



DATE: April 11, 2023

TO: All Medicare Advantage Organizations; Prescription Drug Plan Sponsors;
Medicare-Medicaid Plans

SUBJECT: Supplemental Benefit Coverage of Over-the-Counter Naloxone

This memorandum serves to remind Medicare Advantage (MA) organizations of CMS’s longstanding policy regarding Over-the-Counter (OTC) drug coverage as a supplemental benefit. CMS shares this reminder to complement a recent announcement from the Food and Drug Administration (FDA) regarding the approval of an OTC naloxone product, NARCAN®.

Naloxone is a medicine that can help reduce opioid overdose deaths and, when administered timely (usually within minutes of the first signs of an opioid overdose), can counter overdose effects. On March 29, 2023, the Food and Drug Administration (FDA) announced the approval of NARCAN® (naloxone HCl), a 4 mg nasal spray, for nonprescription, OTC use.¹ To date, this is the only OTC naloxone product that the FDA has approved.

MA plans, as well as Medicare-Medicaid Plans (MMPs), must cover the benefits covered under Medicare Part A and Part B (“Traditional Medicare”), excluding hospice benefits and acquisition of kidneys for transplant, and may choose to cover additional, supplemental benefits that are not covered under Part A, B or D. If a plan chooses to cover such supplemental benefits, the requirements for supplemental benefits in 42 CFR § 422.100(c)(2) must be met. Through these supplemental benefits, plans can cover drugs that do not meet the definition of Part D drug, including OTC drugs, unless such OTC drugs are provided under a Part D OTC program.² If the OTC item is provided through a Part D OTC program available to the enrollee, the requirement that the item not be covered under Medicare Part A, B or D at § 422.100(c)(2)(ii)(C) is not met.

Within Traditional Medicare, Medicare Part B covers naloxone if provided by an Opioid Treatment Program (OTP) along with other opioid use disorder treatment services, and if all applicable requirements are met. MA plans must also cover the Part B OTP benefit. In addition, all Medicare Part D plans must cover prescription naloxone, including MA plans with Part D prescription drug coverage (MA-PD). If an MA-PD plan does not pay for NARCAN® under an optional Part D OTC program and the NARCAN® is furnished under circumstances when it would not be covered by the Part B benefit as part of an OTP, it may be covered through a Part C supplemental benefit for OTC items.

¹ <https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray>

² See the definition of Part D drug at 42 CFR § 423.100.

MA plans may choose to cover OTC naloxone as a supplemental benefit so long as two additional conditions are met. First, the benefit offering must be reflected as a supplemental in the MA plan's bid for the applicable contract year. Second, if the plan describes its Part C OTC benefit in its bid using general categories rather than by listing specific items, such categories must reasonably include OTC naloxone. Plans may indicate their decision to cover OTC NARCAN® in their Part C OTC benefit for contract year 2024 and beyond by noting this in their Plan Benefit Package submission. CMS encourages, but does not require, plans to consider adding OTC naloxone to their benefit coverage for contract year 2024.

CMS also notes that the NARCAN® 4mg nasal spray is the only dosage form and strength of naloxone which is currently FDA-approved for OTC usage. We note that this guidance would also be applicable should the FDA approve additional OTC naloxone products in the future. Other naloxone products will still require a prescription and, as such, may not be covered as an OTC benefit.

If you have any questions about this memorandum, please submit an inquiry at <https://dpap.lmi.org>.