THE SOCIETY FOR POST-ACUTE AND LONG-TERM CARE MEDICINE™

Respiratory Syncytial Virus Vaccination in PALTC: Resources for Clinicians

October 2, 2023

Abstract

In May 2023, the Food and Drug Administration approved two much-anticipated vaccines for respiratory syncytial virus (RSV), which can cause lower respiratory tract infections and result in serious illness. The Advisory Committee on Immunization Practices (ACIP) officially recommended the vaccine for use in older adults with shared clinical decision making. AMDA-The Society for Post-Acute and Long-Term Care Medicine developed this brief toolkit to provide healthcare providers in post-acute and long-term care settings with the information and resources they need to talk with their patients about the RSV vaccine and its benefits, and to support its use when appropriate.

RSV Vaccination Toolkit: Resources for Clinicians

Included Content:

- RSV Vaccine for Older Adults: A Decision-Making Tool for Residents in Long-Term Care Settings
- Centers for Disease Control and Prevention (CDC) Fact Sheet: RSV Vaccination for Adults 60 Years and Older
- IPRO Information Sheet: RSV Vaccine Risk/Benefit Analysis
- AHCA: Medicare Billing Guidance for Respiratory Vaccines in LTC

RSV Vaccine for Older Adults:
A Decision-Making Tool for Long-Term Care Residents & Their Families

Background on respiratory syncytial virus (RSV) and the RSV vaccine recommendation

Respiratory syncytial virus (RSV) circulates seasonally in the United States, causing severe illness, hospitalizations, and sometimes death in older adults with certain medical conditions. Residents in nursing homes are at increased risk for more severe disease and RSV related hospitalization because they are often frail and have several underlying illnesses. They are also at increased risk of being exposed to RSV due to frequent, close contact with staff, other residents, and visitors.

RSV infections commonly occur in fall and winter. The virus is transmitted by close contact to sick individuals' secretions resulting in upper respiratory tract infection. In some cases, the infection progresses to the lower respiratory tract, causing bronchitis or pneumonia. RSV can also lead to worsening of chronic pulmonary disease such as chronic obstructive pulmonary disease (COPD) and heart failure.

On June 21, 2023, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) determined that adults ages 60 and over may receive a single dose of the RSV vaccine, using shared clinical decision-making. RSV vaccination might prevent substantial morbidity in older adults at risk for severe RSV disease.

ACIP recommends that RSV vaccination be targeted to those at highest risk of severe illness, including residents of nursing homes and older adults with underlying illness such as:

- heart disease
- chronic lung diseases such as COPD and asthma
- diabetes
- neurologic conditions
- kidney, liver, or blood disorders
- immune compromise
- other underlying conditions that the health care provider determines might increase the risk of severe respiratory illness.

This decision support tool will review conditions that increase the risk for severe RSV infection in older adults, along with vaccine effectiveness and safety. It can help you and your healthcare provider decide if the vaccine is right for you.

What is shared clinical decision making?

Shared clinical decision-making for vaccination means the decision whether to vaccinate is decided on an individual basis and informed by discussions between you and a health care provider. A healthcare provider may be anyone who provides or administers vaccines in your facility, including physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists. The decision to vaccinate may be informed by your health status, risk of severe RSV disease, the health care provider's clinical judgment, and other factors.

More about the new RSV vaccines

There are two new RSV vaccines, Arexvy from GSK and Abrysvo from Pfizer, both are approved by the FDA and recommended by ACIP. Both vaccines are recombinant protein vaccines that cause the immune system to produce protective RSV antibodies. GSK's vaccine includes an adjuvant (the same adjuvant used in GSK's recombinant zoster vaccine [Shingrix]), which is a component that is intended to enhance the immune response to vaccination. Pfizer's vaccine does not contain an adjuvant. The ACIP does not have a preferential recommendation for either vaccine. Older adults can receive either vaccine.

RSV vaccine is recommended as a single dose. Studies are ongoing to determine whether (and if so, when) revaccination may be needed.

Both vaccines were shown to be effective in preventing severe illness due to RSV. Although both vaccines had acceptable safety profiles, there were 6 cases of rare neurologic events that could have occurred due to chance or may have been associated with RSV vaccination (three of 17,922 participants of the GSK vaccine and three of 20,255 participants of Pfizer vaccine). Until additional evidence is available, RSV vaccination should be targeted to those who are at highest risk for severe RSV disease and therefore most likely to benefit from vaccination.

