

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS INFLUENZA TREATMENT & PREVENTION
(NEURAMINIDASE INHIBITORS)

**BRAND NAME
(GENERIC)** RELENZA
(zanamivir)

TAMIFLU CAPSULES/SUSPENSION
(oseltamivir)

Status: CVS Caremark Criteria

Type: Post Limit Prior Authorization

POLICY

FDA APPROVED INDICATIONS

Relenza

Treatment of Influenza

Relenza Inhalation Powder is indicated for treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients 7 years of age and older who have been symptomatic for no more than 2 days.

Prophylaxis of Influenza

Relenza is indicated for prophylaxis of influenza in adults and pediatric patients aged 5 years and older.

Important Limitations on Use of Relenza

Relenza is not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease) due to risk of serious bronchospasm. Relenza has not been proven effective for treatment of influenza in individuals with underlying airways disease. Relenza has not been proven effective for prophylaxis of influenza in the nursing home setting.

Relenza is not a substitute for early influenza vaccination on an annual basis as recommended by the Centers for Disease Control's Immunization Practices Advisory Committee. Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Relenza. There is no evidence for efficacy of Relenza in any illness caused by agents other than influenza virus A and B. Patients should be advised that the use of Relenza for treatment of influenza has not been shown to reduce the risk of transmission of influenza to others.

Tamiflu

Treatment of Influenza

Tamiflu is indicated for treatment of acute, uncomplicated illness due to influenza infection in patients 2 weeks of age and older who have been symptomatic for no more than 2 days.

Prophylaxis of Influenza

Tamiflu is indicated for the prophylaxis of influenza in patients 1 year and older.

Limitations of Use

The following points should be considered before initiating treatment or prophylaxis with Tamiflu:

Efficacy of Tamiflu in patients who begin treatment after 48 hours of symptoms has not been established. Tamiflu is not a substitute for early influenza vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. There is no evidence for efficacy of Tamiflu in any illness caused by agents other than influenza viruses Types A and B. Influenza viruses change over time. Emergence of resistance substitutions could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Tamiflu.

COVERAGE CRITERIA

- Post quantity limits for Relenza will be covered with prior authorization when the following criteria are met:
 - Relenza is being prescribed for any of the following:
 - Treatment of a current infection with influenza A or B in a pregnant or critically/severely ill patient 7 years of age or older OR
 - Treatment of a current infection with influenza A or B in a patient 7 years of age or older with an onset of symptoms within the previous 48 hours (2 days) OR
 - Prevention of influenza A or B in a patient 5 years of age or older after being exposed to another person with influenza within the previous 36 hours (1.5 days) OR
 - Continuation of therapy for a patient currently using the drug for prevention of influenza A or B after exposure to a community outbreak OR
 - Prevention of influenza A or B in a patient 5 years of age or older who has been exposed to a community outbreak of influenza within the previous 5 days

OR

- Tamiflu will be covered with prior authorization when the following criteria are met:
 - Tamiflu is being prescribed for any of the following:
 - Continuation of therapy for a patient currently using the drug for prevention of influenza A or B after exposure to a community outbreak OR
 - Treatment of a current infection with influenza A or B in a pregnant or critically/severely ill patient 2 weeks of age or older OR
 - Treatment of a current infection with influenza A or B in a patient 2 weeks of age or older with an onset of symptoms within the previous 48 hours (2 days) OR
 - Prevention of influenza A or B in a patient 1 year of age or older following close contact with another person with influenza OR
 - Prevention of influenza A or B in a patient 1 year of age or older who has been exposed to a community outbreak of influenza

Quantity Limits apply.

POST LIMIT QUANTITY FOR APPROVAL

The post limit quantity chart below should be used to determine the quantity for approval for each prescribed medication.

Medication	Indication	Quantity Limit
Tamiflu	Continuation of therapy for a patient currently using the drug for prevention of influenza A or B after exposure to a community outbreak	6 months for a TOTAL quantity of: 28 Capsules of 75 mg or 45 mg OR 56 Capsules of 30 mg OR 360 mL Suspension
Tamiflu	-Treatment of a current infection with influenza A or B in a pregnant or critically/severely ill patient 2 weeks of age or older OR -Treatment of a current infection with influenza A or B in a patient 2 weeks of age or older with an onset of symptoms within the previous 48 hours (2 days) OR -Prevention of influenza A or B in a patient 1 year of age or older following close contact with another person with influenza	6 months for a TOTAL quantity of: 10 Capsules of 75 mg or 45 mg OR 20 Capsules of 30 mg OR 180 mL Suspension
Tamiflu	Prevention of influenza A or B in a patient 1 year of age or older who has been exposed to a community outbreak of influenza	6 months for a TOTAL quantity of: 42 Capsules of 75 mg or 45 mg OR 84 Capsules of 30 mg OR 540 mL Suspension
Relenza	-Treatment of a current infection with influenza A or B in a pregnant or critically/severely ill patient 7 years of age or older -Treatment of a current infection with influenza A or B in a patient 7 years of age or older with an onset	6 months for a TOTAL quantity of 20 Blisters

	of symptoms within the previous 48 hours (2 days) -Prevention of influenza A or B in a patient 5 years of age or older after being exposed to another person with influenza within the previous 36 hours (1.5 days) -Continuation of therapy for a patient currently using the drug for prevention of influenza A or B after exposure to a community outbreak	
Relenza	Prevention of influenza A or B in a patient 5 years of age or older who has been exposed to a community outbreak of influenza within the previous 5 days	6 months for a TOTAL quantity of 60 Blisters

REFERENCES

1. Relenza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2013.
2. Tamiflu [package insert]. South San Francisco, CA: Genentech, Inc.; December 2014.
3. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed December 2015.
4. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed December 2015.
5. 2015-2016 Influenza Antiviral Medications: Summary for Clinicians. Atlanta, GA: Centers for Disease Control and Prevention; 2015. Available at: <http://www.cdc.gov/flu/pdf/professionals/antivirals/antiviral-summary-clinician.pdf>. Accessed December 2015.