

# PRIOR AUTHORIZATION CRITERIA

**DRUG CLASS****INFLUENZA TREATMENT & PREVENTION****BRAND NAME\*  
(generic)****RELENZA  
(zanamivir)****TAMIFLU  
(oseltamivir)****XOFLUZA  
(baloxavir)****Status: CVS Caremark Criteria****Type: Post Limit Prior Authorization****Ref # 111-J**

*\*Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

**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 of Use

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<sup>4-8</sup>

**Tamiflu**Treatment of Influenza

Tamiflu is indicated for the 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<sup>4-8</sup>

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<sup>4-8</sup>

## **Xofluza**

### Treatment of Influenza

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 who are: otherwise healthy, or at high risk of developing influenza-related complications.

### Post-Exposure Prophylaxis of Influenza

Xofluza is indicated for post-exposure prophylaxis of influenza in persons 12 years of age and older following contact with an individual who has influenza.

### Limitations of Use

Influenza viruses change over time, and factors such as the virus type or subtype, emergence of resistance, or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Consider available information on drug susceptibility patterns for circulating influenza virus strains when deciding whether to use Xofluza.

## **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The request is for Xofluza (baloxavir) for a patient 12 years of age or older for any of the following: A) Treatment of acute uncomplicated influenza, B) Post-exposure prophylaxis of influenza
- OR
- The request is for Tamiflu (oseltamivir) for the prophylaxis of influenza A or B viral infection in a patient 3 months of age or older who has been exposed to a community outbreak
- OR
- The request is for Relenza (zanamivir) for the prophylaxis of influenza A or B viral infection in a patient 5 years of age or older who has been exposed to a community outbreak
- OR
- The requested drug, i.e., Tamiflu or Relenza, is being prescribed for the prophylaxis (prevention) or the treatment of influenza A or B viral infection

Quantity Limits apply.

## **RATIONALE**

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. 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. Relenza is indicated for prophylaxis of influenza in adults and pediatric patients aged 5 years and older.<sup>1</sup> Tamiflu (oseltamivir) is indicated for the 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. Tamiflu is indicated for the prophylaxis of influenza A and B in patients 1 year and older.<sup>2</sup>

Xofluza (baloxavir) 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 who are: otherwise healthy, or at high risk of developing influenza-related complications. Xofluza is indicated for post-exposure prophylaxis of influenza in persons 12 years of age and older following contact with an individual who has influenza.<sup>3</sup>

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.<sup>1</sup>

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.<sup>2</sup>

Influenza viruses change over time, and factors such as the virus type or subtype, emergence of resistance, or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Consider available information on drug susceptibility patterns for circulating influenza virus strains when deciding whether to use Xofluza.<sup>3</sup>

The initial limits for Relenza and Tamiflu are based on the Center for Disease Control and Prevention (CDC) recommendation to allow a quantity to accommodate at least 2 weeks of community setting prophylaxis, at least 14 doses, up to 20 doses (due to packaging), once every 90 days. The limits for Relenza and Tamiflu are also based on the recommended dosing regimen for the treatment or household prevention of influenza, providing quantity sufficient for 5 days of treatment or 10 days of household prevention, twice every 90 days (10 doses each course for 2 courses, for a total of 40 blisters of Relenza, 20 capsules of Tamiflu 75mg or 45 mg, 40 capsules of Tamiflu 30mg [two capsules for 60mg dosing], or 6 bottles of Tamiflu suspension). The initial limits for Xofluza are based on the recommended dosing regimen for the treatment or post-exposure prophylaxis of influenza providing quantity sufficient for 1 day of therapy, twice every 90 days (1 dose each course for 2 courses, for a total of 2 tablets of the Xofluza 40mg (1 tablet per blister pack) or Xofluza 80mg (1 tablet per blister pack) or 4 tablets of Xofluza 20mg (2 tablets per blister pack) or Xofluza 40mg (2 tablets per blister pack) or 4 bottles of suspension).

