Respiratory Syncytial Virus (RSV) Vaccines for Adult and Maternal Use

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- Medical Clinical Policy Bulletins

Number: 1027

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Policy

Scope of Policy

This Clinical Policy Bulletin addresses respiratory syncytial virus (RSV) vaccine.

1. **Medical Necessity**

   Aetna considers the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations for a single, one-time, intramuscular injection of the respiratory syncytial virus (RSV) vaccine, Arexvy (GSK) or Abrysvo (Pfizer), medically necessary for the prevention of lower respiratory tract disease (LRTD) caused by RSV when *either* of the following criteria is met:

   1. Use of Arexvy or Abrysvo in members 75 years of age and older; *or*
   2. Use of Arexvy or Abrysvo in members 60 to 74 years of age who are at increased risk of severe RSV disease (see Appendix); *or*
   3. Seasonal administration of Abrysvo (only) in pregnant members at 32 through 36 weeks gestational age of pregnancy for prevention of severe LRTD caused by RSV in infants from birth through 6 months of age.

   Notes per CDC's ACIP:

   1. Seasonality: Seasonal administration is during September - January in most of the continental United States. In jurisdictions with seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on timing of administration.
   2. Use with nirsevimab: Most infants will only need protection from either the maternal RSV vaccine (Abrysvo) or infant immunization (nirsevimab), but not both. However, there may be circumstances for which infant immunization with nirsevimab can be considered when maternal RSV vaccine was received prior to birth. For infant immunization with nirsevimab, see CPB 1038 - Nirsevimab-alip (Beyfortus).

2. **Experimental, Investigational, or Unproven**

   Aetna considers the respiratory syncytial virus (RSV) vaccine experimental, investigational, or unproven for the following (not an all-inclusive list) because the effectiveness has not yet been established:

   1. For members less than 60 years of age who do not meet criteria in Section I
   2. For pregnant members less than 32 weeks or greater than 36 weeks gestational age of pregnancy
   3. Revaccination.

3. **Related Policies**

   - CPB 0155 - Ribavirin (Virazole) Inhalation
   - CPB 0318 - Palivizumab (Synagis)
   - CPB 0650 - Polymerase Chain Reaction Testing: Selected Indications

- CPB 1038 - Nirsevimab-alip (Beyfortus)

CPT Codes / HCPCS Codes / ICD-10 Codes

CPT codes covered if selection criteria are met:

Code	Code Description
90678	Respiratory syncytial virus vaccine, preF, subunit, bivalent, for intramuscular use
90679	Respiratory syncytial virus vaccine, preF, recombinant, subunit, adjuvanted, for intramuscular use

Other CPT codes related to the CPB:

90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid).
90472	each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96380	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional
96381	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection

ICD-10 codes covered if selection criteria are met:

Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV) [if over age 60 or pregnant 32 – 36 week gestational age of pregnancy]
Z3A.32	32 weeks gestation of pregnancy
Z3A.33	33 weeks gestation of pregnancy
Z3A.34	34 weeks gestation of pregnancy
Z3A.35	35 weeks gestation of pregnancy
Z3A.36	36 weeks gestation of pregnancy

ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):

B97.4	Respiratory syncytial virus as the cause of disease classified elsewhere
J12.1	Respiratory syncytial virus pneumonia
J20.5	Acute bronchitis due to respiratory syncytial virus
J21.5	Acute bronchiolitis due to respiratory syncytial virus

Background

Respiratory syncytial virus (RSV) is a single-stranded, negative-sense ribonucleic acid (RNA) virus of the *Pneumovirdae* family that can cause acute respiratory tract illness in persons of all ages. RSV is considered a common respiratory pathogen typically resulting in self-limited, mild, cold-like symptoms that can last around one to two weeks. However, for some people, the virus can lead to an infection that spreads to the lower respiratory tract, causing bronchiolitis or pneumonia, resulting in a severe or life-threatening illness. Those who are most vulnerable for severe infection include infants (especially premature infants), older adults (especially those 65 years and older), people with certain comorbid conditions (e.g., cardiac and pulmonary disease), and those who are immunocompromised. In most parts of the United States, RSV circulation is seasonal, typically starting during the fall and peaking in the winter. It is transmitted from person to person through close contact with someone who is infected.

