1-888-694-2686 (1-888-MYGAMUNEX)

ELIGIBILITY CRITERIA FOR COPAY ASSISTANCE*

Patients can receive up to $10,000 of copay assistance per calendar year for GAMUNEX-C

- Eligibility:
  - Patients must provide consent to Gamunex Connexions before the second and subsequent claims for copay assistance can be processed
  - Patients must have commercial insurance that covers medication costs for GAMUNEX-C and allows for copay assistance
  - Patients must have a diagnosis of CIDP† or PIDD‡. Covered ICD codes are listed under Billing Information on **gamunex-c.medmonk.com**
- Copay Assistance Program covers deductibles, copayment, and coinsurance for medication costs only
  - Patients may be eligible for IV (intravenous) administration in CIDP and both IV and SC (subcutaneous) administration in PIDD
  - No monthly caps or infusion limits

RESTRICTIONS

Patients are ineligible for copay assistance if they participate in Medicare, Medicaid, Medigap, Veterans Affairs, Department of Defense, Tricare, or any other federal or state-funded programs

This program is subject to change or discontinuation by Grifols at any time, for any reason, and with or without prior notice.
The copay portal is administered by Medmonk for the GAMUNEX-C Copay Assistance Program.

*See complete terms and conditions for the copay assistance program at: **www.gamunex-c.com/en/hcp/cidp/gamunex-support-program**
†CIDP, chronic inflammatory demyelinating polyneuropathy
‡PIDD, primary immunodeficiency disease

GRIFOLS

Please see Important Safety Information on the following page and refer to accompanying full Prescribing Information for GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified).

IMPORTANT SAFETY INFORMATION

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

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

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