Administering RSV vaccine with one or more other vaccines at the same time might increase side effects, such as fever and soreness at the injection site. Data are currently only available for co-administration of RSV and influenza vaccines, and evidence is mixed regarding the strength of the immune system response when given at the same time. More research is needed on the safety of co-administration with other vaccines in older adults, such as COVID-19 vaccine and pneumococcal vaccines. Until that time, it is recommended to wait at least two weeks between RSV vaccination and other vaccines.

Other ways to reduce your risk of getting RSV

In addition to the RSV vaccine, which you can decide whether to take after a discussion with your healthcare provider, the CDC recommends the same familiar precautions you take to reduce risk of cold, flu and COVID-19. These precautions include avoiding close contact with people who are sick, covering coughs, and washing hands often.

Now that you have learned more about RSV and the new vaccines available, go through the following 5 steps with your healthcare provider to decide if you should get the RSV vaccine this year.

STEP 1: In addition to residing in a nursing home, what are your other risk factors?

- Lung disease (such as chronic obstructive pulmonary disease [COPD] and asthma)
- Chronic heart diseases (such as congestive heart failure and coronary artery disease)
- Diabetes mellitus
- Chronic or progressive neurologic or neuromuscular conditions
- Chronic kidney disease

- Chronic liver disease
- Hematologic disorders
- Immune compromise
- Frailty (may include weakness, slow walking speed, low physical activity, self-reported exhaustion, and unintentional weight loss)
- Older than 60 years of age
- Other underlying conditions that a health care provider determines might increase the risk for severe respiratory disease

STEP 2: Do you have one or more risk factors that increase your risk for severe illness due to RSV?

- Yes
- No

Step 3: Identify what is important to you.

Before you make a choice about getting the RSV vaccine, take a moment to think about what is important to you. Consider how important the listed options are to you and rate them on a scale of 1 (does not matter) to 10 (matters a lot).

	Does Not Matter								Matters a Lot	
Lowering my risk of getting RSV	1	2	3	4	5	6	7	8	9	10
Lowering my risk of getting others sick with RSV (such as friends, staff, and visitors)	1	2	3	4	5	6	7	8	9	10
Not experiencing side effects from the vaccine	1	2	3	4	5	6	7	8	9	10
Avoiding getting stuck with a needle	1	2	3	4	5	6	7	8	9	10
Cost of vaccine/insurance coverage	1	2	3	4	5	6	7	8	9	10

Adapted with permission from The Gerontological Society of America.

Step 4: Evaluate where you are in the decision-making process.

Which way are you leaning now?

- ☐ Getting the RSV vaccine
- ☐ Undecided
- ☐ Not getting the RSV vaccine

Do you feel as though you know enough about your RSV options to make a decision?

- ☐ Yes
- ☐ No
- ☐ Unsure

Who else might be involved in your decision?

- ☐ Name: _____
- ☐ Is this person pressuring you? Yes/No
- ☐ What does this person want for you? (RSV vaccine or no RSV vaccine)
- ☐ How can this person support you in making a decision?
  _____

What other information do you need to make a decision?

- ☐ Costs associated with vaccine and whether my insurance covers my vaccine.
- ☐ Other (please specify): _____

Adapted with permission from The Gerontological Society of America.

Step 5: Decide what's next.

- I do not need to do anything else. I am ready to make my decision.
- I want to discuss my options with: _____
- Other (please specify): _____

Summary of Vaccine, Benefits, and Side Effects

	Get an RSV Vaccine	**Don't Get an RSV Vaccine**
What is involved?	A needle and syringe will be used to give you this vaccine in your arm.	You do nothing and accept the risk that becoming severely ill due to RSV may be higher when not vaccinated, based on certain health conditions and/or if you reside in a nursing home.
What are the benefits?	The vaccine was between 82.6% and 88.9% effective against lower respiratory tract diseases during the first respiratory season, after vaccine administration.	You avoid the possible side effects of the vaccine.
What are the risks and side effects?	Side effects can include pain, redness or swelling at the injection site, headache, muscle ache, malaise, fever, chills, nausea, vomiting diarrhea. A higher number of people reported atrial fibrillation after vaccination. Rare, serious neurologic events were reported in 6 individuals. It is not clear if this was chance or associated with the vaccine.	You have a higher chance of getting RSV symptoms, which can be serious including pneumonia along with worsening of other underlying health conditions.