Prior to 2023, there had not been a vaccine readily available to prevent RSV. However, palivizumab, a humanized monoclonal antibody against the RSV F glycoprotein, has been available for prevention of serious RSV lower respiratory tract disease in children, but only for those at high risk of RSV disease, and is only administered during RSV season. In July 2023, the FDA approved nirsevimab-alip (Beyfortus) (Sanofi Pasteur and AstraZeneca), a monoclonal antibody against the RSV F glycoprotein with an extended half-life, to protect all infants through their first RSV season. Approval also included use for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Palivizumab and nirsevimab are classified as an immunoprophylactic drug, not a vaccine. They act similarly to a vaccine; however, instead of prompting the

immune system to develop antibodies to the virus (considered active immunization), they deliver the antibodies directly to the bloodstream (considered passive immunization).

RSV Immunization for Older Adults

On July 21, 2023, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) published their recommendation that adults aged 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision-making. The ACIP acknowledged that the GlaxoSmithKline and Pfizer RSV vaccines demonstrated moderate to high efficacy in preventing symptomatic RSV-associated lower respiratory tract disease (LRTD), and were generally well-tolerated with an acceptable safety profile. However, in the clinical trials, there were 6 cases of inflammatory neurologic events (including Guillain-Barre syndrome and acute disseminated encephalomyelitis) that occurred, but it remains unclear if it was random or whether the vaccine increased the risk. Thus, until evidence from postmarketing surveillance becomes available, the ACIP state that RSV vaccination "should be targeted to those at highest risk for severe RSV disease", therefore benefitting from the vaccine. For that reason, the ACIP recommends vaccination using shared clinical decision-making, "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" (Melgar et al, 2023).

"RSV vaccination is currently approved and recommended for administration as a single dose; sufficient evidence does not exist at this time to determine the need for revaccination. Optimally, vaccination should occur before the onset of the RSV season; however, typical RSV seasonality was disrupted by the COVID-19 pandemic and has not returned to prepandemic patterns. For the 2023–24 season, clinicians should offer RSV vaccination to adults aged ≥60 years using shared clinical decision-making as early as vaccine supply becomes available and should continue to offer vaccination to eligible adults who remain unvaccinated" (Melgar et al, 2023).

Per the ACIP, coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable. "Administering RSV vaccine with one or more other vaccines at the same visit might increase local or systemic reactogenicity. Data are only available for coadministration of RSV and influenza vaccines, and evidence is mixed regarding increased reactogenicity. Data are lacking on the safety of coadministration with other vaccines that might be recommended for persons in this 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 contains the same adjuvant). When deciding whether to coadminister other vaccines with an RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preferences. Postlicensure efficacy and safety monitoring of coadministered RSV vaccines with other vaccines will further direct guidance" (Melgar et al, 2023).

In June 2024, the ACIP voted to approve the following recommendations for the RSV vaccine in adults based on epidemiologic evidence:

- Adults 75 years of age and older receive a single dose of RSV vaccine;
- Adults 60 to 74 years of age and older who are at increased risk of severe RSV disease receive a single dose of RSV vaccine.

These recommendations supplant the current recommendation that adults 60 years of age and older may receive RSV vaccination, using shared clinical decision-making. Adults 60 to 74 years of age who are not at increased risk of severe RSV disease are not recommended to receive RSV vaccination. These recommendations have been adopted by the CDC Director on June 26, 2024 and are now official (CDC, 2024a, 2024b).

RSV vaccination is recommended as a single lifetime dose only. Persons who have already received RSV vaccination are not recommended to receive another dose. Regarding timing of vaccination, for patients who have not already received an RSV vaccine and decide to get one, the CDC encourages healthcare providers to maximize the benefit of RSV vaccination by giving them their RSV vaccine in late summer or early fall (CDC, 2024b).

