



OUR ONGOING COMMITMENT TO YOU AND YOUR PATIENTS

*Supporting the transplant community
for more than 15 years*

Valcyte®

valganciclovir HCl tablets and for oral solution

INDICATIONS

Adult Patients: Valcyte (valganciclovir hydrochloride) tablets are indicated for the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS).

Valcyte tablets are indicated for the prevention of CMV disease in kidney, heart, or kidney-pancreas transplant patients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]).

Pediatric Patients: Valcyte (valganciclovir hydrochloride) for oral solution and tablets are indicated for the prevention of CMV disease in kidney or heart transplant patients (4 months to 16 years of age) at high risk.

Limitations of Use:

- Valcyte is not indicated for use in either adult or pediatric liver transplant patients
- The safety and efficacy of Valcyte have not been established for:
 - Prevention of CMV disease in solid organ transplants other than those indicated
 - Prevention of CMV disease in pediatric solid organ transplant patients <4 months of age
 - Treatment of congenital CMV disease

IMPORTANT SAFETY INFORMATION

WARNING: HEMATOLOGIC TOXICITY, CARCINOGENICITY, TERATOGENICITY, AND IMPAIRMENT OF FERTILITY

- Clinical toxicity of Valcyte, which is metabolized to ganciclovir, includes granulocytopenia, anemia, and thrombocytopenia
- In animal studies, ganciclovir was carcinogenic, teratogenic, and caused aspermatogenesis

Please see accompanying full Prescribing Information for Valcyte, including Boxed WARNING, for additional Important Safety Information.

CellCept®

(mycophenolate mofetil)

INDICATION

CellCept® (mycophenolate mofetil) is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. CellCept should be used concomitantly with cyclosporine and corticosteroids.

CellCept Intravenous is an alternative dosage form to CellCept capsules, tablets and oral suspension. CellCept Intravenous should be administered within 24 hours following transplantation. CellCept Intravenous can be administered for up to 14 days; patients should be switched to oral CellCept as soon as they can tolerate oral medication.

IMPORTANT SAFETY INFORMATION

WARNING

Immunosuppression may lead to increased susceptibility to infection and possible development of lymphoma. Only physicians experienced in immunosuppressive therapy and management of renal, cardiac or hepatic transplant patients should use CellCept. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

Female users of childbearing potential must use contraception. Use of CellCept during pregnancy is associated with increased rates of pregnancy loss and congenital malformations.

Please see accompanying full Prescribing Information for CellCept, including Boxed WARNING and Medication Guide, for Important Safety Information.

TABLE OF CONTENTS

| | |
|---------------------------------------|----|
| Genentech® Transplant Access Services | 6 |
| What We Offer | 8 |
| How to Contact Us | 9 |
| The Valcyte Co-pay Card Program | 10 |
| The CellCept Coupon Card Program | 12 |
| Online Product Resources for Patients | 14 |
| Educational Resources | 15 |
| Sponsorships | 15 |
| Valcyte Important Safety Information | 16 |
| CellCept Important Safety Information | 18 |



GENENTECH® TRANSPLANT ACCESS SERVICES

At Genentech®, we believe therapies should be accessible for the patients who need them.

Genentech® Transplant Access Services (GTAS) is designed to connect eligible patients in need to coverage and reimbursement services and assistance programs that best suit their circumstances.

Since 1985, when our first product was approved, Genentech has donated approximately \$1.5 billion in free medicine to uninsured patients through the Genentech® Access to Care Foundation (GATCF) and other product donation programs.

GATCF was established to help patients with unmet medical needs who meet specific insurance, financial and medical criteria to receive Valcyte and/or CellCept free of charge.*

In the following pages, you will find everything you need to help your patients get the most out of the coverage support for Valcyte and CellCept.

IMPORTANT SAFETY INFORMATION

Valcyte is contraindicated in patients with hypersensitivity to valganciclovir, ganciclovir, or any component of the formulation.