#### **INITIAL QUANTITY LIMIT\*\***

<b>LIMIT CRITERIA</b>		
<b>Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.</b>		
<b>Medication</b>	<b>Strength</b>	<b>Limit*</b>
Relenza (zanamivir)	5 mg blister per inhalation	40 blisters / 90 days
Tamiflu (oseltamivir)	6 mg/mL suspension	360 mL / 90 days
	30 mg per capsule	40 capsules / 90 days
	45 mg per capsule	20 capsules / 90 days
	75 mg per capsule	20 capsules / 90 days
Xofluza (baloxavir marboxil)	20 mg per tablet (2 tablets per blister card)	4 tablets / 90 days
	40 mg per tablet (1 tablet per blister card)	2 tablets / 90 days
	40 mg per tablet (2 tablets per blister card)	4 tablets / 90 days

	80 mg per tablet (1 tablet per blister card)	2 tablets / 90 days
	40 mg/20mL suspension	80 mL / 90 days
*These drugs are for short-term acute use; therefore the 3 month limit will be the same as the 1 month limit.		

The post limit quantities for Relenza and Tamiflu are based on the recommended dosing regimen for extended community setting prophylaxis use for illnesses caused by influenza A and B virus. The post limit quantity for approval may cover 1 month of Relenza or 6 to 12 weeks of Tamiflu for extended community setting prophylaxis, per 3 months. The post limit quantity may cover for another course of therapy as 10 doses for Tamiflu or Relenza, or for another course of therapy as 1 dose for Xofluza, per 3 months, (20 blisters of Relenza, 10 capsules of Tamiflu 75mg or 45 mg, 20 capsules of Tamiflu 30mg [30mg or 60mg dosing], 3 bottles of Tamiflu suspension, 1 tablet of Xofluza 40mg (1 tablet per blister pack), 1 tablet of Xofluza 80mg (1 tablet per blister pack), 2 tablets of Xofluza 20mg (2 tablets per blister pack), 2 tablets of Xofluza 40mg (2 tablets per blister pack) or 2 bottles of Xofluza suspension).

The CDC states that influenza activity often begins to increase in October. Most of the time flu activity peaks between December and February, although activity can last as late as May.<sup>6-8</sup> When indicated, antiviral treatment should be started as soon as possible after illness onset, ideally within 48 hours of symptom onset.<sup>6-8</sup> The CDC states that antiviral treatment might have some benefits in patients with severe, complicated or progressive illness, and in patients at higher risk for influenza complications when started after 48 hours of illness onset.<sup>4-8</sup>

The CDC does not recommend widespread or routine use of antiviral medications for chemoprophylaxis so as to limit the possibilities that antiviral resistant viruses could emerge. To be effective as chemoprophylaxis, an antiviral medication must be taken each day for the duration of potential exposure to a person with influenza and continued for 7 days after the last known exposure. For persons taking antiviral chemoprophylaxis after inactivated influenza vaccination, the recommended duration is until immunity after vaccination develops (antibody development after vaccination takes about two weeks in adults and can take longer in children depending on age and vaccination history). For control of outbreaks in institutional settings (e.g., long-term care facilities for elderly persons and children) and hospitals, the CDC recommends antiviral chemoprophylaxis for a minimum of 2 weeks and continuing up to 1 week after the last known case was identified.<sup>4-8</sup>

## Relenza (zanamivir)

### Prophylaxis – Community

The recommended dose of Relenza for prophylaxis of influenza in adults and adolescents in a community setting is 10mg once daily for 28 days. There are no data on the effectiveness of prophylaxis with Relenza in a community outbreak when initiated more than 5 days after the outbreak was identified in the community. The safety and effectiveness of prophylaxis with Relenza have not been evaluated for longer than 28 days' duration.

The Relenza 10-mg dose is provided by 2 inhalations (one 5-mg blister per inhalation). Relenza is supplied in five Rotadisks each containing 4 blisters of the drug (20 blisters), packaged in a carton with 1 Diskhaler inhalation device.

