



Oseltamivir (Tamiflu®) Critical Shortage

November 30, 2022

Situation

A nationwide critical shortage of oseltamivir (Tamiflu®) is impacting BJC hospitals and pharmacies.

Background

- Four influenza antivirals are recommended for use in the U.S. during the 2022-2023 influenza season: oral oseltamivir, inhaled zanamivir, intravenous peramivir, and oral baloxavir.
- The Centers for Disease Control and Prevention (CDC) recommends antiviral treatment as soon as possible, regardless of illness duration, and without waiting for test results for the following:
 - all hospitalized patients
 - severe, complicated, or progressive illness
 - patients at high risk* for influenza complications

Early antiviral treatment may reduce complications (e.g., otitis media in young children, pneumonia, respiratory failure), hospital admission, and mortality in hospitalized patients.

*Patients at high risk for influenza complications include: < 5 yrs; > 65 yrs; chronic heart, lung, liver, renal, hematologic, neurologic, metabolic disease; < 19 yrs on long-term salicylates; immunocompromised; pregnant or postpartum (within 2 weeks of delivery); morbid obesity (BMI > 40); long-term care facility resident; Black, Hispanic/Latino, American Indian, or Alaskan native.

- The CDC notes that antiviral treatment of non-high-risk outpatients can be considered if it can be initiated within 48 hours of illness onset. Treatment may shorten illness by about one day and reduce household transmissions.

Assessment

- BJC hospitals currently have ~30 days of oseltamivir on hand for inpatient/Emergency Department administration.
- BJC retail pharmacies currently have ~75 courses on hand for outpatient prescriptions.
- Supply estimates may change depending on demand and future allocations.
- There have been reports of difficulty obtaining oseltamivir in the community.
- There is limited availability of oseltamivir 30 mg capsules. Alternative dosing strategies will be needed in patients with renal insufficiency.
- Oseltamivir demand will likely outpace forecasted supply given the trajectory of increasing influenza cases and projected allocations.
- Oseltamivir conservation strategies are necessary to preserve use for patients most likely to benefit.

Recommendations

1. Vaccination should be encouraged for all patients 6 months and older as it is the most effective way to prevent influenza infection and its complications. Influenza vaccines are widely available at community pharmacies, BJCMG clinics, and WUSM clinics.

2. The tables below outline priority considerations for influenza antiviral use in the outpatient/ED setting (Table 1) and the inpatient setting (Table 2). These recommendations are intended to provide guidance on prioritization of and alternatives to oseltamivir and are not intended to supersede clinical judgement.

TABLE 1

Outpatient/Ambulatory Emergency Department Influenza Antiviral Priority Considerations		
Therapy/Duration	Inclusion Criteria	Exclusion Criteria
Oseltamivir (5 days)	Highest Priority <ul style="list-style-type: none"> • Complicated/progressive illness • Pregnant/breastfeeding • < 5 years • Immunocompromised • High-risk [baloxavir may be considered for certain outpatients (not to start in ED)— <i>see baloxavir information below</i>] Lower Priority (use baloxavir or zanamivir where appropriate - see below) <ul style="list-style-type: none"> • Prophylaxis: ≥ 3 months for post-exposure prophylaxis for high-risk outpatients if within 48 hours of exposure AND unable to take baloxavir or zanamivir (7 days duration) • Treatment of an otherwise healthy person within 48 hours of illness duration AND unable to take baloxavir or zanamivir 	Healthy and illness onset > 48 hours (unlikely to benefit)
Baloxavir (Single dose) <ul style="list-style-type: none"> • ~\$194 out-of-pocket • MO and IL Medicaid require prior authorization 	Treatment: <ul style="list-style-type: none"> • ≥ 5 years and healthy and within 48 hours of illness onset • High-risk and ≥ 12 years Prophylaxis: <ul style="list-style-type: none"> • ≥ 5 years for post-exposure prophylaxis for high-risk outpatients if within 48 hours of exposure 	<ul style="list-style-type: none"> • < 5 yrs old • High-risk and < 12 yrs old • Complicated or progressive illness • Pregnant/breastfeeding • Immunocompromised • Barriers to cost • Healthy and illness onset > 48 hours (unlikely to benefit)
Zanamivir (inhaled) (5 days) Check pharmacy for availability <ul style="list-style-type: none"> • ~\$79 out-of-pocket • Not covered by MO or IL Medicaid • Check pharmacy for availability. 	Treatment: <ul style="list-style-type: none"> • ≥ 7 years and healthy and within 48 hours of illness onset Prophylaxis: <ul style="list-style-type: none"> • ≥ 5 years for post-exposure prophylaxis for high-risk outpatients if within 48 hours of exposure 	<ul style="list-style-type: none"> • < 7 yrs old • Complicated or progressive illness • Respiratory disease (e.g., asthma, COPD) • Milk protein/lactose allergy • Unable to use dry-powder inhaler properly • Barriers to cost • Healthy and illness onset > 48 hours (unlikely to benefit)

