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 indication: 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 regarding that only physicians experienced in either immunosuppressive therapy in the treatment of renal transplant or in aplastic anemia patients should use this antithymocyte globulin (equine). Patients should be treated with this product in facilities equipped and staffed with adequate laboratory and supportive medical resources. Before the first infusion, patients should undergo a skin test and observed for adverse reactions. A systemic reaction such as a generalized rash, tachycardia, dyspnea, hypotension, or anaphylaxis precludes any additional administration of Atgam (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. Only physicians experienced in immunosuppressive therapy in the treatment of renal transplant or aplastic anemia patients should use Atgam in facilities equipped and staffed with adequate laboratory and supportive medical resources (1).

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