RSV Immunization in Pregnancy

Simões et al (2022) conducted a Phase 2b trial to evaluate the efficacy, immunogenicity, and safety of a bivalent RSV prefusion F protein-based (RSVpreF) vaccine in pregnant women and their infants. The authors randomly assigned pregnant women, at 24 through 36 weeks' gestation, to receive either 120 or 240 µg of RSVpreF vaccine (with or without aluminum hydroxide) or placebo. The trial included safety end points and immunogenicity end points that, in this interim analysis, included 50% titers of RSV A, B, and combined A/B neutralizing antibodies in maternal serum at delivery and in umbilical-cord blood, as well as maternal-to-infant transplacental transfer ratios. This interim analysis included 406 women and 403 infants, of which 327 women (80.5%) received the RSVpreF vaccine. The authors found that most post-vaccination reactions were mild to moderate, and that the incidence of local reactions was higher among women who received RSVpreF vaccine containing aluminum hydroxide than among those who received RSVpreF vaccine without aluminum hydroxide. The incidences of adverse events in the women and infants were similar in the vaccine and placebo groups, and the type and frequency of these events were consistent with the

background incidences among pregnant women and infants. The geometric mean ratios of 50% neutralizing titers between the infants of vaccine recipients and those of placebo recipients ranged from 9.7 to 11.7 among those with RSV A neutralizing antibodies and from 13.6 to 16.8 among those with RSV B neutralizing antibodies. Transplacental neutralizing antibody transfer ratios ranged from 1.41 to 2.10 and were higher with nonaluminum formulations than with aluminum formulations. Across the range of assessed gestational ages, infants of women who were immunized had similar titers in umbilical-cord blood and similar transplacental transfer ratios. The authors concluded that RSVpreF vaccine elicited neutralizing antibody responses with efficient transplacental transfer and without evident safety concerns (ClinicalTrials.gov number, NCT04032093).

Pfizer is preparing for regulatory applications for both infants through maternal immunization and older adults to help protect against RSV. In November 2022, Pfizer announced a positive interim analysis of its Phase 3 clinical trial (NCT04424316) MATISSE (MATernal Immunization Study for Safety and Efficacy) investigating its bivalent RSV prefusion vaccine candidate, RSVpreF or PF-06928316, when administered to pregnant participants to help protect their infants from RSV disease after birth.

On September 22, 2023, the CDC's ACIP voted, 11-1, to recommend maternal RSV vaccine (Pfizer’s bivalent RSVpreF, Abrysvo) for pregnant people during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants. Seasonal administration for most of the continental United States is during September–January. In jurisdictions with seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on timing of administration.

The CDC's ACIP also voted to approve the Abrysvo vaccine for the Vaccines for Children Program (applying to pregnant people under 19 years of age). Per the CDC's ACIP, "Most infants will likely only need protection from either the maternal RSV vaccine or infant immunization [nirsevimab], but not both. However, for example, if a baby is born less than two weeks after maternal immunization, then a doctor may recommend that the baby also receive the infant immunization". Thus, nirsevimab can be considered in rare circumstances even though the mother received an RSV vaccine when, per the clinical judgment of the healthcare provider, the potential incremental benefit of administration is warranted (CDC, 2023).

Arexvy

On May 3, 2023, the U.S. Food and Drug Administration (FDA) approved GlaxoSmithKline's respiratory syncytial virus (RSV) vaccine, adjuvanted (Arexvy) for the prevention of LRTD caused by RSV in individuals 60 years of age and older. FDA approval is based on positive efficacy outcomes from the pivotal AReSVi-006 phase III, randomized, placebo-controlled, observer-blind clinical trial (NCT04886596) conducted in 17 countries. The trial included 24,960 participants randomized equally to receive 1 dose of Arexvy (n = 12,466) or placebo (n = 12,494). At the time of the primary efficacy analysis, participants had been followed for the development of RSV-associated LRTD for up to 10 months (median of 6.7 months). The trial excluded participants who were immunocompromised, but allowed pre-existing, chronic, stable disease such as diabetes, hypertension, or cardiac disease if considered to be medically stable at the time of vaccination. In the trial, the vaccine showed statistically significant and clinically meaningful overall efficacy of 82.6% (96.95% CI, 57.9–94.1, 7 of 12,466 vs 40 of 12,494) against RSV-LRTD in adults aged 60 years and older, meeting the primary endpoint. In addition, efficacy was 94.6% (95% CI, 65.9–99.9, 1 of 4,937 vs 18 of 4,861) in older adults with at least one underlying medical condition of interest, such as certain cardiorespiratory and endocrine-metabolic conditions. Efficacy against severe RSV-LRTD, defined as an RSV-associated LRTD episode preventing normal, everyday activities, was 94.1% (95% CI, 62.4–99.9, 1 of 12,466 vs 17 of 12,494) (GSK, 2023a, 2023b).

