PHARMACIST POCKET GUIDE

INTENDED FOR US HEALTHCARE PROFESSIONALS ONLY.

RSV STOPS HERE

AREXVY is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in:

- individuals 60 years of age and older;
- individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

Vaccination may not protect all recipients.[1]

Strengthen Your Recommendation for AREXVY

Not an actual patient.

Important Safety Information

- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of AREXVY
- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of AREXVY

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

AREXVY
(RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED)

GSK

The CDC Updates RSV Vaccine Recommendation

The CDC recommends:

Adults 75 years of age and older receive a single dose of RSV vaccine[2]

Adults 60-74 years of age who are at increased risk of severe RSV disease receive a single dose of RSV vaccine[2]

Additional information from the CDC

Eligible adults are currently recommended to receive a single dose of RSV vaccine; adults who have already received RSV vaccination should not receive another dose. Eligible adults may be vaccinated at any time of year, but vaccination will have the most benefit if administered in late summer or early fall, just before the RSV season.[3]

These recommendations replace the June 2023 shared clinical decision-making recommendation for RSV vaccination for adults aged ≥60 years. Based on currently available evidence, ACIP concluded that the benefits of RSV vaccination did not clearly outweigh the potential harms in adults aged 60-74 years without risk factors for severe RSV disease.[3]

ACIP=Advisory Committee on Immunization Practices;
CDC=Centers for Disease Control and Prevention.

Important Safety Information (cont.)

- Syncope (fainting) may occur in association with administration of injectable vaccines, including AREXVY. Procedures should be in place to avoid injury from fainting
- Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to AREXVY

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

List of CDC-Identified Risk Factors for Severe RSV Disease[3]

Qualified vaccinators, including pharmacists, nurse practitioners, and other providers (based on state and jurisdictional law) may determine patient eligibility for RSV vaccination based on clinical assessment even in the absence of medical documentation of a named risk condition. Patient attestation is sufficient evidence of the presence of a risk factor; vaccinators should not deny RSV vaccination to a person because of lack of documentation.[3]

- **Chronic cardiovascular disease** (eg, heart failure, coronary artery disease, or congenital heart disease [excluding isolated hypertension])
- **Chronic lung or respiratory disease** (eg, chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, or cystic fibrosis)
- **End-stage renal disease or dependence on hemodialysis or other renal replacement therapy**
- **Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end-organ damage, or requiring treatment with insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor**
- **Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness** (eg, poststroke dysphagia, amyotrophic lateral sclerosis, or muscular dystrophy [excluding history of stroke without impaired airway clearance])
- **Chronic liver disease** (eg, cirrhosis)
- **Chronic hematologic conditions** (eg, sickle cell disease or thalassemia)
- **Severe obesity** (body mass index ≥40 kg/m^2)
- **Moderate or severe immune compromise**
- **Residence in a nursing home**
- **Other chronic medical conditions or risk factors that a healthcare provider determines would increase the risk for severe disease due to viral respiratory infection** (eg, frailty,* situations in which healthcare providers have concern for presence of undiagnosed chronic medical conditions, or residence in a remote or rural community where transportation of patients with severe RSV disease for escalation of medical care is challenging†)

*Frailty is a multidimensional geriatric syndrome that reflects a state of increased vulnerability to adverse health outcomes. Although no consensus definition exists, one frequently used tool for determination is the Fried frailty phenotype assessment in which frailty is defined as a clinical syndrome with 3 or more of the following symptoms present: unintentional weight loss (10 lbs [4.5 kg] in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, or low physical activity.

†Healthcare providers caring for adults aged 60-74 years residing in these communities may use clinical judgement, knowledge of local RSV epidemiology, and community incidence of RSV-associated hospitalization to recommend vaccination for a broader population in this age group.

Data on the safety and efficacy of AREXVY in individuals with these risk factors for severe RSV disease as described by the CDC may be limited[1]

Exceptional Efficacy for Your Patients 60 Years of Age and Older[1]

STUDY 1: PRIMARY ENDPOINT[1]

82.6%

OVERALL EFFICACY AGAINST RSV-LRTD

(96.95% CI, 57.9, 94.1)

AREXVY (7 cases out of 12,466), placebo (40 cases out of 12,494)

STUDY 1: SECONDARY ENDPOINT[1]

94.6%

EFFICACY AGAINST RSV-LRTD IN PARTICIPANTS WITH AT LEAST 1 COMORBIDITY*

(95% CI, 65.9, 99.9)

AREXVY (1 case out of 4937), placebo (18 cases out of 4861)

At the time of this analysis, median follow-up was 6.7 months.[1]

Study 1 Design[1]: Study 1, an ongoing, phase 3, randomized, placebo-controlled, observer-blind study in individuals aged ≥60 years, evaluated the efficacy of AREXVY in preventing RSV-LRTD during the first season, with follow-up planned for up to 36 months. Participants in the primary population for efficacy analysis received 1 dose of AREXVY (n=12,466) or placebo (n=12,494).

