Title: 2019-2020 Influenza Vaccine Products and Ordering Information

SBAR: Situation-Background-Assessment-Recommendation

Initiation and Feedback Phase

Situation:
An annual evaluation of influenza vaccines is necessary to determine which products will be purchased and supported in the Trinity Health electronic health record (EHR) for administration to inpatients, Trinity Health colleagues and licensed independent practitioners (LIPs). The following plan includes guidance on vaccine types, manufacturers, and specific products for use and the approved distributor for ordering and procurement for the 2019-2020 flu season.

Background:
- Trinity Health purchased over 400,000 doses of flu vaccine for flu season 2018-2019
- Due to the short time allotment between contracting and pre-order deadlines (less than 2 months), an "Influenza group" consisting of infection preventionists, pharmacists, physician(s), and nurses (infection prevention and employee health) meet to review clinical guidance and the contracted vaccine products
- The guiding principles for the Trinity Health Influenza group for the annual evaluation are:
  - To follow the recommendations of the Advisory Committee on Immunization Practices (ACIP) for seasonal influenza vaccines
  - Presentation preference: prefilled syringes, latex free and preservative free products
- There are 2 flu vaccine suppliers on contract with Healthtrust: Seqirus and Sanofi-Pasteur
  - Product options include quadrivalent, a trivalent adjuvanted, and a trivalent high dose
- Utilizing a distributor instead of placing direct orders with manufacturers allows system level data that provides more transparency on how orders are managed and fulfilled

Assessment:

Special Patient Populations
- Live attenuated influenza vaccine (LAIV) (FluMist, intranasal formulation)\(^1\)
  - Due to concerns over efficacy compared to injectable vaccine, the American Academy of Pediatrics (AAP) – recommend the injectable influenza vaccine as the primary choice for children due to its consistent protection against all influenza strains in the recent years.
  - Sites may choose to purchase a small amount of the LAIV for ambulatory sites with the aim of adequate vaccination coverage and optimal protection in all children (i.e. children who would not otherwise receive the flu shot, as long as they are >2 years of age and healthy).
  - For colleagues that prefer the LAIV formulation, please verify that he/she meets the manufacturer and CDC/ACIP requirements for receipt of a live virus (https://www.cdc.gov/flu/about/qa/nasalspray.htm). If the ACIP includes the option of the LAIV in its annual recommendation for the 2019-2020 season, then receipt will meet the Trinity Health system vaccine requirement.

- Trivalent High Dose or Adjuvanted Trivalent for ages 65 years and older\(^1-7\)
  - The CDC and its Advisory Committee on Immunization Practices (ACIP) have extensively reviewed the available data for vaccine response and outcomes for these two products. Based on limitations of the current data, they have not expressed a preference for any specific flu vaccine for people 65 and older.
  - ACIP guidance for Older Adults: "No preference is expressed for any one vaccine type. Vaccination should not be delayed if a specific product is not readily available. \textit{For persons aged \textgreater 65 years, any age-appropriate Inactivated influenza vaccine (IIV) formulation (standard-dose or high dose, trivalent or quadrivalent, unadjuvanted or adjuvanted) or RIV4 are acceptable options.}"\(^8\)

- Egg allergy\(^1,2\)
For persons who report a history of egg allergy, ACIP recommends any licensed, recommended, and age-appropriate influenza vaccine. Sites may choose to order small amounts of the Flublok product for those who refuse a vaccine formula with any amount of egg protein.

Persons who report having had reactions to egg protein involving symptoms other than urticaria (hives), such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, should be administered the vaccine in an inpatient or outpatient medical setting (including, but not necessarily limited to hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions.

A previous severe allergic reaction to influenza vaccine, regardless of the component suspected of being responsible for the reaction, is a contraindication to future receipt of the vaccine.

Updated approval information for Fluzone Quadrivalent
- Fluzone Quadrivalent vaccine 0.5mL dose is now approved to be used in children 6 months of age and older. This offers the simplicity of using the same 0.5mL dose for all eligible patients when immunizing against the flu in settings that provide care for adults and children.

2019-2020 Influenza vaccine ordering and additional information:
- ASD is the sole Trinity Health authorized distributor for Influenza program 2019-2020. All flu vaccine orders for 2019-2020 must be placed through ASD.
  - A 3% rebate is paid to accounts that placed orders through ASD
  - All pre-booking through ASD needs to be completed by March 31st
- There is a 1-2 day turnaround time after ASD receives vaccines from the manufacturer
  - For orders placed by March 31st, vaccine shipments are based on shipment schedule listed above vs. order date
- Contract specifics
  - Return policy: see program flyer
  - Failure to supply
    - Seqirus: Based on product availability, Seqirus may provide substitution of comparable product, at the price of the originally ordered product or the contract price of the substituted product if lower. If Seqirus is unable to provide an adequate substitution within 7 days post the original delivery commitment, then Seqirus shall pay a $1.00 for each product dose late in the form of a credit memo rebate to the GPO member for each late dose delivered, accepted, and retained beyond the seven (7) day period. This will only pertain to the corresponding delivery schedule.
    - Sanofi Pasteur: Credit of $1 per dose for higher priced competitive purchases made due to Sanofi’s inability to ship; credit may be applied to future purchases of Sanofi influenza vaccines