The vaccine is administered as a single dose intramuscularly and was generally well tolerated with an acceptable safety profile. The most commonly reported solicited local adverse reaction (10% or more) included injection site pain (60.9%). The most commonly reported solicited systemic adverse reactions (10% or more) included fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%).

An open-label, phase 3 study evaluated the concomitant use of Arexvy and Fluarix in participants 60 years of age and older. Participants received 1 dose of Arexvy and Fluarix quadrivalent at Month 0 (n = 442) or 1 dose of Fluarix quadrivalent at Month 0 followed by a dose of Arexvy at Month 1 (n = 443). There was no evidence for interference in the immune response to any of the antigens contained in both concomitantly administered vaccines. The criteria for non-inferiority of the immune responses in the control versus “co-administration” group were met. Data are not available for concomitant administration with other vaccines (GSK, 2023a).

A clinical trial is under way which aims to expand the population who may benefit from RSV vaccination into adults aged 50-59, including participants with underlying comorbidities (GSK, 2023b).

Abrysvo

In December 2022, Pfizer Inc. announced that the FDA accepted for priority review a Biologics License Application (BLA) for their investigational RSV vaccine candidate, PF-06928316 or RSVpreF, as submitted for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA on the RSVpreF application is in May 2023. The unadjuvanted bivalent vaccine candidate is composed of equal amounts of recombinant RSV prefusion F, a key form of the viral fusion protein (F) that RSV uses to enter human cells, from subgroups A and B.

The regulatory submission is supported by results of the phase 3 clinical trial (NCT05035212) RENOIR (RSV vaccine Efficacy study iNOlder adults Immunized against RSV disease). Per Pfizer, RENOIR is a global, randomized, double-blind, placebo-controlled study designed to assess the efficacy, immunogenicity, and safety of a single dose of RSVpreF in adults 60 years of age and older. RENOIR has enrolled approximately 37,000 participants, randomized to receive RSVpreF 120 µg or placebo in a 1:1 ratio. In August 2022, Pfizer announced positive top-line results of an interim efficacy analysis for RENOIR.

On May 31, 2023, the FDA approved Pfizer's bivalent recombinant stabilized RSV prefusion F (RSVpreF) vaccine, Abrysvo, for the prevention of LRTD caused by RSV in adults 60 years of age and older. The approval was based on the efficacy and safety data from the pivotal phase 3 RENOIR trial (Walsh et al, 2023).

