

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

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| POLICY | Viral Infections | P&T DATE | 5/9/2017 |
| THERAPEUTIC CLASS | Infectious Disease | REVIEW HISTORY | 5/16 |
| LOB AFFECTED | Medi-Cal | (MONTH/YEAR) | |

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

OVERVIEW

Antiviral medications are used to treat viral infections. Examples of infections caused by viruses include: influenza (flu), cytomegalovirus, herpes, cold sores, shingles, and HIV. The purpose of this coverage policy is to review the coverage criteria of HPSJ's formulary antiviral agents (*Table 1*).

Table 1: Available Antivirals (Current as of 4/2017)

| Generic (Brand) | Strength & Dosage form | Formulary Limits | Cost per Rx* | Notes |
|---|--|------------------|--------------|--|
| Flu | | | | |
| Rimantadine (Flumadine) | Rimantadine HCL 100 mg tablet | NF | --- | |
| Oseltamivir (Tamiflu) | Tamiflu 6 mg/ml suspension | QL, FL | \$224.75 | Limit 120 ml per fill. Limit 2 fills per 6 months. |
| | Oseltamivir 30 mg capsule | QL, FL | \$145.82 | Limit 20 capsules per fill. Limit 2 fills per 6 months. |
| | Tamiflu 30 mg capsule | | \$228.98 | |
| | Oseltamivir 45 mg capsule | QL, FL | \$85.55 | Limit 10 capsules per fill. Limit 2 fills per 6 months. |
| | Tamiflu 45 mg capsule | | \$131.89 | |
| | Oseltamivir 75 mg capsule | | \$100.37 | |
| | Tamiflu 75 mg capsule | QL, FL | \$142.57 | |
| Zanamivir (Relenza) | Relenza 5 mg diskhaler | FL | \$60.18 | Limit 2 fills per 6 months. |
| Peramivir (Rapivab) | Rapivab 200 mg/20 ml vial | NF | --- | |
| Cytomegalovirus | | | | |
| Valganciclovir (Valcyte) | Valganciclovir 450 mg tablet | PA, SP | \$1,796.22 | Approval is determined by medical necessity criteria. |
| | Valcyte 450 mg tablet | PA, SP | --- | |
| | Valganciclovir 50 mg/ml oral solution | NF | \$816.26 | |
| | Valcyte 50 mg/ml oral solution | | \$1,029.78 | |
| Herpes Simplex Virus, Herpetic Keratitis, Cold Sores, & Shingles | | | | |
| Acyclovir (Zovirax) | Acyclovir 5% ointment | NF | --- | |
| | Zovirax 5% cream | NF | --- | |
| | Acyclovir 200 mg capsule | - | \$8.26 | |
| | Acyclovir 400 mg tablet | - | \$3.66 | |
| | Acyclovir 800 mg tablet | - | \$10.82 | |
| | Acyclovir 200 mg/5 ml suspension | - | \$114.57 | |
| Famciclovir | Famciclovir 500 mg tablet | NF | \$84.86 | |
| Penciclovir (Denavir) | Denavir 1% cream | NF | --- | |
| Valacyclovir (Valtrex) | Valacyclovir 500 mg tablet | NF | \$7.36 | |
| | Valacyclovir 1 gram tablet | NF | \$24.86 | |
| HIV/AIDS | | | | |
| Didanosine (Videx EC) | Didanosine DR 125 mg capsule | - | --- | |
| | Didanosine DR 200 mg capsule | - | --- | |
| | Didanosine DR 250 mg capsule | - | --- | |
| | Didanosine DR 400 mg capsule | - | --- | |
| | Videx EC 400 mg capsule | NF | --- | |
| | Videx 2 gram 10 mg/ml oral solution | - | --- | |
| | Videx 4 gram 10 mg/ml oral solution | - | --- | |
| Zidovudine (Retrovir) | Zidovudine 100 mg capsule | - | --- | |
| | Zidovudine 300 mg tablet | - | \$8.90 | |
| | Retrovir 10 mg/ml intravenous solution | - | --- | |
| | Zidovudine 50 mg/5 ml syrup | - | \$36.38 | |

PA = Prior Authorization; SP = Specialty Pharmacy; QL = Quantity Limit; FL = Fill Limit; NF = Non-formulary
*Cost/Rx based on HPSJ Medi-Cal utilization historical data from May 2016 through April 2017

⊕ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed & approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HSPJ Medical Review Guidelines (UM06).

