Original Effective Date: 10/01/2012
Current Effective Date: 03/27/2026
Last P&T Approval/Version: 01/28/2026
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Policy Number: C4960-A

Valcyte (valganciclovir)

PRODUCTS AFFECTED

Valcyte (valganciclovir), valganciclovir

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS), Prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk, Prevention of CMV disease in kidney and heart transplant patients at high risk, Prevention of CMV disease in other solid organ transplant, Cytomegalovirus disease (mild to moderate), CMV esophagitis or colitis treatment in patients with HIV, CMV, preemptive therapy (hematopoietic cell transplant recipients), CMV treatment (solid organ transplant recipients)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight,

body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CYTOMEGALOVIRUS (CMV) PROPHYLAXIS IN SOLID ORGAN TRANSPLANT:
1. a) Documentation member has a history within 200 days of a kidney, heart, or kidney-pancreas transplant
AND
b) Documentation organ donor or recipient is cytomegalovirus (CMV) seropositive
OR
2. a) Documentation member has a history of liver or lung transplant
AND
b) Documentation organ donor or recipient is cytomegalovirus (CMV) seropositive

B. CYTOMEGALOVIRUS (CMV) RETINITIS/ESOPHAGITIS/COLITIS:
1. Documented diagnosis of cytomegalovirus (CMV) retinitis, esophagitis, or colitis
AND
2. Documentation member has HIV and is concurrently on antiretroviral therapy (ART)

C. CYTOMEGALOVIRUS (CMV) PREEMPTIVE THERAPY- POST HEMATOPOIETIC STEM CELL TRANSPLANT:
1. Documentation of date member is scheduled for hematopoietic stem cell transplant (HSCT) (must be within the next 90 days from request)

D. CYTOMEGALOVIRUS (CMV) DISEASE TREATMENT:
1. (a) Documented diagnosis of primary cytomegalovirus (CMV) infection
AND
(b) Member is immunocompromised with severe manifestations of CMV infection (i.e., protracted CMV mononucleosis or other organ-specific complications)
OR
2. Documented diagnosis of symptomatic congenital CMV infection in an infant

CONTINUATION OF THERAPY:

A. CYTOMEGALOVIRUS (CMV) RETINITIS/ESOPHAGITIS/COLITIS:
1. Adherent to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Adherent to antiretroviral therapy (ART) as evidenced by pharmacy claims history
AND
3. Documentation of ONE of the following:
a) CD4 count is < 100 cells/mm3 (within the last 3 months)
OR
b) Continuation of therapy is recommended and rationale for continued medical necessity is provided
AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

B. CMV PROPHYLAXIS POST SOLID ORGAN TRANSPLANT OR POST HEMATOPOIETIC STEM CELL TRANSPLANT:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Request for continuation of treatment aligns with a duration of therapy that is supported by FDA label, treatment guidelines, or compendia supported OR Documentation that continuation of therapy is recommended and rational for continued medical necessity is provided

C. CYTOMEGALOVIRUS (CMV) DISEASE TREATMENT:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of persistent viremia and symptoms that require continued treatment

DURATION OF APPROVAL:
Initial authorization:
Kidney (donor positive, recipient negative): 6 months, recipient positive: 3 months
Pancreas AND kidney/pancreas: (donor positive, recipient negative): 3-6 months, recipient positive: 3 months
Heart OR Liver (FDA caution): (donor positive, recipient negative): 3-6 months, recipient positive: 3 months
Lung or Heart/Lung: (donor positive, recipient negative): 6-12 months, recipient positive: 6-12 months
Intestinal OR Composite Tissue Allograft: (donor positive, recipient negative): 6 months, recipient positive:3 months
Treatment of CMV retinitis/esophagitis/colitis: 6 months
Hematopoietic stem cell transplant: up to Day 100 after HCT
CMV disease treatment: 6 months

