FLUCELVAX® Influenza Vaccine

**The first and only enhanced flu vaccine approved for 6+ months*[1]**

Recommended by ACIP and AAP[2,3]

AN ENHANCED FLU VACCINE BUILT FOR

# REAL-WORLD PROTECTION

**RWE offers a complementary approach to clinical trials to assess seasonal influenza vaccine effectiveness**

## CLINICAL TRIAL DATA

- FLUCELVAX demonstrated absolute efficacy in children 2 through 17 years and adults 18 through 49 years[1]
- FLUCELVAX showed non-inferior immunogenicity and seroconversion vs egg-based vaccines in children 6 months through 3 years and adults 18 years and older[1]
- FLUCELVAX is the only flu vaccine made with advanced technology to demonstrate a safety profile similar to standard egg-based flu vaccines in patients 6+ months[1]

*Enhanced is defined as being differentiated compared to standard egg-based influenza vaccines for persons 6 months and older.

## ROBUST REAL-WORLD EVIDENCE

FLUCELVAX has shown greater reductions in flu and hospitalizations from flu complications vs standard egg-based vaccines in both children and adults[4-8]

## CLOSER MATCH TO CIRCULATING STRAINS

Cell-grown viruses were shown to be consistently more similar to circulating strains than standard egg-grown viruses†[9,10]

## THE ONLY CELL-BASED FLU VACCINE

FLUCELVAX is the only flu vaccine approved for patients 6+ months that is made with advanced technology to avoid mutations during production that can reduce vaccine effectiveness[1,10-12]

**Only FLUCELVAX has shown a real-world clinical benefit vs standard egg-based vaccines in both children and adults‡[13]**

†Based on CDC antigenic characterization of the percentage of circulating A/H3N2 flu viruses that were similar to egg- or cell-grown reference viruses across the 2012-2013 through 2019-2020 US influenza seasons.

‡Based on a PubMed search conducted 3/17/25 for published English-language RWE studies that included relative vaccine effectiveness vs a standard flu vaccine comparator.

## FLUCELVAX® (Influenza Vaccine) INDICATION AND IMPORTANT SAFETY INFORMATION

### INDICATION AND USAGE

FLUCELVAX 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 is approved for use in persons 6 months of age and older.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

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

**Please see Important Safety Information throughout and the full US Prescribing Information for FLUCELVAX.**

For US Healthcare Professional Use Only

CSL Seqirus

FLUCELVAX®
Influenza Vaccine

# ASSOCIATED WITH GREATER PROTECTION

## THAN STANDARD EGG-BASED FLU VACCINES[4-8]

## IN PATIENTS 6 MONTHS-64 YEARS

**The primary outcomes reported in these studies contain information not included in the Prescribing Information. These study findings should be interpreted with caution given the study limitations. This is not inclusive of all peer-reviewed RWE studies, which include different outcomes and age groups.**

The data of FLUCELVAX (quadrivalent) is relevant to FLUCELVAX (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions.

CI=confidence interval; COPD=chronic obstructive pulmonary disease; ER=emergency room; FDA=Food and Drug Administration; rVE=relative vaccine effectiveness

### WARNINGS AND PRECAUTIONS

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

Please see Important Safety Information throughout and the full US Prescribing Information for FLUCELVAX.

**Study design:** 2 retrospective, test-negative, case-controlled studies estimating the rVE of FLUCELVAX vs standard egg-based vaccines among individuals 6 months-64 years across 2 flu seasons

### 6 MONTHS–64 YEARS

**UP TO 20%**

**FEWER TEST-CONFIRMED** Flu Medical Visits

vs standard vaccines

2022-2023: (N=43,086)
**rVE 7.7% (95% CI 0.9, 13.9)**[4]

2023-2024: (N=106,779)
**rVE 19.8% (95% CI 15.7, 23.8)***[5]

### HIGH-RISK SUBGROUP ANALYSIS:

2023-2024: (N=57,139)
**rVE 14.7% (95% CI 8.7, 20.3)**†[5]

*A subgroup analysis of children 6 months-17 years had an rVE of 19.6% (95% CI 13.6, 25.3) (N=60,990) and a subgroup analysis of adults 18-64 years had an rVE of 18.5% (95% CI 12.1, 24.5) (N=45,789)

†Included a subgroup analysis of individuals with CDC-defined risk factors for severe influenza outcomes during the 2023-2024 flu season[14]

**Key study limitations:** Influenza test confirmation was obtained as part of routine care and not performed according to preset screening criteria; potential for residual and unmeasured confounding factors

**Study design:** 3 separate retrospective cohort studies estimating the rVE of FLUCELVAX vs standard egg-based vaccines among individuals 4-64 years across 3 influenza seasons

### 4–64 YEARS

**UP TO 14%**

**FEWER FLU-RELATED** Hospital/ER Visits

vs standard vaccines

2017-2018: (N=3,080,510)
**rVE 14.4% (95% CI 8.8, 19.6)**[6]

