

Utilization Management and Clinical Medical Policy

Policy Name: Antithymocyte Globulin Equine (Atgam®)	Policy Number: MP-RX-FP-008-23	Scope: ☒ MMM MA ☒ MMM MultiHealth	Origination Date: 11/30/2023 Last Review Date: 08/19/2026	Effective Date: 08/19/2026 Frequently Revision: Annual
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Service Category:

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| ☐ Anesthesia | ☐ Medicine Services and Procedures |
| ☐ Surgery | ☐ Evaluation and Management Services |
| ☐ Radiology Procedures | ☐ DME/Prosthetics or Supplies |
| ☐ Pathology and Laboratory Procedures | ☐ Other: Part B Drugs |

Service Description:

This document addresses the use of Antithymocyte Globulin Equine (Atgam®), a drug approved by the Food and Drug Administration (FDA) for the management of allograft rejection in renal transplant patients and for the treatment of moderate to severe aplastic anemia in patients unsuitable for bone marrow transplantation.

Background Information:

Atgam Sterile Solution contains lymphocyte immune globulin, anti-thymocyte globulin [equine]. It is the purified, concentrated, and sterile gamma globulin, primarily monomeric IgG, from hyperimmune serum of horses immunized with human thymus lymphocytes. Atgam is a transparent to slightly opalescent aqueous protein solution. It may appear colorless to faintly pink or faintly brown and is nearly odorless. It may develop a slight granular or flaky deposit.

Atgam is composed of antibodies that bind a wide variety of proteins on the surface of lymphocytes. In addition, Atgam binds to granulocytes, platelets, bone marrow cells, and other cell types. The mechanism of Atgam-induced immunosuppression has not been determined. Published data indicate that the primary mechanism is the depletion of circulating lymphocytes, with greatest effect on T lymphocytes. Lymphocyte depletion may be caused by complement dependent lysis and/or activation-induced apoptosis. In addition, immunosuppression may be mediated by the binding of antibodies to lymphocytes which results in partial activation and induction of T lymphocyte anergy.

The mechanism of Atgam therapy for aplastic anemia is attributed to its immunosuppressive actions. In addition, Atgam directly stimulates the growth of hematopoietic stem cells and release of hematopoietic growth factors such as interleukin-3 and granulocyte/macrophage colony stimulating factor.

Approved Indications

- A. **Renal Allograft Rejection:** Atgam is indicated for the management of allograft rejection in renal transplant patients; when administered with conventional therapy at the time of rejection Atgam increases the frequency of resolution of the acute rejection episode.
- B. **Aplastic Anemia:** Atgam is indicated for the treatment of moderate to severe aplastic anemia in patients unsuitable for bone marrow transplantation.

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.

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Other Uses:

NCCN includes the following Category 2A uses for antithymocyte globulin, equine (Atgam®):

- Management of CAR T-Cell and Lymphocyte Engager-Related Toxicities: May be considered for grade 4 cytokine release syndrome (CRS) refractory to high-dose corticosteroids and anti-IL-6 therapy. Use should be balanced against potential safety concerns, such as infection risk.
- Hematopoietic Cell Transplantation / Graft-vs-Host Disease: May be used for GVHD prophylaxis after hematopoietic cell transplant in HLA-matched, haploidentical, and HLA-mismatched donor settings as part of specified immunosuppressive regimens; as additional therapy for acute steroid-refractory GVHD; and as part of reduced-intensity conditioning in combination with cladribine and busulfan.
- Immunotherapy-Related Toxicities: May be used as additional immunosuppression for immunotherapy-related myocarditis if there is no improvement within 24–48 hours of high-dose methylprednisolone, and may also be considered as corticosteroid-sparing immunosuppression for select severe hepatic toxicities and severe or very severe aplastic anemia when there is inadequate response to corticosteroids.
- Myelodysplastic Syndromes: May be used for lower-risk myelodysplastic syndromes in select patients with clinically relevant thrombocytopenia, neutropenia, or symptomatic anemia, either alone or in combination with cyclosporine and/or eltrombopag.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Antithymocyte Globulin Equine, (Atgam®)

Note: This policy has an applicable National Coverage Determination (NCD). NCD 260.7 applies to lymphocyte immune globulin, anti-thymocyte globulin (equine) only for the management of allograft rejection episodes in renal transplantation. This NCD does not apply to aplastic anemia or NCCN-supported compendial uses, which should be reviewed under the applicable medical necessity criteria and benefit coverage. For details regarding NCD-260.7 including service description, indications and limitations of coverage, please visit [NCD - Lymphocyte Immune Globulin, Anti-Thymocyte Globulin \(Equine\) \(260.7\) \(cms.gov\)](#)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.*)

