

 <b>WELLMED</b> Doctors helping patients for more than 25 years	<b>Effective Date:</b> 01/21/2026	<b>Revision Date(s):</b> 10/26/18, 2/13/2020, 3/11/2021, 04/21/22, 07/31/24, 06/18/25, 07/25/25, 01/21/2026
<b>Department: PHARMACY</b>	<b>MMC Review/ Approval Date(s):</b> 11/13/18, 3/18/20, 3/19/21, 05/26/22, 08/01/24, 01/21/2026	<b>Total Number of Page(s):</b> 7
<b>Policy Number: 017.004</b>  <b>Title: Coverage Determination Policy for Basiliximab (Simulect) (Intravenous)</b>		

Regions:  **Texas**     **Florida**     **New Mexico**

<b>Impacted Areas:</b> <input checked="" type="checkbox"/> Network Management/Provider Services <input checked="" type="checkbox"/> Utilization Management <input type="checkbox"/> Member services <input type="checkbox"/> Case management <input type="checkbox"/> Quality Management <input type="checkbox"/> Disease management <input type="checkbox"/> Credentialing <input checked="" type="checkbox"/> Claims <input type="checkbox"/> IT <input type="checkbox"/> Human resources <input type="checkbox"/> Administration <input type="checkbox"/> Finance <input type="checkbox"/> Compliance/delegation <input checked="" type="checkbox"/> Pharmacy <input type="checkbox"/> ALL	
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<b>Approved by:</b>  Megan Ortiz, MD FACOG Senior Medical Director		Date:
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<b>Reviewed by:</b>  Sherien Zaid, Pharm.D Director of Clinical Pharmacy		Date:
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**Available LCD/NCD/LCA:** None

**Disclaimer:**  
 WellMed determines coverage decisions based on Medicare guidelines, including applicable statutes, regulations, NCDs (National Coverage Determinations), and LCDs (Local Coverage Determinations). In situations where no specific coverage criteria exist, or when NCDs/LCDs allow for clinical discretion, WellMed applies internal coverage policy. This internal coverage policy is informed by a structured review process that evaluates peer-reviewed scientific literature, broadly accepted clinical guidelines, and expert consensus to determine whether a service is reasonable and necessary for the diagnosis or treatment of an illness or to enhance patient function. Application of the internal coverage policy ensures alignment with evidence-based clinical standards when Medicare guidance is absent or insufficient to fully establish medical necessity.

**Title: Coverage Determination Policy for Basiliximab (Simulect) (Intravenous)**

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### Coverage Determination (New Requests):

**According to patient transplant coverage of benefits and transplant phase, WellMed Medical Management will cover Basiliximab (Simulect®) as medically necessary when ALL of the following are met:**

- a) Basiliximab is prescribed by or in consultation with a transplant specialist or nephrologist experienced in immunosuppression therapy and management of organ transplantation patients.
- b) Basiliximab should only be administered once it has been determined that the patient will receive the kidney transplant and concomitant immunosuppression.
- c) Basiliximab will be used in combination with an immunosuppressive regimen that includes cyclosporine and corticosteroids either alone or in combination with other immunosuppressant.
- d) Basiliximab is initiated according to FDA recommended dosing.

### FDA Approved Indications and Dosing

Indication	Approved Dosing
<b>Renal transplant (prophylaxis of acute rejection):</b> in combination with cyclosporine (modified) and corticosteroids	20 mg intravenous given within 2 hours before transplantation surgery, then 20 mg intravenous given 4 days after transplantation. The second dose should be withheld if complications such as severe hypersensitivity reactions to Simulect or graft loss occur.

## Non-FDA Approved Uses (off-label)

Indication	Approved Dosing
<b>Acute graft-versus-host disease (aGVHD), refractory (treatment)</b>	20 mg intravenous on days 1, 3 or 4, and day 8 of treatment days; may repeat weekly for recurrent acute GVHD
<b>Heart transplant (prophylaxis of acute rejection)</b> (in combination with other immunosuppressants)	20 mg administered immediately prior to transplant or within the first hours postoperatively on the day of transplant, then 20 mg intravenous given 4 days after transplantation
<b>Liver transplant (prophylaxis of acute rejection)</b> (in combination with other immunosuppressant's)	20 mg intravenous on the day of transplant (day 0), then 20 mg intravenous given 4 days after transplantation
<b>Lung transplant (prophylaxis of acute rejection)</b> (in combination with other immunosuppressants)	20 mg intravenous prior to transplantation, then 20 mg intravenous given 4 days after transplantation
<b>Pancreas transplant (prophylaxis of acute rejection)</b> (in combination with other immunosuppressants)	20mg intravenous on the day of transplant, then 20mg given 4 days after transplantation

### General Background:

Basiliximab is a chimeric (murine/human) monoclonal antibody that binds to the alpha subunit of interleukin-2 (IL-2) receptor complex and inhibits IL-2 binding. This prevents activation of lymphocytes; thereby, blocking the response of immune system to antigen. Basiliximab is used in combination with cyclosporine (modified) and corticosteroids as immunosuppressant agents to prevent immediate renal transplant rejection. Patients on basiliximab treatment with other immunosuppressant may have increased risk of opportunistic infections and lymphoproliferative disorders. The Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines for care of kidney transplant recipients recommend interleukin 2 receptor antagonist (eg, basiliximab) as the first line induction agent for acute rejection prophylaxis except in those patients at high immunologic risk.