Flu

Rimantadine (Flumadine), Oseltamivir (Tamiflu), Zanamivir (Relenza)

Oseltamivir (Tamiflu), Zanamivir (Relenza)

- Coverage Criteria:** None
- Limits:** Restricted to 2 fills per 6 months. Limit 120 ml per fill (Tamiflu 6 mg/ml suspension). Limit 20 capsules per fill (Tamiflu 30 mg). Limit 10 capsules per fill (Tamiflu 45 mg, 75 mg).
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Rimantadine (Flumadine)

Cytomegalovirus

Valganciclovir (Valcyte)

- Coverage Criteria:** Approval is determined by medical necessity criteria.
- Limits:** None
- Required Information for Approval:** Relevant clinical documentation
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Herpes Simplex Virus, Herpetic Keratitis, Cold Sores, & Shingles

Acyclovir (Zovirax), Famciclovir, Penciclovir (Denavir), Valacyclovir (Valtrex)

Acyclovir (Zovirax) capsules, tablets, and suspension

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Acyclovir 5% ointment & cream, Famciclovir, Penciclovir (Denavir), Valacyclovir (Valtrex)

HIV/AIDS

Didanosine (Videx EC), Zidovudine (Retrovir)

Didanosine, Videx oral solution, Zidovudine (Retrovir)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Videx EC

⊕ CLINICAL JUSTIFICATION

HPSJ'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 Given the similar efficacy and cross-resistance among these three agents, oral acyclovir is the only antiviral agent on HPSJ's formulary for herpetic infections. 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 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 2015 Guidelines.⁴

☒ REFERENCES

1. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2015. *Morbidity and Mortality Weekly Report*. 2015;64(3):1-137.
2. 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. National Institutes of Health Web Site. http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Updated November 4, 2015. Accessed February 2, 2016.

☒ REVIEW & EDIT HISTORY

| Document Changes | Reference | Date | P&T Chairman |
|--------------------|---|--------|-----------------------|
| Creation of Policy | HPS Coverage Policy – Infections Disease – Viral Infections 2016-02.docx | 2/2016 | Johnathan Yeh, PharmD |
| Update to Policy | HPS Coverage Policy – Infections Disease – Viral Infections 2016-02-revised in may.docx | 5/2016 | Johnathan Yeh, PharmD |
| Update to Policy | HPS Coverage Policy – Infections Disease – Viral Infections 2017-05.docx | 5/2017 | Johnathan Yeh, PharmD |

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

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| <ul style="list-style-type: none"> ☒ Please refer to Hepatitis C and Liver Diseases Coverage Policies for coverage criteria of Hepatitis C and Hepatitis B medications, respectively. ☒ Please refer to Immunizations Coverage Policy for coverage criteria of vaccines. ☒ Please refer to Eye & Ear Inflammatory Disorders Coverage Policy for coverage criteria of ophthalmic antiviral medications. ☒ All HIV and flu medications not mentioned in this coverage policy are specifically carved out from Medi-Cal Managed Care Plans, and should be billed directly to Medi-Cal Fee-For-Service. The Managed Medi-Cal Prescription Drug Carve-Out list can be found at www.hpsj.com/medication-coverage-policies/ or www.hpsj.com/pharmacy. Please note that Medi-Cal FFS may require submission of a Treatment Authorization Request (TAR) to determine appropriateness of the treatment prior to coverage. |
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