Simulect (basiliximab)
Policy Number: C9972-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
12/1/2016	9/9/2020	9/9/2021
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J0480-Injection, basiliximab, 20mg	RxPA	Q4 2020 20201028C9972-A

PRODUCTS AFFECTED:
Simulect (basiliximab)

DRUG CLASS:
Monoclonal Antibodies

ROUTE OF ADMINISTRATION:
Intravenous

PLACE OF SERVICE:
Buy and Bill

AVAILABLE DOSAGE FORMS:
Simulect SOLR 10MG, Simulect SOLR 20MG

FDA-APPROVED USES:
indicated for the 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. The efficacy of Simulect for the prophylaxis of acute rejection in recipients of other solid organ allografts has not been demonstrated.

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
prophylaxis of acute organ rejection

REQUIRED MEDICAL INFORMATION:
A. ACUTE ORGAN REJECTION PROPHYLAXIS:

1. Documentation Member has received a kidney transplant
   AND
2. Documentation the patient's prophylaxis therapy includes cyclosporine modifiedAND corticosteroids OR everolimus AND cyclosporine modified (reduced dose) AND corticosteroids
   AND
3. Documentation Member is considered low risk for kidney rejection

DURATION OF APPROVAL:
5 days

QUANTITY:
IV-20 mg within 2 hours prior to transplant surgery, followed by a second 20 mg dose 4 days after transplantation. Pediatric: <35 kg 10 mg each dose; >35 kg 20 mg each dose. Patients previously administered basiliximab should only be re-exposed to a subsequent course of therapy with extreme caution.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a transplant specialist or nephrologist. 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 with adequate laboratory and supportive medical resources

AGE RESTRICTIONS:
None

CONTINUATION OF THERAPY:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Simulect
(basiliximab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Patients previously administered basiliximab should only be re-exposed to a subsequent course of therapy with extreme caution.

OTHER SPECIAL CONSIDERATIONS:

BACKGROUND:

APPENDIX:

REFERENCES:

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Rejection Among Renal Allograft Recipients Treated With Basiliximab, a Chimeric Anti-Interleukin-2-Receptor Monoclonal Antibody. United States Simulect Renal Study Group," Transplantation, 1999, 67(2):276-84.
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14. Simulect (basiliximab) (prescribing information). East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2018.