Recommendation:
- ASD is the sole Trinity Health authorized distributor for Influenza program 2019-2020. All flu vaccine orders for 2019-2020 must be placed through ASD.
- The Afluria and Fluzone vaccine products (in the chart below) are the primary agents that will be purchased and supported in the Trinity Health electronic health record (EHR) for administration to inpatients, Trinity Health colleagues, and licensed independent practitioners (LIPs) for the 2019-2020 flu season.
  - Other influenza vaccine products ordered outside of these recommendations will not be supported in the inpatient electronic medical record build.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Age Indication</th>
<th>Cost per dose</th>
<th>Minimum Shipping commitment for orders pre-booked by March 31st: *</th>
</tr>
</thead>
</table>
Shipment commitment dates from the manufacturer to distributor. Includes cost of product and Federal Excise Tax (FET) cost of $7.50 per box

- Please refer to the attached order form. The Trinity Health primary agents are highlighted in yellow on the form.
- Ambulatory care providers/points of care can order any of the available formulas to meet their needs.
- For clinically related questions please contact Maria Pusnik at Maria.Pusnik@trinity-health.org; for supply chain related (contracts and ordering) questions please contact Agnieszka Lowery at Agnieszka.Hanulak@trinity-health.org.

Afluria Quadrivalent PFS
0.5 mL pre-filled syringes, no needles, 10 per box
0.5 mL dose approved for ages 3 years and above
$14.41*
20% by August 15th
50% by September 15th
100% by October 1st

Fluzone Quadrivalent PFS
0.5 mL pre-filled syringes, no needles, 10 per box
0.5 mL dose approved for all ages ≥ 6 months
$15.71*
35% by August 31st
75% by September 30th
100% by October 25th

References/Citations:

Submitted by: Maria Pusnik, PharmD, BCPS; Russell N. Olmsted CIC
CEC/CLG/CSG: Pharmacy CLG
Date 2-20-19
### CLG Decision for Implementation

1. **What were final decisions? Would include any changes to the recommendations out for feedback**
   - a. The Afluria and Fluzone vaccine products are the primary agents that will be purchased and supported in the Trinity Health electronic health record (EHR) for administration to inpatients, Trinity Health colleagues, and licensed independent practitioners (LIPs) for the 2019-2020 flu season.

2. **Who owns the next steps?**
   - a. Purchasers at the RHMs should pre-book the selected influenza products for inpatient use prior to March 31st
   - b. Trinity Health system office informatics will select a date to virtualize the influenza screening for Cerner sites. Further information to follow.

3. **Regional ICLT to communicate to functional leads and areas.**

<table>
<thead>
<tr>
<th>Teams</th>
<th>Actions</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMO</td>
<td>Share background and decision with medical staff for support, awareness and understanding.</td>
<td>Upon receipt of information</td>
</tr>
<tr>
<td>CNO</td>
<td>Share background and decision with nursing staff for support, awareness, and understanding.</td>
<td>Upon receipt of information</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Share background and decision with staff and coordinate efforts with any ambulatory sites to pre-book influenza vaccine products.</td>
<td>By 3-31-19</td>
</tr>
<tr>
<td>Informatics</td>
<td>Coordinate efforts with ICS team to manage product build and screening for Cerner sites</td>
<td>TBD</td>
</tr>
</tbody>
</table>

Finalized by: Maria Pusnik, PharmD, BCPS; Russell N. Olmsted CIC
CEC/CLG/CSG: Pharmacy CLG
Date: 2-20-19
The FluFirst Program

Preorders
- It is recommended all preorders are submitted by March 31, 2019, after which totals will be sent to the manufacturer.
- ASD Healthcare accepts and honors preorders received later in the season, however placing a preorder after March 31, 2019 may affect when you receive your product.
- Reminders of the products preordered will be sent to each ministry in May 2019.

Shipping
- Any shipping and product availability timelines communicated by manufacturers are a general guideline. Manufacturers work diligently to meet deadlines and keep production on track as much as possible. ASD Healthcare will work with Trinity Corporate to keep you aware of any possible delays by the manufacturers.
- Once product is received at ASD Healthcare’s distribution center, it is typically shipped to customers within 1-2 business days. Product will be delivered directly to each ministry. ASD Healthcare allocates an even percentage of a product for delivery to each ministry that ordered. Your ASD Healthcare Flu Territory Manager will attempt to notify each ministry via email prior to any product shipments.

