


ISSUE DATE April 10, 2024	EFFECTIVE DATE April 10, 2024	NUMBER 01-24-04, 08-24-05, 09-24-04, 10-24-05, 24-24-03, 31-24-05, 33-24-04
SUBJECT Over-the-Counter Oral Contraceptives	BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs	

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISE-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to advise providers that the Department of Human Services (Department) provides coverage and payment for over-the-counter (OTC) oral contraceptives.

SCOPE:

This bulletin applies to physicians, physician assistants, certified registered nurse practitioners, certified nurse midwives, outpatient hospital-based medical clinics, independent medical/surgical clinics, family planning clinics, federally qualified health centers, rural health clinics and pharmacies enrolled in the Medical Assistance (MA) Program who render services to MA beneficiaries in the Fee-for-Service (FFS) and managed care delivery systems.

BACKGROUND/DISCUSSION:

The MA Program covers outpatient drugs when they meet the definition in federal law of a covered outpatient drug, which includes that the drug be approved by the U.S. Food and Drug Administration (FDA) and that the drug manufacturer has entered into a rebate agreement with the Secretary of the federal Department of Health and Human Services.

On July 13, 2023, the FDA approved Opill, the first OTC oral contraceptive. Opill has a marketing start date of March 4, 2024. Opill and other OTC oral contraceptives that meet the

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service provider service center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:

<https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>

federal Medicaid coverage requirements will be covered in the MA Program. OTC drugs, as with all drugs covered by the MA Program, must be prescribed. 42 U.S.C. § 1396r-8(k); 42 CFR 447.502. The Department will add OTC oral contraceptives to the Statewide Preferred Drug List (PDL) and provide coverage when prescribed by a MA enrolled licensed practitioner.

PROCEDURE:

The MA Program will cover FDA approved OTC oral contraceptives that meet the conditions for Medicaid coverage and are prescribed by a MA enrolled licensed practitioner. The guidelines for determining medical necessity of oral contraceptives apply to OTC oral contraceptives. The current guidelines can be found in MA Bulletin 01-22-24, entitled "Prior Authorization of Contraceptives, Oral – Pharmacy Services," available on the Department's website at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Documents/Clinical%20Guidelines%20SW%20PDL/Contraceptives,%20Oral%202020901.pdf>. Any revised requirements for prior authorization and corresponding guidelines to determine the medical necessity of drugs will be issued in separate MA Bulletins. The managed care organizations use the same prior authorization guidelines for drugs and products included in the Statewide PDL as are used in the FFS delivery system. Providers should refer to the Statewide PDL for the list of preferred and non-preferred statuses of OTC oral contraceptives. The Statewide PDL is available on the Department's website at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/default.aspx>.

NOTE: Provider type 10, specialty 100 (physician assistant) is included because physician assistants can be listed as the rendering provider pursuant to MA Bulletin 01-22-05, 08-22-05, 09-22-04, 10-22-01, 31-22-05, entitled "Billing Procedure Update for Certified Registered Nurse Practitioners and Physician Assistants," available on the Department's website at: <https://www.dhs.pa.gov/docs/Publications/Documents/FORMS%20AND%20PUBS%20OMAP/MAB2022010701.pdf>.