MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Transplant	**P&T DATE:**	12/9/2025
THERAPEUTIC CLASS	Immunosuppressive Agents	**REVIEW HISTORY** (MONTH/YEAR)	12/25, 01/24, 12/22, 09/21, 9/20, 9/19, 9/18, 5/17, 5/16
LOB AFFECTED	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-calrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.
Any biosimilars pending litigations or not officially available in the US Market for consumer use is not an available treatment option or covered on the medical benefit. Biosimilars that are FDA approved and available in the US Market for consumer use will follow the reference brand name criteria as available per our PH05 - Prior Authorizations processes. Certain biosimilars may be subject to alternative criteria based on the preferences of Health Plan.

This coverage policy is updated on an annual basis. For more recent or up-to-date criteria, reference the Medi-Cal Provider Manual and/or the Medicare National Coverage Determination/Local Coverage Determination (NCD/LCD) for specific criteria. If the Medi-Cal Provider Manual and/or the Medicare NCD/LCD do not have medical necessity criteria, please refer to the "Evaluation Criteria" section in this policy for specific criteria. It is also important to reference the Medicare Benefit Manuals - Chapter 15 and Chapter 16 - when determining benefit coverage and criteria for review of physician administered drugs on the Medicare benefit.

OVERVIEW

Organ transplant is a complex, high risk, and costly procedure. To minimize organ rejection, transplant patients usually take immunosuppressive therapy lifelong. However, these immunosuppressive agents carry their own risks, many related to increased risk of infections, metabolic syndrome, etc. The goal of immunosuppression therapy for organ transplant prevention is to minimize the side effects of immunosuppressants without compromising their efficacy. The below criteria, limits, and requirements for certain agents are in place to ensure appropriate use of those agents. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on Medical Necessity criteria as described in Health Plan Medical Review Guidelines (UM06).

Intravenous Immunosuppressant
Basiliximab (Simulect)

- ❒ **Coverage Criteria:** Approval is determined by medical necessity criteria.
- ❒ **Limits:** NONE

- ❒ **Required Information for Approval:** Please submit clinic notes with documentation of acute organ rejection in patients receiving kidney or liver transplant.

Intravenous Immunosuppressant
Antithymocyte Globulin (Thymoglobulin, Atgam)

- ❒ **Coverage Criteria:** Approval is determined by medical necessity criteria.
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Please submit clinic notes with documentation of acute organ rejection in patients receiving kidney transplant.

Intravenous Immunosuppressant
Belatacept (Nulojix)

- ❒ **Coverage Criteria:** Approval is determined by medical necessity criteria.
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Please submit clinic notes with documentation of organ transplant in patients who are EBV seropositive.

Intravenous Immunosuppressant
Alemtuzumab (Lemtrada)

- ❒ **Coverage Criteria:** Approval is determined by medical necessity criteria.
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Approval is determined by medical necessity criteria. Please submit clinic notes with documentation of acute organ rejection in patients receiving kidney transplant where Basiliximab or Antithymocyte Globulin is inappropriate.
- ❒ **Notes:** Can cause significant lymphopenia that can lasts from 6 months to several years. Occasionally used off-label for kidney transplants.

Intravenous *Immunoglobulins*
Alyglo; Asceniv; Bivigam; Carimune NF; Cutaquig; Cuvitru; Flebogamma DIF; GamaSTAN; Gammagard; Gammagard S/D Less IgA; Gammaked; Gammaplex; Gamunex-C; Hizentra; Hyqvia; Octagam; Panzyga; Privigen; Xembify

- ❒ **Coverage Criteria:** Reserved for patients with one or more of the following:
  - **Prevention of acute humoral rejection** for high-risk solid organ transplant patients, including those who are highly sensitized, have positive cross match, or have a live donor with ABO incompatibility.
  - **Treatment of acute humoral rejection** for patients with documentation of antibody-mediated rejection (AMR) post-transplant.
  - **Hypogammaglobulinemia** to prevent post-transplant infections for patients with documented low IgG levels (e.g. <400 mg/dL).
  - **Refractory BK viremia** in kidney transplant patients who have persistent viral titers despite reduced immunosuppression.
  - Other off-label indications supported by society guidelines
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Approval is determined by medical necessity criteria. Relevant information for approval may include high panel-reactive antibody (PRA) levels, presence of donor-specific antibodies (DSAs) pre-transplant, documented ABO incompatibility, histological evidence of AMR (e.g. via biopsy), presence of donor-specific antibodies during AMR, clinical signs of graft dysfunction, IgG levels, history of recurrent infections, BK virus titer.
- ❒ **Notes: N/A**

Allogeneic Cellular Therapy
Remestemcel-L-rknd (Ryoncil)

- ❒ **Coverage Criteria:** Reserved for patients with all of the following:
  - Steroid-refractory acute graft versus host disease (SR-aGvHD)
  - For pediatric patients 2 months to ≤ 17 years of age

- Progression of aGVHD within 3 days of ≥ 2 mg/kg/day methylprednisolone or equivalent therapy OR no clinical improvement within 7 consecutive days of ≥ 2 mg/kg/day methylprednisolone or equivalent therapy

- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Documentation that previous steroid treatment(s) were tried and had inadequate response, intolerance, or contraindication.
- ❒ **Notes: N/A**

Colony Stimulating Factor-1 Receptor (CSF-1R) Inhibitor
Axatilimab-csfr (Niktimvo)

- ❒ **Coverage Criteria:** Reserved for patients with all of the following:
  - Chronic graft-versus-host disease (cGVHD)
  - Previous failure of at least two prior lines of systemic therapy
  - Adult and pediatric patients weighing at least 40 kg
  - No concurrent JAK inhibitors and BTK inhibitors will be used with Niktimvo.
  - No known active relapse of the underlying hematologic malignancy.
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Documentation that other appropriate therapies (including steroids, calcineurin inhibitors, JAK inhibitors, BTK inhibitors, etc) were tried and had inadequate response, intolerance, or contraindication. Documented history of allogeneic hematopoietic stem cell transplantation (HSCT).
- ❒ **Notes:** Patients may have acute GVHD (graft-versus-host disease) if there is overlapping cGVHD.

⌗ REFERENCES

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⌖ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	HPSJ Coverage Policy – Immunology – Transplant 2016-05.docx	5/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Immunology – Transplant 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Immunology – Transplant 2018-09.docx	9/2018	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Immunology – Transplant 2019-09.docx	9/2019	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Immunology – Transplant 2020-09.docx	9/2020	Matthew Garrett, PharmD
Update to Policy	Transplant	9/2021	Matthew Garrett, PharmD
Review of Policy	Transplant	12/2022	Matthew Garrett, PharmD
Review of Policy	Transplant	1/2024	Matthew Garrett, PharmD
Update to Policy	Transplant	12/2024	Matthew Garrett, PharmD
Update to Policy	Transplant	12/2025	Matthew Garrett, PharmD

Note: All changes are approved by the Health Plan P&T Committee before incorporation into the utilization policy