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:** 1/4/18

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:

- 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.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
1/4/2018	1. Policy reviewed: no changes made.
10/9/2016	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	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" f**or 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	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

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
	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". 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.