Continuation of Therapy:
CMV prophylaxis post solid organ transplant or post hematopoietic stem cell transplant: up to 12 months total after transplant
Treatment of CMV retinitis/esophagitis/colitis:12 months
CMV disease treatment: 6 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
Prevention of CMV in kidney transplant: 4 months of age and older
Prevention of CMV in heart transplant and CMV associated gastrointestinal disease: 1 month of

age and older
Congenital CMV infection: neonate up to 1 year of age
CMV disease treatment: 1 year of age and older

QUANTITY:
Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
CMV Agents

FDA-APPROVED USES:
VALCYTE is indicated for:
Adult Patients
• Treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS).
• Prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk.
Pediatric Patients
• Prevention of CMV disease in kidney and heart transplant patients at high risk

COMPENDIAL APPROVED OFF-LABELED USES:
Cytomegalovirus disease (mild to moderate), CMV esophagitis or colitis treatment in patients with HIV, CMV preemptive therapy (hematopoietic cell transplant recipients), CMV treatment (solid organ transplant recipients), treatment of congenital cytomegalovirus (CMV) in an infant who is symptomatic, prevention of CMV infection in post-hematopoietic stem cell transplant (HSCT), CMV prophylaxis after lung or liver transplant, Castleman Disease (NCCN Castleman Disease Relapsed/Refractory or Progressive Disease CD-6)

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Based on the 2009 Solid Organ Transplant Guidelines for CMV prophylaxis and the 2010 International guidelines, 3 to 6 months of prophylaxis therapy is recommended for donor+/recipient- heart transplant recipients and kidney/pancreas recipients. Three months of prophylactic therapy is recommended for recipient+ heart transplant recipients.
Based on the results of the IMPACT study, Valcyte prophylaxis for 200 days in kidney transplant patients resulted in a reduction in CMV disease. At 2 years post-transplant, CMV disease occurred in significantly less patients in the 200- vs. the 100-day group:21.3% vs. 38.7%,

respectively (P<0.001).

Although Valcyte is not FDA approved for the prevention of CMV disease in liver transplant patients, consensus treatment guidelines support the use of Valcyte in this transplant type.

Data supporting the use of Valcyte for lung transplant patients come from Finlen et al, who concluded that 12 months of Valcyte prophylaxis compared with 3 months provided a protective benefit with a CMV incidence of 12% vs 55% respectively (HR 0.13, CI: 0.03-0.61, p = 0.009). In another randomized clinical trial by Palmer et al, extending the duration of Valcyte prophylaxis from 3 months to 12 months decreased the incidence of CMV disease from 64% to 10% (p < 0.001).

The prescribing information contains a boxed warning regarding potential hematologic toxicity, impairment of fertility, fetal toxicity, mutagenesis, and carcinogenesis.

Per CDC guidelines for the treatment of CMV retinitis, Valcyte may be used in combination with ganciclovir intraocular implant for patients with immediate sight threatening lesions (adjacent to the optic nerve or fovea). The safety and efficacy of Valcyte for oral solution and tablets have not been established in children for prevention of CMV disease in pediatric liver transplant patients, in kidney transplant patients less than 4 months of age, in heart transplant patients less than 1 month of age, in pediatric AIDS patients with CMV retinitis, and in infants with congenital CMV infection. In 2010, the FDA added an upper limit to pediatric dosing calculation to prevent Valcyte overdosing in children with low body weight, surface area and below normal serum creatinine.

2019 Cytomegalovirus in solid organ transplant recipients – Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice

TABLE 4 Recommendations for cytomegalovirus prevention in solid organ transplant recipients

