

1. What naloxone products are approved for over-the-counter (OTC) use?

As of August 1, 2023, the Food and Drug Administration (FDA) has approved three naloxone products for over-the-counter (OTC) use:

- Narcan 4mg naloxone nasal spray, manufactured by Emergent BioSolutions, was [approved](#) for OTC use on March 29, 2023.
- A generic naloxone 4mg nasal spray, manufactured by Padagis, was [approved](#) for OTC use on July 18, 2023.¹
- RiVive 3mg naloxone nasal spray, manufactured by [Harm Reduction Therapeutics](#), was [approved](#) for OTC use on July 28, 2023.²

2. How does FDA's approval of OTC Narcan and RiVive affect other naloxone products currently on the market?

The effect of FDA's approval of OTC Narcan and RiVive varies by product:

- Other generic 4mg naloxone nasal spray products that are based on the Narcan brand name product (e.g., generic versions manufactured by Teva) are likely to be authorized for OTC use, but their manufacturers must first submit updated labeling to FDA.
- **FDA has indicated that it will address the status of other brand name naloxone nasal spray products of 4mg or less “on a case-by-case basis.”** [Prior FDA guidance](#) suggests FDA will eventually require these products to either be approved for OTC use or removed from the market. However, no additional public information is available currently.
- **The status of other naloxone products is unaffected.** This means that these products – including intramuscular/injectable naloxone, naloxone autoinjectors, and nasal naloxone products that contain dosages greater than 4mg (e.g., Kloxxado) – will remain available by prescription only. There is no indication that FDA is actively considering OTC status for intramuscular/injectable naloxone, high-dose nasal naloxone, or non-naloxone opioid overdose reversal drugs such as nalmefene (e.g., Opvee).³

3. When, where, and how will OTC naloxone be available?

OTC Narcan will be publicly available by late summer 2023, according to its manufacturer Emergent BioSolutions. Harm Reduction Therapeutics anticipates making RiVive available in early 2024.⁴ Although Padagis [announced](#) the launch of its generic OTC naloxone nasal spray on August 8, 2023, the announcement did not specify when the product will be available.

Most states do not restrict the types of retailers that can sell OTC medications or require retailers to obtain an additional license, permit, or registration to do so. This means that **OTC naloxone can be sold anywhere other common medications like Tylenol and Ibuprofen are available such as grocery stores, convenience stores, or gas stations.** Although a handful of states require an additional license, permit, or registration to sell OTC medications,⁵ these states generally allow a wider variety of stores to obtain this additional authorization, meaning that sales of OTC naloxone likely will not be limited to pharmacies even in these states. Most states also allow OTC medications to be sold via vending machines.

The decision about whether and how to sell OTC naloxone – including whether the medication will be freely available on store shelves, stored behind locked windows on store shelves, or remain behind the pharmacy counter – will be made by individual retailers.

4. How much will OTC naloxone cost?

Consumer prices will be set by individual retailers. However, Emergent BioSolutions' [stated](#) goal is for out-of-pocket costs for its OTC Narcan product “to be consistent with [its] public interest pricing” of approximately \$50 for a carton of two 4mg doses. Harm Reduction Therapeutics has [stated](#) that RiVive will cost \$36 for a pack of two 3mg doses. Both OTC Narcan and RiVive will be significantly more expensive than other available formulations, such as intramuscular naloxone obtained through [Remedy Alliance](#), and are likely too expensive to provide meaningful access to those who would benefit most from the increased availability of OTC naloxone.⁶

5. How will OTC naloxone affect naloxone access programs?

Making naloxone available OTC is a long overdue step towards increasing access to a proven overdose prevention strategy, but **OTC naloxone is not a substitute for state, local, and community-based programs that provide free or low-cost naloxone.** The high cost of OTC naloxone means that these programs will remain critical to achieving naloxone saturation and ensuring naloxone is available when and where it's needed most.

Recommendation – Ensuring Low/No Cost Naloxone: States should continue to fund existing free naloxone access programs and establish such programs where none currently exist. Federal funding such as State Opioid Response (SOR) grants may be used to purchase and distribute naloxone, including OTC formulations. States should also assess what, if any, effect the approval of OTC naloxone will have on their supply agreements (e.g., cost, availability, ordering processes).