Each dose of Relenza is provided by 2 inhalations, which is 2 blisters. Therefore, the community outbreak prophylaxis limit will be 60 blisters which allows for 30 doses (due to packaging) of 2 inhalations per dose accommodating a 28 day course of therapy.

### Treatment and Prophylaxis – Household

The recommended dose of Relenza for treatment of influenza in adults and pediatric patients aged 7 years and older is 10mg twice daily for 5 days.

The recommended dose of Relenza for prophylaxis of influenza in adults and pediatric patients aged 5 years and older in a household setting is 10mg once daily for 10 days.

Therefore, the treatment or household prophylaxis limit will be 20 blisters which allows for 1 course of therapy of 10 doses of 2 inhalations per dose.

## Tamiflu (oseltamivir)

### Prophylaxis – Community

The recommended dosage of Tamiflu for prophylaxis of influenza in adults and adolescents 13 years and older is 75mg (one 75mg capsule or 12.5mL of oral suspension) orally once daily for up to 6 weeks during a community outbreak. In immunocompromised patients, Tamiflu may be continued for up to 12 weeks.

Prophylaxis in pediatric patients is recommended up to 6 weeks during a community outbreak. The recommended oral dosage of Tamiflu for prophylaxis of influenza in pediatric patients 1 year to 12 years of age is based on body weight, see table. Although not part of the FDA-approved indications, use of oral oseltamivir (Tamiflu) for chemoprophylaxis in infants 3 months to 1 year of age if necessary is recommended by the CDC and the American Academy of Pediatrics.<sup>4-8</sup>

Weight	Treatment Dosage for 5 days	Prophylaxis Dosage for 10 days	Oral Suspension (6 mg/mL) for each Dose	Bottles to Dispense	Capsules to Dispense (Strength)
<b>Patients from 2 Weeks to less than 1 Year of Age</b>					
Any weight	3mg/kg twice daily	Not applicable	0.5mL/kg	1 bottle	Not applicable
<b>Patients 1 to 12 Years of Age Based on Body Weight</b>					
15kg or less	30mg twice daily	30mg once daily	5mL	1 bottle	10 capsules (30mg)
15.1kg to 23kg	45mg twice daily	45mg once daily	7.5mL	2 bottles	10 capsules (45mg)
23.1kg to 40kg	60mg twice daily*	60mg once daily*	10mL	2 bottles	20 capsules (30mg)
40.1kg or more	75mg twice daily	75mg once daily	12.5mL	3 bottles	10 capsules (75mg)

Tamiflu capsules are available in 30mg, 45mg, and 75mg strengths in blister packs of 10. Tamiflu is also available as an oral suspension for constitution delivering 360mg/60mL (6mg/mL). Constituted oral suspension can be stored under refrigeration for up to 17 days or for up to 10 days at controlled room temperature.

Each dose of Tamiflu is provided by 1 to 2 capsules or up to 12.5mL oral suspension. Therefore, the community outbreak prophylaxis limit will be 42 capsules of 45mg or 75mg, 84 capsules of 30mg (two capsules for 60mg dose), or 540mL of oral suspension, which allows for 42 doses, per 3 months.

For immunocompromised patients the community outbreak prophylaxis limit will be 84 capsules of 45mg or 75mg, or 168 capsules of 30mg (two capsules for 60mg dose), or 1080mL of oral suspension, which allows for 84 doses.

#### Treatment

The recommended oral dosage of Tamiflu for treatment of influenza in adults and adolescents 13 years and older is 75mg (one 75mg capsule or 12.5mL of oral suspension) twice daily for 5 days. The recommended oral dosage of Tamiflu for treatment of influenza in pediatric patients 2 weeks of age through 12 years of age is based on body weight, see table. Although not part of the FDA-approved indications, use of oral oseltamivir (Tamiflu) for treatment in infants less than 2 weeks of age if necessary is recommended by the CDC and the American Academy of Pediatrics.<sup>4-8</sup>

#### Prophylaxis - Household

The recommended dosage of Tamiflu for prophylaxis of influenza in adults and adolescents 13 years and older is 75mg (one 75mg capsule or 12.5mL of oral suspension) orally once daily for at least 10 days following close contact with an infected individual.