2018-2019: (N=3,731,827)
**rVE 6.5% (95% CI 0.1, 12.5)**[7]

2019-2020: (N=5,074,953)
**rVE 5.3% (95% CI 0.5, 9.9)**[8]

**UP TO 12%**

**FEWER ALL-CAUSE** Hospitalizations

vs standard vaccines

2017-2018: (N=3,080,510)
**rVE 11.8% (95% CI 10.4, 13.1)**[6]

2018-2019: (N=3,731,827)
**rVE 7.9% (95% CI 6.6, 9.1)**[7]

**UP TO 8%**

**FEWER RESPIRATORY** Hospital/ER Visits

vs standard vaccines

2017-2018: (N=3,080,510)
**rVE 6.9% (95% CI 4.9, 8.8)**‡[6]

2018-2019: (N=3,731,827)
**rVE 7.7% (95% CI 6.1, 9.4)**[7]

2019-2020: (N=5,074,953)
**rVE 8.2% (95% CI 6.5, 9.8)**[8]

**Key study limitations:** Potential for residual confounding; lack of laboratory confirmation; retrospective studies can only establish associations and not causal relationships; identification of all outcomes relied on observation of diagnosis codes so the potential for miscoding, misdiagnosis, or misclassification may still exist; study sample comprised of individuals who were largely commercially or self-insured

The select primary endpoints are presented here; asthma/COPD/bronchial hospitalizations and pneumonia hospitalizations were also evaluated.

‡Represents respiratory events other than pneumonia and asthma/COPD/bronchial hospitalizations

FLUCELVAX®
Influenza Vaccine

# ASSOCIATED WITH GREATER PROTECTION

## THAN STANDARD EGG-BASED FLU VACCINES[5-7]

## IN CHILDREN 6 MONTHS-17 YEARS

**The primary outcomes reported in these studies contain information not included in the Prescribing Information. These study findings should be interpreted with caution given the study limitations. This is not inclusive of all peer-reviewed RWE studies, which include different outcomes and age groups.**

The data of FLUCELVAX (quadrivalent) is relevant to FLUCELVAX (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions.

**WARNINGS AND PRECAUTIONS (continued)**

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUCELVAX.

Please see Important Safety Information throughout and the full US Prescribing Information for FLUCELVAX.

**Study design:** Retrospective, test-negative, case-controlled study estimating the rVE of FLUCELVAX vs standard egg-based vaccines among individuals 6 months-64 years with a subgroup analysis of children 6 months-17 years (N=60,990) during the US 2023-2024 flu season

### 6 MONTHS–17 YEARS

**20%**

**FEWER TEST-CONFIRMED**
Flu Medical Visits
vs standard vaccines

2023-2024: (N=60,990)
**rVE 19.6% (95% CI 13.6, 25.3)**[5]

**Key study limitations: These data are derived from the same studies as the previous page. Please see that page for the key study limitations**

**Study design:** 2 separate retrospective cohort studies estimating the rVE of FLUCELVAX vs standard egg-based vaccines among individuals 4-64 years with subgroup analyses focused on children aged 4–17 years across 2 US influenza seasons

### CHILDREN 4–17 YEARS

**UP TO 13%**

**FEWER FLU-RELATED**
Hospital/ER Visits
vs standard vaccines

2017-2018: (N=852,834)
**rVE 13.1% (95% CI -3.7, 27.1)**[6]

2018-2019: (N=914,048)
**rVE 8.5% (95% CI -7.1, 21.9)**[7]

**UP TO 33%**

**FEWER PNEUMONIA**
Hospital/ER Visits
vs standard vaccines

2017-2018: (N=852,834)
**rVE 33% (95% CI 13.7, 48)**[6]

2018-2019: (N=914,048)
**rVE 21.5% (95% CI 4.3, 35.6)**[7]

**13%**

**FEWER ASTHMA/COPD/ BRONCHIAL**
Hospital/ER Visits
vs standard vaccines

2017-2018: (N=852,834)
**rVE 13.4% (95% CI 4.4, 21.6)**[6]

2018-2019: (N=914,048)
**rVE 13% (95% CI 4.7, 20.5)**[7]

**Key study limitations: These data are derived from the same studies as the previous page. Please see that page for the key study limitations**

The select primary endpoints are presented here; all-cause hospitalization and respiratory hospitalizations were also evaluated. FLUCELVAX received FDA approval for patients 6 months and older in October 2021, after these studies were conducted.

