

FDA gives nod to RSV vaccine for people in their 50s

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The U.S. Food and Drug Administration on Friday has for the first time approved the use of a respiratory syncytial virus (RSV) vaccine for people in their 50s who are at increased risk for the illness.

Drugmaker GSK's Arexvy vaccine, as well as vaccines from Pfizer and Moderna, are already approved for use in adults 60 and older, since age brings higher risk from RSV disease.

Arexvy is the first to get the nod for people ages 50 to 59 with certain health risk factors.

"A systematic review of studies in the US showed that RSV is estimated to cause 42,000 hospitalizations each year in adults aged 50-64 years old," GSK said in a [company statement](#) released Friday.

"Adults with underlying medical conditions, such as [chronic obstructive pulmonary disease](#) (COPD), asthma, [heart failure](#) and diabetes are at increased risk for severe consequences from an RSV infection compared to those without these conditions," the company added. "RSV can exacerbate these conditions and lead to pneumonia, hospitalization or death."

Experts at the U.S. Centers for Disease Control and Prevention are expected to meet in June and October, at which time they might also sign off on the use of Arexvy in people in their 50s. Doing so would give the green light for insurance coverage.

According to CBS News, Pfizer and Moderna are also testing their RSV vaccines for use in younger patients.

Arexvy's safety profile among people in their 50s appears to be similar to that among older people. Less than 10% of people in their 50s who got the shots had any reaction, GSK said, with the most common being injection site pain, fatigue, muscle ache and headache.

According to CBS News, the CDC's advisory panel has been weighing the risk of a neurological condition, Guillain-Barré syndrome (GBS),

seen in very rare cases after RSV vaccination. The CDC pegs the rate of GBS at 1.5 cases per million doses.

GSK's latest trial data failed to reveal any "concerning" trends of GBS cases in the 50-to-59 age group, Dr. Phil Dormitzer, senior vice president and global head of vaccines research and development at GSK, told CBS News.

"The risk of GBS tends to go up, it's another one of those risks that tends to go up, with age. But there's nothing to indicate that there's any particular risk of GBS," he said.

New data will be presented to the CDC this month on spacing RSV booster shots for [older adults](#), Dormitzer said.

"This is a really key question," he said. "People originally anticipated it might have to be an every year immunization. But then we found the duration of protection actually lasts for more than one season, clearly."

Trials looking at the use of Arexvy in 18- to 49-year-olds are expected in the later half of the year, GSK said.

More information: Find out more about RSV in older adults at the [CDC](#).

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