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

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 corticosteroids.

Unlabeled Uses: Treatment of refractory acute graft-versus-host disease; prevention of liver or cardiac transplant rejection.

Note: Per VCHCP policy, unlabeled uses are not covered unless specific information is submitted. See VCHCP Policy on Coverage for Prescription Medication for Off-Label Use.

Dosing: **Adults:** IV: 20 mg two hours prior to transplantation then 20mg 4 days after transplantation; **Pediatric:** <35 kg 10 mg each dose; >35 kg 20 mg each dose

Reconstituted **Simulect** should be given either as a bolus injection or diluted to a volume of 25 mL (10-mg vial) or 50 mL (20-mg vial) with normal saline or dextrose 5% and administered as an intravenous infusion over 20 to 30 minutes. NOTE: Bolus administration may be associated with nausea, vomiting and local reactions, including pain.

How Supplied: Lyophilized: 10mg, 20mg (reconstitute with 5 mL sterile water)

Contraindications/Warnings: Only physicians experienced in immunosuppression therapy and management of organ transplantation patients should prescribe Simulect. The physician responsible for Simulect administration should have complete information requisite for the follow-up of the patient. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. While neither the incidence of lymphoproliferative disorders nor opportunistic infections was higher in Simulect-

treated patients than in placebo-treated patients, patients on immunosuppressive therapy are at increased risk for developing these complications and should be monitored accordingly.

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.

Major Drug Interactions: inactivated vaccines, BCG (diminished effect); live vaccines (enhanced effects); potentiate effects of other immunosuppressants

REFERENCES

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2. Nashan B, Moore R, Amlot P, et al, "Randomised Trial of Basiliximab Versus Placebo for Control of Acute Cellular Rejection in Renal Allograft Recipients," *Lancet*, 1997, 350(9086):1193-8.
3. Offner G, Toenshoff B, Höcker B, et al, "Efficacy and Safety of Basiliximab in Pediatric Renal Transplant Patients Receiving Cyclosporine, Mycophenolate Mofetil, and Steroids," *Transplantation*, 2008, 86(9):1241-8
4. Schmidt-Hieber M, Feitz T, Knauf W, et al, "Efficacy if the Interleukin-2 Receptor Antagonist Basiliximab in Steroid-Refractory Acute Graft-Versus-Host Disease, *Br J Haematol*, 2005, 130(4):568-74.
5. www.uptodate.com: Basiliximab: Drug Guidelines

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