Reference number(s)
3100-A

SUPPLEMENTAL SPECIALTY PA

VALCYTE (valganciclovir hydrochloride)
valganciclovir hydrochloride

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Valcyte is indicated for the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS)
2. Valcyte is indicated for the prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk (donor CMV seropositive/recipient CMV seronegative [D+/R-]).
3. Valcyte is indicated for the 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.

B. Compendial Uses
1. Prevention of CMV infection in adult and pediatric patients post solid organ transplant or post hematopoietic stem cell transplant (HSCT)
2. Treatment of CMV infection in solid organ transplant recipients
3. Symptomatic congenital cytomegalovirus infection
4. Treatment of CMV gastrointestinal disease in human immunodeficiency virus (HIV) infection
5. Multicentric Castleman's disease, human herpesvirus-8 positive

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Treatment of CMV infection in HIV-infected patients
1. Authorization of 12 months may be granted for induction or maintenance treatment of CMV retinitis in HIV-infected members.
2. Authorization of 12 months may be granted for treatment of CMV gastrointestinal (GI) disease (e.g., colitis, esophagitis) in HIV-infected members.

B. Prevention of CMV infection in transplant recipients
Authorization of 12 months may be granted for prevention (either prophylaxis or preemptive treatment) of CMV infection when the member is post solid organ transplant or post hematopoietic stem cell transplant (HSCT).

C. Treatment of CMV infection in solid organ transplant recipients
Authorization of 12 months may be granted for treatment of mild to moderate CMV infection when the member is post solid organ transplant.

D. Symptomatic congenital CMV infection
Authorization of 12 months total may be granted for treatment of symptomatic congenital CMV infection.

E. Multicentric Castleman's disease (CD)
Authorization of 12 months may be granted for treatment of multicentric CD in members who are human herpesvirus-8 positive.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when either of the following criteria is met:

A. For symptomatic congenital CMV infection: The member meets all initial authorization criteria in Section II and has received less than 12 months of therapy.
B. For all other indications: The member meets all initial authorization criteria in Section II.

IV. REFERENCES

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2. Paya C, Humar A, Dominguez E, et al. Efficacy and safety of valganciclovir vs. oral ganciclovir for prevention of cytomegalovirus disease in solid organ transplant recipients. *Am J of Transplantation*. 2004;611-620.
3. Bilavsky E, Shahar-Nissan K, Pardo J, et al. Hearing outcome of infants with congenital cytomegalovirus and hearing impairment. *Arch Dis Child*. 2016 May;101(5):433-8.
4. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/09/2021).
5. Kimberlin DW, Jester PM, Sanchez PJ, et al. Valganciclovir for symptomatic congenital cytomegalovirus disease. *N Engl J Med.* 2015 Mar 5;372(10):933-43.
6. Lexi-Comp (electronic version). Wolters Kluwer Clinical Information, Hudson, Ohio. Available at: https://online.lexi.com (cited: 11/09/2021).
7. Kotton CN, Kumar D, Caliendo AM, et al. The Third International Consensus guidelines on the management of cytomegalovirus in solid-organ transplantation. *Transplantation*. 2018;102(6):900-931.
8. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 9, 2021.
9. Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Adult_OI.pdf. Accessed November 9, 2021.
10. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. URL: https://www.clinicalkey.com/pharmacology/. Accessed November 9, 2021.