CellCept is contraindicated in patients with a hypersensitivity to mycophenolate mofetil, mycophenolic acid or any component of the drug product. CellCept Intravenous is contraindicated in patients who are allergic to Polysorbate 80 (TWEEN).

*Certain exceptions apply for patients transitioning from the Roche Patient Assistance Program for a limited time.

Please see accompanying full Prescribing Information for Valcyte, including Boxed WARNING, for Important Safety Information.

GTAS SUPPORT FOR VALCYTE AND CELLCEPT

Genentech Transplant Access Services (GTAS) can help you and your patients get answers to questions about their drug prescription coverage and reimbursement for Valcyte and CellCept, including:

- **Full Benefits Investigation (BI)**

A BI can determine the extent to which Genentech transplant medications are covered by a patient's health insurance plan.

- **Prior authorization assistance**

If prior authorization is required by an insurance policy, physicians may be required to submit paperwork, such as payor-specific forms, lab reports, and/or a letter of medical necessity.

- **Appeals support[†]**

If your patient's health insurance plan has issued a denial for Valcyte or CellCept, your Transplant Access Services Reimbursement Specialist can guide you in the process as you prepare an appeal submission, as per your patient's plan requirements.[‡]

[†]This description is provided for informational purposes only. The submission and completion of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare professional. Genentech makes no representation or guarantee concerning reimbursement or coverage for any service or item.

[‡]Each health insurance plan and each patient case could require different information. Please review each denial and the health insurance plan's guidelines to determine what to include in your patient's appeal. Your Transplant Access Services Reimbursement Specialist has plan-specific knowledge and can help you determine the specific requirements for your patient.



TRANSPLANT ACCESS SERVICES

Please see accompanying full Prescribing Information for CellCept, including Boxed WARNING and Medication Guide, for Important Safety Information.

WHAT WE OFFER

GTAS connects patients to three categories of assistance programs:

| Patient-Specific Solutions | |
|----------------------------|---|
| Out-of-pocket expenses | <p>Valcyte Co-pay Card With this card, eligible patients can save up to 80% toward out-of-pocket expenses on every Valcyte prescription and refill. Patients can receive up to \$1500, or up to \$4000 with demonstrated financial need, over a 12-month period. Please see full terms and conditions by visiting www.valcytecopaycard.com</p> <p>CellCept Coupon Card This card allows eligible patients to receive up to \$100 toward out-of-pocket expenses on every CellCept prescription and refill. Please see full terms and conditions by visiting www.cellcept.com</p> |
| INOs | <p>Referrals to independent, nonprofit organizations (INOs) Genentech® Transplant Access Services (GTAS) can refer patients to an INO that provides co-pay assistance for their specific disease state</p> |
| GATCF | <p>Genentech® Access to Care Foundation (GATCF) GATCF was established to help qualified patients with unmet medical needs who are uninsured or rendered uninsured by payor denial and who meet specific insurance, financial, and medical criteria to receive Valcyte or CellCept free of charge</p> |

Please see accompanying full Prescribing Information for Valcyte, including Boxed WARNING, for Important Safety Information.

HOW TO CONTACT US

You can contact specific patient assistance programs at the following numbers:

| Patient Assistance Programs | Direct Contact Information |
|--|---|
| GTAS Hotline | 1-888-754-7651 7:00 AM to 7:00 PM Eastern Time Monday – Friday |
| Valcyte Co-pay Card | 1-877-MY-VAL49 (698-2549) 8:00 AM to 8:00 PM Eastern Time Monday – Friday |
| CellCept Coupon Card | 1-877-509-2235 9:00 AM to 7:00 PM Eastern Time Monday – Friday |
| Independent, non-profit organization (INO) referrals | 1-888-754-7651 9:00 AM to 7:00 PM Eastern Time Monday – Friday |

For more information, please visit www.TransplantAccessServices.com

Please see accompanying full Prescribing Information for CellCept, including Boxed WARNING and Medication Guide, for Important Safety Information.

