

FDA advisers back full approval of Paxlovid

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Paxlovid, a medication that has helped millions of high-risk COVID-19 patients avoid hospitalization and death since late 2021, moved one step closer to getting full approval from the U.S. Food and Drug

Administration on Thursday.

An FDA [advisory panel](#) voted 16-1 that the Pfizer drug remains a safe and effective treatment and should be given full approval. It has only received emergency use authorization until now, but the FDA is expected to make a final decision on full approval by May, the Associated Press reported. The [vote](#) was not a surprise, given that Paxlovid continues to be a well-used treatment while other drugs no longer work against a mutated virus.

While data for [healthy adults](#) show the drug makes no meaningful difference, it shows significant benefits for high-risk adults. Paxlovid reduces the chance of hospitalization and death by about 60 to 85 percent for seniors and adults who have [health issues](#) that include obesity, diabetes, [lung disease](#), and immune system disorders, the AP reported.

Paxlovid could prevent 1,500 deaths and 13,000 hospitalizations each week, according to the FDA. The United States still sees about 4,000 COVID-19 deaths and 35,000 hospitalizations weekly, according to the AP.

One issue the panel addressed is whether Paxlovid increases the chances of COVID rebound. The panel agreed there was not a clear link, the AP reported. About 10 to 16 percent of patients in multiple Pfizer studies had symptoms return, but that was true even if they received a placebo. These cases "likely reflect natural COVID-19 progression," the FDA concluded. About 95 percent of Americans have protection against COVID-19 from at least one vaccine dose and/or prior infection.

The panelists said prescribing Paxlovid will remain a case-by-case decision, the AP reported.

More information: [Associated Press Article](#)

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