

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



POLICY	Viral Infections	P&T DATE	9/10/2024
THERAPEUTIC CLASS	Infectious Disease	REVIEW HISTORY (MONTH/YEAR)	9/23, 12/22, 12/21, 12/20, 12/19, 12/18, 5/17, 5/16
LOB AFFECTED	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ/MVHP Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://medi-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Antiviral medications are used to treat viral infections. Examples of infections include: influenza (flu), cytomegalovirus, herpes, cold sores, shingles, and HIV. The purpose of this coverage policy is to review the coverage criteria of Health Plan of San Joaquin/Mountain Valley Health Plan's (Health Plan) physician administered antiviral agents.

For updated information on COVID-19 medication coverage please access the following resources:

- Provider link: <https://www.hpsj.com/covid-19-provider-information/>
- Member link: <https://www.hpsj.com/covid-19-members-information/>

The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Table 1: Available Antivirals

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Influenza				
--	Amantadine	100 mg capsule	Yes	No
		68.5 mg ER capsule therapy pack		
		137 mg ER capsule therapy pack		
		100 mg tablet		
		129 mg 24 hour tablet		
		193 mg 24 hour tablet		
		258 mg 24 hour tablet		
		129 & 193 mg tablet therapy pack		
	50mg/5mL solution			
--	Rimantadine (Flumadine)	100 mg tablet	Yes	No
--	Oseltamivir (Tamiflu)	6mg/mL suspension	Yes	No
		30 mg capsule		
		45 mg capsule		
		75 mg capsule		
--	Zanamivir (Relenza)	5 mg diskhaler	Yes	No
J2547 INJECTION, PERAMIVIR, 1 MG	Peramivir (Rapivab)	200 mg/20 ml vial	No	Yes (PA for facility based)
--	Baloxavir marboxil (Xofluza)	20 mg tablet	Yes	No
		40 mg tablet		
Cytomegalovirus				
J0740 INJECTION, CIDOFOVIR, 375 MG	Cidofovir (Vistide)	75 mg/mL solution	Yes	Yes (auth not required)

J0850 INJECTION, CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN), PER VIAL	Cytomegalovirus immune globulin (Cytogam)	50 mg/mL injection solution	No	Yes (PA)
J1455 INJECTION, FOSCARNET SODIUM, PER 1,000 MG	Foscarnet (Foscavir)	6000 mg/250 mL injection solution	Yes	Yes (auth not required)
J1570 INJECTION, GANCICLOVIR SODIUM, 500 MG	Ganciclovir (Cytovene)	500 mg injection solution	Yes	Yes (PA)
		500 mg/250 mL injection solution		
		500 mg/10 mL injection solution		
J7310 GANCICLOVIR, 4.5 MG, LONG-ACTING IMPLANT	Ganciclovir (Vitrasert)	--	Discontinued	
--	Ganciclovir (Zirgan)	0.15% ophthalmic gel	Yes	No
J3490 UNCLASSIFIED DRUGS	Letermovir (Prevymis)	240 mg tablets	Yes	No
		480 mg tablets	Yes	Yes (PA)
		240 mg/12 ml injection solution		
		480 mg/24 ml injection solution		
--	Valganciclovir (Valcyte)	450 mg tablet	Yes	No
		50 mg/ml oral solution		
Herpes Simplex Virus, Herpetic Keratitis, Cold Sores, & Shingles				
J0133 INJECTION, ACYCLOVIR, 5 MG	Acyclovir (Zovirax)	5% ointment	Yes	No
		5% cream		
		200 mg capsule		
		400 mg tablet		
		800 mg tablet		
		200 mg/5 ml suspension		
		50 mg/mL vial	No	Yes (PA for facility based)
--	Famciclovir	125 mg tablet	Yes	No
		250 mg tablet		
		500 mg tablet		
--	Penciclovir (Denavir)	1% cream	Yes	No
--	Valacyclovir (Valtrex)	500 mg tablet	Yes	No
		1 gram tablet		
HIV/AIDS*				
S0137 DIDANOSINE (DDI), 25 MG	Didanosine (Videx EC)	DR 250 mg capsule	Yes	No
		DR 400 mg capsule		
S0104 ZIDOVUDINE, ORAL, 100 MG	Zidovudine (Retrovir)	100 mg capsule	Yes	No
J3485 INJECTION, ZIDOVUDINE, 10 MG		300 mg tablet		
		50 mg/5 ml syrup		
		10 mg/ml IV solution		
J1452 INJECTION, FOMIVIRSEN SODIUM, INTRAOCULAR, 1.65 MG	Fomiversen (Vitravene)	--	Discontinued	Discontinued
S0140 SAQUINAVIR, 200 MG	Saquinavir (Invirase)	200 mg capsule, 500 mg tablet	Discontinued	Discontinued
J0741 INJECTION, CABOTEGRAVIR AND RILPIVIRINE, 2 MG/3 MG	Cabotegravir/Rilpivirine (Cabenuva)	400 mg/600 mg per 2 mL (4 mL) 600 mg/900 mg per 3 mL (6 mL)	Yes	No
J0739 INJECTION, CABOTEGRAVIR 1 MG	Cabotegravir (Apretude, Vocabria)	600 mg/3mL IM suspension ER	Yes	No
		30 mg tablet	Yes	No
J1961 INJECTION, LENACAPAVIR 1 MG	Lenacapavir (Sunlenca)	300 mg tablet 463.5 mg per 1.5 mL	Yes	Yes (FFS)

PA = Prior Authorization

*HIV agents are carved out to Medi-Cal FFS

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the Health Plan Pharmacy & Therapeutics (P&T) Advisory

Committee. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on Medical Necessity criteria as described in Health Plan Medical Review Guidelines (UM06).