THE VALCYTE CO-PAY CARD PROGRAM



The Valcyte Co-pay Card Program provides eligible patients with up to 80% toward out-of-pocket expenses on every Valcyte prescription and refill.

- In a 12-month period, eligible patients may receive up to \$1500 in assistance, or up to \$4000 for patients with a demonstrated financial need

To be eligible for the Valcyte Co-Pay Card, patients must:

- Be taking Valcyte according to the approved label:
 - **Adult patients:**
 - Treatment of CMV retinitis in patients with AIDS
 - Prevention of CMV disease in kidney, heart, or kidney-pancreas transplant patients at high risk
 - **Pediatric patients:**
 - Prevention of CMV disease in kidney or heart transplant patients (4 months to 16 years of age) at high risk
- Be aged 18 years or older (or have a legal guardian over age 18)
- Reside in the United States or Puerto Rico; offer not valid for residents of Massachusetts
- Not participate in any federal or state healthcare program such as Medicare or Medicaid, Medigap, VA, DOD, or TRICARE
- Not participate in the Genentech® Access to Care Foundation (GATCF)

Please see Co-pay Card or visit www.valcytecopaycard.com for additional terms and conditions.

For eligible patients, Valcytecopaycard.com offers easy 24/7 access to:

- **Activate** their Valcyte Co-pay Card
- **Enroll** in the Co-pay Card Program
- **Request** a replacement Co-pay Card

Patients can also activate their cards by calling 1-877-MY-VAL49 (1-877-698-2549), with live operators available 8 AM to 8 PM, Eastern Time, Monday through Friday.

Providers: You may not advertise or otherwise use the card as a means of promoting your services or Genentech's products to patients.

Other terms and conditions: No person or entity may seek reimbursement from any third-party payor for any amount provided using the card program. Genentech reserves the right to deny payment under the card to anyone deemed ineligible in accordance with the stated program criteria. Use of this card must be consistent with all relevant health insurance requirements and payor agreements. Participating patients and pharmacies are obligated to inform third-party payors about this card as provided for under the applicable insurance or as otherwise required by contract or law. Limit one card per patient.

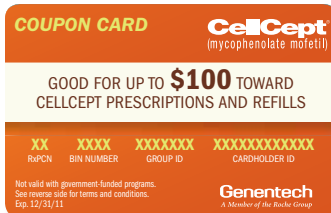
IMPORTANT SAFETY INFORMATION

Adult Patients: The most common adverse events and laboratory abnormalities reported in at least one indication by $\geq 20\%$ of patients treated with Valcyte tablets are diarrhea, pyrexia, nausea, tremor, neutropenia, anemia, graft rejection, thrombocytopenia, and vomiting.

Pediatric Patients: The most common adverse events and laboratory abnormalities reported in $>10\%$ of solid organ transplant recipients treated with Valcyte for oral solution or tablets are diarrhea, pyrexia, hypertension, upper respiratory tract infection, vomiting, anemia, neutropenia, constipation, nausea, and cough.

Please see accompanying full Prescribing Information for Valcyte, including Boxed WARNING, for Important Safety Information.

THE CELLCEPT COUPON CARD PROGRAM



This card allows your eligible patients to receive up to \$100 toward out-of-pocket expenses on every CellCept prescription and refill.*

Patients can download a Coupon Card by visiting www.cellcept.com and clicking on the "Patient Web site" tab. Coupon Cards are also available from transplant centers or by calling 1-877-509-2235.

To be eligible for the 2011 CellCept Coupon Card, patients must:

- Be taking CellCept for a kidney, heart or liver transplant
- Be aged 18 years or older (or have a legal guardian over age 18)
- Reside in the United States or Puerto Rico; offer not valid for residents of Massachusetts
- Not participate in any federal or state healthcare program such as Medicaid, Medicare or TRICARE
- Not participate in the Genentech® Access to Care Foundation (GATCF)

IMPORTANT SAFETY INFORMATION

The principal adverse reactions associated with the administration of CellCept include diarrhea, leukopenia, sepsis, vomiting, and there is evidence of a higher frequency of certain types of infections, eg, opportunistic infections (see **WARNINGS** in full Prescribing Information). Phlebitis and thrombosis have been reported with intravenous administration. Please refer to the full Prescribing Information for additional **ADVERSE REACTIONS**.