RSV-LRTD was defined as ≥2 lower respiratory symptoms/signs, including ≥1 lower respiratory sign for at least 24 hours, or ≥3 lower respiratory symptoms for at least 24 hours.[1]

***Comorbidities of interest[1]:** COPD, asthma, any chronic respiratory/pulmonary disease, chronic heart failure, diabetes mellitus type 1 or type 2, and advanced liver or renal disease.

COPD=chronic obstructive pulmonary disease; RSV-LRTD=respiratory syncytial virus-associated lower respiratory tract disease.

Important Safety Information (cont.)

- In adults 60 years of age and older, the most commonly reported adverse reactions (≥10%) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%)

A Demonstrated Safety Profile[1]

Percentage of participants with solicited local and systemic adverse reactions within 4 days of vaccination in individuals aged 60 years and older (solicited safety set with 4-day diary card)

STUDY 1: SAFETY DATA

	AREXVY %	Placebo[a] %
Local Adverse Reactions	**N=879**	**N=874**
Pain, Any[b]	60.9	9.3
Pain, Grade 3[b]	1	0
Erythema, >20 mm	7.5	0.8
Erythema, >100 mm	0.2	0
Swelling, >20 mm	5.5	0.6
Swelling, >100 mm	0.2	0
Systemic Adverse Reactions	**N=879**	**N=878**
Fatigue, Any[c]	33.6	16.1
Fatigue, Grade 3[c]	1.7	0.5
Myalgia, Any[c]	28.9	8.2
Myalgia, Grade 3[c]	1.4	0.3
Headache, Any[c]	27.2	12.6
Headache, Grade 3[c]	1.3	0
Arthralgia, Any[c]	18.1	6.4
Arthralgia, Grade 3[c]	1.3	0.6
Fever, ≥38.0 °C/100.4 °F[d]	2.0	0.3
Fever, >39.0 °C/102.2 °F[d]	0.1	0.1

In the solicited safety set, the local administration site adverse reactions reported with AREXVY had a median duration of 2 days, and the systemic adverse reactions reported with AREXVY had a median duration ranging between 1 and 2 days.[1]

Similar rates of serious adverse events (4.2% vs 4.0%) and potential immune-mediated diseases (0.3% vs 0.3%) were reported between AREXVY (n=12,467) and placebo (n=12,499), respectively.[1]

Deaths were reported in 0.8% and 0.9% of participants who received AREXVY (n=12,470) and placebo (n=12,503), respectively.[1]

N=exposed set for solicited safety set included all participants with at least 1 documented dose.

[a]Placebo was a saline solution.

[b]Any grade pain: Defined as any pain neither interfering with nor preventing normal everyday activities (Grade 1), painful when limb is moved and interferes with everyday activities (Grade 2), or significant pain at rest and prevents normal everyday activities (Grade 3).

[c]Any grade fatigue, myalgia, headache, arthralgia: Defined as event easily tolerated (Grade 1), interfering with normal activity (Grade 2), or preventing normal activity (Grade 3).

[d]Temperature taken by any route (oral, axillary, or tympanic).

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

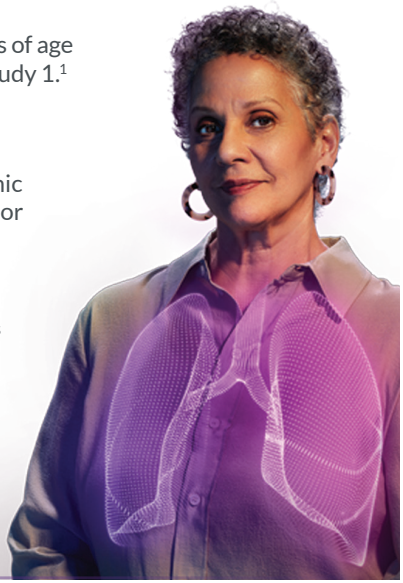
Effective for Patients 50-59 Years of Age Who Are at Increased Risk for RSV-LRTD[1]

Effectiveness of AREXVY in individuals 50 through 59 years of age with chronic medical conditions* was assessed by a comparison of RSV neutralizing antibody responses induced by AREXVY in this age group to antibody responses of individuals 60 years of age and older. The comparison met the criteria for immunobridging.[1]

Vaccine efficacy in adults 60 years of age and older was demonstrated in Study 1.[1]

***Medical conditions defined as[1]:**
chronic pulmonary disease, chronic cardiovascular disease, diabetes, or chronic kidney or liver disease.