The RENOIR trial (Walsh et al, 2023) included randomization, in a 1:1 ratio, of a single intramuscular injection of RSVpreF (Abrysvo) vaccine at a dose of 120 µg (RSV subgroups A and B, 60 µg each) or placebo in adults 60 years of age or older. Healthy adults and adults with stable chronic diseases were included. Among enrolled participants 15% had stable chronic cardiopulmonary conditions such as chronic obstructive pulmonary disease (COPD), asthma, or congestive heart failure (CHF). The two primary end points were vaccine efficacy against seasonal RSV-associated lower respiratory tract illness with at least 2 or at least 3 signs or symptoms. The secondary end point was vaccine efficacy against RSV-associated acute respiratory illness. At the interim analysis, of the 34,284 participants, 17,215 received RSVpreF vaccine and 17,069 received placebo. The investigators found that RSV-associated lower respiratory tract illness with at least 2 signs or symptoms occurred in 11 participants in the vaccine group and 33 participants in the placebo group (vaccine efficacy, 66.7%; 96.66% confidence interval [CI], 28.8 to 85.8); 2 cases and 14 cases, respectively, occurred with at least 3 signs or symptoms (vaccine efficacy, 85.7%; 96.66% CI, 32.0 to 98.7). They also found that RSV-associated acute respiratory illness occurred in 22 participants in the vaccine group and 58 participants in the placebo group (vaccine efficacy, 62.1%; 95% CI, 37.1 to 77.9). The incidence of local reactions was higher with vaccine (12%) than with placebo (7%); the incidences of systemic events were similar (27% and 26%, respectively). Similar rates of adverse events through 1 month after injection were reported (vaccine, 9.0%; placebo, 8.5%), with 1.4% and 1.0%, respectively, considered by the investigators to be injection-related. Severe or life-threatening adverse events were reported in 0.5% of vaccine recipients and 0.4% of placebo recipients. Serious adverse events were reported in 2.3% of participants in each group through the data-cutoff date. In conclusion, the study met the pre-specified success criteria for demonstration of efficacy of RSVpreF (Abrysvo) vaccine for the primary objectives of prevention of RSV-associated lower respiratory tract illness with ≥2 symptoms and prevention of RSV-associated lower respiratory tract illness with ≥3 symptoms. The median duration of follow-up for efficacy was 7 months. RSVpreF (Abrysvo) vaccine was also found to prevent RSV-associated acute respiratory illness in adults 60 years of age and older, without evident safety concerns. The RENOIR trial is ongoing with efficacy data being collected in the second RSV season in the study.

In clinical trials, the most commonly reported (10% or more) adverse reactions for individuals 60 years of age and older were fatigue (15.5%), headache (12.8%), pain at the injection site (10.5%), and muscle pain (10.1%).

In August 2023, the FDA approved Abrysvo for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age. FDA approval is based on the safety and efficacy data from the Phase 3 MATISSE trial which found that Abrysvo reduced the risk of severe LRTD by 81.8% within 90 days after birth, and 69.4% within 180 days after birth (FDA, 2023).

The MATISSE trial (Kampmann et al, 2023) is an ongoing, randomized, double-blinded, placebo-controlled, multicenter international clinical study that evaluated the safety, efficacy, and immunogenicity of the RSVpreF vaccine (Abrysvo) against LRTD and severe LRTD due to RSV in infants born to healthy individuals vaccinated during pregnancy. The study included pregnant individuals less than or equal to 49 years of age with uncomplicated, singleton pregnancies. High-risk pregnancies were excluded from the study (BMI greater than 40 kg/m^2 prior to pregnancy, pregnancies resulting after in vitro fertilization, preeclampsia, eclampsia, uncontrolled gestational hypertension, placental abnormalities, polyhydramnios or oligohydramnios, significant bleeding or blood clotting disorder, unstable endocrine disorders including untreated disorders of glucose intolerance or thyroid disorders). Pregnant women at 24 through 36 weeks' gestation were randomized 1:1 to receive either a single intramuscular (IM) injection of 120 µg of Abrysvo (n = 3682) or placebo (n =3676); 3570 and 3558 infants were evaluated. The two primary efficacy end points were medically attended severe RSV-associated LRTD and medically attended RSV-associated LRTD in infants within 90, 120, 150, and 180 days after birth. A lower boundary of the confidence interval (CI) for vaccine efficacy (99.5% CI at 90 days; 97.58% CI at later intervals) greater than 20% was considered to meet the success criterion for vaccine efficacy with respect to the primary end points. The investigators found that medically attended severe LRTD occurred within 90 days after birth in 6 infants of women in the vaccine group and 33 infants of women in the placebo group (vaccine efficacy, 81.8%; 99.5% CI, 40.6 to 96.3); 19 cases and 62 cases, respectively, occurred within 180 days after birth (vaccine efficacy, 69.4%; 97.58% CI, 44.3 to 84.1). Medically attended RSV-associated LRTD occurred within 90 days after birth in 24 infants of women in the vaccine group and 56 infants of women in the placebo group (vaccine efficacy, 57.1%; 99.5% CI, 14.7 to 79.8), which did not meet the prespecified statistical success criterion; however, clinically meaningful efficacy was observed after 90 days through 180 days after birth. No safety signals were detected in maternal participants or in infants and toddlers up to 24 months of age. The incidences of adverse events reported within 1 month after injection or within 1 month after birth were similar in the vaccine group (13.8% of women and 37.1% of infants) and the placebo group (13.1% and 34.5%, respectively). The investigators concluded that a single IM injection of Abrysvo administered during pregnancy was effective against medically attended severe RSV-associated LRTD in infants without identified safety concerns.