*Offer good through December 31, 2011 or earlier, at Genentech's sole discretion.



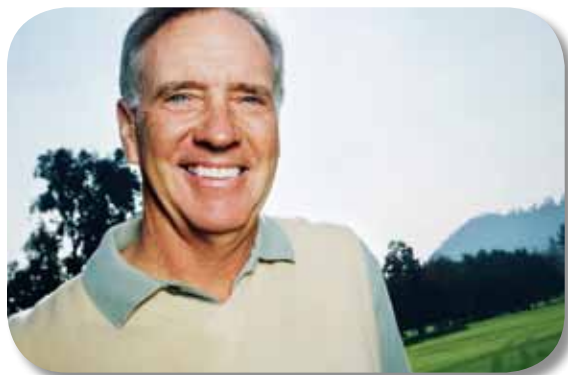
Providers: You may not advertise or otherwise use the card as a means of promoting your services or Genentech's products to patients.

Other terms and conditions: This program is paid for by Genentech. Offer good through 12/31/11 or earlier, at Genentech's sole discretion. No person or entity may seek reimbursement from any third-party payor for any amount provided using the card program. Genentech reserves the right to deny payment under the card to anyone deemed ineligible in accordance with the stated program criteria. Use of this coupon must be consistent with all relevant health insurance requirements and payor agreements. Participating patients and pharmacies are obligated to inform third-party payors about this coupon as provided for under the applicable insurance or as otherwise required by contract or law. Limit one card per patient.

Please see full terms and conditions by visiting www.cellcept.com.

Please see accompanying full Prescribing Information for CellCept, including Boxed **WARNING** and Medication Guide, for Important Safety Information.

ONLINE PRODUCT RESOURCES FOR PATIENTS



Valcyte and CellCept provide free online resources for patients receiving organ transplants. These resources include Genentech Transplant Access Services (GTAS), a comprehensive, free service designed to assist patients and healthcare providers gain access to Valcyte and CellCept.

Patients can visit www.valcyte.com and click on the “I am a Patient or Caregiver” link, or www.cellcept.com and click on the “patient Web site” link, to find valuable information on:

- Healthy living after a transplant, including real-life stories from transplant recipients
- The Valcyte Co-pay Card Program and 2011 CellCept Coupon Card Program
- Independent Non-profit Organizations (INOs) that may offer support for certain patients

Please encourage your patients to visit www.valcyte.com and www.cellcept.com today!

Please see accompanying full Prescribing Information for Valcyte, including Boxed WARNING, for Important Safety Information.

Please see accompanying full Prescribing Information for CellCept, including Boxed WARNING and Medication Guide, for Important Safety Information.

EDUCATIONAL RESOURCES

Genentech® provides healthcare professionals and patients with medically relevant pre- and post-transplant resource materials that include the following topics:

- Living kidney donation
- Heart and kidney pre-transplantation
- Donor testimonials
- Healthy tips for patients
- Life after transplantation
- Managing medications
- Basic exercise
- Definitions of commonly used transplant terms

For more information about obtaining these resources for your patients, please contact your Genentech Transplant Sales Specialist.