Prophylaxis in pediatric patients is recommended for 10 days following close contact with an infected individual. The recommended oral dosage of Tamiflu for prophylaxis of influenza in pediatric patients 1 year to 12 years of age is based on body weight, see table. Although not part of the FDA-approved indications, use of oral oseltamivir (Tamiflu) for chemoprophylaxis in infants 3 months to 1 year of age if necessary is recommended by the CDC and the American Academy of Pediatrics.<sup>4-8</sup>

Therefore, the treatment or household prophylaxis limit will be 10 capsules of 45mg or 75mg, 20 capsules of 30mg (two capsules for 60mg dose), or 180mL of oral suspension which allows for 1 course of therapy of 10 doses.

### **Xofluza (baloxavir marboxil)**

#### Treatment or Post-Exposure Prophylaxis

Xofluza should be taken as a single dose as soon as possible and within 48 hours of influenza symptom onset for treatment of acute uncomplicated influenza or following contact with an individual who has influenza. The recommended dose of Xofluza in patients 12 years of age or older is a single weight-based dose as follows:

Recommended Xofluza Dosage in Adults and Adolescents 12 Years and Older	
Patient Body Weight (kg)	Recommended Oral Dose
Less than 80 kg	One 40mg tablet (blister card contains one 40mg tablet)

	40mg/20mL (1 bottle) taken as a single dose
At least 80 kg	One 80mg tablet (blister card contains one 80mg tablet)  80mg/40mL (2 bottles) taken as a single dose

Per the prescribing information, Xofluza is available as 1 x 40mg tablet per blister card and 1 x 80mg tablet per blister card.<sup>3</sup> According to the compendia, Xofluza is also still available as 2 x 20mg tablets per blister card, and 2 x 40mg tablets per blister card.<sup>5</sup> Xofluza is also available as an oral suspension for constitution containing 40mg/20mL (2mg/mL). This dosage form can be used for oral or enteral use. Constituted oral suspension can be stored at room temperature. Xofluza for oral suspension contains no preservative and must be administered within 10 hours after constitution.<sup>3</sup>

Each dose of Xofluza is provided by 1 or 2 tablets (depending on the tablet strength), or the maximum of 2 bottles based on body weight. Therefore, the limit will be 2 tablets of 20mg (2 tablets per blister card), 2 tablets of 40mg (2 tablets per blister card), 1 tablet of 40mg (1 tablet per blister card), 1 tablet of 80mg (1 tablet per blister card), or 40mL (2 bottles of 40mg/20mL), which allows for 1 course of therapy of 1 dose.

These drugs are for short-term acute use; therefore, the duration of approval will be 3 months.

## REFERENCES

1. Relenza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; June 2018.
2. Tamiflu [package insert]. South San Francisco, CA: Genentech, Inc.; August 2019.
3. Xofluza [package insert]. South San Francisco, CA: Genentech USA, Inc. March 2021.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed August 10, 2021.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed August 10, 2021.
6. Centers for Disease Control and Prevention Seasonal Influenza (Flu) – Health Professionals – Antiviral Drugs. Available at: <https://www.cdc.gov/flu/professionals/antivirals/index.htm>. Accessed August 2020.
7. American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for Prevention and Control of Influenza in Children, 2019–2020. *Pediatrics*. 2019;144(4).
8. Uyeki T, Bernstein H, Bradley J, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza. *Clinical Infectious Diseases*. 2019; 68(6), e1–e47.