Study 4 Design–Immunobridging[1]:
In Study 4, individuals 50 through 59 years of age with chronic medical conditions* were randomized to receive AREXVY (n=386) or saline placebo (n=191). A comparator group of individuals 60 years and older also received AREXVY (n=381).



Not an actual patient.

Important Safety Information (cont.)

- In adults 50 through 59 years of age, the most commonly reported adverse reactions (≥10%) were injection site pain (75.8%), fatigue (39.8%), myalgia (35.6%), headache (31.7%), arthralgia (23.4%), erythema (13.2%), and swelling (10.4%)
- There are no data on the use of AREXVY in pregnant or breastfeeding individuals. AREXVY is not approved for use in persons <50 years of age

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

Safety Profile for Participants Aged 50-59 Years[1]

Percentage of participants with solicited local adverse reactions and systemic adverse reactions within 4 days of vaccination from Study 4 (exposed set)

STUDY 4: SAFETY DATA

	AREXVY 50-59 YOA %	Placebo[a] 50-59 YOA %
Local Adverse Reactions	**N=756**	**N=379**
Pain, Any[b]	75.8	12.1
Pain, Grade 3[b]	3.4	0.3
Erythema, >20 mm	13.2	0.5
Erythema, >100 mm	0.5	0
Swelling, >20 mm	10.4	0.8
Swelling, >100 mm	0.1	0
Systemic Adverse Reactions	**N=756**	**N=380**
Fatigue, Any[c]	39.8	18.2
Fatigue, Grade 3[c]	2.8	0.8
Myalgia, Any[c]	35.6	9.7
Myalgia, Grade 3[c]	2.5	0.5
Headache, Any[c]	31.7	16.8
Headache, Grade 3[c]	2.6	1.1
Arthralgia, Any[c]	23.4	7.9
Arthralgia, Grade 3[c]	1.7	0.8
Fever, ≥38.0 °C/100.4 °F[d]	3.2	1.1
Fever, >39.0 °C/102.2 °F[d]	0.1	0.5

The median duration of solicited local and systemic adverse reactions after vaccination with AREXVY was 2-3 days and 1-2 days, respectively.[1]

The rates of solicited local and systemic adverse reactions were similar in participants 50-59 years of age with or without medical conditions associated with an increased risk of RSV-LRTD.[1]

Among participants 50-59 years of age, serious adverse events (2.3% vs 2.1%), deaths (0.5% vs 0.3%), and potential immune-mediated diseases (0.5% vs 0.3%) were reported after receiving AREXVY (N=769) or placebo (N=383), respectively.[1]

YOA=years of age.

N=exposed set included all participants with at least 1 documented dose and with completed diary card.

[a]Placebo was a saline solution.

[b]Any grade pain: Defined as any pain neither interfering with nor preventing normal everyday activities (Grade 1), painful when limb is moved and interferes with everyday activities (Grade 2), or significant pain at rest and prevents normal everyday activities (Grade 3).

[c]Any grade fatigue, myalgia, headache, arthralgia: Defined as event easily tolerated (Grade 1), interfering with normal activity (Grade 2), or preventing normal activity (Grade 3).

[d]Temperature taken by any route (oral or axillary).

Storage[1]

AREXVY should be refrigerated.
DO NOT FREEZE (discard if frozen).

Store in the original package to protect vials from light.

Store adjuvant suspension component vials and lyophilized antigen component vials between 2 °C and 8 °C (36 °F and 46 °F) before reconstitution.

After reconstitution, administer immediately or store between 2 °C and 8 °C (36 °F and 46 °F) or at room temperature up to 25 °C (77 °F) for up to 4 hours prior to use.

Protect from light.

Discard reconstituted vaccine if not used within 4 hours or has been frozen.

Important Safety Information (cont.)