CSL Seqirus

# REAL-WORLD RELIABILITY

FLUCELVAX has met or exceeded all delivery commitments with nearly all committed doses delivered by the end of September for the past 3 seasons.[13]

# REAL-WORLD EFFICIENCIES

No other enhanced flu vaccine offers the operational benefit of a single SKU for all eligible patients 6 months and older.[1]

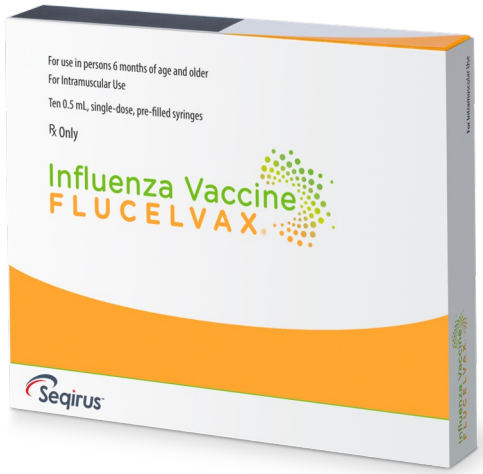
## DIFFERENT VACCINE. DIFFERENT CPT CODE. DIFFERENT REIMBURSEMENT.[15]

Understanding both reimbursement and vaccine cost can help you confirm that your clinical decisions will not leave your organization financially disadvantaged.

**CPT CODE: 90661**
SINGLE-DOSE SYRINGE

**Order FLUCELVAX through CSL Seqirus or your preferred distributor**

Available through Vaccines for Children (VFC)




**WARNINGS AND PRECAUTIONS (continued)**

Syncope (fainting) has been reported following vaccination with FLUCELVAX. Procedures should be in place to avoid injury from fainting.

**Please see Important Safety Information throughout and the full US Prescribing Information for FLUCELVAX.**

# FLUCELVAX® (Influenza Vaccine)
# INDICATION AND IMPORTANT SAFETY INFORMATION

## INDICATION AND USAGE

FLUCELVAX 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 is approved for use in persons 6 months of age and older.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

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

### WARNINGS AND PRECAUTIONS

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

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUCELVAX.

Syncope (fainting) has been reported following vaccination with FLUCELVAX. Procedures should be in place to avoid injury from fainting.

After vaccination with FLUCELVAX, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.

Vaccination with FLUCELVAX may not protect all vaccine recipients against influenza disease.

### ADVERSE REACTIONS

*Data for FLUCELVAX QUADRIVALENT are relevant to FLUCELVAX because both vaccines are manufactured using the same process and have overlapping compositions.*

In children 6 months through 3 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were tenderness (28%), erythema (26%), induration (17%) and ecchymosis (11%). The most common systemic adverse reactions were irritability (28%), sleepiness (27%), diarrhea (18%) and change of eating habits (17%).

In children 4 through 8 years of age who received FLUCELVAX, the most commonly reported local injection-site adverse reactions were pain (29%) and erythema (11%). The most common systemic adverse reaction was fatigue (10%).

In children and adolescents 9 through 17 years of age who received FLUCELVAX, the most commonly reported injection-site adverse reactions were pain (34%) and erythema (14%). The most common systemic adverse reactions were myalgia (15%) and headache (14%).

In adults 18 through 64 years of age who received FLUCELVAX, the most commonly reported injection-site adverse reactions were pain (28%) and erythema (13%). The most common systemic adverse reactions were headache (16%), fatigue (12%), myalgia (11%) and malaise (10%).

In adults ≥65 years who received FLUCELVAX the most commonly reported injection-site reaction was erythema (10%). The most common systemic adverse reactions were fatigue (11%), headache (10%) and malaise (10%).

Other adverse events may occur.

**To report SUSPECTED ADVERSE REACTIONS, contact CSL Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.**

**Before administration, please see the full US Prescribing Information for FLUCELVAX.**

**References: 1.** FLUCELVAX. Package insert. Seqirus Inc. **2.** Grohskopf LA, et al. *MMWR Morb Mortal Wkly Rep*. 2025;74(32):500-507. **3.** Committee on Infectious Diseases. *Pediatrics*. 2025;156(6):e2025073620. **4.** Stein AN, et al. *Influenza Other Respir Viruses*. 2025;19(11):e70180. **5.** Stein AN, et al. *Infect Dis Ther*. 2025;14(12):2693-2718. **6.** Divino V, et al. *Vaccine*. 2020;38(40):6334-6343. **7.** Krishnarajah G, et al. *Vaccines (Basel)*. 2021;9(2):80. **8.** Divino V, et al. *Open Forum Infect Dis*. 2021;9(1):ofab604. **9.** Malosh RE, et al. *Clin Infect Dis*. 2023;76(3):540-549. **10.** Rockman S, et al. *Vaccines (Basel)*. 2022;11(1):52. **11.** Rajaram S, et al. *Ther Adv Vaccines Immunother*. 2020;8:2515135520908121. **12.** CDC. Cell-based flu vaccines. Accessed August 25, 2025. https://www.cdc.gov/flu/vaccine-types/cellbased.html **13.** Data on file. Seqirus Inc; 2025. **14.** CDC. People at increased risk for flu complications. Accessed September 5, 2025. https://www.cdc.gov/flu/highrisk/index.htm **15.** CMS. Vaccine pricing. Accessed September 8, 2025. https://www.cms.gov/medicare/payment/part-b-drugs/vaccine-pricing