Written by: UM Development (LS)  
Date Written: 11/1999  
Revised: 11/2000, 12/2000, 01/2001; (MG) 12/2002, 10/2003; (NB) 10/2004; (MG) 08/2005, 01/2006; (CT) (new indication) 04/2006, 02/2007, 07/2007 (new dosages), 03/2008, 03/2009, 04/2009 (H1N1 flu (swine flu) added), 09/2009 (added new sets 04/2009(2)); (MS) 01/2010; (CY) 12/2010, 07/2011 (updated Tamiflu new strength 6mg/ml 12-2010(2)), 12/2011; (PL) 12/2012; (CF) 12/2013, 12/2014, (LN) 04/2015 (added denial reasons); (CF) 12/2015 (no clinical changes), (TM) 12/2016, (TM) 12/2017, (TM) 10/2018 (add Xofluza), (TM) 12/2018 (split q6, revised q5&10), (TM) 09/2019 (no clinical changes), (TM) 10/2019 (update Xofluza PI), (TM) 08/2020 (no clinical changes), (TM) 11/2020 (add Xofluza new indication & susp), (DFW/AW) 08/2021 (off-cycle – added limit for new Xofluza 40mg/80mg 1 tablet per blister card), 08/2021 (annual review – no clinical changes)  
Reviewed: Medical Affairs 11/1999, 11/2000, 01/2001, 12/2002, 11/2003, 10/2004, 08/2005; (MM) 01/2006, 04/2006; (WF) 02/2007, 07/2007, 03/2008, 03/2009, 04/2009, 09/2009; (KP) 01/2010, 12/2010, 07/2011, 01/2012; (LMS) 12/2012; (DNC) 05/2013; (LMS) 12/2013; (LCB) 12/2014, 04/2016, (JG) 12/2016, (ME) 12/2017, (SD) 11/2018, (EPA) 12/2018, CHART: 09/2019, (CHART) 12/03/2020, (CHART) 08/26/2021  
Legal: 01/2001  
External Review: 05/2001, 03/2003, 12/2003, 11/2004, 08/2005, 04/2006, 06/2007, 06/2008, 05/2009, 06/2009, 02/2010, 05/2011, 03/2012; 04/2013, 3/2014, 04/2014, 02/2015, 04/2015, 04/2017, 02/2018, 11/2018, 04/2019, 12/2019, 12/2020, 12/2021

## CRITERIA FOR APPROVAL

1	Is this request for Xofluza (baloxavir)? [If no, then skip to question 3.]	Yes	No
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2	Is this request for a patient 12 years of age or older for any of the following: A) Treatment of acute uncomplicated influenza, B) Post-exposure prophylaxis of influenza? [If yes, then skip to question 10.] [If no, then no further questions.]	Yes	No
3	Is the requested drug being prescribed for the prophylaxis (prevention) or the treatment of influenza A or B viral infection? [If no, then no further questions.]	Yes	No
4	Is this request for oseltamivir (Tamiflu) for prophylaxis in a patient 3 months of age or older who has been exposed to a community outbreak? [If no, then skip to question 8.]	Yes	No
5	Does the patient require more than a 6-week course of therapy of any of the following quantities: A) 42 capsules of 75mg or 45mg, B) 84 capsules of 30mg, C) 540mL/9 bottles of suspension? [If no, then no further questions.]	Yes	No
6	Is this request for a patient with immune deficiencies? [If no, then no further questions.]  [RPh Note: If no, then deny and enter a partial approval for 3 months for an additional quantity of Tamiflu (oseltamivir): 42 capsules of 75mg, or 42 capsules of 45mg, or 84 capsules of 30mg, or 540mL of suspension.]	Yes	No
7	Does the patient require more than any of the following quantities for 12 weeks: A) 84 capsules of 75mg or 45mg, B) 168 capsules of 30mg, C) 1080mL/18 bottles of suspension? [No further questions.]  [RPh Note: If yes, then deny and enter a partial approval for 3 months for an additional quantity of Tamiflu (oseltamivir): 84 capsules of 75mg, or 84 capsules of 45mg, or 168 capsules of 30mg, or 1080mL of suspension.]	Yes	No
8	Is this request for Relenza (zanamivir) for prophylaxis in a patient 5 years of age or older who has been exposed to a community outbreak? [If no, then skip to question 10.]	Yes	No
9	Does the patient require more than 60 blisters (30 doses)? [No further questions.]  [RPh Note: If yes, then deny and enter a partial approval for 3 months for an additional quantity of 60 blisters of Relenza (zanamivir).]	Yes	No
10	Is this request for more than any of the following for this course of therapy: A) Tamiflu (oseltamivir): 10 capsules of 75mg or 45mg; 20 capsules of 30mg; 180mL/3 bottles of suspension, B) Relenza (zanamivir): 20 blisters, C) Xofluza (baloxavir): 2 tablets of 20mg (2 tablets per blister card); 2 tablets of 40mg (2 tablets per blister card); 1 tablet of 40mg (1 tablet per blister card); 1 tablet of 80mg (1 tablet per blister card); or 40mL/2 bottles of suspension?	Yes	No

