VENTURA COUNTY HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Neoral (cyclosporine emulsion)

Effective Date 1/24/17
Developed 12/8/16 by R. Sterling, MD
Date Approved by P&T Committee: 1/24/17, 1/23/18, 1/22/19
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Neoral is a microemulsion formulation of cyclosporin with predictable pharmacokinetics, superior absorption and less dependent upon bile production. Neoral is safe and results in rapid attainment of therapeutic trough levels. Six months after conversion, the mean Neoral dose was decreased 0.6 mg/kg per patient in one study (Minerva Urol Nefrol. 1998 Jun;50(2):161-4).

Pre-authorization Criteria: **see Cyclosporine Guidelines**

Dosing: **see Cyclosporine Guidelines**

How Supplied: capsules 25 mg, 100 mg; solution 100mg/mL (50 mL)

Adverse Reactions/Precautions: Neoral is not bioequivalent to other cyclosporine formulations and cannot be used interchangeably without close supervision. For given trough concentrations, cyclosporine exposure will be greater with Neoral than with other formulations. If a patient receiving exceptionally high doses of cyclosporin is converted to Neoral, exercise particular caution. Monitor cyclosporine blood concentrations in transplant and rheumatoid arthritis (RA) patients taking Neoral to avoid toxicity due to high concentrations. Make dose adjustments in transplant patients to minimize possible organ rejection due to low concentrations. Comparison of blood concentrations in the published literature with blood concentrations obtained using current assays must be done with detailed knowledge of the assay methods employed.

Drug Interactions: **see Cyclosporine Guidelines**

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REFERENCES:

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Holt DW, Mueller EA, Kovarik JM, et al, "Sandimmune Neoral Pharmacokinetics: Impact of the New Oral Formulation," *Transplant Proc*, 1995, 27(1):1434-7.

Lin CY and Lee SF, "Comparison of Pharmacokinetics Between CsA Capsules and Sandimmune® Neoral®

Niese D, "A Double-Blind Randomized Study of Sandimmune Neoral vs Sandimmune in New Renal Transplant Recipients: Results After 12 Months," *Transplant Proc*, 1995, 27(2):1849-56. in Pediatric Patients," *Transplant Proc*, 1994, 26(5):2973-4.

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Taesch S, Niese D, and Mueller EA, "Sandimmune® Neoral®, A New Oral Formulation of Cyclosporine With Improved Pharmacokinetic Characteristics: Safety and Tolerability in Renal Transplant Patients," *Transplant Proc*, 1994, 26(6):3147-9

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