Pharmacy Immunization Protocol

LIVE ATTENUATED INFLUENZA VACCINE (LAIV4)

<table>
<thead>
<tr>
<th>Last Reviewed</th>
<th>23 August 2019</th>
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<tbody>
<tr>
<td>Last Revised</td>
<td>23 August 2019</td>
</tr>
<tr>
<td>This order expires</td>
<td>30 June 2020</td>
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</tbody>
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1. What’s new

Live attenuated influenza vaccine for use in the 2019–2020 influenza season (Northern Hemisphere) contains the following:

Quadrivalent:
- A/Brisbane/02/2018 (H1N1) pdm09-like virus (updated)
- A/Kansas/14/2017 (H3N2)-like virus (updated)
- B/Colorado/06/2017-like (Victoria lineage) virus
- B/Phuket/3073/2013-like (Yamagata lineage) virus

Based on recommendations from the Advisory Committee on Immunization Practices:

PP Live Attenuated Influenza Vaccines
A. Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.

B. Children aged 6 months through 8 years who require 2 doses should receive their first dose as soon as possible after vaccine becomes available, and the second dose ≥4 weeks later. Children who receive the first dose at age 8 years and turn 9 during flu season should still receive the 2nd dose in the same season.

C. Persons with a history of egg allergy of any severity may receive any licensed, recommended, and age-appropriate influenza vaccine.

D. For those requiring only one dose in the current season, early vaccination (i.e., in July and August) is likely to be associated with suboptimal immunity before the end of the influenza season, particularly among older adults. See separate order for inactivated (IIV) and recombinant (RIV) influenza vaccines.

2. Oregon immunization model standing order:

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines. This is recommended, but not required, for influenza administration only.

B. Screen clients for contraindications.

C. Provide a current Vaccine Information Statement (VIS), answering any questions.

D. Record all required data elements in the client’s permanent health record.

E. Give FluMist® Intranasally. See section II for schedule.

F. May be given with all ACIP-recommended child and adult vaccinations.

__________________________________________
Immunizing Pharmacist Date
3. Vaccine schedule

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
<th>No. of Doses</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>7–8 years</td>
<td>0.2 mL, 0.1 mL per nostril</td>
<td>1 or 2*</td>
<td>Intranasal</td>
</tr>
<tr>
<td>9–49 years</td>
<td>0.2 mL, 0.1 mL per nostril</td>
<td>1</td>
<td>Intranasal</td>
</tr>
</tbody>
</table>

4. Licensed influenza vaccine

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Presentation</th>
<th>Acceptable Age Range</th>
<th>Thimerosal (µg Hg/0.5 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FluMist®1 Quadrivalent</td>
<td>0.2 mL pre-filled intranasal sprayer</td>
<td>2–49 years</td>
<td>None</td>
</tr>
</tbody>
</table>

5. Recommendations for use

A. All persons 2 – 49 years of age without contraindications. Children <9 years of age receiving flu vaccine for the first time need 2 doses. Doses should be separated by 28 days. Children who receive the first dose at age 8 years and turn 9 during flu season should still receive the 2nd dose in the same season.

B. Do not use LAIV in pregnant women.

C. Persons with a history of egg allergy of any severity may receive any licensed, recommended, and age-appropriate influenza vaccine. Vaccine administration should be supervised by a health care provider who is able to identify and manage severe allergic reactions.

D. For those requiring only one dose in the current season, early vaccination (i.e., in July and August) is likely to be associated with suboptimal immunity before the end of the influenza season, particularly among older adults.

E. Providers should offer flu vaccination to unvaccinated persons by the end of October, if possible. Vaccination should continue to be offered as long as
unexpired vaccine is available.

* Minimum spacing 28 days

6. Contraindications

A. A severe allergic reaction (requiring epinephrine or emergency medical attention) to a previous dose of influenza vaccine.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Potential allergen(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FluMist®¹ Quadrivalent</td>
<td>Monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA).</td>
</tr>
</tbody>
</table>

B. Concomitant aspirin or salicylate-containing therapy in children and adolescents through age 17 years of age.

C. Children aged 2 through 4 years who have received a diagnosis of asthma or 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.²

D. Children and adults who are immunocompromised due to any cause (including immunosuppression caused by medications or by HIV infection).