References

- Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices-United States, 2023 https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm
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Shared Clinical Decision-Making (SCDM)

RSV Vaccination for Adults 60 Years and Older

- Respiratory syncytial virus (RSV) is a cause of severe respiratory illness across the lifespan. Each year in the United States, RSV leads to approximately 60,000-160,000 hospitalizations and 6,000-10,000 deaths among adults 65 years and older.
- Adults 60 years of age and older now have the option to receive one dose of RSV vaccine based on a SCDM process between a patient and their health care provider.
- Consider multiple factors when discussing RSV vaccination with your patients. SCDM recommendations are optional and are informed by whether the patient has any risk factors for severe RSV disease; a patient's risk of exposure to RSV; a patient's preferences for RSV vaccination; and the clinical discretion of the health care provider.

Underlying medical conditions associated with increased risk for severe RSV disease include:


Chronic lung disease (e.g., COPD and asthma)


Chronic kidney disease


Moderate or severe immunocompromise


Chronic cardiovascular disease (e.g., CHF and CAD)


Chronic liver disease


Chronic hematologic disorders


Chronic or progressive neurologic or neuromuscular conditions


Diabetes Mellitus


Any underlying *condition* that a provider determines might increase the risk of severe RSV disease

Other factors associated with **increased** risk for severe RSV disease include:


Frailty or advanced age, as determined by the healthcare provider


Residence in a nursing home or other long-term care facility


Any underlying *factor* a provider determines might increase the risk of severe RSV disease

Other points to **consider**:

- Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported after RSV vaccination in clinical trials. However, it is unclear whether the vaccine caused these events.
- Persons with history of severe allergic reaction (e.g., anaphylaxis) to any component of RSV vaccine should not receive the vaccine.

Additional Information:

CDC RSV Vaccine Information:
https://www.cdc.gov/vaccines/vpd/rsv/index.html

MMWR Report:

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm?s_cid=mm7229a4_w

U.S. Department of Health and Human Services
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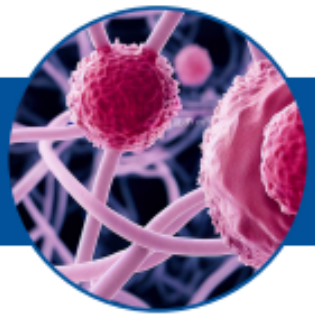

Respiratory Syncytial Virus (RSV) Vaccine Risk/Benefit Analysis

Respiratory Syncytial Virus (RSV) is a cause of severe respiratory illness in older adults leading to an estimated 60,000–160,000 hospitalizations and 6,000–10,000 deaths each year. The FDA approved the first vaccines for prevention of RSV-associated lower respiratory tract disease in May 2023. The Advisory Committee on Immunization Practices (ACIP) voted to recommend that adults ≥60 years may receive a single dose of an RSV vaccine, using shared clinical decision making. Until additional evidence becomes available from post-marketing Adverse Drug Events (ADE) surveillance clarifying the existence of any potential risk, RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease and therefore most likely to benefit from vaccination. The recommendation for shared clinical decision-making is intended to allow flexibility for providers and patients to consider individual risk for RSV disease, while considering patient preferences.

Unlike routine and risk-based vaccine recommendations, recommendations based on shared clinical decision-making do not target all persons in a particular age group or an identifiable risk group. For RSV vaccination, the decision to vaccinate a patient should be based on a discussion between the health care provider and the patient, which might be guided by the patient's risk for disease and their characteristics, values, and preferences; the provider's clinical discretion; and the characteristics of the vaccine.

