VISTIDE® (cidofovir) INJECTION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Vistide is an antiviral medication for the treatment of cytomegalovirus (CMV) retinitis in individuals with AIDS. Vistide has also been investigated for treatment of laryngeal and respiratory papillomatosis.

Criteria:

- Vistide is considered medically necessary for the treatment of cytomegalovirus (CMV) retinitis in individuals with AIDS.
VISTIDE (cidofovir) INJECTION (cont.)

Criteria: (cont.)

- Vistide for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, but are not limited to:

- Benign neoplasm of the larynx
- CMV infections other than CMV retinitis in individuals with AIDS
- CMV disease in non-HIV infected individuals
- Congenital cytomegalovirus infection
- Congenital or neonatal CMV disease
- Laryngeal polyps / papillomas
- Macroglobulinemia
- Waldenstroms macroglobulinemia

Resources:


VISTIDE (cidofovir) INJECTION (cont.)

Resources: (cont.)

FDA Product Approval Information for Vistide:


- FDA-approved dosage: The recommended induction dose for patients with a serum creatinine of less than or equal to 1.5 mg/dL, a calculated creatinine clearance greater than 55 mL/min, and a urine protein less than 100 mg/dL (equivalent to less than 2 + proteinuria) is 5 mg/kg body weight (given as an IV infusion at a constant rate over 1 hr) administered once weekly for two consecutive weeks *.

  The recommended maintenance dose is 5 mg/kg body weight (given as an IV infusion at a constant rate over 1 hr) administered once every two weeks.

* See the FDA-approved package insert for specific detail regarding creatinine clearance calculation.