⊞ CLINICAL JUSTIFICATION

Health Plan's viral infections management policy is based on recommendations by the *Centers for Disease Control and Prevention (CDC)*, *Infectious Diseases Society of America (IDSA)*, and *Advisory Committee on Immunization Practices (ACIP)*. In general, viral infections can be effectively managed with oral therapies. According to the CDC 2015 Sexually Transmitted Diseases Treatment Guidelines and the IDSA 2007 Recommendations for the Management of Herpes Zoster, use of topical antiviral therapy is discouraged due to lack of efficacy.^{1,2} Valacyclovir hydrochloride (a prodrug of acyclovir) is rapidly converted to acyclovir in the body. Acyclovir, famciclovir, and valacyclovir are equally effective for episodic genital herpes. However, famciclovir appears less effective for suppression of viral shedding and acyclovir has the most evidence of safety and efficacy for suppression of recurrent genital herpes.¹ According to the ACIP 2011 Recommendations for Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza, amantadine and rimantadine should not be used due to high levels of resistance, while oseltamivir and zanamivir are recommended for the prevention and treatment of influenza. Oseltamivir is indicated for treatment of influenza for patients of all ages. Zanamivir is indicated for treatment of influenza for patients age 6 and older.³ Most recent recommendations from the CDC include the options of Baloxavir (newly approved treatment for acute, uncomplicated influenza) and Peramivir (infusion option for influenza treatment).⁷ A summary of the recommendations by the CDC for influenza treatment is available (Table 2). Valganciclovir is the current standard oral antiviral agent for treatment of cytomegalovirus (CMV) according to the Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents 2018 Guidelines.⁴

Table 2. Summary of Recommendations and Adverse Events of Each Influenza Treatment Agent per CDC⁷

	Oseltamivir	Zanamivir	Peramivir	Baloxavir
Acute, uncomplicated influenza	X	X	X	X
Severe, complicated, or progressive influenza illness who are not hospitalized	X			
Hospitalized influenza	X			
Pregnancy	X			
Chemoprophylaxis	X	X		X
Renal impairment	X		X	
Adverse Events	-Nausea -Vomiting -Headache -Serious skin reactions -Sporadic, transient neuropsychiatric events	-Risk of bronchospasm -Serious skin reactions -Sporadic, transient neuropsychiatric events	-Diarrhea -Serious skin reactions -Sporadic, transient neuropsychiatric events	-None
<i>Oseltamivir is the primary recommended drug by the CDC. Baloxavir has no noted adverse events that differed from placebo.</i>				

⊞ REFERENCES

- Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2021. *Morbidity and Mortality Weekly Report*. 2021;70(4):1-186.
- Infectious Diseases Society of America. Recommendations for the Management of Herpes Zoster. *Clinical Infectious Diseases*. 2007;44:S1-26.

3. Advisory Committee on Immunization Practices. Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza. *Morbidity and Mortality Weekly Report*. 2011;66(RR01):1–24.
4. 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. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf>. Accessed September 1, 2023.
5. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf>. Accessed September 1, 2023.
6. Xofluza™ (baloxavir marboxil) [package insert]. San Francisco, CA: Genentech USA, Inc.; 2018.
7. Centers for Disease Control and Prevention. Influenza Antiviral Medications: Summary for Clinicians. December, 2021; <https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm#overview>. Accessed December 2, 2021.
8. Apretude (cabotegravir) [package insert]. Research Triangle Park, NC: ViiV Healthcare; 2021.
9. Sunlenca (lenacapavir) [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2022.

⌘ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	HPSJ Coverage Policy – Infectious Disease – Viral Infections 2016-02.docx	2/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Viral Infections 2016-02-revised in may.docx	5/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Viral Infections 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Viral Infections 2018-12.docx	12/2018	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Viral Infections 2019-12.docx	12/2019	Matthew Garrett, PharmD
Review of Policy	Viral Infections	12/2020	Matthew Garrett, PharmD
Review of Policy	Viral Infections	12/2021	Matthew Garrett, PharmD
Review of Policy	Viral Infections	12/2022	Matthew Garrett, PharmD
Review of Policy	Viral Infections	09/2023	Matthew Garrett, PharmD
Review of Policy	Viral Infections	09/2024	Matthew Garrett, PharmD

Note: All changes are approved by the Health Plan P&T Committee before incorporation into the utilization policy