Ordering Additional Inventory
- In the event additional inventory is needed, ASD Healthcare will make every attempt to facilitate the request and ship it as quickly as possible. Manufacturers typically ship product to ASD Healthcare based on the preorders submitted and it may take a little longer than usual to get additional inventory.
- Ministries may continue to place new orders until the manufacturer has announced they are sold out and inventory has been depleted from ASD Healthcare’s distribution center.

Returns
- Ministries may submit returns for the 2019-2020 season starting in January 2020, based on the following:
  - Seqirus product* is returnable up to 20% per presentation
  - Sanofi Pasteur product* is returnable up to 20% of aggregated PFS, MDV, SDV, and pediatric presentations
  - GlaxoSmithKline (GSK) product is non-returnable
- Additional returns information will be available in Fall 2019.

* As part of the HealthTrust agreement, orders for Seqirus and Sanofi Pasteur products will be eligible for a 3% rebate to be paid to HealthTrust at the end of the flu season.
 ACCOUNT INFORMATION  □ Please open a new account for my facility

- **Account Name**: ASD Account #
- **Contact Name**: Phone
- **Email**: PO #

 ACCOUNT INFORMATION  □ Please open a new account for my facility

- **Account Name**: ASD Account #
- **Contact Name**: Phone
- **Email**: PO #

 PRODUCT INFORMATION
Influenza vaccines sold in units, NOT doses.

**SANOFI PASTEUR**

- **Flublok® Quadrivalent (Sanofi Pasteur)** Indicated for persons 18+ years of age
  - Box of 10 0.5 mL pre-filled syringes
  - Unit: boxes
  - Quantity: $428.44
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $435.94

- **Fluzone® Quadrivalent (Sanofi Pasteur)** Indicated for persons 6+ months of age
  - Box of 10 0.5 mL single-dose vials
  - Unit: boxes
  - Quantity: $149.67
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $157.17

- **Fluzone® Quadrivalent (Sanofi Pasteur)** Indicated for persons 6+ months of age
  - 5 mL multi-dose vial (10 doses/vial)
  - Unit: vials
  - Quantity: $139.67
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $147.17

- **Fluzone® Quadrivalent (Sanofi Pasteur)** Indicated for persons 65+ years of age
  - Box of 10 0.5 mL pre-filled syringes
  - Unit: boxes
  - Quantity: $149.67
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $157.17

- **Fluzone® Quadrivalent Pediatric (Sanofi Pasteur)** Indicated for persons 6-35 months of age
  - Box of 10 0.25 mL pre-filled syringes
  - Unit: boxes
  - Quantity: $149.67
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $157.17

**SEQIRUS**

- **Afluria® Quadrivalent (Seqirus)** Indicated for persons 6+ months of age
  - 5 mL multi-dose vial (10 doses/vial)
  - Unit: vials
  - Quantity: $127.54
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $135.04

- **Afluria® Quadrivalent (Seqirus)** Indicated for persons 3+ years of age
  - Box of 10 0.5 mL pre-filled syringes
  - Unit: boxes
  - Quantity: $136.61
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $144.11

- **Afluria® Quadrivalent Pediatric (Seqirus)** Indicated for persons 6-35 months of age
  - Box of 10 0.25 mL pre-filled syringes
  - Unit: boxes
  - Quantity: $136.61
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $144.11

- **Flucelvax® Quadrivalent (Seqirus)** Indicated for persons 4+ years of age
  - 5 mL multi-dose vial (10 doses/vial)
  - Unit: vials
  - Quantity: $152.30
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $159.80

- **Flucelvax® Quadrivalent (Seqirus)** Indicated for persons 4+ years of age
  - Box of 10 0.5 mL pre-filled syringes
  - Unit: boxes
  - Quantity: $160.99
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $168.49

- **Fluad® Trivalent (Seqirus)** Indicated for persons 65+ years of age
  - Box of 10 0.5 mL pre-filled syringes
  - Unit: boxes
  - Quantity: $380.76
  - List Price: $7.50
  - FET Price: $7.50
  - Total Cost: $388.26

**By signing below, I am ordering the quantities listed above and agree to the terms that apply.**

**CUSTOMER SIGNATURE (Required)**  Date

Customer must provide appropriate licensure for sale and delivery before your order can be shipped. All sales of flu vaccines are subject to the terms and conditions contained in ASD Healthcare’s Customer Application. ASD Healthcare ships flu vaccines based on availability from the manufacturer and will not be held liable for product unavailability, shortages or delays. Volume rebates may be available. Contact the ASD Healthcare Flu team for more information. Product availability is subject to change. Pricing is subject to change; pricing will not increase from products shown.

*FET refers to Federal Excise Tax*