Anti-Influenza Agents Quantity Limit Program Summary

This program applies to Commercial, GenPlus, NetResults A series, Blue Partner, SourceRx and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Anti-Influenza Agent Quantity Limit is to help encourage appropriate dosage according to FDA label and/or guidelines. The program accommodates for two rounds of influenza treatment or 20 days of prophylaxis in a 120 day period. Requests for larger quantities will be evaluated through the Clinical Review process when the prescriber provides evidence that dosing with higher quantities is appropriate for the patient.

PROGRAM QUANTITY LIMITS

Brand (generic)	GPI	Multisource Code	Quantity per 120 days
Relenza (zanamivir)			
5 mg blister	12504080008020	M, N, O, or Y	40 blisters
Tamiflu (oseltamivir)[a]			
30 mg capsule	12504060200110	M, N, O, or Y	20 capsules
45 mg capsule	12504060200115	M, N, O, or Y	20 capsules
75 mg capsule	12504060200120	M, N, O, or Y	20 capsules
6 mg/ml suspension	12504060201910	M, N, O, or Y	360 ml
12 mg/ml suspension	12504060201920	M, N, O, or Y	150 ml
Xofluza (baloxavir marboxil)			
20 mg tablets	1250202020B720	M, N, O, or Y	4 tablets
40 mg tablets	1250202020B735	M, N, O, or Y	4 tablets

a – generic available

QUANTITY LIMIT AUTHORIZATION CRITERIA FOR APPROVAL

Requests above the set quantity limit will be approved when BOTH of the following are met:

1. ONE of the following:
   a. The patient requires additional courses of therapy due to additional episodes of acute influenza infection
   OR
   b. The patient requires additional courses or increased duration of therapy for prophylaxis after exposure to an influenza infected person

   AND
2. ONE of the following:
   a. There is no shortage of the prescribed agent and ONE of the following:
      i. BOTH of the following:
         1. The requested quantity (dose) is less than or equal to the FDA labeled dose
         AND
         2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

      OR

      ii. BOTH of the following:
         1. The requested quantity (dose) is greater than the FDA labeled dose
         AND
         2. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

OR

b. There is a shortage of the prescribed agent and ONE of the following:
    i. The requested quantity (dose) is less than or equal to the FDA labeled dose
    OR
    ii. BOTH of the following:
        1. The requested quantity (dose) is greater than the FDA labeled dose
        AND
        2. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 4 months

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.

FDA APPROVED INDICATIONS AND DOSAGE[1,2]

Agent	Indication	Dosage & Administration

Relenza® (zanamivir) oral inhalation powder	Treatment of influenza in patients aged 7 years and older who have been symptomatic for no more than 2 days.
	
	Prophylaxis of influenza in patients aged 5 years and older.
	
	Important limitations on use of zanamivir:
	• Not recommended for treatment or prophylaxis of influenza in:
	  ○ Individuals with underlying airways disease
	• Not proven effective for:
	  ○ Treatment in individuals with underlying airways disease.
	  ○ Prophylaxis in nursing home residents.
		Treatment of influenza:
		• 10 mg twice daily for 5 days
		
		Prophylaxis of influenza:
		• Household setting: 10 mg once daily for 10 days
		• Community Outbreak: 10 mg once daily for 28 days
		
		The 10-mg dose is provided by 2 inhalations (one 5-mg blister per inhalation).

Agent	Indication	Dosage & Administration
Tamiflu® (oseltamivir)[a] capsules, oral suspension	Treatment of acute, uncomplicated influenza in patients 2 weeks of age and older who have been symptomatic for no more than 2 days. Prophylaxis of influenza in patients 1 year and older. Important limitations of use: • Efficacy not established in patients who begin therapy after 48 hours of symptoms. • Not a substitute for annual influenza vaccination. • No evidence of efficacy for illness from agents other than influenza viruses types A and B. • Consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use.	Treatment of influenza: • Adults and adolescents (13 years and older): 75 mg twice daily for 5 days • Pediatric patients 1 to 12 years of age: Based on weight twice daily for 5 days • Pediatric patients 2 weeks to less than 1 year of age: 3mg/kg twice daily for 5 days • Renally impaired adult patients (creatinine clearance >30-60 mL/min): Reduce to 30 mg twice daily for 5 days • Renally impaired adult patients (creatinine clearance >10-30 mL/min): Reduce to 30 mg once daily for 5 days • ESRD patients on hemodialysis: Reduce to 30 mg after every hemodialysis cycle. Treatment duration not to exceed 5 days • ESRD patients on CAPD: Reduce to a single 30 mg dose administered immediately after a dialysis exchange Prophylaxis of influenza: • Adults and adolescents (13 years and older): 75 mg once daily for at least 10 days - Community outbreak: 75 mg once daily for up to 6 weeks • Pediatric patients 1 to 12 years of age: Based on weight once daily for 10 days - Community outbreak: Based on weight once daily for up to 6 weeks • Renally impaired adult patients (creatinine clearance >30-60 mL/min): Reduce to 30 mg once daily • Renally impaired adult patients (creatinine clearance >10-30 mL/min): Reduce to 30 mg once every other day • ESRD patients on hemodialysis: Reduce to 30 mg after alternate hemodialysis cycles for the recommended duration of prophylaxis • ESRD patients on CAPD: Reduce to 30 mg once weekly immediately after dialysis exchange for the recommended duration of prophylaxis

a – generic available

CLINICAL RATIONALE

Guidelines

The Center for Disease Control and Prevention (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. Indiscriminate use of chemoprophylaxis might promote resistance to antiviral medications, or reduce antiviral medication availability for treatment of persons at higher risk for influenza complications or those who are severely ill.

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).[3]

Safety

Zanamivir is contraindicated in patients with history of allergic reaction to any ingredient of Relenza, including milk proteins.[1]

Oseltamivir is contraindicated in patients with known serious hypersensitivity to oseltamivir or any of the components of Tamiflu.[2]

REFERENCES

1. Relenza prescribing information. GlaxoSmithKline. August 2016.
2. Tamiflu prescribing information. Gilead Sciences, Inc. June 2016.
3. Influenza Antiviral Medications: Summary for Clinicians. Center for Disease Control and Prevention. Accessed on 5/11/2017. https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm.