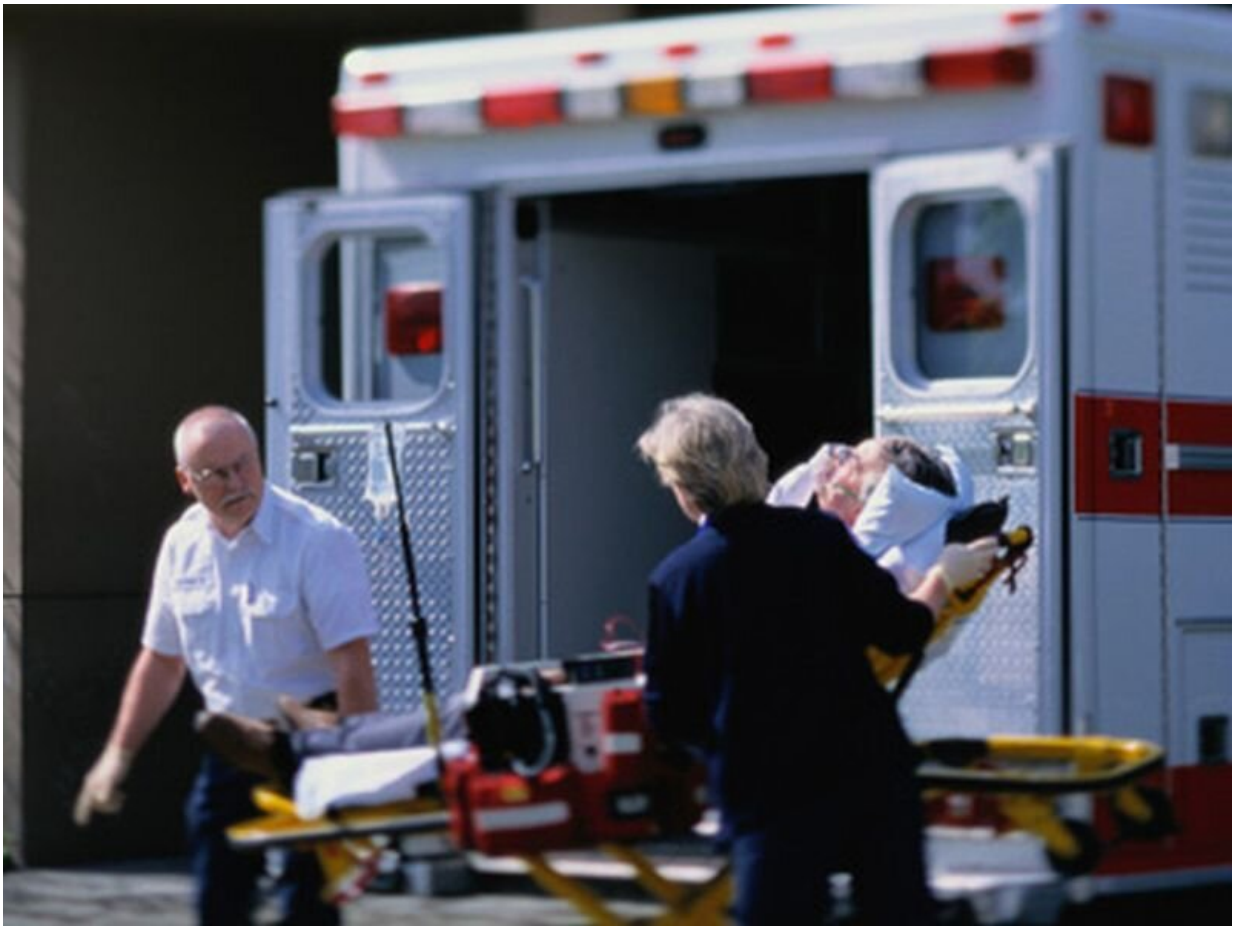
FDA approves higher-dose naloxone hydrochloride nasal spray

May 4 2021



(HealthDay)—The U.S. Food and Drug Administration approved use of

a higher dose of naloxone hydrochloride nasal spray for treating opioid overdose, the agency announced Friday.

The newly approved dose of 8 mg provides an additional option to the 2-mg and 4-mg doses already approved for use.

In a statement, the FDA said this decision follows other steps the agency has taken to improve naloxone product availability, including the requirement that drug manufacturers for all opioid pain relievers and medicines to treat opioid use disorder add recommendations about naloxone to prescribing information and the extension of the shelf life of naloxone nasal spray from two to three years.

Naloxone may cause opioid withdrawal in patients who are opioid-dependent. Withdrawal symptoms include body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

"By approving a higher dose of naloxone hydrochloride nasal spray product to treat opioid overdose, the FDA is making sure the overdose-reversing drug is potent enough to counteract the increasingly lethal and illicitly manufactured fentanyl and fentanyl analogs," Patrice Harris, M.D., chair of the American Medical Association Opioid Task Force, said in a statement. "Now, we must make sure that the new version of naloxone is placed on the lowest cost-sharing tier with low or no cost-sharing and also available in pharmacies. Communities are looking for tools to respond to the epidemic of drug overdoses, and the FDA action today adds a powerful one."

Approval was granted to Hikma Pharmaceuticals through the 505(b)(2) approval pathway under the Federal Food, Drug, and Cosmetic Act.

More information: More Information
AMA Statement