SPONSORSHIPS

Genentech continues its commitment to the transplant community by supporting transplant-related activities of numerous professional societies and charitable organizations. Professional societies supported:

- American Society of Transplantation (AST)
- American Society of Transplant Surgeons (ASTS)
- International Society for Heart and Lung Transplantation (ISHLT)
- NATCO, The Organization for Transplant Professionals
- Society for Transplant Social Workers (STSW)
- Transplant Financial Coordinators Association (TFCA)
- International Transplant Nurses Society (ITNS)
- United Network for Organ Sharing (UNOS)
- National Kidney Foundation (NKF)

VALCYTE IMPORTANT SAFETY INFORMATION

IMPORTANT DOSING INFORMATION

- Adult patients should use Valcyte tablets, not Valcyte for oral solution
- Valcyte should be taken with food
- The bioavailability of ganciclovir for Valcyte is significantly higher than from ganciclovir capsules. Therefore, Valcyte tablets cannot be substituted for ganciclovir capsules on a one-to-one basis
- Valcyte tablets should not be broken or crushed
- Valcyte for oral solution must be prepared by the pharmacist prior to dispensing to patient
- Mycophenolate mofetil (MMF): May increase ganciclovir concentrations and levels of MMF metabolites in patients with renal impairment. Monitor for ganciclovir and MMF toxicity

WARNING: HEMATOLOGIC TOXICITY, CARCINOGENICITY, TERATOGENICITY, AND IMPAIRMENT OF FERTILITY

- **Clinical toxicity of Valcyte, which is metabolized to ganciclovir, includes granulocytopenia, anemia, and thrombocytopenia**
- **In animal studies ganciclovir was carcinogenic, teratogenic, and caused aspermatogenesis**

CONTRAINDICATION

Valcyte is contraindicated in patients who have had a demonstrated clinically significant hypersensitivity reaction to valganciclovir, ganciclovir, or any component of the formulation.

WARNINGS AND PRECAUTIONS

- Severe leukopenia, neutropenia, anemia, thrombocytopenia, pancytopenia, bone marrow aplasia, and aplastic anemia have been observed
- **Do not administer if the absolute neutrophil count is <500 cells/ μ L, the platelet count is <25,000/ μ L, or the hemoglobin is <8 g/dL**
- Use with caution in patients with pre-existing cytopenias, or who have received or who are receiving myelosuppressive drugs or irradiation
- Advise women of childbearing potential to use effective contraception during treatment and for at least 30 days following treatment with Valcyte. Advise men to practice barrier contraception during and for at least 90 days following treatment
- Acute renal failure may occur in:
 - Elderly patients with or without reduced renal function
 - Patients receiving potential nephrotoxic drugs
 - Patients without adequate hydration

ADVERSE REACTIONS

Adult Patients: The most common adverse events and laboratory abnormalities reported in at least one indication by $\geq 20\%$ of patients treated with Valcyte tablets are diarrhea, pyrexia, nausea, tremor, neutropenia, anemia, graft rejection, thrombocytopenia, and vomiting.

Pediatric Patients: The most common adverse events and laboratory abnormalities reported in $>10\%$ of solid organ transplant recipients treated with Valcyte for oral solution or tablets are diarrhea, pyrexia, hypertension, upper respiratory tract infection, vomiting, anemia, neutropenia, constipation, nausea, and cough.

Please see accompanying full Prescribing Information, including Boxed WARNING, for additional Important Safety Information.

CELLCEPT IMPORTANT SAFETY INFORMATION

WARNING

Immunosuppression may lead to increased susceptibility to infection and possible development of lymphoma. Only physicians experienced in immunosuppressive therapy and management of renal, cardiac or hepatic transplant patients should use CellCept. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

Female users of childbearing potential must use contraception. Use of CellCept during pregnancy is associated with increased rates of pregnancy loss and congenital malformations.

CONTRAINDICATIONS

CellCept is contraindicated in patients with a hypersensitivity to mycophenolate mofetil, mycophenolic acid or any component of the drug product. CellCept Intravenous is contraindicated in patients who are allergic to Polysorbate 80 (TWEEN).