- Vaccination with AREXVY may not result in protection of all vaccine recipients

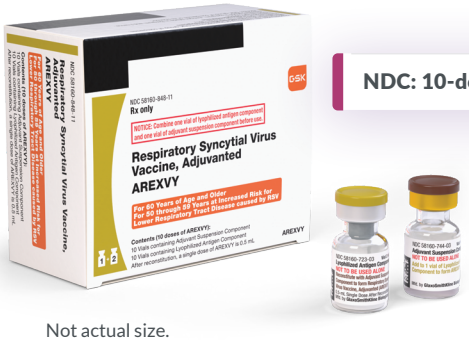
Dosing and Administration[1]

AREXVY is supplied in 2 vials that must be reconstituted prior to administration.

Administer 1 dose (0.5 mL) of AREXVY as an intramuscular injection.

Please refer to the full Prescribing Information for AREXVY for comprehensive details.

Use the following code when billing AREXVY:



Not actual size.

NDC: 10-dose carton 58160-848-11

For payers who require NDCs in an 11-digit format, please use: 58160-0848-11

NDC=National Drug Code.

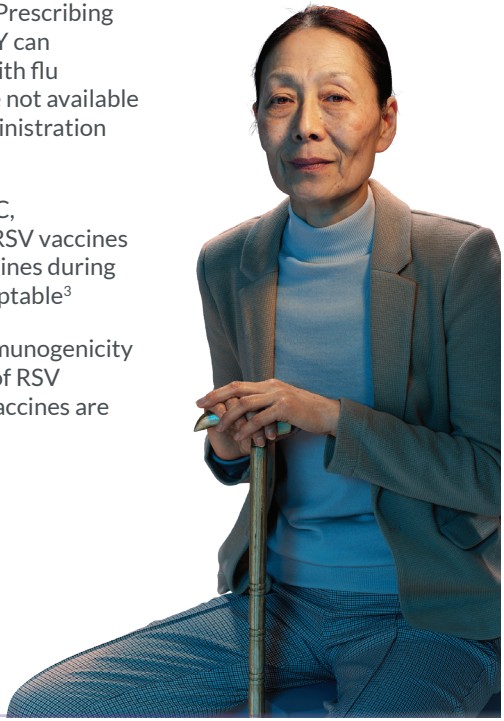
Important Safety Information

- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of AREXVY
- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of AREXVY

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

Coadministration of AREXVY in Adults 60+ With Other Adult Vaccines

- According to the US Prescribing Information, AREXVY can be coadministered with flu vaccination. Data are not available for concomitant administration with other vaccines[1]
- According to the CDC, coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable[3]
- Available data on immunogenicity of coadministration of RSV vaccines and other vaccines are currently limited[2]



Not an actual patient.

Important Safety Information (cont.)

- Syncope (fainting) may occur in association with administration of injectable vaccines, including AREXVY. Procedures should be in place to avoid injury from fainting
- Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to AREXVY

Steps to Help Protect Eligible Patients

1

EDUCATE

Identify appropriate patients and discuss the risk of severe RSV based on **age** and certain **underlying conditions**

2

RECOMMEND

Review the benefits and risks of AREXVY and strongly recommend vaccination for appropriate patients based on their medical history and/or age

3

SUPPORT

Address patient questions about cost—and ensure patient insurance benefits are verified

4

VACCINATE

Establish a plan that works for your patient to ensure they receive AREXVY

Important Safety Information (cont.)

- In adults 60 years of age and older, the most commonly reported adverse reactions (≥10%) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%)

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

Download helpful resources at AREXVYhcp.com

Important Safety Information (cont.)

- In adults 50 through 59 years of age, the most commonly reported adverse reactions (≥10%) were injection site pain (75.8%), fatigue (39.8%), myalgia (35.6%), headache (31.7%), arthralgia (23.4%), erythema (13.2%), and swelling (10.4%)
- There are no data on the use of AREXVY in pregnant or breastfeeding individuals. AREXVY is not approved for use in persons <50 years of age
- Vaccination with AREXVY may not result in protection of all vaccine recipients

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

References: 1. Prescribing Information for AREXVY. **2.** Healthcare providers: RSV vaccination for adults 60 years of age and over. Centers for Disease Control and Prevention. Accessed July 9, 2024. https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html **3.** Britton A, Roper LE, Kotton CN, et al. Use of respiratory syncytial virus vaccines in adults aged ≥60 years: updated recommendations of the Advisory Committee on Immunization Practices — United States, 2024. *MMWR*. Published online August 6, 2024. doi:10.15585/mmwr.mm7332e1

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AREXVY
(RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED)

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