CellCept® (mycophenolate mofetil) – Expanded indication

- On June 6, 2022, the FDA approved Genentech's CellCept (mycophenolate mofetil), for the prophylaxis of organ rejection, in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart or liver transplants, in combination with other immunosuppressants.
    - This approval expands the use of CellCept in the prophylaxis of organ rejection to pediatric recipients of allogenic heart and liver transplants, respectively. It was previously only approved in adults for this use.
- The use of CellCept for the expanded indication in pediatric heart transplant and liver transplant patients was supported by adequate and well-controlled studies and pharmacokinetic data in adult heart transplant and liver transplant patients. Additional supportive data include pharmacokinetic data in pediatric kidney transplant and pediatric liver transplant patients and published evidence of clinical efficacy and safety in pediatric heart transplant and pediatric liver transplant patients.
- CellCept carries a boxed warning for embryofetal toxicity, malignancies, and serious infections.
- The recommended starting dosage of CellCept oral suspension for pediatric heart transplant patients or liver transplant patients 3 months and older is 600 mg/m^2, administered twice daily. If well tolerated, the dose can be increased to a maintenance dosage of 900 mg/m^2 twice daily (maximum total daily dose of 3 g or 15 mL of the oral suspension). The dose may be individualized based on clinical assessment.
    - Pediatric patients with body surface area (BSA) ≥ 1.25 m^2 may be dosed with capsules or tablets. Refer to the CellCept drug label for complete dosing information.
- Refer to the CellCept drug label for dosing for its other uses.