

Valcyte Medical Supply Program

FAX (02-764 89 59) / E-Mail (xavier.poire@uclouvain.be) this signed form to the BHS Decision Committee (X. Poiré ; J. Maertens ; P. Zachée)

Center:
 Physician : Tel: Fax: E-mail:
 Address: Postcode: City:
 Pharmacist : Tel: Fax:

Patient initials:(First name) (Last name) Gender: Male Female
 Date of birth:(Day) /(Mo) / (Year) Age: yrs Weight: Kg
 Allogeneic transplantation Date:(Day) /(Mo) / (Year)
 Donor: Sibling Unrelated Cord blood Haplo-identical
 Alemtuzumab treatment Date started:(Day) /(Mo) / (Year)

Request for 1 box of Valcyte, 450 mg - 60 tablets (recommended adult dose = 2 tablets bid until PCR-neg, then 1 tablet bid for 1 wk, to be adapted for renal function)

- 2nd or later episode of asymptomatic CMV reactivation (patient had ≥ 1 previous episode of CMV reactivation)
 2 consecutive positive CMV viral loads within 1 week > 1000 copies/ml (blood /plasma):
please document, add copies

Documentation of previous episode of CMV reactivation

Date of onset of CMV reactivation:(Day) /(Mo) / (Year)
 Symptomatic: No Yes, specify :

Treatment given: <u>Drugs + dose</u>	<u>Start on</u>	<u>Stop on</u>	<u>Response (CMV negative)</u>
...../...../20...../...../20.....
...../...../20...../...../20.....
...../...../20...../...../20.....

Current patient information

- Patient **not** hospitalized: Yes No
 ANC > 500/μl (0.5 x 10⁹/L): Yes No
 Able to take oral medication: Yes No
No active gastrointestinal GVHD: Yes No
No symptom of CMV disease: Yes No

Signature of requesting physician:(Day) /(Mo) / (Year)

BHS committee decision

- Request accepted: 1 box of Valcyte (450 mg, 60 tablets)

Attributed patient code

- Request not accepted – reason (optional):

Date: ____/____/____ Name: _____ Signature: _____

In order to receive samples of Valcyte, the requesting physician must fax :

- Copy of the request form approved by the BHS decision committee
- A signed and stamped prescription for 1 box of Valcyte, mentioning the patient code (max. 8 boxes / physician / year).

Roche : Fax 02/558.93.54

**We thank you for allowing some time for handling your request:
 5 working days for the BHS & 3 working days for Roche**

DISCLAIMER

Roche and/or the members of the Decision Committee shall not be liable towards physicians and their patients for not allowing patients into this Valcyte off label sampling program.

Roche and/or the Decision Committee Members shall be under no obligation to include the applicants into the program. Decisions are taken on strict and scientifically inclusion criteria and quotas are used.

The treating physician must inform the patient on the advantages and the disadvantages of the off label use as well as of the risks of off label use. The physician must also inform the patient that allowance to the program is not guaranteed. The physician must obtain the informed consent of the patient for off label use.

Roche and/or the members of the Decision Committee shall not be liable towards the physicians and patients for any adverse or unwanted effect caused by the off label use of Valcyte in the treatment plan of the patients. The start of a patient in an off label use program is done on the own personal liability of the treating physician.

Inclusion criteria (all criteria must be met) :

- Allogeneic stem cell transplantation
or
Treatment with Alemtuzumab
- Age \geq 16 yrs
- 2nd or later episode of asymptomatic CMV reactivation (patient had \geq 1 documented previous episode of CMV reactivation)
- 2 consecutive positive CMV viral loads within 1 week $>$ 1000 copies/ml
- **No** symptom of CMV disease:
- Patient not hospitalized
- ANC $>$ 500/ μ l (0.5 x 10⁹/L)
- Able to take oral medication
- No active gastrointestinal GVHD

Procedure :

- The requesting physician fills out the "Valcyte Medical Supply" form with all the needed information.
- The request form is sent to the BHS decision committee by E-mail or by fax.
- Only requests for patients who meet the inclusion criteria mentioned in the form will be considered for approval.
- The requests will be reviewed within 5 working days and should be approved by at least 2 members of the BHS decision committee. Members of the BHS decision committee cannot approve their own requests. In case of no response within 5 working days, the coordinator may take the final decision alone.
- Once the BHS decision committee has approved the request, the requesting physician will be notified by fax (tick box on the request form). A patient code will be attributed.
- The requesting physician will then fax to Roche :
 - The request form approved by the BHS decision committee.
 - A signed and stamped prescription for 1 box of Valcyte, mentioning the patient code.
- Roche will send the samples to the pharmacist of the hospital.

Only 1 box of Valcyte will be sent for any patient with an episode of CMV reactivation, covering 2 weeks at full adult dose (900 mg bid) or 4 weeks at half-dose (450 mg bid). It is up to the physician to decide on when and how to use Valcyte in sequence or in combination with ganciclovir.

Another request can be sent for the same patient if he/she presents a later episode of CMV reactivation at least 2 months after the first one for which he/she received Valcyte through this program.