

**University of Maryland Medical System  
Investigational Drug Pharmacy**

**H1N1 Antiviral Agent Procurement Procedure**

**1. Peramivir**

- On October 26, 2009, FDA issued Emergency Use Authorization (EUA) for the emergency use of the unapproved drug IV peramivir administration for treatment of 2009 H1N1 influenza virus in adult and pediatric patients.
- **No need to go through FDA IND application, IRB approval, and consenting**
- How to obtain peramivir?
  - Go to CDC website <http://emergency.cdc.gov/h1n1antivirals>
  - Fill peramivir request on website
- CDC will ship the drug and receive within 24 hours.
- Shipment: CDC ships 30 vials per shipment (up to 10 days supply)
- *Can we use peramivir shipped for patient A to treat patient B?*
  - *A: as of October 27, 2009, CDC does not allow the transfer of peramivir from one patient supply to another patient. But CDC is working on it. If we have left over peramivir from one patient, please do not destroy them and keep it until notice from CDC.*
- Pharmnet order entry is available.

**2. Relenza (Zanamivir)**

- FDA approved zanamivir inhalation for H1N1 treatment. However, *IV formulation zanamivir is not approved drug*. Therefore, if you want to treat your patient with IV zanamivir, it is required to go through **Emergency compassionate Use procedure:**
  - **UMB HRPP Policy I.5.C**
- Contact FDA to obtain IND for a single patient needs
  - Antiviral product division: phone #--- 301-796-1500
- Once you receive IND number, contact GSK for shipment arrangement
  - Glaxo-SmithKline contact person: Annie Cameron 919-483-6958, cell: 919-632-9380, fax: 919-315-5263 e-mail: [annie.m.cameron@gsk.com](mailto:annie.m.cameron@gsk.com)
  - Provide shipping address to IDS pharmacy:  
IDS pharmacy, Room N9E14  
University of Maryland Medical Center  
22 South Greene Street  
Baltimore, MD 21201  
Tel: 410-328-5468
- Contact IRB to let them know that there is emergency compassionate use of zanamivir for your patient. All paper work can submit to IRB after the initiation of treatment.
  - HRPO contact number: 410-706-5037
- Need consenting the patient prior to treatment
- This will be single patient emergency compassionate use. Therefore, any left over drug after completion of treatment should be destroyed and documented.
- Pharmnet order entry is available.

*If you have any questions regarding emergency use of H1N1 antiviral agents, please contact IDS pharmacy @ 410-328-5468.*