



MEDICATION POLICY

Generic Name: Valganciclovir

Therapeutic Class or Brand Name: Valcyte®

Applicable Drugs (if Therapeutic Class):

Preferred: Valganciclovir tablets (generic), Valganciclovir oral solution (generic)

Non-Preferred: Valcyte® tablets, Valcyte® oral solution

Date of Origin: 2/1/13

Date Last Reviewed/Revised: 10/9/16

GPI Code: 1220006610

Prior Authorization Criteria (may be considered medically necessary when criteria I through II are met):

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
 - A. Cytomegalovirus (CMV) retinitis treatment in patients with acquired immunodeficiency syndrome (AIDS) and criterion 1 is met:
 1. Minimum age requirement: 18 years old.
 - B. CMV disease prevention in high risk patients for one of the following solid organ transplants listed in 1 through 3:
 1. Heart transplant AND criterion a is met:
 - a. Minimum age requirement: 1 month old.
 2. Kidney transplant AND criterion a is met:
 - a. Minimum age requirement: 4 months old.
 3. Kidney-pancreas transplant AND criterion a is met:
 - a. Minimum age requirement: 17 years old.
- II. Non-preferred products (i.e. Valcyte® tablets, Valcyte® oral solution) require a documented clinical reason containing details as to why generic valganciclovir is not appropriate or is contraindicated.

Exclusion Criteria:

- Treatment of congenital CMV disease.

Other Criteria:

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- N/A

Quantity/Days Supply Restrictions:

- Doses are limited to 900 mg per day. The quantity is limited to a maximum of a 30 day supply per fill.
 - Exception: 900 mg twice a day may be authorized for the first 21 days of CMV retinitis treatment one time only, followed by 900 mg per day thereafter.

Approval Length:

- **Authorization:**
 - CMV retinitis treatment: 1 year. Induction therapy (BID dosing) for the first 21 days followed by maintenance therapy (QD dosing).
 - CMV disease prevention for:
 - Heart transplant: 100 days.
 - Kidney transplant: 200 days.
 - Kidney-pancreas transplant: 100 days.
- **Re-Authorization:**
 - CMV retinitis treatment: Provider must submit an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.
 - CMV disease prevention: N/A

Appendix:

N/A

References:

1. https://www.healthnet.com/static/general/unprotected/html/national/pa_guidelines/valcyte_natl.html.
2. http://www.fchp.org/providers/pharmacy/~media/Files/FCHP/Imported/Valcyte_valganciclovir.pdf.ashx.
3. Medi-Span.
4. http://www.gene.com/download/pdf/valcyte_prescribing.pdf.

