

From: DMHC Licensing eFiling

Subject: APL 24-004 – Coverage of Over-the Counter FDA Approved Contraceptives

Date: Thursday, February 22, 2024 9:19AM

Attachments: APL 24-004 – Coverage of Over-the Counter FDA Approved Contraceptives (2.22.24)

Dear Health Plan Representative,

The Department of Managed Health Care (DMHC) hereby issues this All Plan Letter (APL) 24-004 to remind health plans, effective January 1, 2024, the rules changed regarding health plan coverage of over-the-counter (OTC) contraceptive drugs, devices, and products approved by the federal Food and Drug Administration (FDA).

Thank you.



Gavin Newsom, Governor
State of California
Health and Human Services Agency
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www.HealthHelp.ca.gov

ALL PLAN LETTER

DATE: February 22, 2024

TO: All Full-Service Commercial Health Care Service Plans¹

FROM: Sarah Ream
Chief Counsel, DMHC

SUBJECT: APL 24-004 – Coverage of Over-the Counter FDA approved contraceptives

As a reminder, on January 1, 2024, the rules changed regarding health plan coverage of over-the-counter (OTC) contraceptive drugs, devices, and products approved by the federal Food and Drug Administration (FDA). Specifically, per Health and Safety Code section 1367.25 (b)(1), the following requirements now apply to any health plan contract issued, amended, renewed, or delivered on or after January 1, 2024:

1. The plan may not condition coverage of an FDA-approved OTC contraceptive drug, device, or product on the enrollee first getting a prescription for the contraceptive.
2. Enrollees must be able to obtain point-of-sale coverage of FDA-approved OTC contraceptive drugs, devices, and products from in-network pharmacies without cost sharing or medical management.

On July 13, 2023, the FDA approved Opill™ (0.075 Oral Norgestrel Tablet) as the first OTC oral birth control pill. Opill™ is not yet available to consumers, but likely will become available in early 2024. Health plans must cover OTC oral birth control pills (i.e. Opill™) without a prescription and with no medical management or cost-sharing when an enrollee obtains Opill from an in-network pharmacy. Per Health and Safety Code section 1367.25(d)(1), a plan may limit an enrollee's coverage of Opill (or any other FDA-approved hormonal contraceptives) to a 12-month supply "when dispensed or furnished at one time for the enrollee by a provider or pharmacist, or at a location

¹ This All Plan Letter does not apply to Medicare Advantage products or to specialized plans. Additionally, this All Plan Letter does not apply to Medi-Cal managed care plans that contract with the Department of Health Care Services (DHCS). A Medi-Cal managed care plan with questions regarding coverage of OTC contraceptives should contact DHCS for further information.

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licensed or otherwise authorized to dispense drugs or supplies.” Plans can also impose reasonable operational quantity limits (e.g., allowing a refill only when some percentage of the medication would likely have been used by the enrollee.)

The FDA has approved the following types of contraceptives to be available over-the-counter.² Health plans must cover at least one therapeutic equivalent of each contraceptive option without cost-sharing or medical management when an enrollee obtains them from an in-network pharmacy:

- emergency contraceptives (e.g., Levonorgestrel, sold under the brand names Plan B One-Step and Julie, or its generic equivalent)
- contraceptive sponges
- spermicide
- male condoms
- female condoms
- oral birth control pills (e.g. Norgestrel, sold under the brand name OPill, or its generic equivalent)

If you have questions regarding this APL, please contact your health plan’s assigned reviewer in the DMHC’s Office of Plan Licensing.

² This list may expand in the future if the FDA approves additional contraceptives.