Cyclosporin Microemulsion (Neoral®)†
A Pharmacoeconomic Review of its Use Compared with Standard Cyclosporin in Renal and Hepatic Transplantation

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Data Selection
Sources: Medical literature published in any language since 1966, identified using AdisBase (a proprietary database of Adis International, Auckland, New Zealand), Medline and EMBASE. Additional references were identified from the reference lists of published articles. Bibliographical information, including contributory unpublished data, was also requested from the company developing the drug.
Selection: Pharmacoeconomic studies in patients who received cyclosporin microemulsion. Relevant pharmacokinetic, clinical and background data were also included.
Index terms: cyclosporin, cyclosporin-microemulsion, pharmacoeconomics, transplantation, cost.

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† Use of trade name is for product identification, and does not imply endorsement.
Abstract

Cyclosporin microemulsion (Neoral®) is a self-emulsifying preconcentrate of cyclosporin which is more rapidly and consistently absorbed than the original oil-based formulation of cyclosporin (standard formulation; Sandimmun®, Sandimmune®). This superior pharmacokinetic profile suggests that cyclosporin microemulsion may be associated with improved therapeutic and economic outcomes compared with the standard formulation.

Clinical studies comparing the 2 formulations of cyclosporin (using the recommended 1 : 1 dosage conversion factor) in de novo or stable renal and de novo liver transplant patients have demonstrated that cyclosporin microemulsion is as efficacious as the standard formulation. Rates of acute and chronic graft rejection are generally unaffected by the formulation of cyclosporin, although a trend toward fewer rejection episodes in cyclosporin microemulsion recipients was noted in several randomised studies (reaching statistical significance in 4 studies).

Most transplant recipients experience adverse events during cyclosporin therapy, and with higher and more reliable maximum blood concentrations achieved by cyclosporin microemulsion, there is a potential risk of more drug-related adverse events. However, most studies have suggested that the frequency of drug-related adverse events (including nephrotoxicity) is not affected by the formulation of cyclosporin.

Analyses of healthcare resource utilisation and associated costs in renal and liver transplant patients in Canadian and European studies have suggested that the cost of using cyclosporin microemulsion may be lower than the cost of using the standard formulation. Lower resource consumption among cyclosporin microemulsion recipients in several studies led to slightly (but not statistically significantly) lower overall healthcare costs in this group. The cost of cyclosporin itself was not included in most of these analyses; however, because the 2 formulations of cyclosporin are used in similar dosages and have similar acquisition costs, this was probably not an important factor in determining relative costs. A single cost analysis comparing cyclosporin microemulsion and tacrolimus suggested that the 2 drugs were associated with similar overall costs.

The available economic data on the use of cyclosporin microemulsion are subject to a number of important limitations. In particular, only partial results and study methodology have been reported for most analyses. Several studies were based on small patient groups (<25) and short periods of follow-up (3 months), although some economic studies included larger patient groups receiving treatment for up to 1 year. Moreover, all of the analyses published to date were ‘protocol driven’ studies, and hence may not reflect resource use in usual clinical practice.

Conclusion: In de novo and stable renal and de novo liver transplant recipients, cyclosporin microemulsion is as effective and well tolerated as the standard formulation of cyclosporin. Economic analyses comparing the 2 formulations indicate a consistent, although small and not statistically significant, reduction in overall healthcare costs associated with use of cyclosporin microemulsion.