Organ	Risk category	Recommendation/Options (see Table 3 for dose and text for special pediatric issues)	Level of evidence
Kidney	D+/R−	Antiviral prophylaxis Drugs: valganciclovir (preferred), intravenous ganciclovir, or valacyclovir Duration: 6 mo	Strong, high
		Preemptive therapy (if logistic support is available) Weekly CMV QNAT (or pp65 antigenemia) for 12 wk after kidney transplantation, and if a positive CMV threshold is reached, treat with (a) valganciclovir 900 mg[b] p.o. BID (preferred), or (b) IV ganciclovir 5 mg/kg IV every 12 h until negative test	Strong, high
	R+	Antiviral prophylaxis Drugs: valganciclovir (preferred), intravenous ganciclovir, or valacyclovir Duration: 3 mo	Strong, high
		Preemptive therapy (if logistic support is available) Weekly CMV QNAT (or pp65 antigenemia) for 12 wk after kidney transplantation, and if a positive CMV threshold is reached, treat with (a) valganciclovir 900 mg[b] po BID (preferred), or (b) IV ganciclovir 5 mg/kg IV every 12 h until negative test	Strong, high
Pancreas and kidney/ pancreas	D+/R−	Antiviral prophylaxis is preferred Drugs: valganciclovir (preferred) or intravenous ganciclovir Duration: 3-6 mo	Strong, high (3-month prophylaxis) Strong, moderate (6-month prophylaxis)
		Preemptive therapy is an option (if logistic support is available) Weekly CMV QNAT (or pp65 antigenemia) for 12 wk after pancreas alone or kidney-pancreas transplantation, and if a positive CMV threshold is reached, treat with (a) valganciclovir 900 mg[b] po BID (preferred), or (b) IV ganciclovir 5 mg/kg IV every 12 h until negative test	Strong, moderate
	R+	Antiviral prophylaxis Drugs: valganciclovir (preferred) or intravenous ganciclovir Duration: 3 mo	Strong, moderate
		Preemptive therapy (if logistic support is available). Weekly CMV QNAT (or pp65 antigenemia) for 12 wk after pancreas alone or kidney-pancreas transplantation, and if a positive CMV threshold is reached, treat with (a) valganciclovir 900 mg[b] po BID (preferred), or (b) IV ganciclovir 5 mg/kg IV every 12 h until negative test	Strong, moderate
Liver	D+/R−	Antiviral prophylaxis Drugs: valganciclovir (note FDA caution[a]) or intravenous ganciclovir Duration: 3-6 mo	Strong, high (3-month prophylaxis) Strong, moderate (6-month prophylaxis)
		Preemptive therapy (if logistic support is available) Weekly CMV QNAT (or pp65 antigenemia) for 12 wk after liver transplantation, and if a positive CMV threshold is reached, treat with (a) valganciclovir 900 mg[b] po BID (preferred), or (b) IV ganciclovir 5 mg/kg IV every 12 h until negative test	Strong, high
	R+	Antiviral prophylaxis Drugs: valganciclovir (note FDA caution[a]) or intravenous ganciclovir Duration: 3 mo	Strong, high
		Preemptive therapy (if logistic support is available) Weekly CMV QNAT (or pp65 antigenemia) for 12 wk after liver transplantation, and if a positive CMV threshold is reached, treat with (a) valganciclovir 900 mg[b] po BID (preferred), or (b) IV ganciclovir 5 mg/kg IV every 12 h until negative test	Strong, high

TABLE 4 (Continued)

