Making prescription drugs more affordable for Californians



California to Purchase CalRx® Branded Over-the-Counter (OTC) Naloxone for \$24

California, disrupting the drug industry through CalRx®, is now set to purchase twin-packs of life-saving OTC naloxone nasal spray for almost half of the current market price.

1. Now that it's received FDA approval, when will the state begin buying the Amneal Pharmaceuticals naloxone nasal product?

The Department of Health Care Services (DHCS) will begin purchasing a small amount of naloxone nasal spray from Amneal Pharmaceuticals in May and June (34K units per month), then gradually increase the number of units in July. This transition will help ensure continuity of supply and a smooth transition operationally from the current vendor.

As part of the CalRx® contract, California business entities may also order OTC naloxone nasal spray at the same \$24 CalRx® price; however, we anticipate these orders will be fairly low to start and may increase over time. At this time, the product is shipped directly from Amneal to the end user. CalRx® is exploring direct-to-consumer options.

2. Will the product the state purchases be labeled CalRx®?

Amneal's packaging has already been approved for national distribution, so in the interest of expedience, early orders may have Amneal packaging while the CalRx® label is finalized and manufactured, which we anticipate in July. Amneal-labeled naloxone product not related to this contract that are sold in CA will not contain the CalRx® label.

3. How can organizations obtain naloxone through this initiative?

There are two ways an entity can procure CalRx® naloxone nasal spray:

- 1. From the California Naloxone Distribution Project (NDP). Additional instructions on how to submit an application to the NDP can be found at the NDP's website.
- 2. California government and business entities that meet certain requirements, including a prohibition against resale, can establish an account with Amneal Pharmaceuticals to purchase OTC naloxone nasal spray. More information on this option can be found at our CalRx® website.

4. Once an entity orders through the NDP, how will long will it take for the local organization to receive the new Amneal Pharmaceuticals product?

DHCS collects and sends NDP orders on a weekly basis. Once the order is received by Amneal Pharmaceuticals, it will take 4-5 business days for the organization to receive the product – the same timeline as today.

5. Will CalRx® naloxone nasal spray be available to purchase in a pharmacy? Can I buy the CalRx® naloxone nasal spray product online?

CalRx® is working on an option for individuals to purchase naloxone nasal spray directly. Please visit our <u>CalRx® website</u> for more information soon. More information on where to find naloxone can be found on <u>California</u>'s <u>opioid response website</u>.

6. Is there any cost involved in acquiring naloxone, and if so, what are the details?

Qualifying organizations can obtain CalRx® naloxone nasal spray free of charge from the NDP by completing an online application located on the <u>DHCS website</u>. The application includes instructions, as well as terms and conditions of participating in the NDP.

Other California-based entities can purchase naloxone directly from Amneal Pharmaceuticals at the same \$24 price per twin pack, subject to certain requirements including establishing an account with Amneal Pharmaceuticals to purchase OTC naloxone nasal spray and a prohibition against resale. More information on this option can be found at our CalRx® website.

7. Is Amneal going to sell naloxone nasal spray to other states or local governments like they are for California? Can other states purchase CalRx® naloxone nasal spray at the \$24 price? Will Amneal make this price available to all customers and consumers?

The \$24 price is for organizations residing within California that meet the requirements of the agreement with Amneal. CalRx® is working on an option for individuals to purchase naloxone nasal spray directly.

Amneal is committed to improving access to this life-saving medicine, and welcomes the opportunity to engage with other government bodies.

8. Is the CalRx® naloxone nasal spray product the same as Narcan®?

The CalRx® naloxone nasal spray product is an FDA-approved generic equivalent to OTC Narcan®. (Narcan® is a registered trademark of Emergent Operations Ireland Limited.)

9. Are the CalRx® naloxone nasal spray product and Amneal product the same?

These naloxone nasal spray products are the same except for the labeling.

10. Will I need a prescription to purchase CalRx® naloxone nasal spray?

No, CalRx® naloxone nasal spray is an over-the-counter product and can be purchased without a prescription.

11. Are there training or educational resources available for the proper use of naloxone?

Instructions for use are available in various formats online at https://amnealnaloxone.com/how-to-use/. The product is packaged with instructions printed on the carton and included with each sprayer device as well.

12. Where is the CalRx®/Amneal product made?

Amneal Pharmaceuticals manufactures its OTC naloxone nasal spray at its U.S.-based facility in New Jersey.

