STATEMENT OF MEDICAL NECESSITY (SMN)

Valcyte® (valganciclovir HCl) tablets and for oral solution

Please write legibly and complete all required fields (*) to prevent delays.

Phone: (888) 754-7651 **Fax: (800) 305-1830**

M-US-00001755(v1.0) 11/19

SERVICES REQUESTED* (check only those that apply)

☐ GATCF† Patient Assistance ☐ Co-pay Assistance

PATIENT

Last name*: _____ First name*: _____ Birth date*: _____ Gender: ☐ Male ☐ Female
Street: _____ City: _____ State*: _____ ZIP: _____
Home phone: (_____) _____ Work/cell phone: (_____) _____ Email: _____
Alternate contact last name: _____ First name: _____ Phone: (_____) _____
Relationship to patient: _____ OK to contact patient? ☐ Yes ☐ No Pt. preferred language (if other than English): _____

INSURANCE

☐ HMO/EPO ☐ PPO ☐ POS ☐ Indemnity
☐ Medicare/Medicaid ☐ PBM ☐ Other: _____
☐ No insurance
Insurance denial/non-coverage policy attached? ☐ Yes ☐ No
Primary insurance (PI) name: _____
PI phone: _____
PI subscriber name: _____
PI subscriber ID #: _____
Policy/group #: _____
Insurance card attached? ☐ Yes ☐ No

☐ HMO/EPO ☐ PPO ☐ POS ☐ Indemnity
☐ Medicare/Medicaid ☐ PBM ☐ Other: _____
☐ No insurance
Insurance denial/non-coverage policy attached? ☐ Yes ☐ No
Secondary insurance (SI) name: _____
SI phone: _____
SI subscriber name: _____
SI subscriber ID #: _____
Policy/group #: _____
Insurance card attached? ☐ Yes ☐ No

DIAGNOSIS/TREATMENT

DIAGNOSIS CODE (highest level of specificity)*:

☐ Z94.0 Kidney transplant status
☐ Z94.1 Heart transplant status
☐ Z94.0/Z94.83 Kidney-pancreas transplant
Other diagnosis code(s): _____

☐ B20/B25.8/H30.89 ____
CMV retinitis treatment/AIDS (complete 6th digit to specify laterality)

Has patient received transplant? ☐ Yes ☐ No Date of scheduled/performed transplant: _____
Has patient started prescribed therapy? ☐ Yes ☐ No If so, last treatment date: _____
☐ NKDA or ☐ Allergies: _____

CONTACT & SHIPPING

IS PATIENT CURRENTLY IN A HOSPITAL AWAITING A TRANSPLANT? ☐ Yes ☐ No
Transplant coordinator name: _____ Phone: (_____) _____
PRIMARY CONTACT: ☐ Transplant coordinator ☐ Physician (See PRESCRIBER section for contact information.)
Please send this supply of medication to: *(If not indicated, medication will ship to the patient's address.)*
☐ Patient address ☐ Prescriber address ☐ Hospital/other address: _____
Specialty pharmacy needed for dispensing? ☐ Yes ☐ No (Local retail or mail-order pharmacy to be used)
Preferred specialty pharmacy: _____

PRESCRIPTION

DISPENSE VALCYTE® (valganciclovir HCl) (check 1 box in each column):

☐ 50-mg/mL convenience pack ☐ 450-mg tablets	☐ QD ☐ Other	☐ 30-day supply ☐ 90-day supply ☐ 60-day supply ☐ Other	Refill _____ times Length of therapy: ☐ 100 days ☐ 200 days

PRESCRIBER

Prescriber's last name*: _____ First name*: _____
Practice name: _____ Specialty: _____
Street*: _____ City*: _____ State*: _____ ZIP*: _____
Phone: (_____) _____ Fax: (_____) _____
Prescriber Tax ID: _____ Prescriber NPI‡: _____
DEA #: _____ Group NPI: _____ State license #*: _____ PTAN§: _____
Reimbursement/clinical contact last name: _____ First name: _____
Reimbursement/clinical contact phone: (_____) _____ Fax: (_____) _____

UNAPPROVED USE WARNING: Please read the FDA-approved label for Valcyte before prescribing. If the indication for which you are prescribing Valcyte is not listed in the label, you are prescribing Valcyte for an "unapproved" use. The fact that the use for which you are prescribing Valcyte is not listed in the FDA-approved label indicates that the FDA has not approved the efficacy, dosage amount or safety of Valcyte when used for such a use. Nevertheless, GATCF will consider providing Valcyte for your patient with this admonition, based upon your medical order, within program requirements.

By signing below, I certify that (a) the above therapy is medically necessary, (b) I have received the necessary authorization to release the above-referenced information and other protected health information (as defined by the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) to Genentech, Inc., and contracted dispensing pharmacy or other contractors for the purpose of requesting reimbursement, assisting in initiating or continuing therapy and/or the evaluation of the patient's eligibility for GATCF related to Genentech products, as a break in treatment would negatively impact the patient's therapeutic outcome and (c) I will not attempt to seek reimbursement for free product provided directly to the patient.

I agree to comply with the program guidelines as established by Genentech, Inc. and understand that GATCF, at its sole and absolute discretion, reserves the right to modify or discontinue the program at any time and to verify the accuracy of the information submitted.

If applying for GATCF, I certify that this patient has no medical insurance coverage or otherwise meets the financial criteria for the pharmaceutical identified above and is not eligible for other public health insurance programs.

Special Note: Prescribers in all states must follow applicable law for a valid prescription. For prescribers in states with official prescription form requirements, such as New York, please submit prescriptions on an official state prescription blank along with this form.

Sign and date here

Prescriber's Signature*: _____ Date*: _____
(Original signature required. This form cannot be processed without a prescriber's signature.)

*Required field. †Genentech® Access to Care Foundation. ‡National Provider Identifier. §Provider Transaction Access Number.

STATEMENT OF MEDICAL NECESSITY (SMN)

Please write legibly and complete all required fields (*) to prevent delays.

SERVICES REQUESTED

- Check the appropriate services requested on behalf of the patient. GATCF cannot perform services without your specific request

DIAGNOSIS/TREATMENT

- Enter the appropriate Diagnosis Code to the highest level of specificity
- If selecting the ICD-10-CM code for CMV retinitis treatment/AIDS, complete the 6th digit to specify laterality

CONTACT & SHIPPING

- If patient is awaiting transplant, please indicate the transplant coordinator contact information
- Identify the primary contact (transplant coordinator or physician)

PRESCRIPTION

- Complete the dose and refill fields along with the dispense instructions

PRESCRIBER

- Stamped prescription signatures are not accepted

REQUIRED FIELDS

- All required fields are indicated with an asterisk (*)
- GATCF cannot process your SMN unless these fields are completed

ATTACH TO COMPLETED SMN

- Attach a signed and dated Patient Authorization and Notice of Release for Transmission of Health Information (PAN) form to Genentech Access Solutions and GATCF. GATCF cannot work on your patient's behalf without a signed and dated PAN form

PROVIDING ADDITIONAL DOCUMENTS OR INFORMATION WITH THIS FORM, OTHER THAN WHAT IS REQUESTED, WILL DELAY PROCESSING.

REMINDER: This form cannot be processed without a prescriber's signature and date, as well as a signed and dated PAN form.

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