Protocol for the Administration of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal

***Please compare the Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal package insert with the LAIV package insert and LAIV protocol. Some of the recommendations in this protocol are not included in the package insert for Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal, but they can be found in the LAIV package insert and LAIV protocol and are considered prudent guidance by the Kentucky Immunization Program.**

Indications and Usage: Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal is indicated for the active immunization of individuals against influenza disease caused by pandemic (H1N1) 2009 virus. It is a live, nasally administered vaccine approved for use ONLY among healthy **nonpregnant** persons aged 2 through 49 years.

Vaccination efforts with Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should focus **initially** on persons likely to come in contact with influenza viruses as part of their occupation and could transmit influenza viruses to others in medical care settings, or are close contacts of infants aged less than 6 months (who are too young to be vaccinated).

Persons for whom vaccination with Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal is recommended

Initially:

- Healthy children, adolescents and adults (aged 2 through 24 years) except for pregnant adolescents and adults;
- Healthy healthcare and emergency medical services personnel (HCP and EMS personnel), aged 49 years or less, except for pregnant HCP and EMS personnel);
- Healthy household contacts and caregivers (aged 2 through 49 years), except for pregnant women, of infants aged less than 6 months (e.g., parents, siblings, and daycare providers).

Per ACIP, health-care personnel (HCP) recommended for priority vaccination include those in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics. The recommendations also apply to persons who provide home health care and emergency medical services.

Simultaneous administration of seasonal and H1N1 influenza vaccines

- You can administer both the inactivated seasonal influenza vaccine and the inactivated Influenza A (H1N1) 2009 Monovalent Vaccine at the same visit (using separate syringes and sites) or at any time before or after each other.
- You can administer the inactivated seasonal influenza vaccine and Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal together or at any time before or after each other.
- You can administer the seasonal live attenuated influenza virus vaccine and inactivated Influenza A (H1N1) 2009 Monovalent Vaccine together or at any time before or after each other.
- Administering both the seasonal live attenuated influenza virus vaccine and Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal at the same visit **IS NOT RECOMMENDED** because of concerns about competition between the two vaccine viruses. If you have only seasonal live attenuated influenza virus vaccine and Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal available, you should separate the doses of the two live attenuated influenza virus vaccines by at least 4 weeks.

Dosage and Route

Age group	Dosage Schedule
Children (aged 2 through 9 years)	2 doses (0.2 mL each approximately 1 month apart)
Children, adolescents and adults (aged 10 through 49 years)	1 dose (0.2 mL)

Each 0.2 mL dose is administered as 0.1 mL per nostril. Note that the age groups for the two dose schedule is for children aged 2 through 9 years, whereas the two dose series for seasonal Live Attenuated Influenza Vaccine is for children aged 2 through 8 years.

To administer the vaccine (See the product package insert for complete step-by-step instructions):

- Place the recipient in an upright position
- Remove the rubber tip protector from the sprayer. Do not remove the dose-divider clip at the other end of the sprayer.
- Place the tip just inside the first nostril
- With a single motion, depress plunger **as rapidly as possible** until the dose-divider clip prevents you from going further
- Pinch and remove the dose-divider clip from the plunger
- Place the tip just inside the other nostril and with a single motion, depress plunger **as rapidly as possible** to deliver remaining vaccine

Anatomical Site: Intranasal [**Under no circumstances should Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal be administered by the intramuscular, intradermal, or intravenous route.]**

Precautions

- If Guillain-Barré Syndrome has occurred with any prior influenza vaccination, the decision to give Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should be based on careful consideration of the potential benefits and risks.
- Moderate or severe illness with or without fever, postpone administration of the vaccine until recovery from the acute phase of moderate or severe illness.
- Because antivirals reduce replication of influenza viruses, Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should not be administered until 48 hours after cessation of influenza antiviral therapy and influenza antiviral medications should not be administered for two weeks after receipt of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal. Persons receiving antivirals within the period 2 days before to 14 days after vaccination with Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should be revaccinated at a later date with any approved Influenza A (H1N1) 2009 vaccine formulation.
- Defer administration of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal if nasal congestion is present.

Contraindications

- Persons with a history of hypersensitivity, including anaphylaxis, to eggs, egg proteins, gentamicin, gelatin, arginine or any previous influenza vaccination;
- Persons aged less than 2 years or those aged 50 years and older;
- Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurological/neuromuscular, hematological, or metabolic disorders (including diabetes mellitus);
- Adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV);
- Children aged 2 through 4 years whose parents or caregivers report that a health-care provider has told them during the preceding 12 months that their child had wheezing or asthma, or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;
- Children or adolescents aged 2 years through 18 years receiving aspirin or other salicylates (because of the association of Reye's syndrome with wild-type influenza virus infection);
- Pregnant women;
- Close contacts of immunosuppressed persons who require a protected environment.

Screening for asthma or wheezing illness (or history of wheezing illness) when considering use of Live Influenza A (H1N1) 2009 Monovalent Vaccine for children aged 2 through 4 years

- Clinicians and vaccination programs should screen for asthma or wheezing illness (or history of wheezing illness) when considering use of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal for children aged 2 through 4 years, and should avoid use of this vaccine in children with asthma or a recent wheezing episode within the previous 12 months.
- Health-care providers should consult the medical record, when available, to identify children aged 2 through 4 years with asthma or recurrent wheezing that might indicate asthma.
- In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal, parents or caregivers of children aged 2 through 4 years should be asked: "**In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?**"
- Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record during the preceding 12 months **should not** receive Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal.

Warnings

The following children, adolescents, and adults **SHOULD NOT** be vaccinated with Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal but should receive Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine if 6 months of age or older:

- Children aged less than 2 years;
- Adults aged 50 years and older;
- Persons with asthma, reactive airways disease or other chronic disorders of the pulmonary or cardiovascular systems;
- Persons with other underlying medical conditions, such as the metabolic diseases, diabetes, renal dysfunction, and hemoglobinopathies;
- Pregnant women;
- Household or other close contacts of a person with severe immunosuppression requiring care in a protective environment.

Adverse Events—See the product's package insert.

Storage and Handling

- Store between 35°-46°F (2°-8°C) DO NOT FREEZE.
- The product must be used before the expiration date on the sprayer label.

Other Important Notes –

Shedding Vaccine virus

- Nasopharyngeal secretions or swabs collected from vaccinees may test positive for influenza virus for up to three weeks post immunization.

Administering Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal

- Severely immunosuppressed persons should not receive Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal.

Healthcare personnel or hospital visitors

- Who have received Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should refrain from contact with severely immunosuppressed patients requiring a protective environment for 7 days after receipt of vaccine. Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine is recommended for vaccinating household members, HCP, and others who have close contact with severely immunosuppressed persons (e.g. patients with hematopoietic stem cell transplants) requiring care in a protective environment.
- Hospital visitors who have received Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should avoid contact with severely immunosuppressed persons in protected environments for 7 days after vaccination but should not be restricted from visiting less severely immunosuppressed patients.

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M.D. Signature **Date**