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Historical Tracking Of Changes Made To Policy	
10/9/2016	<ol style="list-style-type: none"> 1. Changed “N/A” to “Preferred: Valganciclovir tablets (generic), Valganciclovir oral solution (generic); Non-Preferred: Valcyte® tablets, Valcyte® oral solution” following Applicable Drugs. 2. Added “II. Non-preferred products (i.e. Valcyte® tablets, Valcyte® oral solution) require a documented clinical reason containing details as to why generic valganciclovir is not appropriate or is contraindicated” under Prior Authorization Criteria.
5/26/2015	<ol style="list-style-type: none"> 1. Changed “Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis: A. Cytomegalovirus (CMV) retinitis treatment...; B. CMV disease prevention in kidney, heart, or kidney-pancreas transplant patients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]) and criterion 1 is met: 1. Minimum age requirement: 17 years old; C. CMV disease prevention in kidney or heart transplant patients at high risk and criterion 1 is met: 1. Age requirement: 4 months to 16 years old” to “Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. Cytomegalovirus (CMV) retinitis treatment...; B. CMV disease prevention in high risk patients for one of the following solid organ transplants listed in 1 through 3: 1. Heart transplant AND criterion a is met: a. Minimum age requirement: 1 month old; 2. Kidney transplant AND criterion a is met: a. Minimum age requirement: 4 months old; 3. Kidney-pancreas transplant AND criterion a is met: a. Minimum age requirement: 17 years old” under Prior Authorization Criteria. 2. Removed “Liver transplant patients” and “Prevention of CMV disease in solid organ transplants other than those indicated” from Exclusion Criteria. 3. Changed “Quantities of up to 60 tablets per 30 days (the quantity is limited to a maximum of a 30 day supply per fill). Exception: 102 tablets will be authorized for the first 30 days of CMV retinitis treatment one time only, followed by 60 tablets per 30 days thereafter” to “Doses are limited to 900 mg per day. The quantity is limited to a maximum of a 30 day supply per fill. Exception: 900 mg twice a day may be authorized for the first 21 days of CMV retinitis treatment one time only, followed by 900 mg per day thereafter” under Quantity/Days Supply Restrictions. 4. Changed “CMV disease prevention: Heart or kidney-pancreas transplant (over 16 years old): 100 days; Kidney transplant (over 16 years old): 200 days; Kidney or heart transplant (4 months to 16 years old): 100 days” to “CMV disease prevention for: Heart transplant: 100 days; Kidney transplant: 200 days; Kidney-pancreas transplant: 100 days” for Authorization under Approval Length. 5. Updated “http://www.fchp.org/providers/pharmacy/~media/Files/FCHP/Imported/Valcyte_valganciclovir_M.pdf.ashx” to “http://www.fchp.org/providers/pharmacy/~media/Files/FCHP/Imported/Valcyte_valganciclovir.pdf.ashx” under References.
1/20/2014	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI Code. 3. Changed Prior Authorization Criteria from: “Documented diagnosis of one of the Covered Uses listed below: Cytomegalovirus (CMV) retinitis treatment in patients with acquired immunodeficiency syndrome (AIDS); CMV disease prophylaxis in solid organ transplant patients at high risk (Donor CMV seropositive/ Recipient CMV seronegative [D+/R-]); Minimum age requirement: 4 months” to: “Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis: A. Cytomegalovirus (CMV) retinitis treatment in patients with acquired immunodeficiency syndrome (AIDS) and criterion 1 is met: 1. Minimum age requirement: 18 years old; B. CMV disease prevention in kidney, heart, or kidney-pancreas transplant patients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]) and criterion 1 is met: 1. Minimum age

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	<p>requirement: 17 years old; C. CMV disease prevention in kidney or heart transplant patients at high risk and criterion 1 is met: 1. Age requirement: 4 months to 16 years old”.</p> <ol style="list-style-type: none">4. Added “Liver transplant patients; Prevention of CMV disease in solid organ transplants other than those indicated; Treatment of congenital CMV disease” to Exclusion Criteria.5. Changed Quantity/Days Supply Restrictions from “The quantity is limited to a maximum of a 30 day supply per fill; For the first 30 days of CMV retinitis treatment (21 days of BID dosing, followed by QD dosing): 102 tablets one time only; For Maintenance therapy and Disease prophylaxis: 60 tablets per 30 days” to “Quantities of up to 60 tablets per 30 days (the quantity is limited to a maximum of a 30 day supply per fill); Exception: 102 tablets will be authorized for the first 30 days of CMV retinitis treatment one time only, followed by 60 tablets per 30 days thereafter.”.6. Changed Authorization under Approval Length from “Treatment: 1 year. Induction therapy (BID dosing) for the first 21 days followed by Maintenance therapy (QD dosing); Prophylaxis: Lung and liver transplant: 1 year, Heart, kidney, and kidney-pancreas transplant (over 16 years old): 200 days, Kidney and heart transplant (4 months to 16 years old): 100 days” to “CMV retinitis treatment: 1 year. Induction therapy (BID dosing) for the first 21 days followed by maintenance therapy (QD dosing); CMV disease prevention: Heart or kidney-pancreas transplant (over 16 years old): 100 days, Kidney transplant (over 16 years old): 200 days, Kidney or heart transplant (4 months to 16 years old): 100 days”.7. Changed Re-Authorization under Approval Length from “Treatment: Provider must submit an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective; Prophylaxis: N/A” to “CMV retinitis treatment: Provider must submit an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective; CMV disease prevention: N/A”.8. Updated references to include Medi-Span.
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