E. Close contacts and caregivers of severely immunosuppressed persons who require a protected environment.

F. Pregnancy.

G. Receipt of influenza antiviral medication within the previous 48 hours.²

7. Warnings and precautions

A. Persons with moderate or severe illnesses with or without fever should delay immunization until illness has resolved. However, mild acute illness with or without fever, do not contraindicate use of influenza vaccine.⁴

B. Persons with a history of Guillain-Barré Syndrome (GBS) following influenza vaccination have a substantially greater likelihood of subsequently developing GBS than persons without such a history. Whether influenza vaccination might be causally associated with this risk for recurrence is not known. Consult with an individual’s health care provider and consider avoiding a subsequent
influenza vaccination in persons known to have developed GBS within 6 weeks of a previous influenza vaccination. Experts believe that the benefits of influenza vaccination justify yearly vaccination for most persons who have a history of GBS and who are at risk for severe complications from influenza.\textsuperscript{2}

C. Asthma in persons \geq 5 years of age.\textsuperscript{2}

D. Other underlying medical conditions that might predispose to complications after wild-type influenza infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders including diabetes mellitus).\textsuperscript{2}

8. Other considerations

A. \textbf{Adverse events}: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration. Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.\textsuperscript{4}

B. \textbf{Unvaccinated children <9 years of age}: Children <9 years old receiving flu vaccine for the first time need 2 doses. Doses must be separated by 28 days. Children who receive the first dose at age 8 years and turn 9 during flu season should still receive the 2\textsuperscript{nd} dose in the same season. Children with a lifetime history of 2 previous doses in any season(s) only need a single seasonal booster dose.\textsuperscript{2}

C. \textbf{Lactation}: FluMist is not absorbed systemically by the mother following intranasal administration and breastfeeding is not expected to result in exposure of the child to FluMist.\textsuperscript{1}

D. \textbf{Immunity}: Adults have antibody protection against influenza virus about 2 weeks after vaccination.\textsuperscript{2}

E. \textbf{Influenza Antiviral Medications}: May reduce the effectiveness of FluMist\textsuperscript{®} Quadrivalent if administered within 48 hours before, or within 2 weeks after vaccination. If antiviral agents and FluMist\textsuperscript{®} are given concomitantly, revaccination should be considered.\textsuperscript{1}

F. \textbf{Shedding Vaccine Virus}: Nasopharyngeal secretions or swabs collected from vaccines may test positive for influenza virus for up to three weeks post immunization. In rare instances, shed vaccine viruses can be transmitted from vaccine recipients to unvaccinated persons. Persons who care for severely immunosuppressed persons who require a protective environment should not receive FluMist\textsuperscript{®} given the theoretical risk of transmission of the live, attenuated vaccine virus.\textsuperscript{2}

G. \textbf{Administering LAIV}: Severely immunosuppressed persons should not
administer LAIV. However, other persons at high risk from influenza complications may administer LAIV. These include persons with underlying medical conditions placing them at high risk, including pregnant women, persons with asthma and persons ≥50 years of age.²

9. Side effects and adverse reactions¹

| Live attenuated influenza vaccine | 
| Nasal congestion | Up to 58% of recipients |
| Low grade fever, headache, sore throat | 5%–20% |
| Allergic reactions | Rare |

10. Storage and handling ¹

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Temp</th>
<th>Storage Issues</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>FluMist®¹ Quadrivalent</td>
<td>2°–8°C</td>
<td>Do not freeze</td>
<td>A single temperature excursion up to 25°C (77°F) for 12 hours has been shown to have no adverse impact on the vaccine. No further excursions are allowed.</td>
</tr>
<tr>
<td>Keep enclosed in outer carton to protect from light</td>
<td>Once administered or expired, the sprayer should be disposed of according to the standard procedures for medical waster (e.g. sharps container or biohazard container)</td>
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11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at [https://vaers.hhs.gov/reportevent.html](https://vaers.hhs.gov/reportevent.html).

VAERS Reporting Table: [https://vaers.hhs.gov/resources/infoprotocols.html](https://vaers.hhs.gov/resources/infoprotocols.html)
Event and interval from vaccination

<table>
<thead>
<tr>
<th>Event and interval from vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Anaphylaxis or anaphylactic shock within 7 days;</td>
</tr>
<tr>
<td>B. Vasovagal syncope within 7 days;</td>
</tr>
<tr>
<td>C. Guillain-Barré Syndrome within 42 days;</td>
</tr>
<tr>
<td>D. Any acute complication or sequelae (including death) of above events;</td>
</tr>
<tr>
<td>E. Any event described in the manufacturer’s package insert as a contraindication to additional doses of vaccine.</td>
</tr>
</tbody>
</table>

12. References


To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

Electronic copy of this pharmacy protocol is available at: protocols
13. Appendix A

FluMist Administration Procedure¹:

1. **Check expiration date.**
   Product must be used before the date on sprayer label.

2. Remove rubber tip protector. Do not remove dose-divider clip at the other end of the sprayer.

3. With the patient in an upright position, place the tip just inside the nostril to ensure FluMist is delivered into the nose.

4. With a single motion, depress plunger as rapidly as possible until the dose-divider clip prevents you from going further.

5. Pinch and remove the dose-divider clip from plunger.

6. Place the tip just inside the other nostril and with a single motion, depress plunger as rapidly as possible to deliver remaining vaccine.

⚠️ **DO NOT INJECT. DO NOT USE A NEEDLE.**

*Note:* Active inhalation (i.e., sniffing) is not required by the patient during FluMist administration.