

GCHP Medi-Cal Clinical Guidelines Basiliximab (Simulect™)

PA Criteria	Criteria Details										
Covered Uses (FDA Approved Indication)	Prophylaxis of acute organ rejection in patients receiving renal transplantation when used as part of an immunosuppressive regimen that includes cyclosporine, USP (MODIFIED), and corticosteroids.										
Exclusion Criteria	None										
Required Medical Information	<p>Prophylaxis of acute organ rejection in renal transplantation AND</p> <ul style="list-style-type: none">Part of an immunosuppressive regimen that includes cyclosporine, USP (MODIFIED), and corticosteroids. <p>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.</p>										
Age Restriction	None; < 21 years of age – check CCS eligibility										
Prescriber Restrictions	Transplant specialist.										
Coverage Duration	Three months.										
Other Criteria / Information	<table><tr><th>HCP</th><th>CS</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J04</td><td>80</td><td>Basiliximab 20mg injection (Simulect)</td><td><p>Adults: Two doses of 20mg</p><p>Pediatrics: < 35kg – Two doses of 10mg each, > 35kg – Two doses of 20mg each</p><p>First dose given within two hours prior to transplant surgery and second dose given four days after transplant.</p></td></tr></table>			HCP	CS	Description	Dosing, Units	J04	80	Basiliximab 20mg injection (Simulect)	<p>Adults: Two doses of 20mg</p> <p>Pediatrics: < 35kg – Two doses of 10mg each, > 35kg – Two doses of 20mg each</p> <p>First dose given within two hours prior to transplant surgery and second dose given four days after transplant.</p>
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	1/14/2025	N/A	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	N/A
Approved	N/A	2/13/2025	Pharmacy & Therapeutics (P&T) Committee	3/1/2025