VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

SIMULECT (basiliximab)

Effective Date: 10/20/14
Date Developed: 10/14/14
Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20, 2/2/21, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Description: Simulect is a monoclonal antibody produced by recombinant DNA technology that functions as an immunosuppressive agent, binding to and blocking the interleukin-2 receptor on the surface of activated T-lymphocytes. This specific high-affinity binding to IL-2Rα competitively inhibits IL-2-mediated activation of lymphocytes, a critical pathway in the cellular immune response involved in allograft rejection.

Authorization Criteria: Prophylaxis of acute organ rejection in patients receiving renal transplantation when used as part of an immunosuppressive regimen that includes cyclosporine and steroids.

Off-Label Uses: Treatment of refractory acute graft-versus-host disease; prevention of liver, lung or cardiac transplant rejection.

NOTE: To be used as a component of an immunosuppressive regimen that may include a calcineurin inhibitor, adjunctive agent (eg, mycophenolate mofetil, everolimus), and corticosteroids.

NOTE [US Boxed Warning]: Only physicians experienced in immunosuppression therapy and management of organ transplantation patients should prescribe basiliximab.

Dosing: **Adults:** IV: 20 mg two hours prior to transplantation then 20mg 4 days after transplantation (in combination with other immunosuppressants).

Pediatric: <35 kg 10 mg each dose; >35 kg 20 mg each dose

NOTE: Patients previously administered basiliximab should only be re-exposed to a subsequent course of therapy with extreme caution.

NOTE: Timing of basiliximab dosing may vary based on clinical and institutional factors; refer to institutional protocol for specific information.

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NOTE: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

How Supplied:

Reconstituted, Intravenous [preservative free]: 10 mg (1 ea); 20 mg (1 ea)

Major Adverse Reactions: Simulect did not appear to add to the background of adverse events seen in organ transplantation patients as a consequence of their underlying disease and the concurrent administration of immunosuppressants and other medications.

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Revision History:

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Formatting changes; Additional information; Additional references
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Added “and steroids” in the authorization criteria. Removed “**NOTE**: Per VCHCP policy,

			unlabeled off-label uses are not covered unless specific information is submitted. See VCHCP Policy on Coverage for Prescription Medication for Off-Label Use" And Major Drug Interactions.