PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**INFLUENZA TREATMENT & PREVENTION (NEURAMINIDASE INHIBITORS, ORAL)**
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 (zanamivir) inhalation powder is indicated for treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients aged 7 years 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 zanamivir 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.

Compendial Uses:

Treatment of influenza A or B viral infection when administered after 48 hours in patients aged 7 years and older who are at higher risk for influenza complications or in patients aged 7 years and older with severe, complicated, or progressive illness[3-9]

Tamiflu

Treatment of Influenza

Tamiflu is indicated for treatment of acute, uncomplicated illness due to influenza A and B infection in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours.

Prophylaxis of Influenza
Tamiflu is indicated for the prophylaxis of influenza A and B in patients 1 year and older.
Limitations of Use
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.
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.
Tamiflu is not recommended for patients with end-stage renal disease not undergoing dialysis.

Compendial Uses:
Treatment of influenza A or B viral infection when administered after 48 hours in patients who are at higher risk for influenza complications or in patients with severe, complicated, or progressive illness[3-9]
Prophylaxis of influenza A or B viral infection in patients 3 months to 1 year of age if necessary after exposure to another person with influenza[3-9]

COVERAGE CRITERIA
Relenza (zanamivir) will be covered with prior authorization when the following criteria are met:
- Relenza (zanamivir) is being prescribed for the prophylaxis (prevention) or the treatment of influenza A or B viral infection
  AND
  - Continuation of therapy for a patient currently using the drug for prophylaxis after exposure to a community outbreak
    OR
  - Treatment of a current infection in a patient 7 years of age or older with severe, complicated, or progressive illness
    OR
  - Treatment in a patient 7 years of age or older who is at higher risk for influenza complications
    OR
  - Treatment of a current infection in a patient 7 years of age or older with an onset of symptoms within the previous 48 hours (2 days)
    OR
  - Prophylaxis in a patient 5 years of age or older following close contact with another person with influenza within the previous 36 hours (1.5 days)
    OR
  - Prophylaxis in a patient 5 years of age or older who has been exposed to a community outbreak within the previous 5 days

OR
Oseltamivir (Tamiflu) will be covered with prior authorization when the following criteria are met:
- Oseltamivir (Tamiflu) is being prescribed for the prophylaxis (prevention) or the treatment of influenza A or B viral infection
  AND
  - Continuation of therapy for a patient currently using the drug for prophylaxis after exposure to a community outbreak
    OR
  - Treatment of a current infection in a patient with severe, complicated, or progressive illness
    OR
  - Treatment in a patient who is at higher risk for influenza complications
    OR
  - Treatment of a current infection in a patient 2 weeks of age or older with an onset of symptoms within the previous 48 hours (2 days)
    OR
  - Prophylaxis in a patient 3 months of age or older following close contact with another person with influenza
    OR
  - Prophylaxis in a patient 3 months of age or older who has been exposed to a community outbreak

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 -** prophylaxis (prevention) or treatment of influenza A or B viral infection	**Quantity Limit**
Tamiflu	Continuation of therapy for a patient currently using the drug for prophylaxis 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	Continuation of therapy for a patient currently using the drug for prophylaxis after exposure to a community outbreak for a patient with immune deficiencies following close contact with another person with influenza	6 months for a TOTAL quantity of: 70 Capsules of 75 mg or 45 mg OR 140 Capsules of 30 mg OR 900mL Suspension
Tamiflu	A) Treatment in a patient with severe, complicated, or progressive illness, B) Treatment in a patient who is at higher risk for influenza complications, C) Treatment in a patient 2 weeks of age or older with an onset of symptoms within the previous 48 hours (2 days), D) Prophylaxis in a patient 3 months 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	Prophylaxis in a patient 3 months of age or older who has been exposed to a community outbreak	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	A) Treatment in a patient 7 years of age and older with severe, complicated, or progressive illness, B) Treatment in a patient 7 years of age and older who is at higher risk for influenza complications C) Treatment in a patient 7 years of age or older with an onset of symptoms within the previous 48 hours (2 days), D) Prophylaxis in a patient 5 years of age or older following close contact with another person with influenza within the previous 36 hours (1.5 days), E) Continuation of therapy for a patient currently using the drug for prophylaxis after exposure to a community outbreak	6 months for a TOTAL quantity of 20 Blisters
Relenza	Prophylaxis 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

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5. Seasonal Influenza (Flu) Influenza - Flu Basics. Centers for Disease Control and Prevention; 2016-2017. Available at: http://www.cdc.gov/flu/professionals/antivirals/index.htm. Accessed December 2016.
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