

DRUG QUANTITY MANAGEMENT POLICY – STANDARD PER RX

POLICY: baloxavir marboxil oral tablets (Xofluza™ – Genentech USA, Inc.)
Dispensing Limit

DATE REVIEWED: 08/18/2021

DESCRIPTION

Note: Throughout this document the term influenza refers specifically to seasonal influenza.

Four FDA-approved influenza antiviral medications, oral Tamiflu (oseltamivir), inhaled Relenza (zanamivir), oral Xofluza (baloxavir marboxil) and intravenous Rapivab (peramivir) are recommended for use.¹ These medications have activity against both influenza A and B viruses. Tamiflu and Relenza can be used to treat or prevent influenza. Xofluza is indicated for the treatment and post-exposure prophylaxis of influenza. Rapivab is indicated for the treatment of influenza.

Tamiflu and Relenza, both antiviral agents that inhibit the influenza (flu) virus (types A and B), are Food and Drug Administration (FDA)-approved for the prophylaxis and treatment of uncomplicated acute illness due to influenza infection in patients who have been symptomatic for 2 days or less.¹⁻² Tamiflu is FDA-approved for the treatment of influenza in adults and children ≥ 2 weeks of age, and for use as prophylaxis in patients ≥ 3 months of age.¹ Relenza is FDA-approved for the treatment of influenza in adults and children ≥ 7 years of age, and for use as prophylaxis in patients ≥ 5 years of age.² When administered within 2 days of the onset of symptoms, Tamiflu and Relenza have been shown to reduce the duration of uncomplicated influenza A and B illness by approximately 1 day compared to placebo.³ Tamiflu and Relenza are similarly effective in both preventing febrile, laboratory-confirmed influenza illness and treating symptomatic influenza.^{3,6-9} Xofluza is an antiviral agent that is FDA approved for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and for post-exposure prophylaxis.⁴ Tamiflu, Relenza and Xofluza have been shown to reduce the duration of uncomplicated influenza A and B illness by approximately 1 day compared to placebo.^{3,4}

Chemoprophylaxis is generally not recommended if more than 48 hours have elapsed since the last exposure to an infectious person. The CDC does not recommend widespread or routine use of antivirals for chemoprophylaxis as this could promote resistance to antiviral medications or reduce the availability of medication for treatment of persons at higher risk for complications or those who are severely ill. For some persons, early treatment and monitoring are an alternate to chemoprophylaxis after a suspected influenza exposure

Xofluza 40 mg dose (2 x 20 mg dose pack)

Maximum Quantity per Rx = 2 tablets

Xofluza 80 mg dose (2 x 40 mg dose pack)

Maximum Quantity per Rx = 2 tablets

Xofluza 40 mg tablet

Maximum Quantity per Rx = 1 tablet

Xofluza 80 mg tablet

Maximum Quantity per Rx = 1 tablet

Xofluza is indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and for post-exposure prophylaxis.⁴

Recommended dosing of Xofluza for patients 12 years of age or older with acute uncomplicated influenza or post-exposure prophylaxis is provided in the table below:

08/18/2021

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Patient Body Weight (kg)	Recommended Oral Dose
40 kg to less than 80 kg	Single dose of 40 mg
At least 80 kg	Single dose of 80 mg

CRITERIA

Express Scripts does not recommend overriding this quantity limit. Two tablets of 20 mg (40 mg dose pack), 40 mg (80 mg dose pack) OR one 40 mg or 80 mg tablet is sufficient to treat one influenza episode or one post-exposure prophylaxis episode.

REFERENCES

- Centers for Disease Control and Prevention. 2020-2021 Influenza Antiviral Medications: Summary for Clinicians. Accessed August 6, 2021. Available at: <http://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm>.
- Centers for Disease Control and Prevention. Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011. *MMWR*. 2011;60(RR01):1-24. Accessed August 6, 2021. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6001a1.htm>.
- Harper SA, Bradley JS, Englund JA, et al. Seasonal Influenza in Adults and Children-Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America. *Clin Infect Dis*. 2009 Apr 15;48(8):1003-32.
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- Lee C, Loeb M, Phillips A, et al. Zanamivir use during transmission of amantadine-resistant influenza A in a nursing home. *Infect Control Hosp Epidemiol*. 2000;21(11):700-4.