"In a subgroup of pregnant individuals who were 32 through 36 weeks gestational age, of whom approximately 1,500 received Abrysvo and 1,500 received placebo, Abrysvo reduced the risk of LRTD by 34.7%, and reduced the risk of severe LRTD by 91.1% within 90 days after birth when compared to placebo. Within 180 days after birth, Abrysvo reduced the risk of LRTD by 57.3% and by 76.5% for severe LRTD, when compared to placebo" (FDA, 2023).

Abrysvo is administered as a single dose intramuscular injection. Labeled warnings and precautions include potential risk of preterm birth. Thus, it is recommended to avoid administration of Abrysvo before 32 weeks of gestation. The prescribing information states to administer as indicated in pregnant individuals at 32 through 36 weeks gestational age. In addition, pre-eclampsia occurred in 1.8% of pregnant individuals who received Abrysvo compared to 1.4% who received placebo. In the safety studies, low birth weight and jaundice in infants occurred at a higher rate in the pregnant Abrysvo recipients compared to pregnant placebo recipients (FDA, 2023).

The most reported solicited local and systemic adverse reactions in pregnant individuals (10% or more) were pain at the injection site (40.6%), headache (31.0%), muscle pain (26.5%), and nausea (20.0%).

Appendix

Per the CPC, epidemiologic evidence indicates that all adults ages 75 or older and adults ages 60 to 74 with certain risk factors are at increased risk of severe RSV. The following conditions increase the risk of severe RSV:

- Cardiovascular disease (e.g., heart failure; coronary artery disease; congenital heart disease, excluding isolated hypertension),
- Lung disease (e.g., chronic obstructive pulmonary disease [COPD], emphysema, asthma, interstitial lung disease, cystic fibrosis),
- Advanced chronic kidney disease (e.g., stages 4–5, dependence on hemodialysis or other renal replacement therapy),
- Diabetes mellitus with end-organ damage (e.g., diabetic nephropathy, neuropathy, retinopathy, or cardiovascular disease),
- Severe obesity (body mass index ≥40 kg/m2),
- Liver disorders (e.g., cirrhosis),
- Neurologic or neuromuscular conditions (e.g., neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness, excluding history of stroke without impaired airway clearance),
- Hematologic disorders (e.g., sickle cell disease, thalassemia), and
- Moderate or severe immune compromise (either attributable to a medical condition or receipt of immunosuppressive medications or treatment);

As well as:

- People who are frail (defined as a clinical syndrome with 3 or more of the following symptoms: unintentional weight loss (10 lbs [4.5 kg] in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity);
- People who reside in nursing homes or long-term care facilities. Note: Retirement communities and independent living communities for seniors are not considered long-term care facilities. Adults 60-74 living in these facilities may still be recommended to receive RSV vaccination if they have certain medical conditions noted on the list of this appendix; and
- People with other chronic medical conditions or risk factors that a healthcare provider determines might increase the risk of severe disease due to respiratory infection.

Source: CDC, 2024b

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The above policy is based on the following references:

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Policy History

- Last Review 11/05/2024

  Effective: 04/11/2023

  Next Review: 07/24/2025

- Review History

- Definitions

Additional Information

- Clinical Policy Bulletin Notes