# CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

## MYCOPHENOLATE SODIUM
## [Myfortic – Novartis Pharmaceuticals Canada Inc.]

**Description:** Myfortic is an enteric-coated tablet containing mycophenolate as the sodium salt. Mycophenolate, a selective uncompetitive reversible inhibitor of inosine monophosphate dehydrogenase, exerts a cytostatic effect on lymphocytes that results in immunosuppression. Myfortic is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants, administered in combination with cyclosporine and corticosteroids.

**Recommendation:** The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Myfortic be listed in a similar manner as drug plans list mycophenolate mofetil tablets and capsules.

**Reasons for the Recommendation:**

1. Bioavailability studies have demonstrated that mycophenolate sodium enteric-coated tablets are bioequivalent to mycophenolate mofetil tablets.

2. Three randomized controlled trials (RCTs) in renal transplant patients were considered by the Committee. The RCTs demonstrate that there is no difference in efficacy between mycophenolate sodium enteric-coated tablets and mycophenolate mofetil solid formulations.

3. RCTs demonstrate that there is no difference between mycophenolate sodium enteric-coated tablets and mycophenolate mofetil solid formulations in terms of safety or tolerability.

4. At recommended adult doses, mycophenolate sodium [Myfortic] will cost $0.83 per day less than mycophenolate mofetil [CellCept®] solid dosage forms.

**Of Note:**

1. Myfortic is available only as tablets. Liquid mycophenolate mofetil formulations (oral suspension, intravenous infusion) provide therapeutically useful options if a solid oral dosage form is not practical or safe.

2. A statistically significant lower incidence of serious infections was noted with mycophenolate sodium compared with mycophenolate mofetil in one trial and when the data from three trials were pooled. Although unexplained, a real difference remains plausible. The currently available data are insufficient to conclude a therapeutic advantage or disadvantage in terms of risk for developing serious infections.

3. Both published and unpublished information were reviewed and taken into consideration in making this recommendation.