[RPh Note: If yes, then deny and enter a partial approval for 3 months for an additional quantity of Tamiflu (oseltamivir) 10 capsules of 75mg, or 10 capsules of 45mg, or 20 capsules of 30mg, or 180mL of suspension; OR 20 blisters of Relenza (zanamivir); OR Xofluza (baloxavir) 2 tablets of 20mg (2 tablets per blister card), or 2 tablets of 40mg (2 tablets per blister card) or 1 tablet of 40mg (1 tablet per blister card), or 1 tablet of 80mg (1 tablet per blister card), or 40mL of suspension.]

<b>Guidelines for Approval – For MedHOK Use Only</b>			
<b>Duration of Approval</b>		<b>3 Months</b>	
<b>Set 1 Tamiflu community prophylaxis</b>		<b>Set 2 Tamiflu community prophylaxis immune deficient</b>	
<b>Quantity for Approval</b>	<b>An additional quantity of Tamiflu (oseltamivir) 75mg: 42 capsules or 45mg: 42 capsules or 30mg: 84 capsules or suspension: 540mL</b>	<b>Quantity for Approval</b>	<b>An additional quantity of Tamiflu (oseltamivir) 75mg: 84 capsules or 45mg: 84 capsules or 30mg: 168 capsules or suspension: 1080mL</b>
<b>Yes to question(s)</b>	<b>No to question(s)</b>	<b>Yes to question(s)</b>	<b>No to question(s)</b>
3	1	3	1
4	5	4	7
		5	
		6	
<b>Set 3 Relenza community prophylaxis</b>		<b>Set 4 Relenza or Tamiflu household prevent/treatment</b>	
<b>Quantity for Approval</b>	<b>An additional quantity of Relenza (zanamivir) 60 blisters</b>	<b>Quantity for Approval</b>	<b>An additional quantity of Tamiflu (oseltamivir) 75mg: 10 capsules or 45mg: 10 capsules or 30mg: 20 capsules or suspension: 180mL or Relenza (zanamivir) 20 blisters</b>
<b>Yes to question(s)</b>	<b>No to question(s)</b>	<b>Yes to question(s)</b>	<b>No to question(s)</b>
3	1	3	1
8	4		4
	9		8
			10
<b>Set 5 Xofluza</b>			
<b>Quantity for Approval</b>	<b>An additional quantity of Xofluza (baloxavir) 20mg (2 tablets per blister card): 2 tablets or 40mg (1 tablet per blister card): 1 tablet or 40mg (2 tablets per blister card): 2 tablets or 80mg (1 tablet per blister card): 1 tablet or suspension: 40 mL</b>		
<b>Yes to question(s)</b>	<b>No to question(s)</b>		
1	10		
2			

<b>Mapping Instructions</b>			
	<b>Yes</b>	<b>No</b>	<b>DENIAL REASONS – DO NOT USE FOR MEDICARE PART D</b>
1.	Go to 2	Go to 3	
2.	Go to 10	Deny	You do not meet the requirements of your plan.

