FLUCELVAX® QUADRIVALENT (Influenza Vaccine) Suspension for Intramuscular Injection 2016-2017 Formula by Seqirus

Important Update: FLUCELVAX QUADRIVALENT NOW AVAILABLE

Effective May 23, 2016 FLUCELVAX QUADRIVALENT received FDA approval and is NOW AVAILABLE. It is billable using CPT® code:

90674 Influenza virus vaccine, quadrivalent (ccIIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use

See below for detailed billing information for FLUCELVAX QUADRIVALENT using the CMS-1500 and CMS-1450 (UB-04) Form

Indication(s)

FLUCELVAX QUADRIVALENT is an inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUCELVAX QUADRIVALENT is approved for use in persons 4 years of age and older. For children and adolescents 4 through 17 years of age, approval is based on the immune response elicited by FLUCELVAX QUADRIVALENT. Data demonstrating a decrease in influenza disease after vaccination of this age group with FLUCELVAX QUADRIVALENT are not available. (see Clinical Studies in package insert)

For Full Prescribing Information Click here

Important Safety Information

Contraindication

- Do not administer FLUCELVAX QUADRIVALENT to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine.

Please see next page for additional Important Safety Information
Important Safety Information (con’t)

Warnings & Precautions

- **Guillain-Barré Syndrome (GBS):** If GBS has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUCELVAX QUADRIVALENT should be based on careful consideration of the potential benefits and risks.

- **Preventing and Managing Allergic Reactions:** Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

- **Syncope:** Syncope (fainting) can occur in association with administration of injectable vaccines, including FLUCELVAX QUADRIVALENT. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope by maintaining a supine or Trendelenburg position.

- **Altered Immune Competence:** After vaccination with FLUCELVAX QUADRIVALENT, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.

- **Limitations of Vaccine Effectiveness:** Vaccination with FLUCELVAX QUADRIVALENT may not protect all vaccine recipients against influenza disease.

Most Common Adverse Reactions

- The most common (≥10%) local and systemic reactions in adults 18-64 years of age were injection site pain (45.4%) headache (18.7%), fatigue (17.8%) and myalgia (15.4%), injection site erythema (13.4%), and induration (11.6%).

- The most common (≥10%) local and systemic reactions in adults ≥65 years of age were injection site pain (21.6%) and injection site erythema (11.9%).

- The most common (≥10%) local and systemic reactions in children 4 to < 6 years of age were tenderness at the injection site (46%), injection site erythema (18%), sleepiness (19%), irritability (16%), injection site induration (13%), and change in eating habits (10%).

- The most common (≥10%) local and systemic reactions in children 6 through 8 years of age were pain at the injection site (54%), injection site erythema (22%), injection site induration (16%), headache (14%), fatigue (13%), and myalgia (12%).

- The most common (≥10%) local and systemic reactions in children and adolescents 9 through 17 years of age were pain at the injection site (58%), headache (22%), injection site erythema (19%), fatigue (18%) myalgia (16%), and injection site induration (15%).

For additional information on FLUCELVAX QUADRIVALENT [Click here](#)
CMS-1500 and CMS-1450 (UB-04) FORM Information for FLUCELVAX® QUADRIVALENT

Item 21 or Form Locator (FL) 67 – Diagnosis Code

The appropriate ICD-10-CM code should be entered for FLUCELVAX QUADRIVALENT in Item 21 on the CMS-1500 form for physician offices or FL 67 on the CMS-1450 (UB-04) claim form for the hospital outpatient department. Enter the ICD indicator in Item 21 to identify 0 (zero) for ICD-10-CM codes.

Possible ICD-10-CM Code(s)

Z23- Encounter of Immunization

Please note: Covered diagnosis code(s) may vary by payer. Please contact the payer with any questions about payer-specific requirements.

Item 24D or FL 44 – Medication Information

The appropriate CPT® code should be entered for FLUCELVAX QUADRIVALENT in Item 24D on the CMS-1500 form for physician offices or FL 44 on the CMS-1450 (UB-04) claim form for the hospital outpatient department.

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Item 19 or 24A (shaded area) and FL 43- Medication Information

Optional: In Item 19 or 24A (shaded area) on the CMS-1500 form for physician offices, or FL 43 on the CMS-1450 (UB-04) form for the hospital outpatient department, enter the full name of the medication administered, including strength if applicable (e.g., FLUCELVAX QUADRIVALENT 0.5 mL) as well as the NDC (National Drug Code) on the package used (e.g., 70461-0200-01).

Please note: Payer NDC requirements and placement may vary. Please contact the payer with any questions about payer-specific requirements.

<table>
<thead>
<tr>
<th>NDC*</th>
<th>Package Size</th>
<th>Package Quantity</th>
<th>WAC** Pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>70461-0200-01</td>
<td>0.5 mL</td>
<td>Package of 10 pre-filled syringes per carton</td>
<td>$202.44 per 10 pre-filled syringes [includes $7.50 FET† per 10 (0.5 mL) pre-filled syringes ($0.75 FET† per 0.5 mL pre-filled syringe)]</td>
</tr>
</tbody>
</table>

* Note that the product’s NDC has been “zero-filled” to ensure creation of an 11-digit code that meets general billing standards. The zero-fill location is indicated in bold.

**WAC (Wholesale Acquisition Cost) includes the Federal Excise Tax (FET†).

† Federal Excise Tax (FET)
Item 24D or FL 44 – Possible Administration Code(s)

Since FLUCELVAX QUADRIVALENT is administered by intramuscular injection, the appropriate administration code (e.g., 90471) should be entered on a separate line in Item 24D on the CMS-1500 claim form for physician offices or FL 44 on the CMS-1450 (UB-04) claim form for the hospital outpatient department.

90471 Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)

90472 Each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure) (Use 90472 in conjunction with 90471)

G0008 Administration of influenza virus vaccine (For Medicare Part B use)

Item 24G or FL 46 – Units Administered

Billing units should be reported in Item 24G on the CMS-1500 form for physician offices or FL 46 on the CMS-1450 (UB-04) claim form for the hospital outpatient department.

90674 has 1 billable unit of 0.5 mL per the code description (eg., use 1 billable unit per each 0.5 mL dose of FLUCELVAX QUADRIVALENT given).

Item 24F or FL 47 – Medication Charge

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Code Description</th>
<th>WAC** Code Price</th>
<th>WAC Code Price Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>90674</td>
<td>Influenza virus vaccine, quadrivalent (ccIIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use</td>
<td>$20.244 per 0.5 mL (includes $0.75 FET† per 0.5 mL pre-filled syringe)</td>
<td>8/1/2016</td>
</tr>
</tbody>
</table>

**WAC (Wholesale Acquisition Cost) Code Price is calculated from pricing listed in the National Drug Compendia. WAC Code Price includes the Federal Excise Tax (FET†).

Please Note: All prices noted are for the cost of the drug only and do not include the administration charge.

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