Reference number(s)
3100-A

Supplemental Specialty Prior Authorization

valganciclovir-Valcyte

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Valcyte	valganciclovir

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.

FDA-approved Indications[1-3]

- Treatment of cytomegalovirus (CMV) retinitis in adult patients with acquired immunodeficiency syndrome (AIDS)
- Prevention of CMV disease in kidney, heart, and kidney-pancreas transplant adult patients at high risk (donor CMV seropositive/recipient CMV seronegative [D+/R-])
- 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

Compendial Uses[4-13]

- Prevention of CMV infection in post solid organ transplant or post hematopoietic stem cell transplant (HSCT)

- Treatment of CMV infection in solid organ transplant recipients
- Symptomatic congenital CMV infection
- Treatment of CMV gastrointestinal disease and pneumonitis in human immunodeficiency virus (HIV) infection
- Multicentric Castleman disease, human herpesvirus-8 positive

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

Coverage Criteria

Treatment of CMV Infection in HIV-Infected Patients

- Authorization of 12 months may be granted for induction or maintenance treatment of CMV retinitis in HIV-infected members.[1-3]
- Authorization of 12 months may be granted for treatment of CMV gastrointestinal disease (e.g., colitis, esophagitis) and pneumonitis in HIV-infected members.[9,13]

Prevention of CMV Infection in Transplant Recipients[1-5,9]

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).

Treatment of CMV Infection in Solid Organ Transplant Recipients[5,9,10]

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

Symptomatic Congenital CMV Infection[6-8]

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

Multicentric Castleman Disease (MCD)[11-13]

Authorization of 12 months may be granted for treatment of MCD in members who are human herpesvirus-8-positive.

Continuation of Therapy

Symptomatic Congenital CMV Infection

Authorization of 12 months total may be granted for continued treatment in members requesting reauthorization for treatment of symptomatic congenital CMV infection when the member has received less than 12 months of therapy.

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications when the member meets all requirements for coverage in the coverage criteria.

References

1. Valcyte [package insert]. South San Francisco, CA: Genentech USA, Inc.; December 2021.
2. valganciclovir oral solution [package insert]. Memphis, TN: Northstar Rx LLC; January 2024.
3. valganciclovir tablet [package insert]. East Brunswick, NJ: Strides Pharma Inc.; January 2024.
4. Hakki M, Aitken SL, Danziger-Isakov L, et al. American Society for Transplantation and Cellular Therapy Series: #3-prevention of cytomegalovirus infection and disease after hematopoietic cell transplantation. Transplant Cell Ther. 2021;27(9):707-719. doi:10.1016/j.jtct.2021.05.001
5. Razonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients-Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13512.
6. 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.
7. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/11/2024).
8. 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.
9. Lexi-Comp (electronic version). Wolters Kluwer Clinical Information, Hudson, Ohio. Available at: https://online.lexi.com. Accessed November 11, 2024.
10. 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.
11. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 11, 2024.
12. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Castleman Disease. Available at: http://www.nccn.org. Version 1.2024.

13. Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV. National Institutes of Health, HIV Medicine Association, and Infectious Diseases Society of America. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection. Accessed November 11, 2024.