WARNINGS

- Patients receiving immunosuppressive regimens involving combinations of drugs, including CellCept, as part of an immunosuppressive regimen are at increased risk of developing lymphomas and other malignancies, particularly of the skin.
- CellCept has been administered in combination with the following agents in clinical trials: antithymocyte globulin, OKT3, cyclosporine and corticosteroids. The efficacy and safety of the use of CellCept in combination with other immunosuppressive agents have not been determined.
- Oversuppression of the immune system can also increase susceptibility to infection, including opportunistic infections, fatal infections and sepsis.
- Immunosuppressed patients are at increased risk of opportunistic infections, including activation of latent viral infections. These include sometimes fatal cases of progressive multifocal leukoencephalopathy (PML) and BK virus-associated nephropathy (BKVAN).

Cases of PML have been reported in patients treated with CellCept. Hemiparesis, apathy, confusion, cognitive deficiencies and ataxia were the most frequent clinical features observed. In immunosuppressed patients with neurological symptoms, consider PML in the differential diagnosis and consult with a neurologist as clinically indicated. Consider reducing the amount of immunosuppression and be cognizant of the risk that reduced immunosuppression represents to the graft.

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

BKVAN is associated with serious outcomes, including deteriorating renal function and renal graft loss. Monitoring may help detect patients at risk for BKVAN. Consider reducing immunosuppression for patients who develop evidence of BKVAN.

- Teratogenic effects: Pregnancy Category D. CellCept can cause fetal harm when administered to a pregnant woman. A patient who is planning a pregnancy should not use CellCept unless she cannot be successfully treated with other immunosuppressant drugs.

Do not initiate CellCept therapy until a negative pregnancy test report is obtained within 1 week prior to beginning therapy. If this drug is used during pregnancy, apprise the patient of the potential hazard to the fetus.

Women of childbearing potential taking CellCept must receive contraceptive counseling, use effective contraception (2 reliable forms of contraception, unless abstinence is chosen) and begin using their chosen contraceptive methods 4 weeks prior to starting CellCept therapy and should continue contraceptive use during therapy and for 6 weeks after stopping CellCept.

- Monitor patients for neutropenia. If neutropenia develops [absolute neutrophil count (ANC) $<1.3 \times 10^3/\mu\text{L}$], dosing with CellCept should be interrupted or the dose reduced, appropriate diagnostic tests performed and the patient managed appropriately.
- Cases of pure red cell aplasia (PRCA) have been reported in patients treated with CellCept in combination with other immunosuppressive agents.
- CAUTION: NEVER ADMINISTER CELLCEPT INTRAVENOUS SOLUTION BY RAPID OR BOLUS INTRAVENOUS INJECTION.

PRECAUTIONS

- Gastrointestinal bleeding (requiring hospitalization) has been observed.
- During treatment with CellCept, avoid the use of live attenuated vaccines and advise patients that vaccinations may be less effective.
- Care should be taken if CellCept Oral Suspension is administered to patients with phenylketonuria.

ADVERSE REACTIONS

- The principal adverse reactions associated with the administration of CellCept include diarrhea, leukopenia, sepsis, vomiting, and there is evidence of a higher frequency of certain types of infections, eg, opportunistic infections (see **WARNINGS** in full Prescribing Information). Phlebitis and thrombosis have been reported with intravenous administration. Please refer to the full Prescribing Information for additional **ADVERSE REACTIONS**.

IMPORTANT CONTACT INFORMATION

Genentech® Transplant Access Services
1-888-754-7651
www.TransplantAccessServices.com

Valcyte (valganciclovir HCl) Co-pay Card
1-877-MY-VAL49 (698-2549)
www.valcyte.com

CellCept (mycophenolate mofetil) Coupon Card
1-877-509-2235
www.cellcept.com

Valcyte® (valganciclovir HCl tablets and for oral solution)

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Limitations of Use:

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 - Prevention of CMV disease in solid organ transplants other than those indicated
 - Prevention of CMV disease in pediatric solid organ transplant patients <4 months of age
 - Treatment of congenital CMV disease

CellCept® (mycophenolate mofetil)

INDICATION

CellCept® (mycophenolate mofetil) is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. CellCept should be used concomitantly with cyclosporine and corticosteroids.

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Please see accompanying full Prescribing Information for CellCept, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Genentech

A Member of the Roche Group