WellMed Doctors helping patients for more than 25 years	**Effective Date:** 06/06/22	**Revision Date(s):** 10/26/18, 2/13/2020, 3/11/2021, 04/21/22
Department: PHARMACY	**MMC Review/ Approval Date(s):** 11/13/18, 3/18/20, 3/19/21, 05/26/22	**Total Number of Page(s):** 8

Policy Number: 017.003

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

Regions: ☒ **Texas** ☐ **Florida** ☐ **Indiana** ☐ **New Jersey** ☒ **New Mexico**

Impacted Areas:

☒ Network Management/Provider Services	☒ Utilization Management
☐ Member services	☐ Case management
☐ Quality Management	☐ Disease management
☐ Credentialing	☒ Claims
☐ IT	☐ Human resources
☐ Administration	☐ Finance
☐ Compliance/delegation	☒ Pharmacy
	☐ ALL

Approved by: Vincent Huerta, MD, CHCQM Senior Medical Director	Vincent F Huerta Jr, MD, CHCQM Digitally signed by Vincent F Huerta Jr, MD, CHCQM Date: 2022.06.06 13:05:37 -05'00' *Signature of Approver*	Date: 06/06/2022
Reviewed by: Pathik Tripathi, PharmD, MS Director of Clinical Pharmacy	Pathik Tripathi Digitally signed by Pathik Tripathi Date: 2022.06.06 09:44:36 -05'00' *Signature of Reviewer*	Date: 06/06/2022

Available LCD/NCD/LCA: None

Disclaimer:
WellMed Coverage Determination Policies are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support WellMed coverage decision making. WellMed may modify these Policy Guidelines at any time. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the WellMed Coverage Determination Policies is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Doctors helping patients for more than 25 years

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Coverage Policy Number: 017.003

Line of Business: Medicare Part B

Policy Type: Prior Authorization

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
Renal transplant (prophylaxis of acute rejection): 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
Acute graft-versus-host disease (aGVHD), refractory (treatment)	20 mg intravenous on days 1 and 4 of treatment days; may repeat for recurrent acute GVHD
Heart transplant (prophylaxis of acute rejection) (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
Liver transplant (prophylaxis of acute rejection) (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
Lung transplant (prophylaxis of acute rejection) (in combination with other immunosuppressants)	20 mg intravenous prior to transplantation, then 20 mg intravenous 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 basilixumab 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:

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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. Accessed on Feb 16th, 2021
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. 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