*Medicare does not have a National Coverage Determination (NCD) for basiliximab. There is no Local Coverage Determination (LCD) that addresses basiliximab.*

### **Black Box Warning:**

Only physicians experienced in immunosuppression therapy and management of organ transplantation patients should prescribe basiliximab. The physician responsible for basiliximab 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

## Clinical Evidence:

The safety and efficacy of Simulect® in prophylaxis of organ rejection in cadaveric or living-donor renal transplantation has been demonstrated in two studies (US study). Two 20 mg doses of Simulect® were compared in a randomized, double-blind, placebo-controlled clinical studies. Simulect® 20 mg intravenous or placebo were given within 2 hours of transplantation surgery, then 20 mg intravenous given 4 days after transplantation in combination with cyclosporine (modified) and corticosteroids. The primary end point was the incidence of death, graft lost or an episode of acute rejection during the first 6 months post transplantation. The studies concluded that patients receiving Simulect® experienced significantly lower incidence of biopsy-confirmed rejection episode.

Results from double-blind randomized placebo-controlled clinical studies demonstrated basiliximab improved treatment response as immunoprophylaxis after liver transplantation. The trial was conducted in Europe, Canada, and the United States. Three hundred and eighty one (381) men and women were randomized. Basiliximab 20 mg intravenous or placebo was administered within 6 hours after reperfusion of the graft. The second dose was administered day 4 after transplantation. Cyclosporine microemulsion and steroids were administered to maintain Immunosuppression. Patients who experienced at least one (treated) biopsy-proven acute rejection episode, death or graft loss within 6 months of the start of study medication were evaluated for primary efficacy. The study showed that patients who received basiliximab in combination with cyclosporine microemulsion and steroids had reduced episode of acute rejection.

## HCPCS Code:

**Basiliximab (Simulect): J0480**

## Acronyms:

Interleukin-2 (IL-2), Kidney Disease: Improving Global Outcomes (KDIGO), National Coverage Determination (NCD), Local Coverage Determinations (LCD)

## References:

1. Basiliximab In: DRUGDEX System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/>.
2. Basiliximab . UpToDate. Accessed at [https://www.uptodate.com/contents/basiliximab-drug-information?search=basiliximab&source=search\\_result&selectedTitle=1~30&usage\\_type=default&display\\_rank=1#F139100](https://www.uptodate.com/contents/basiliximab-drug-information?search=basiliximab&source=search_result&selectedTitle=1~30&usage_type=default&display_rank=1#F139100). Accessed 5/31/25.
3. Simulect (basiliximab) (prescribing information). East Hanover, NJ: Novartis Pharmaceuticals Corporation; Revised: August 2020
4. Kidney Disease: Improving Global Outcomes. “KDIGO Clinical Practice Guideline for the Care of Kidney Transplant Recipients,” *American Journal of Transplantation* 2009; 9 (Suppl 3): S131–S155
5. Penninga L, Møller CH, Gustafsson F, Gluud C, Steinbrüchel DA. Immunosuppressive T-cell antibody induction for heart transplant recipients. *Cochrane Database Syst Rev.* 2013 Dec 2;2013(12):CD008842. Doi:10.1002/14651858.CD008842.pub2. PMID: 24297433; PMCID:PMC1559623.
6. Neuhaus P, Clavien P, Kittur D, et al, “ Improved Treatment Response With Basiliximab Immunoprophylaxis After Liver Transplantation: Results from a Double-Blind Randomized Placebo-Controlled Trial” *Liver Transplantation, Vol 8, No 2 (February), 2002: pp 132-142.*

### Policy History/Revision Information:

Date Revised	Type of Changes	List Significant Changes and/or Status of policy
10/26/2018	New	New coverage criteria created. – O. Emmanuel Adeyemi, PharmD
01/17/2020	Minor	FDA Approved dosing updated – Anand Patel, PharmD
02/17/2021	Minor	Updated criteria to reflect new template criteria. Included contents page. Updated coverage determination section. Included Black box warning. Updated references and format. Anand Patel, PharmD
04/21/2022	Minor	Updated coverage determination sections a and b. Clarified dosing wording under FDA approved dosing section. Updated overall format. Luis Valdivieso, PharmD
07/31/2024	None	Annual revision, No updates on policy – Pathik Tripathi, PharmD
05/31/25	Minor	Annual revision. Added off-label indication and reference for heart transplant. L. Bernstein, Pharm.D.
07/25/25	Minor	Disclaimer section updated. S. Zaid, PharmD