DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Antivirals – Famciclovir Drug Quantity Management Policy – Per Rx
- Famciclovir tablets (generic only)

REVIEW DATE: 04/08/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Famciclovir is an orally administered prodrug of the anti-alpha herpes viral agent penciclovir.[1] It is indicated for:

- Immunocompetent Adults:
  - Treatment of recurrent **herpes labialis** (cold sores).
  - Treatment and chronic suppressive therapy of recurrent episodes of **genital herpes**.
  - Treatment of **herpes zoster**.
- Human Immunodeficiency Virus (HIV)-Infected Adults:
  - Treatment of recurrent episodes of **orolabial or genital herpes**.

Dosing/Availability

Famciclovir is available as 125 mg, 250 mg, and 500 mg tablets.[1] Recommended dosing is provided in Table 1. The maximum number of tablets needed per course

of treatment is 21 tablets, unless famciclovir is being used for the suppression of recurrent genital herpes; then, it may be used for up to 1 year.

Table 1. FDA-Approved Indications and Dosing.[1]

Indication	Normal Dose (CrCl ≥ 60 mL/min)	Renal Dosing Adjustments			
		CrCl 40 to 59 mL/min	CrCl 20 to 39 mL/min	CrCl < 20 mL/min	Hemodialysis
Immunocompetent Adults					
Recurrent herpes labialis (cold sores)	1,500 mg single dose	750 mg single dose	500 mg single dose	250 mg single dose	250 mg single dose following dialysis
Recurrent genital herpes	1 gram BID for 1 day	500 mg Q12H for 1 day	500 mg single dose	250 mg single dose	250 mg single dose following dialysis
Suppression of recurrent genital herpes	250 mg BID for up to 1 year	250 mg Q12H for up to 1 year	125 mg Q12H for up to 1 year	125 mg Q24H for up to 1 year	125 mg following each dialysis for up to 1 year
Herpes zoster (shingles)	500 mg Q8H for 7 days	500 mg Q12H for 7 days	500 mg Q24H for 7 days	250 mg Q24H for 7 days	250 mg following each dialysis for 7 days
HIV-Infected Adults					
Recurrent orolabial and genital herpes infection	500 mg BID for 7 days	500 mg Q12H for 7 days	500 mg Q24H for 7 days	250 mg Q24H for 7 days	250 mg following each dialysis for 7 days

CrCl – Creatinine clearance; BID – Twice daily; Q12H – Once every 12 hours; Q24H – Once every 24 hours; Q8H – Once every 8 hours; HIV – human immunodeficiency virus.

Off-Label Dosing

There are data and/or guidelines to support several off-label uses of famciclovir. Quantity limits for famciclovir provide for 21 tablets per dispensing at retail or 63 tablets per dispensing at home delivery for the 125 mg and 500 mg tablets. The quantity limits for the famciclovir 250 mg tablets provide for 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery. This provides a quantity sufficient for the majority of labeled and off-label doses. Below are situations where additional quantities of famciclovir may be needed.

- Herpes simplex virus (HSV): In adults and adolescents with HIV, famciclovir 500 mg BID is recommended for chronic suppression of HSV.[2] Valacyclovir 500 mg BID is also recommended for HSV prophylaxis in immunocompromised patients who have undergone solid organ transplant who are not already receiving CMV prophylaxis.[3] In this same population in patients with severe mucocutaneous HSV, after initial intravenous (IV) therapy, oral therapy can be used as oral lesions begin to regress (famciclovir 500 mg BID continued until lesions are completely healed).
- Herpes zoster (shingles): In adults and adolescents with HIV, guidelines recommend famciclovir 500 mg TID for 7 to 10 days (or longer if lesions are slow to resolve) for the treatment of acute, localized, dermatomal herpes zoster (shingles).[2]
- Varicella zoster virus (VZV) [chickenpox]: In adults and adolescents with HIV, guidelines recommend famciclovir TID for 5 to 7 days for the treatment of

uncomplicated cases of primary varicella infection (chickenpox).[2] For severe or complicated cases, patients are treated with IV therapy and are then transitioned to oral therapy with famciclovir 500 mg TID after defervescence if no evidence of visceral involvement is notes is noted.

- Viral ophthalmic infections: Famciclovir dosed TID is recommended for the treatment of viral ocular infections, including acute retinal necrosis, an ophthalmic reactivation of herpes zoster virus, following initial IV antiviral treatment.[2,4,5]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of famciclovir. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Famciclovir tablets (generic only)	125 mg tablets	21 tablets	63 tablets
	250 mg tablets	60 tablets	180 tablets
	500 mg tablets	21 tablets	63 tablets

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Famciclovir 125 mg tablets

1. If the patient meets BOTH of the following criteria (A and B), approve the requested quantity, not to exceed 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery:
   A) The medication is being requested for chronic suppression or prevention of recurrent genital herpes; AND
   B) Patient has reduced renal function.

2. If the medication is being requested for a viral ophthalmic infection, approve the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Famciclovir 250 mg tablets

1. If the medication is being requested for a viral ophthalmic infection, approve the requested quantity, not to exceed 90 tablets per dispensing at retail or a 270 tablets per dispensing at home delivery.

Famciclovir 500 mg tablets

1. If the medication is being requested for the chronic suppression or prevention of herpes simplex virus in an immunocompromised patient, approve the requested quantity, not to exceed 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.

2. If the medication is being requested for the treatment of herpes simplex virus in an immunocompromised patient, approve the requested quantity, not to exceed 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.

3. If the medication is being requested for a viral ophthalmic infection, approve the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

4. If the medication is being requested for the treatment of varicella zoster virus infection in an immunocompromised patient, approve the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

5. If the medication is being requested for the treatment of acute local dermatomal herpes zoster in an immunocompromised patient, approve the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

REFERENCES

1. Famciclovir tablets [prescribing information]. Parippany, NJ: Teva; November 2022.
2. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: 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. Updated February 25, 2026. Available at: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/whats-new. Accessed March 31, 2026.
3. Lee DH, Zuckerman RA, et al. Herpes simplex virus infections in solid organ transplantation: guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant.* 2019;33(9):e13526.
4. Powell B, Wang D, Llop S, et al. Management strategies of acute retinal necrosis: current perspectives. *Clin Ophthalmol*. 2020;14:1931-1943.
5. Schoenberger SD, Kim SJ, Thorne JE, et al. Diagnosis and treatment of acute retinal necrosis: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2017;124(3):382-392.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	• **Famciclovir 125 mg tablets:** Override criteria to approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery if the medication is being requested for an ophthalmic infection were updated to approve the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery, if the medication is being requested for a viral ophthalmic infection. • **Famciclovir 250 mg tablets:** Override criteria to approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery if the medication is being requested for an ophthalmic infection were updated to approve the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery, if the medication is being requested for a viral ophthalmic infection. • **Famciclovir 500 mg tablets:** Override criteria for patients requesting famciclovir for the chronic suppression or prevention or treatment of "Mucocutaneous herpes (genital, perianal, oral)" were clarified to chronic suppression or prevention of "herpes simplex virus". Override criteria to approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery if the medication is being requested for an ophthalmic infection were updated to approve the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery, if the medication is being requested for a viral ophthalmic infection.	04/19/2024
Annual Revision	No criteria changes.	04/03/2025
Annual Revision	No criteria changes.	04/08/2026