TABLE 2

Inpatient Influenza Antiviral Priority Considerations		
Treatment should be started as soon as possible, regardless of illness duration, and without waiting for test results.		
Therapy	Inclusion Criteria	Exclusion Criteria
Oseltamivir (5 days) <i>A longer duration may be considered in immunocompromised patients or based on virologic testing of lower respiratory tract specimens in severe, prolonged illness</i>	<ul style="list-style-type: none"> Preferred in all hospitalized patients 	<ul style="list-style-type: none"> Inpatient post-exposure prophylaxis. Utilize close monitoring and early treatment.
Baloxavir (restricted) (Single dose)	<ul style="list-style-type: none"> Documented allergy or intolerance to neuraminidase inhibitors Suspected oseltamivir/peramivir resistance In combination with oseltamivir or peramivir for severely immunocompromised patients or patients with severe/complicated influenza 	<ul style="list-style-type: none"> < 5 years High-risk and < 12 years Pregnant/breastfeeding Must meet an inclusion criterion
Peramivir (IV) (restricted)	<ul style="list-style-type: none"> Given as a one-time dose for patients with uncomplicated influenza who cannot tolerate or absorb oral or enterally-administered oseltamivir Given daily for patients with severe/complicated influenza who cannot tolerate or absorb oral or enterally-administered oseltamivir 	<ul style="list-style-type: none"> < 6 months Must meet an inclusion criterion

3. For patients with renal insufficiency, alternative dosing (in red) is recommended due to limited availability of the 30 mg capsules.

	CrCl (mL/min)					
Indication	≥ 61	31-60	≤ 30	IHD	PD	CVVHD, SLED
FDA approved standard treatment dose	75 mg q12h	30 mg q12h	30 mg q24h	30 mg now , then 30 mg 3x weekly after HD	30 mg once (to provide a 5 day duration)	30 mg q12h
Alternative dosing during shortage	75 mg q12h	75 mg q24h	75 mg q48h	30 mg now , then 30 mg 3x weekly after HD	30 mg once (to provide a 5-day duration)	75 mg q24h

Pediatric standard dosing is not impacted by the 30 mg capsule shortage. Recommended dosing is provided below for reference.

Tamiflu (Oseltamivir) Dosing Recommendations

Age	Weight	Treatment Dose	Prophylaxis Dose
NICU & Neonates (Corrected Gestational Age)	---		
≤ 28 weeks		1 mg/kg PO q24h x 5 days	Not recommended unless situation judged critical due to limited data on use in this age group. If needed, follow treatment dosing guidelines Please contact ID Fellow with questions or concerns
29-37 weeks		1 mg/kg PO q12h x 5 days	
38-40 weeks		1.5 mg/kg PO q12h x 5 days	
> 40 weeks		3 mg/kg PO q12h x 5 days	
Non-NICU 1 to < 3 months	---	3 mg/kg/dose BID x 5 days	Not recommended unless situation judged critical due to limited data on use in this age group. If needed, follow treatment dosing guidelines Please contact ID Fellow with questions or concerns
3 to 11 months	---	3 mg/kg/dose po BID x 5 days	3 mg/kg/dose po once daily x 7 days
≥ 12 months	≤ 15 kg	30 mg po BID x 5 days	30 mg po once daily x 7 days
	16-23 kg	45 mg po BID x 5 days	45 mg po once daily x 7 days
	24 -40 kg	60 mg po BID x 5 days	60 mg po once daily x 7 days
	> 40 kg	75 mg po BID x 5 days	75 mg po once daily x 7 days

BJC will continue to monitor and provide updates as the situation evolves. For more guidance on testing and future updates, visit the [BJC Intranet homepage](#).

For questions or concerns, please contact Helen Newland at helen.newland@bjc.org.