- i. For the management of *allograft rejection in renal transplant patients (Label, NCD 260.7)*; **AND**
 - A. Individual is a renal transplant recipient; **AND**
 - B. Atgam is used for the treatment of acute allograft rejection at the time of rejection; **OR**
 - C. Atgam is used with conventional/concomitant immunosuppressive therapy.
- OR**
- ii. For the management of *aplastic anemia (Label)*; **AND**
 - A. Individual has moderate to severe disease; **AND**
 - B. Individual is unsuitable for bone marrow transplantation.
- OR**
- iii. For *Allogeneic Hematopoietic Stem Cell Transplantation (NCCN 2A)*; **AND**
 - A. Atgam is used as conditioning as part of a reduced-intensity regimen prior to allogeneic hematopoietic stem cell transplantation; **AND**
 - B. Atgam is being used in combination with cladribine and busulfan; **AND**
- OR**
- iv. For *Graft-Versus-Host Disease Prophylaxis after Allogeneic Hematopoietic Stem Cell Transplantation (NCCN 2A)*; **AND**
 - A. Atgam is being used for graft-versus-host disease (GVHD) prophylaxis after hematopoietic cell transplant; **AND**
 - B. Individual has one of the following:
 - 1. An HLA-matched donor; **AND**
 - a. Atgam is being used as part of an antithymocyte globulin, cyclosporine, and methotrexate (MTX) regimen; **OR**

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	b. Atgam is being used as part of an antithymocyte globulin, tacrolimus, and methotrexate (MTX) regimen; OR 2. A haploidentical donor; AND a. Atgam is being used as part of a post-transplant cyclophosphamide (PTCy) and antithymocyte globulin regimen; OR 3. An HLA-mismatched donor; AND a. Atgam is being used as part of a post-transplant cyclophosphamide (PTCy) and antithymocyte globulin regimen. OR v. For <i>Graft-Versus-Host Disease</i> (NCCN 2A); AND A. Individual has acute disease; AND B. Individual's disease is steroid-refractory, with no response to first-line therapy options; AND C. Atgam will be used as additional therapy in conjunction with systemic corticosteroids; AND D. Atgam may be used in conjunction with the original immunosuppressive agent. OR vi. For <i>Immune Checkpoint Inhibitor-Related Toxicities</i> (NCCN 2A); AND A. Individual has received at least one immune checkpoint inhibitor. <i>Note:</i> Immune checkpoint inhibitors include but are not limited to: Opdivo (nivolumab intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Bavencio (avelumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), Yervoy (ipilimumab intravenous infusion); AND B. Atgam is used in <i>one</i> of the following settings: 1. As additional immunosuppression for immunotherapy-related myocarditis; AND a. Individual has not improved within 24–48 hours of starting high-dose methylprednisolone; OR 2. As additional corticosteroid-sparing immunosuppression for one of the following immunotherapy-related toxicities: a. Grade 2 elevated ALT/AST if liver enzymes suggest worsening or no improvement after 3–7 days of prednisone; OR b. Grade 3 or Grade 4 elevated ALT/AST if no improvement after 1–2 days of prednisone/methylprednisolone; OR c. Grade 2 elevated alkaline phosphatase (predominant) with or without bilirubin/AST/ALT elevations if alkaline phosphatase worsens or does not improve within 3 days after initiating corticosteroids; OR
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- d. Grade 3 or Grade 4 elevated alkaline phosphatase (predominant) with or without bilirubin/AST/ALT elevations if no improvement after 1–2 days of prednisone/methylprednisolone and ursodiol; **OR**
- e. Severe or very severe aplastic anemia if no response to corticosteroids after 7 days.

OR

- vii. For *Management of CAR T-Cell and Lymphocyte Engager-Related Toxicities* (NCCN 2A); **AND**

- A. Individual has received Cart-T Cell therapy or lymphocyte engager therapy; **AND**
Note: CAR T-cell therapies include but are not limited to: Tisagenlecleucel (Kymriah), Axicabtagene ciloleucel (Yescarta), Brexucabtagene autoleucel (Tecartus), Lisocabtagene maraleucel (Breyanzi), Idecabtagene vicleucel (Abecma), and Ciltacabtagene autoleucel (Carvykti); **AND**
- B. Individual has grade 4 cytokine release syndrome (CRS); **AND**
- C. Individual's condition is refractory to both, high-dose corticosteroids and anti-IL-6 therapy (tocilizumab product); **AND**

Note: Use for this indication should be balanced against potential safety concerns, such as infection risk.

OR

- viii. For *Low Risk Myelodysplastic Syndrome* (NCCN 2A); **AND**

- A. Individual has lower-risk disease.
Note: Lower risk disease is defined as IPSS-Revised (IPSS-R) risk of very low, low, or intermediate; **AND**
- B. Individual meets *one* of the following:
 - 1. Individual has clinically relevant thrombocytopenia or neutropenia; **AND**
 - a. Individual is a select patient, generally 60 years of age or younger and with 5% or fewer marrow blasts, or has hypocellular marrow, PNH clone positivity, or STAT3-mutant cytotoxic T-cell clones; **AND**
 - b. Atgam will be used in one of the following ways:
 - i. as a single agent; **OR**
 - ii. in combination with cyclosporine; **OR**
 - iii. in combination with eltrombopag; **OR**
 - iv. in combination with cyclosporine and eltrombopag.

OR

- 2. Individual has symptomatic anemia; **AND**
 - a. Individual has no del(5q), with or without other cytogenetic abnormalities, and has ring sideroblasts <15% or ring sideroblasts <5% with an SF3B1 mutation; **AND**
 - b. Individual has serum erythropoietin >500 mU/mL; **AND**
 - c. Individual has a good probability to respond to immunosuppressive therapy; **AND**

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- d. Atgam will be used in combination with cyclosporine with or without eltrombopag.

OR

3. Individual has symptomatic anemia; **AND**
- Individual has del(5q), with or without one other cytogenetic abnormality (except abnormalities involving chromosome 7); **AND**
 - Individual has a good probability to respond to immunosuppressive therapy; **AND**
 - Atgam will be used in combination with cyclosporine with or without eltrombopag; **AND**
 - Individual has had no response to or relapse after lenalidomide or no response to or relapse after an erythropoiesis-stimulating agent (ESA).

OR

4. Individual has symptomatic anemia; **AND**
- Individual has no del(5q), with or without other cytogenetic abnormalities, and has ring sideroblasts $\geq 15\%$ or ring sideroblasts $\geq 5\%$ with an SF3B1 mutation; **AND**
 - Individual has a good probability to respond to immunosuppressive therapy; **AND**
 - Atgam will be used in combination with cyclosporine with or without eltrombopag; **AND**
 - Individual has had no response to or relapse after one of the following treatment sequences:
 - luspatercept-aamt followed by imetelstat; **OR**
 - luspatercept-aamt followed by an erythropoiesis-stimulating agent (ESA) with or without granulocyte-colony stimulating factor (G-CSF); **OR**
 - luspatercept-aamt followed by lenalidomide; **OR**
 - imetelstat followed by luspatercept-aamt; **OR**
 - imetelstat followed by lenalidomide.

B. Criteria For Continuation of Therapy

- Not applicable. Atgam is administered as a short-course therapy, and continuation beyond the initial approval period is not generally required. Requests beyond the initial approval period should be reviewed as a new request based on the applicable indication and treatment course.

C. Authorization Duration

- Initial Approval Duration: 1 month
- Reauthorization Approval Duration: Not applicable

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D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. For the management of allograft rejection in non-renal solid organ transplantation; **OR**
- ii. For aplastic anemia in individuals who are suitable candidates for bone marrow transplantation;
OR
- iii. For aplastic anemia secondary to neoplastic disease, storage disease, myelofibrosis, Fanconi's syndrome, or in individuals known to have been exposed to myelotoxic agents or radiation;
OR
- iv. When the above criteria are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Antithymocyte Globulin Equine (Atgam®) inj. 50 mg/mL solution	Allograft rejection in renal transplant patients: 10 to 15 mg/kg administered intravenously daily for 14 days - May administer every other day for 7 more doses for a total of 21 doses in 28 days. Aplastic Anemia 10 to 20 mg/kg administered intravenously daily for 8 to 14 days - May administer every other day for 7 more doses for a total of 21 doses in 28 days. Allogeneic Hematopoietic Stem Cell Transplantation - Up to 40 mg/kg administered intravenously daily as a single dose, or divided and given twice daily for up to 4 days. Acute Graft-Versus-Host Disease 30 mg/kg every other day for 6 doses; OR 5 mg/kg twice daily for 10 doses Immune Checkpoint Inhibitor-Related Toxicities - Up to 15 mg/kg administered intravenously daily for 14 days. - Up to seven additional doses can be administered intravenously every other day for a maximum total of 21 doses in 28 days. Myelodysplastic Syndrome 40 mg/kg/day administered intravenously for 4 days in combination with prednisone
Exceptions	
None	

