BlueCross BlueShield
Federal Employee Program

ATGAM

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

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.