GCHP Medi-Cal Clinical Guidelines
Hyaluronic Acid Derivatives
Belatacept (Nulojix™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	Prophylaxis of organ rejection concomitantly with basiliximab induction, mycophenolate mofetil, and corticosteroids in adult Epstein-Barr virus seropositive kidney transplant recipients. *Non-FDA approved indication or off-label use will be reviewed if there is sufficient documentation of efficacy and safety in published literature.*
Exclusion Criteria	• Active infection • Untreated latent or active tuberculosis • Concurrent administration of live vaccine • History of liver transplant • History of systemic malignancy
Required Medical Information	Must meet ALL of the following: • Administered in combination with basiliximab, mycophenolate mofetil, and corticosteroids • Epstein-Barr virus seropositive • Kidney transplant AND i. Initial course of organ rejection prophylaxis or ii. Subsequent course of organ rejection prophylaxis or iii. Switch from calcineurin inhibitor-based regimen (e.g., cyclosporine, tacrolimus) due to nephrotoxicity, dyslipidemia, or new-onset diabetes. **Off-label indications:** 1) The requested unlabeled use must represent reasonable and current prescribing practices based on current medical literature, provider organizations, or academic & professional specialists. 2) In addition, one of the following is required: a. Documentation of trial & failure (or contraindication) to on-label treatments, or b. There are no FDA-approved drug treatments for the diagnosis.
Age Restriction	18 years of age and older; 18 – 21 years of age of age – Check CCS
Prescriber Restrictions	Transplant specialist
Coverage Duration	Six months

Other Criteria / Information	

HCPCS	Description	Dosing, Units
J0485	Injection, belatacept, 1mg (Nulojix™)	Initial phase 10mg/kg on day one (day of transplant, prior to implantation) and on day five (~96 hours after day one dose), followed by 10mg/kg at the end of week two, four, eight and 12 following transplantation. Maintenance phase 5mg/kg every four weeks (+three days) beginning at the end of week 16 following transplantation). Maximum dosage is 10mg/kg for initial phase; 5mg/kg for maintenance phase.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	8/5/2024	8/5/2024	Yoonhee Kim, Interim Director of Pharmacy Services	N/A
Approved	N/A	8/14/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025