6. How does OTC naloxone affect the need for standing orders?

Standing orders will remain critical even after OTC naloxone products are commercially available. Standing orders can ensure the continued availability of all formulations of naloxone, including more affordable injectable formulations preferred by many people who use drugs, and serve as a prescription where necessary for insurance coverage purposes.

Recommendation – State Standing Orders: States should evaluate their naloxone standing order(s) and, if necessary, revise their existing or issue new standing order(s) to explicitly cover all naloxone formulations regardless of OTC or prescription-only status.

States should also ensure their standing order(s) allow community-based organizations that are not pharmacies to distribute all naloxone formulations.

7. How will OTC naloxone affect insurance coverage for the medication?

This varies by type of insurance:⁷

- **Private Insurance:** Non-grandfathered individual and small group plans required to cover [Essential Health Benefits](#) (EHBs) under the Affordable Care Act, including plans purchased through Marketplaces, likely must continue to cover at least some formulations of naloxone when obtained via a patient-specific prescription or standing order.⁸ It is currently unknown if or how self-insured plans, such as those offered by many large employers, and grandfathered plans will cover naloxone products approved for OTC use, or if the approval of OTC naloxone products will affect these plans' coverage of formulations that remain available only with a prescription.
- **Medicaid:** State Medicaid programs vary as to whether they cover OTC medications and the extent of any coverage. **Importantly, even when a state opts to provide Medicaid coverage for an OTC medication, federal funding is available only when an individual has a prescription for that medication.**⁹

Recommendation – Medicaid Coverage: States can act now to ensure that their state Medicaid programs continue to cover both OTC and prescription-only formulations of naloxone. Depending on the state, this may require legislation, regulatory changes, sub-regulatory actions, and/or amendments to the state Medicaid plan.¹⁰

- **Medicare:** Traditional Medicare does not cover OTC medications, although some Medicare Advantage and supplemental plans do offer such coverage. Authorizing Medicare coverage of OTC naloxone products would require federal action.

8. Are there any training requirements for OTC naloxone?

There are no federal training requirements for OTC naloxone. FDA's approval of OTC Narcan and RiVive means the agency determined that people could understand how to properly use the medications simply by reading the [package labels](#). Some state naloxone access laws and/or naloxone standing orders impose training requirements. Whether and how these training requirements apply to OTC naloxone will vary by state.

Recommendation – Training Requirements: States should assess and, where necessary, modify or remove training requirements to ensure they do not impede widespread naloxone access.¹¹

9. Do I face any potential liability for distributing OTC naloxone? Do liability protections in existing state naloxone access laws apply to OTC naloxone?

As with the distribution of prescription-only naloxone,¹² the distribution of FDA-approved OTC naloxone products will not create any significant liability risk. Moreover, state naloxone access laws often provide additional protections from civil, criminal, and professional liability related to the distribution and administration of naloxone.¹³ Whether and how these additional liability protections apply to OTC naloxone depends on the specific language of a state's naloxone access law.

Recommendation – Liability Protections: Although liability risks are low even in states where the naloxone access law does not clearly apply to OTC naloxone, these states can address any concerns by amending the law to extend liability protections to the distribution and administration of OTC naloxone.¹⁴

10. I've heard that current prescription-only Narcan products will be considered "misbranded" after the approval of OTC Narcan. What does this mean?

Under the federal Food, Drug, and Cosmetic Act (FDCA), a prescription drug product is considered "misbranded" if its label does not include the "Rx only" symbol.¹⁵ Conversely, non-prescription drugs (i.e., over-the-counter medications) are considered misbranded if their label includes the "Rx only" symbol.¹⁶ This has raised concerns that Narcan products currently on the market – all of which bear the "Rx only" symbol – will be considered misbranded given FDA's approval of OTC Narcan.

Although the intricacies of misbranding are beyond the scope of this brief, it is important to note that FDA [stated](#) it "will work with all stakeholders to help facilitate the continued availability of naloxone nasal spray products during the time needed to implement the Narcan switch from prescription to OTC status, which may take months." **Stakeholders can likely continue to distribute Narcan products bearing the "Rx only" symbol in the same way they did prior to FDA's approval of OTC Narcan (e.g., pursuant to a state naloxone access law or standing order) until FDA or Emergent BioSolutions provide contrary guidance.**

Additional Resources

FDA Approves First Over-the-Counter Naloxone Nasal Spray

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray>

FDA Approves Second Over-the-Counter Naloxone Nasal Spray Product

<https://www.fda.gov/news-events/press-announcements/fda-approves-second-over-counter-naloxone-nasal-spray-product>

