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5.20.001

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Biologicals	**Original Policy Date:**	June 9, 2011
Subject:	Atgam	**Page:**	1 of 5

Last Review Date: March 7, 2025

Atgam

Description

Atgam (lymphocyte immune globulin, anti-thymocyte globulin [equine])

Background
Atgam is a lymphocyte-selective immunosuppressant used for the prevention and management of allograft rejection in renal transplantation. When administered with conventional therapy at the time of rejection, it increases the frequency of resolution of the acute rejection episode. The drug has also been administered as an adjunct to other immunosuppressive therapy to delay the onset of the first rejection episode. Data accumulated to date have not consistently demonstrated improvement in functional graft survival associated with therapy to delay the onset of the first rejection episode (1).

When administered with a regimen of supportive care, Atgam may induce partial or complete hematologic remission for the treatment of moderate to severe aplastic anemia in patients unsuitable for bone marrow transplantation. In a controlled trial, patients receiving Atgam showed a statistically significantly higher improvement rate (defined in terms of sustained increase in peripheral blood counts and reduced transfusion needs) compared with standard supportive care at 3 months. Examples of concurrent supportive therapy are transfusions, steroids, antibiotics, and antihistamines (1).

Regulatory Status
FDA-approved indications: Atgam is an immunoglobulin G indicated for: (1).

- Renal transplant rejection

- Aplastic anemia (moderate to severe) in patients unsuitable for bone marrow transplantation

Limitations of Use:
The usefulness of Atgam has not been demonstrated in patients with aplastic anemia who are suitable candidates for bone marrow transplantation or in patients with aplastic anemia secondary to neoplastic disease, storage disease, myelofibrosis, Fanconi's syndrome, or in patients known to have been exposed to myelotoxic agents or radiation (1).

When administered with other immunosuppressive therapy, such as antimetabolites and corticosteroids, the patient's own antibody response to horse gamma globulin is minimal (1).

Atgam carries a boxed warning stating that antithymocyte globulins can cause anaphylaxis when injected intravenously. Although Atgam is processed to reduce the level of antibodies that will react to non-T cells, physicians should be prepared for the potential risk of anaphylaxis and monitor patients for signs and symptoms during infusion. Skin testing before treatment is strongly recommended to identify those patients at greatest risk for serious immune-mediated reactions (1).

Discontinue treatment with Atgam if any of the following occurs: symptoms of anaphylaxis, severe and unremitting thrombocytopenia or leukopenia in renal transplant patients. Patients receiving Atgam for the treatment of aplastic anemia may need prophylactic platelet transfusions to maintain platelets at clinically acceptable levels (1).

To date, safety and efficacy have not been established in circumstances other than renal transplantation and aplastic anemia (1).

Related policies
IVIG, SCIG

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Atgam may be considered **medically necessary** if the conditions indicated below are met.

Atgam may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Renal Transplantation (for management of allograft rejection)

2. Moderate to severe aplastic anemia
    a. Patient is unsuitable for bone marrow transplantation
    b. **NOT** secondary to neoplastic disease
    c. **NOT** secondary to storage disease
    d. **NOT** secondary to myelofibrosis
    e. **NOT** secondary to Fanconi's syndrome
    f. Patient has not been exposed to myelotoxic agents or radiation

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity A total of 21 doses given on an alternate day basis for both approved indications.

Duration 6 weeks. Use beyond 6 weeks is unsupported.

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Atgam is indicated for the management of allograft rejection in renal transplant patients. When administered with conventional therapy at the time of rejection, it increases the frequency of resolution of the acute rejection episode. The drug has also been administered as an adjunct to

other immunosuppressive therapy to delay the onset of the first rejection episode. When administered with a regimen of supportive care, Atgam may induce partial or complete hematologic remission for the treatment of moderate to severe aplastic anemia in patients who are unsuitable for bone marrow transplantation. Physicians should be prepared for the potential risk of anaphylaxis and monitor patients for signs and symptoms during infusion (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Atgam while maintaining optimal therapeutic outcomes.

References

1. Atgam [package insert]. New York, NY: Pfizer Inc.; September 2023.

Policy History

Date	Action
February 2006	Atgam (lymphocyte Immune Globulin, LIG; antithymocyte globulin, ATG, equine) is a lymphocyte selective immunosuppressant
December 2012	Annual review and update Eliminated bone marrow transplant, post-transplant immunodeficiency from covered indications. No supporting literature
September 2013	Annual editorial review and reference update Defined aplastic anemia as moderate to severe and that the patient is not a candidate for a bone marrow transplant Addition of renewal limits of 21 doses
December 2013	Annual editorial review and update
June 2014	Annual review and reference update
September 2015	Annual editorial review
June 2016	Annual editorial review and reference update Policy code changed from 5.05.01 to 5.20.01
December 2017	Annual editorial review
November 2018	Annual review and reference update
September 2019	Annual review
March 2020	Annual review
March 2021	Annual editorial review and reference update
March 2022	Annual review and reference update
March 2023	Annual review. Changed policy number to 5.20.001
March 2024	Annual review and reference update
September 2024	Annual review and reference update
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.