### Valcyte

**Description**

Valcyte (valganciclovir)

**Background**

Valcyte (valganciclovir) is an orally administered antiviral prodrug with no antiviral activity until converted in the body to ganciclovir. Ganciclovir is used in the treatment of Cytomegalovirus (CMV) by interfering with DNA synthesis (1).

**Regulatory Status**

FDA-approved indications: Valcyte is a deoxynucleoside analogue cytomegalovirus (CMV) DNA polymerase inhibitor indicated for: (1)

- **Adult Patients**
  2. 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**
  1. Prevention of CMV Disease in kidney transplant patients (4 months to 16 years of age) and heart transplant patients (1 month to 16 years of age) at high risk.

**Off-label indications:** (2-3).

- Treatment of cytomegalovirus (CMV) disease in symptomatic patients
- Prevention of CMV infection in post-hematopoietic stem cell transplant (HSCT)
• Prevention of CMV infection in post solid organ transplant (including liver or lung)

Adult patients should use Valcyte tablets, not Valcyte for oral solution. Both the tablets and solution are indicated in pediatric patients (1).

Cytomegalovirus (CMV) infections are among the most common infections that occur following solid organ transplantation. Organ transplant recipients at highest risk of CMV infection are those who are seronegative before transplantation and receive an organ from a seropositive donor (a combination commonly referred to as donor-positive/recipient-negative [D+/R-]); in these patients, latent CMV can be transmitted with the organ and subsequently reactivate, causing de novo or primary infection. The incidence of CMV disease in D+/R- transplantations is <5% (4).

Valcyte has a boxed warning of hematologic toxicity, carcinogenicity, teratogenicity, and impairment of fertility. Clinical toxicity of Valcyte includes leukopenia, neutropenia, anemia, thrombocytopenia, pancytopenia and bone marrow failure including aplastic anemia (1).

Valcyte should be avoided if the absolute neutrophil count is <500 cells/µL, the platelet count is <25,000/µL, or the hemoglobin is <8 g/dL (1).

Use with caution in patients with pre-existing cytopenias, or who have received or who are receiving myelosuppressive drugs or irradiation. Cytopenia may occur at any time during treatment and may worsen with continued dosing. Cell counts usually begin to recover within 3 to 7 days after discontinuing drug (1).

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 (1).

Acute renal failure may occur in elderly patients with or without reduced renal function, patients receiving concomitant nephrotoxic drugs, or patients without adequate hydration. Monitor CBC with differential, platelets, ophthalmic, and renal function. Patients must maintain adequate hydration (1).

*Look alike / sound alike precaution:* Valtrex (valacyclovir).

**Related policies**

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*
Valcyte may be considered medically necessary for the treatment of Cytomegalovirus (CMV) disease in symptomatic patients, or for the prevention of CMV disease in patients who are post solid organ transplant (including heart, liver, lung, kidney, or kidney-pancreas), or post hematopoietic cell transplant (HCT); and if the conditions indicated below are met.

Valcyte is considered investigational for all other indications.

**Prior-Approval Requirements**

*Patients with an HIV diagnosis (one or more anti-retroviral claims in the last 12 months) are exempt from this PA requirement.*

**Diagnoses**

Patient must have ONE of the following:

1. *Treatment* of Cytomegalovirus (CMV) disease in symptomatic patients

2. *Prevention* (either prophylaxis or preemptive therapy) of CMV disease in patients who are:

   **AND ONE** of the following:
   a. Post solid organ transplant (including heart, liver, lung, kidney, or kidney-pancreas)
   b. Post hematopoietic stem cell transplant (HSCT)

   **AND NOT** the following:
   a. CMV sero-negative recipient of solid organ transplant from a CMV sero-negative donor (R-/D-)

   **AND ALL** of the following for BOTH diagnoses:
   1. Absolute neutrophil count (ANC) > 500 cells/μL
   2. Platelet count > 25,000/μL
   3. Hemoglobin > 8 g/dL

**Prior – Approval Renewal Requirements**

**Diagnoses**

Patient must have ONE of the following:

1. *Treatment* of Cytomegalovirus (CMV) disease in symptomatic patients
2. **Prevention** (either prophylaxis or preemptive therapy) of CMV disease in patients who are:

   **AND ONE** of the following:
   a. Post solid organ transplant (including heart, liver, lung, kidney, or kidney-pancreas)
   b. Post hematopoietic stem cell transplant (HSCT)

   **AND ALL** of the following for **BOTH** diagnoses:
   1. Absolute neutrophil count (ANC) > 500 cells/µL
   2. Platelet count > 25,000/µL
   3. Hemoglobin > 8 g/dL

### Policy Guidelines

#### Pre - PA Allowance
None

#### Prior - Approval Limits
Duration 12 months

#### Prior – Approval **Renewal** Limits
Same as above

### Rationale

**Summary**
Valcyte (valganciclovir) is an orally administered antiviral prodrug with no antiviral activity until converted in the body to ganciclovir. Valcyte is used for the treatment of Cytomegalovirus (CMV) disease in symptomatic patients, or for the prevention of CMV disease in patients who are post solid organ transplant (including heart, liver, lung, kidney, or kidney-pancreas), or post hematopoietic cell transplant (HCT) (1-3).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Valcyte while maintaining optimal therapeutic outcomes.

### References
2. Personal Communication, Gerald Medoff, MD, Infectious Diseases, Washington University Hospital, March 1, 2012, for treatment of symptomatic CMV infection, and off-label use post-transplant by recipients of lung and liver transplants.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>New Addition</td>
<td>Off-label: Added lung and liver to post solid organ transplant</td>
</tr>
<tr>
<td>March 2013</td>
<td>Annual editorial review</td>
<td></td>
</tr>
<tr>
<td>June 2014</td>
<td>Annual editorial review</td>
<td></td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update</td>
<td>Policy code changed from 5.03.22 to 5.01.22</td>
</tr>
<tr>
<td>December 2017</td>
<td>Annual editorial review and reference update</td>
<td>Addition of the labs in the renewal section</td>
</tr>
<tr>
<td>March 2018</td>
<td>Annual review</td>
<td></td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review and reference update</td>
<td></td>
</tr>
</tbody>
</table>

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.