Organ	Risk category	Recommendation/Options (see Table 3 for dose and text for special pediatric issues)	Level of evidence
Heart	D+/R−	Antiviral prophylaxis is preferred. Drugs: valganciclovir (preferred), or intravenous ganciclovir. Some centers add adjunctive CMV immune globulin. Duration: 3-6 mo	Strong, high (3-month prophylaxis) Strong, moderate (6-month prophylaxis) Weak, low (immune globulin)
		Preemptive therapy is an option (if logistic support is available), but not preferred. Weekly CMV QNAT (or pp65 antigenemia) for 12 wk after heart transplantation, and if a positive CMV threshold is reached, treat with (a) valganciclovir 900 mg[b] po BID (preferred), or (b) IV ganciclovir 5 mg/kg IV every 12 h until negative test	Weak, low
	R+	Antiviral prophylaxis Drugs: valganciclovir (preferred) or intravenous ganciclovir. Some centers add adjunctive CMV immune globulin. Duration: 3 mo	Strong, moderate Weak, low (immune globulin)
		Preemptive therapy Weekly CMV QNAT (or pp65 antigenemia) for 12 wk after heart transplantation, and if a positive CMV threshold is reached, treat with (a) valganciclovir 900 mg[b] po BID (preferred), or (b) IV ganciclovir 5 mg/kg IV every 12 h until negative test	Strong, moderate
Lung, heart-lung	D+/R−	Antiviral prophylaxis Drugs: valganciclovir or intravenous ganciclovir Duration: at least 6-12 mo. Some centers prolong prophylaxis beyond 12 mo. Some centers add CMV immune globulin.	Strong, high (12-month prophylaxis) Strong, low (6-month prophylaxis) Weak, low (>12 mo prophylaxis) Weak, low (immune globulin)
	R+	Antiviral prophylaxis Drugs: valganciclovir or intravenous ganciclovir Duration: 6-12 mo.	Strong, moderate
Intestinal	D+/R−, R+	Antiviral prophylaxis Drugs: valganciclovir or intravenous ganciclovir Duration: 3 mo for CMV R+; 6 mo for D+/R−.	Strong, low
Composite tissue allograft	D+/R−, R+	Antiviral prophylaxis Drugs: valganciclovir or intravenous ganciclovir Duration: 3 mo for CMV R+; 6 mo for D+/R−.	Strong, low

The above recommendations do not represent an exclusive course of action. Several factors influence the precise nature and duration of antiviral prophylaxis or preemptive therapy. Antiviral prophylaxis should be started within 10 d after transplantation (strong, high). Oral ganciclovir is no longer commercially available. Preemptive therapy is NOT recommended for lung and heart-lung recipients (strong, low). Preemptive therapy is less preferred for intestinal and composite tissue allograft transplantation (weak, low).

[a]The US FDA has cautioned against valganciclovir prophylaxis in liver recipients due to high rate of tissue-invasive disease compared to oral ganciclovir. However, many experts still recommend its use as prophylaxis in liver recipients (strong, moderate). CMV D−/R− SOT recipients do not require anti-CMV prophylaxis, but if they are HSV1- or HSV2-seropositive, they should receive anti-HSV prophylaxis during the early period after transplantation (strong, high; see separate HSV guidelines). If blood transfusion is required, CMV D−/R− patients should receive CMV-seronegative or leuko-reduced blood products (strong, high).

[b]Pediatric valganciclovir Dose is mg = 7 × BSA × Creatinine clearance.

Transplant guideline updates in 2025 do not materially change from previous.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Valcyte (valganciclovir) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Valcyte (valganciclovir) include: hypersensitivity to valganciclovir or ganciclovir, absolute neutrophil count is less than 500 cells/mm3, the platelet count is less than 25,000/mm3, or the hemoglobin is less than 8 g/dL, pregnancy including in females with male partners taking Valcyte.

OTHER SPECIAL CONSIDERATIONS:

Valcyte (valganciclovir) has a black box warning for hematologic toxicity, impairment of fertility, fetal

toxicity, mutagenesis, and carcinogenesis.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Valcyte SOLR 50MG/ML
Valcyte TABS 450MG
valGANciclovir HCl SOLR 50MG/ML
valGANciclovir HCl TABS 450MG

REFERENCES

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11. Kotton, C. N., Kumar, D., Manuel, O., Chou, S., Hayden, R. T., Danziger-Isakov, L., … Humar, A. (2025). The Fourth International Consensus Guidelines on the Management of Cytomegalovirus in Solid Organ Transplantation. Transplantation, 109(7), 1066–1110. https://doi.org/10.1097/tp.0000000000005374

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Age Restrictions References	Q1 2026
REVISION- Notable revisions: Diagnosis Required Medical Information Compendial Approved Off-Labeled Uses References	Q1 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Background References	Q1 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file