			<p>Your plan covers additional quantities of this drug when you are 12 years of age or older and you meet one of these conditions:</p> <ul style="list-style-type: none"> <li>- You have acute uncomplicated influenza</li> <li>- You need to prevent influenza</li> </ul> <p>Your request has been denied based on the information we have. [Short Description: No approvable diagnosis, Xofluza]</p>
3.	Go to 4	Deny	<p>You do not meet the requirements of your plan. Your plan covers additional quantities of the requested drug when you meet one of these conditions:</p> <ul style="list-style-type: none"> <li>- You have influenza A or B viral infection</li> <li>- You need to prevent influenza A or B viral infection</li> </ul> <p>Your request has been denied based on the information we have. [Short Description: No approvable diagnosis, Relenza or Tamiflu]</p>
4.	Go to 5	Go to 8	
5.	Go to 6	Approve, 3 months for an additional quantity of Tamiflu (oseltamivir) 75mg: 42 capsules or 45mg: 42 capsules or 30mg: 84 capsules or Suspension: 540mL	
6.	Go to 7	Deny	<p>You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to:</p> <ul style="list-style-type: none"> <li>- 42 capsules of Tamiflu (oseltamivir) 75mg or</li> <li>- 42 capsules of Tamiflu (oseltamivir) 45mg or</li> <li>- 84 capsules of Tamiflu (oseltamivir) 30mg or</li> <li>- 9 bottles (540mL) of Tamiflu (oseltamivir) suspension</li> </ul> <p>Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 3 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity, Tamiflu community outbreak without immune deficiency]</p>
7.	Deny	Approve, 3 months for an additional quantity of Tamiflu (oseltamivir) 75mg: 84 capsules or 45mg: 84 capsules or 30mg: 168 capsules or Suspension: 1080mL	<p>You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to:</p> <ul style="list-style-type: none"> <li>- 84 capsules of Tamiflu (oseltamivir) 75mg or</li> <li>- 84 capsules of Tamiflu (oseltamivir) 45mg or</li> <li>- 168 capsules of Tamiflu (oseltamivir) 30mg or</li> <li>- 18 bottles (1080mL) of Tamiflu (oseltamivir) suspension</li> </ul> <p>Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 3 months. Your request for additional quantities of the requested drug and strength has been denied.</p>

			[Short Description: Over max quantity, Tamiflu community outbreak with immune deficiency]
8.	Go to 9	Go to 10	
9.	Deny	Approve, 3 months for an additional quantity of Relenza (zanamivir) 60 Blisters	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 60 blisters of Relenza (zanamivir). Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 3 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity, Relenza community outbreak]
10.	Deny For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.	Approve, 3 months for an additional quantity of: oseltamivir (Tamiflu) 75mg: 10 capsules or 45mg: 10 capsules or 30mg: 20 capsules or 180mL Suspension or Relenza (zanamivir) 20 blisters or Xofluza (baloxavir) 20mg (2 tablets per blister card): 2 tablets or 40mg (1 tablet per blister card): 1 tablet or 40mg (2 tablets per blister card): 2 tablets or 80mg (1 tablet per blister card): 1 tablet or 40mL Suspension	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to: - 10 capsules of Tamiflu (oseltamivir) 45mg or - 10 capsules of Tamiflu (oseltamivir) 75mg or - 20 capsules of Tamiflu (oseltamivir) 30mg or - 3 bottles (180mL) of Tamiflu (oseltamivir) suspension or - 20 blisters of Relenza (zanamivir) or - 2 tablets of Xofluza (baloxavir) 20mg (2 tablets per blister card) or - 1 tablet of Xofluza (baloxavir) 40mg (1 tablet per blister card) or - 2 tablets of Xofluza (baloxavir) 40mg (2 tablets per blister card) or - 1 tablet of Xofluza (baloxavir) 80mg (1 tablet per blister card) or - 2 bottles (40mL) of Xofluza (baloxavir) Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 3 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity, additional course for treatment or household prevention]