Vaccine Benefit Analysis

- RSV vaccine should be considered in adults with certain medical conditions including COPD, asthma, CHF, CAD, CVD, DM, CKD due to their increased risk for RSV-associated hospitalization and death, as well as residents of long-term care facilities and persons who are frail or of advanced age. In adults, RSV-associated hospitalizations increase with age; individuals who are older than 75 years have the highest risk. RSV can also cause severe disease in persons with compromised immunity, including recipients of hematopoietic stem cell transplantation and patients taking immunosuppressive medications.
- The two approved vaccines have an efficacy of 82.6% and 88.9% respectively, against lower respiratory tract diseases during the first respiratory season, after vaccine administration. Protection was detected during the second season, albeit at slightly lower levels. Long-term protection and the need for a booster vaccine is still unclear.
- Arexvy/GSK and Abrysvo/Pfizer efficacy trials demonstrated that the frequency of severe adverse events (SAEs) across trials was similar in intervention and control groups.
- Co-administration of RSV and seasonal influenza vaccines met non-inferiority criteria for immunogenicity except for the FluA/Darwin H3N2 strain when the GSK RSV vaccine was co-administered with adjuvanted quadrivalent inactivated influenza vaccine. RSV and influenza antibody titers were somewhat lower with co-administration; however, the clinical significance of this is unknown.

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Vaccine Risk Analysis

- Arexvy/GSK and Abrsyvo/Pfizer efficacy trials were not powered to estimate efficacy against hospitalization, severe disease requiring respiratory support or death.
- RSV vaccine studies included limited numbers of frail adults and adults with advanced age. Residents of long-term care facilities and persons with compromised immunity were excluded. Therefore, the efficacy of vaccine in these high-risk individuals is unknown.
- Although severe adverse effects were similar for both intervention and control groups for both vaccines, a higher number of participants in the intervention group than in the control group for both vaccines reported atrial fibrillation within the 30 days after injection.
- Inflammatory neurologic events were reported in six study participants within 42 days of administration of the combined Arexvy and Abrysvo clinical trials (three of 17,922 participants of the GSK vaccine and three of 20,255 participants of Pfizer vaccine). The inflammatory neurologic events included Guillain-Barre (GBS), acute disseminated encephalomyelitis (ADEM), Miller Fisher syndrome, and undifferentiated motor sensory axonal polyneuropathy. The CDC will monitor adverse events through the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink. Both Pfizer and GSK will also perform studies to evaluate the risks for neurologic disease and atrial fibrillation.
- Administering RSV vaccine with one or more other vaccines at the same visit might increase local or systemic reactogenicity. Data are currently only available for co-administration of RSV and influenza vaccines, and evidence is mixed regarding increased reactogenicity. Data are currently lacking on the safety of co-administration with other vaccines that might be recommended for persons in the ≥60 years age group, such as COVID-19 vaccines; pneumococcal vaccines; adult tetanus, diphtheria, and pertussis vaccines; and the recombinant zoster vaccine (the recombinant zoster vaccine and GSK's RSV vaccine contain the same adjuvant).
- RSV vaccination should be delayed for persons experiencing moderate or severe acute illness with or without fever (precaution).

Source: https://bit.ly/45vsZRW

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Medicare Billing Guidance for Respiratory Vaccines in LTC

#GET VACCINATED

FOR THE FOUR VACCINES (RSV, INFLUENZA, PNEUMOCOCCAL AND COVID), LONG TERM CARE (LTC) FACILITIES CAN BILL MEDICARE.

All Part B vaccines (e.g., Influenza, Pneumococcal and COVID) are subject to consolidated billing and must be submitted by the Skilled Nursing Facility (SNF) on either a separate inpatient or outpatient Part B claim. It is paid separate from any Part A bundled rate when it is for preventative and not therapeutic purposes.

Part D vaccines (which includes RSV) are covered only under Part D and are not covered by Part A or B. RSV vaccine is also not subject to consolidated billing. It can be billed by any outside pharmacy or other entity regardless of SNF Part A (if preventative) or long-stay status. Therapeutic use of a Part D vaccine (e.g., tetanus for a person exposed) during a Part A stay would be bundled into the Part A per-diem rate (Part A is primary payer) and could not be billed separately to Part D.

So, for the RSV Vaccine that is not covered by Part B benefits but is a covered Part D benefit:

- If administered for preventive purposes: Part D plan would pay any approved entity that administers the vaccine regardless of Part A status (Not subject to SNF consolidated billing).

The Medicare Claims Processing Manual Chapter 6, Section 20.4 Screening and Preventive Services (updated 11-04-2021) are copied on the subsequent pages. Key provisions are highlighted.