13. Whom do I contact if I have side effects or suspect there is something wrong with my CalRx®/Amneal OTC naloxone nasal spray?

To report an adverse event related to an Amneal/CalRx® product contact the Amneal Drug Safety at <u>1-877-835-5472</u>, option 3 or at <u>DrugSafety@amneal.com</u>.

14. I live in California. How can I get the CalRx® naloxone nasal spray product?

CalRx® is working on an option for an individual to buy CalRx® naloxone nasal spray directly. Please visit our <u>CalRx® website</u> for more information soon. More information on where to find naloxone can be found on <u>California's opioid response website</u>.

15. Can I get CalRx® naloxone nasal spray if I don't live in California?

The special pricing for CalRx® OTC naloxone is currently limited to organizations and residents residing in California that meet the requirements of the agreement with Amneal. However, Amneal welcomes the opportunity to work with other state entities to provide the same, high quality OTC naloxone nasal spray product.

16. Does California recommend people buy naloxone as a precautionary measure?

The <u>CDC recommends</u> carrying naloxone to help save the life of someone experiencing an overdose until emergency medical help arrives, especially if you or someone you know is at increased risk of overdose.

17. Will this product be free for California residents?

Qualifying organizations can obtain CalRx® naloxone nasal spray free of charge from the NDP by completing an online application located on the <u>DHCS website</u>. CalRx® is working on an option for an individual to buy CalRx® naloxone nasal spray directly. Please visit our <u>CalRx®</u> website for more information soon.

18. Do Medicaid/Medicare patients get the product for free, and if so, how?

In California, Medi-Cal covers naloxone with no copayment, making it accessible at no cost for Medi-Cal beneficiaries. Medicare coverage for naloxone can vary; some Medicare Advantage plans cover over-the-counter naloxone. It's important to check your specific plan for coverage details.

19. Will insurance pay for my CalRx® naloxone nasal spray product? Will my insurance cover the CalRx® naloxone nasal spray product?

Insurance coverage for over-the-counter naloxone varies by plan. While it's common for health insurance plans not to cover over-the-counter medications, many are starting to include naloxone due to its importance in reversing opioid overdoses. The coverage depends on the individual insurance plan, so it's recommended to check with your specific insurer to see if they cover naloxone now that it is available over-the-counter.

20. If I buy a naloxone product from a pharmacy, can I get the California price?

At this time, there are 2 methods to obtain CalRx® naloxone nasal spray within California: 1) Free of charge as a qualifying entity through the NDP, and 2) California entities can set up a direct-purchase agreement with Amneal, subject to certain requirements including establishing an account with Amneal Pharmaceuticals to purchase OTC naloxone nasal spray and a prohibition against resale. CalRx® is working on an option for an individual to buy CalRx® naloxone nasal spray directly. Please visit our CalRx® website for more information soon.

21. Can I use my flexible spending account (FSA) funds to purchase CalRx® naloxone nasal spray product?

The Coronavirus Aid, Relief, and Economic Security (CARES) Act, enacted in March 2020, expanded the list of eligible expenses to include several OTC drugs, medicines, and products without the need for a prescription. However, it's important to always check with your benefits administrator to determine which medications are eligible.

- **22.** How do I get this price for the Narcan® branded product?

 The \$24 price is only for the CalRx® and Amneal branded naloxone nasal spray products under this landmark agreement.
- 23. If I recently purchased naloxone, can I apply to get this price?

Organizations wishing to purchase naloxone nasal spray at the \$24 CalRx® price can do so after April 29, 2024. The price cannot be retroactively applied to already-made purchases.

24. Can I get CalRx® naloxone nasal spray product at my local pharmacy?

CalRx® is working on an option for an individual to buy CalRx® naloxone nasal spray directly. Please visit our CalRx® website for more information soon.

25. Where do I go if I want to find out more information?

California <u>launched</u> a new, comprehensive opioid website that gives Californians a single resource for prevention, data, treatment, and support information. The website, <u>opioids.ca.gov</u>, is part of Governor Newsom's multi-pronged approach to connect Californians with information to prevent and reduce overdoses and deaths and support those struggling with substance use and addiction.

All Californians should visit <u>opioids.ca.gov</u> to learn more and help us spread awareness and save lives. Together we can make a difference in combating this crisis.

26. Is this product FDA approved?

Yes, it received FDA approval on April 23rd, 2024.