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
C93.10	Chronic myelomonocytic leukemia not having achieved remission
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.A	Myelodysplastic syndromes
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.Z	Other myelodysplastic syndromes
D61.1	Drug-induced aplastic anemia
D61.9	Aplastic anemia, unspecified
D89.810	Acute graft-versus-host disease
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
D89.834	Cytokine release syndrome, grade 4
D89.839	Cytokine release syndrome, grade unspecified
I30.8	Other forms of acute pericarditis
I30.9	Acute pericarditis, unspecified
I40.8	Other acute myocarditis
I40.9	Acute myocarditis, unspecified
K71.0	Toxic liver disease with cholestasis
K71.10	Toxic liver disease with hepatic necrosis, without coma
K71.11	Toxic liver disease with hepatic necrosis, with coma
K71.50	Toxic liver disease with chronic active hepatitis without ascites
K71.51	Toxic liver disease with chronic active hepatitis with ascites
K71.9	Toxic liver disease, unspecified
R74.01	Elevation of levels of liver transaminase levels
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XS	Complication of immune effector cellular therapy, sequela
T80.89XA	Other complications following infusion, transfusion and therapeutic injection, initial encounter

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T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.09	Other complications of bone marrow transplant
T86.11	Kidney transplant rejection
Z29.89	Encounter for other specified prophylactic measures
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status
Z94.89	Other transplanted organ and tissue status
Z94.9	Transplanted organ and tissue status, unspecified

HCPCS Codes:

Codes	Description
J7504	Lymphocyte immune globulin, Antithymocyte globulin equine, parenteral, 250 mg

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Reference Information:

- Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) (260.7). Accessed June 9, 2026.
- DailyMed - atgam- equine thymocyte immune globulin injection, solution. U.S. National Library of Medicine. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bd545ba1-2366-4df1-bd67-10dfd7632b54>.
- NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/drug_compndium/content/. Accessed on June 9, 2026.
 - Management of Immune Checkpoint Inhibitor-Related Toxicities. Version 1.2026. Revised: October 23, 2025.
 - Myelodysplastic Syndromes. Version 3.2026. Revised: January 12, 2026.
 - Hematopoietic Cell Transplantation. Version 2.2026. Revised April 3, 2026.
 - Management of CAR-T Cell and Lymphocyte Engager-Related Toxicities. Version 2.2026. Revised November 11, 2025.
- Pfizer Inc. ATGAM® (lymphocyte immune globulin, anti-thymocyte globulin [equine]) sterile solution, for intravenous use only: Prescribing information. Revised September 2023. Accessed June 9, 2026.
- UpToDate. Antithymocyte globulin (horse derived) (Atgam): Drug information. Retrieved June 9, 2026, from UpToDate.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated medical policy to align with the current FDA Prescribing Information and NCCN recommendations. Updated Other Uses, and Criteria for Initial Approval; clarified that NCD 260.7 applies only to renal allograft rejection; updated continuation of therapy and authorization duration to reflect short-course use; expanded Conditions Not Covered. Coding reviewed: removed ICD-10 codes K71.1-K71.11 and added 71.10, K71.11; added ICD-10 Z29.89, Z94.84, Z94.9, T86.01, T86.02, T86.09, D61.1, and D89.811; edited description of HCPCS code J7504. Updated quantity limits table and reference information. Wording and formatting changes and incorporated new policy template.	8/14/2026	8/19/2026
Annual Review	Coding reviewed: No changes. Minimal wording changes and formatting.	9/5/2025	9/16/2025
Annual Review	Added NCCN supported uses in the Other Uses section (background section); Added used in combination with cladribine and busulfan when used for Allograft Rejection in Solid Organ Transplant; clarified criteria to use in immune checkpoint inhibitor-related toxicities to make it specific for immunotherapy-related myocarditis, and added Car T Cell related CRS use and criteria as per NCCN compendia guidelines; Added the following statement to the criteria of all NCCN supported uses: Atgam will be used in a compendia (NCCN) recommended regimen; Added Continuation Criteria statement; Added Conditions Not Covered section; Wording and formatting changes; Coding reviewed: Added the following codes: D89.810, D89.812, D89.813, T86.09, Z94.81, Z94.89, Z94.9, I30.8, I30.9, I40.8, I40.9, K71.1-K71.9, K71.0, K71.10, K71.11, K71.50, K71.51, R74.01, T80.82XA, T80.82XS, T80.89XA, D89.834, D89.839, C93.10, D46.0, D46.1, D46.20, D46.21, D46.4, D46.9, D46.A, D46.B, D46.Z.	2/18/2025	3/6/2025
Policy Inception	09/27/2023: Policy reviewed and approved by P&T Committee.	10/30/2023	11/30/2023