COVID-19 vaccine coverage under Part B is also addressed on CMS (Centers for Medicare &Medicaid Services) webpage: COVID-19 Vaccines & Monoclonal Antibodies - VACCINE PRICING and in a July 13, 2023, CMS Letter to Payors Regarding Coverage of COVID-19 Vaccines.

Medicare Billing Guidance for Respiratory Vaccines in LTC

#GET VACCINATED

20.4 - Screening and Preventive Services

(Rev.4163, Issued: 11-02-18, Effective: 12-04-18, Implementation: 12-04-18)

The Part A SNF benefit is limited to services that are reasonable and necessary to "diagnose or treat" a condition that has already manifested itself. Accordingly, this benefit does not encompass screening services (which serve to check an at-risk individual for the possible presence of a specific latent condition, before it manifests any overt symptoms to diagnose or treat) or preventive services (which are aimed at warding off the occurrence of a particular condition altogether rather than diagnosing or treating it once it occurs). Coverage of screening and preventive services (e.g., screening mammography, pneumococcal pneumonia vaccine, influenza vaccine, hepatitis B vaccine) is a separate Part B inpatient benefit when rendered to beneficiaries in a covered Part A stay and is paid outside of the Part A payment rate. For this reason, screening and preventive services must not be included in the global Part A bill. However, screening and preventive services remain subject to consolidated billing and, thus, must be billed separately by the SNF under Part B.

Accordingly, even though the SNF itself must bill for these services, it submits a separate Part B inpatient bill for them rather than including them on its global Part A bill. Screening and preventive services must be billed with a 22X type of bill. Swing Bed providers must use TOB 12x for eligible beneficiaries in a Part A SNF level of care. **NOTE:** For beneficiaries residing in the Medicare non-certified area of the facility, these services should be billed on a 23x type of bill. In transmittals for A/B MAC (A) billing providing the annual update list of HCPCS codes affected by SNF consolidated billing, such services are referred to as "Major Category IV." See §10.1 above for the link to where transmittals providing current lists of HCPCS codes used for Major Category IV can be found.

There are certain limited circumstances in which a vaccine would no longer be considered preventive in nature, and this can affect how the vaccine is covered. For example, while a booster shot of tetanus vaccine would be considered preventive if administered routinely in accordance with a recommended schedule, it would not be considered preventive when administered in response to an actual exposure to the disease (such as an animal bite, or a scratch on a rusty nail).

Medicare Billing Guidance for Respiratory Vaccines in LTC

#GET VACCINATED

In the latter situation, such a vaccine furnished to an SNF's Part A resident would be considered therapeutic rather than preventive in nature, as its use is reasonable and necessary for treating an existing condition.

In terms of billing for an SNF's Part A resident, a vaccine that is administered for therapeutic rather than preventive purposes would be included on the SNF's global Part A bill for the resident's covered stay. Alternatively, if a vaccine is preventive in nature and is one of the three types of vaccines (i.e., pneumococcal pneumonia, hepatitis B, or influenza virus) for which a Part B benefit category exists (see §50.4.4.2 of the Medicare Benefit Policy Manual, Chapter 15), then the SNF would submit a separate Part B bill for the vaccine. (Under section 1888(e)(9) of the Social Security Act (the Act) and the implementing regulations at 42 CFR 413.1(g)(2)(ii), payment for an SNF's Part B services is made in accordance with the applicable fee schedule for the type of service being billed (see the Medicare Claims Processing Manual, Chapter 7, §10.5).

However, when these three types of vaccines are furnished in the SNF setting, Part B makes payment in accordance with the applicable instructions contained in the Medicare Claims Processing Manual, Chapter 7, §80.1, and Chapter 18, §10.2.2.1.)

If the resident receives a type of vaccine that is preventive in nature but for which no Part B benefit category exists (e.g., diphtheria), then the vaccine would not be covered under either Parts A or B and, as a consequence, would become coverable under the Part D drug benefit. This is because priority of payment between the various parts of the Medicare law proceeds in alphabetical order: Part A is primary to Part B (see section 1833(d) of the Act), and both Parts A and B are primary to Part D (see section 1860D-2(e)(2)(B) of the Act).