Remedy Alliance / For The People

<https://remedyallianceftp.org>

Harm Reduction Legal Project

<https://www.networkforphl.org/resources/topics/projects/harm-reduction-legal-project>

Naloxone Insurance Coverage Mandates (Harm Reduction Legal Project)

<https://www.networkforphl.org/resources/naloxone-insurance-coverage-mandates/>

Naloxone is Now Available Over-the-Counter. Will it Still be Affordable? (National Health Law Program)

<https://healthlaw.org/naloxone-is-now-available-over-the-counter-will-it-still-be-affordable/>

Disclaimer: The legal information in this document does not constitute legal advice or legal representation. For legal advice, individuals should consult with an attorney licensed to practice in their state.

Last updated August 3, 2023.

Endnotes

- 1 The generic 4mg naloxone nasal spray manufactured by Padagis is based on Emergent BioSolutions brand name Narcan 4mg nasal spray.
- 2 Unlike Narcan nasal spray, which had been on the market since 2015 and merely switched from a prescription-only to an OTC product, RiVive is an entirely new product that sought OTC status as part of its initial approval.
- 3 FDA [previously announced](#) its preliminary assessment that naloxone autoinjector products containing up to 2mg are suitable for over-the-counter use. However, it is unknown whether any manufacturers are actively seeking OTC approval for any such products.
- 4 Harm Reduction Therapeutics [stated](#) “that RiVive will be available in early 2024 primarily to U.S. harm reduction organizations and state governments” (emphasis added).
- 5 Connecticut, for example, requires retailers to obtain a [“Non-Legend Drug Permit”](#) from the state Department of Consumer Protection.
- 6 Harm Reduction Therapeutics has, however, [committed](#) to making at least 200,000 doses available for free. See also [“Partnership to Save Lives: Harm Reduction Therapeutics to donate 200,000 RiVive™ naloxone doses to Remedy Alliance for free distribution.”](#)
- 7 The Regan-Udall Foundation’s March 2023 Naloxone Economic View Summary Report includes a detailed discussion of considerations related to insurance coverage for OTC naloxone. The report is available at <https://reaganudall.org/sites/default/files/2023-03/Naloxone%20Report%20FINAL%203.8.23.pdf>.
- 8 It is unclear whether these plans will be required to cover OTC naloxone when an individual does not have a patient-specific prescription or standing order, and whether insurers may restrict coverage under these plans to formulations that remain available by prescription only (e.g., intramuscular naloxone). Specific coverage requirements may also vary depending on a state’s Essential Health Benefits benchmark plan. For more information about Medicaid and private insurance coverage following approval of OTC naloxone, read the National Health Law Program’s blog post, [“Naloxone is Now Available Over-the-Counter. Will it Still be Affordable?”](#)
- 9 States can maintain standing orders for naloxone – even for formulations available over the counter – to provide the prescription necessary to allow for Medicaid coverage using federal funding.
- 10 See the National Health Law Program’s blog post [“Naloxone is Now Available Over-the-Counter. Will it Still be Affordable?”](#) for additional information.
- 11 The Legislative Analysis and Public Policy Association’s (LAPPA) [“Naloxone: Summary of State Laws”](#) resource includes information on state naloxone training and education requirements. However, not all existing training requirements will apply to OTC naloxone. A state-by-state analysis is required to determine if and how training requirement(s) may apply to OTC naloxone.
- 12 See, e.g., Davis CS, Burris S, Beletsky L, Binswanger I. Co-prescribing naloxone does not increase liability risk. *Subst Abus.* 2016 Oct-Dec;37(4):498-500. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5567808/>.
- 13 See Naloxone Overdose Prevention Laws, <https://pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139>.
- 14 See, e.g., 2023 N.C. House Bill 190, § 13.1 (amending North Carolina’s naloxone access law, N.C. Gen. Stat. § 90-12.7, to extend liability protections to include administration of an opioid antagonist obtained over the counter).
- 15 21 USC § 353(b)(4)(A).
- 16 21 USC § 353(b)(4)(B). See also 87 Fed. Reg. 68711 (“Absent a clinically meaningful difference between the products, simultaneous marketing of two drug products with the same active ingredient as, respectively, a prescription and a nonprescription drug product would result in one of the two products being misbranded.”)