

Preventive Care for Purposes of Qualifying as a High Deductible Health Plan under Section 223

Notice 2024-75

I. PURPOSE

This notice expands the list of preventive care benefits permitted to be provided by a high deductible health plan (HDHP) under section 223(c)(2)(C) of the Internal Revenue Code (Code) without a deductible, or with a deductible below the applicable minimum deductible for the HDHP, to include over-the-counter (OTC) oral contraceptives (including emergency contraceptives) and male condoms.¹ This notice also clarifies that (1) all types of breast cancer screening for individuals who have not been diagnosed with breast cancer are treated as preventive care under section 223(c)(2)(C), (2) continuous glucose monitors for individuals diagnosed with diabetes are generally treated as preventive care under section 223(c)(2)(C), and (3) the new safe harbor for absence of a deductible for certain insulin products in section 223(c)(2)(G) applies without regard to whether the insulin product is prescribed to treat an individual diagnosed with diabetes or prescribed for the purpose of preventing the exacerbation of diabetes or the development of a secondary condition.

II. BACKGROUND

A. Preventive Care

Section 223 of the Code permits eligible individuals to establish tax-favored Health Savings Accounts (HSAs). Among the requirements to qualify as an eligible

¹ For purposes of this notice, a “male condom” refers to an external condom and a “female condom” refers to an internal condom.

individual under section 223(c)(1) is that the individual be covered under an HDHP and have no disqualifying health coverage. As defined in section 223(c)(2), an HDHP is a health plan that satisfies certain requirements, including requirements with respect to minimum deductibles and maximum out-of-pocket expenses.

Generally, under section 223(c)(2)(A), an HDHP is not permitted to provide benefits for any year until the minimum deductible for that year is satisfied. However, section 223(c)(2)(C) provides a safe harbor for the absence of a deductible for preventive care. Under section 223(c)(2)(C), “[a] plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care (within the meaning of section 1861 of the Social Security Act, except as otherwise provided by the Secretary).” Therefore, an HDHP may provide preventive care benefits without a deductible, or with a deductible below the minimum annual deductible otherwise required by section 223(c)(2)(A). To be a preventive care benefit as defined for purposes of section 223, the benefit must either be described as preventive care for purposes of section 1861 of the Social Security Act (SSA) or be determined to be preventive care in guidance issued by the Department of the Treasury (Treasury Department) and the Internal Revenue Service (IRS).²

Section 2713 of the Public Health Service Act³ (PHS Act) requires non-grandfathered group health plans and health insurance issuers offering non-

² The determination of whether an item or service is preventive care for these purposes is separate and distinct from the determination of whether an amount paid for an item or service is medical care under section 213(d) of the Code as an amount paid for the prevention of disease. See Rev. Rul. 79-66, 1979-1 C.B. 114; *Daniels v. Commissioner*, 41 T.C. 324 (1963); and *Stringham v. Commissioner*, 12 T.C. 580 (1949) *acq.*, 1950-2 C.B. 4, *aff'd per curiam*, 183 F.2d 579 (6th Cir. 1950).

³ See 42 U.S.C. chapter 6A.

grandfathered group or individual health insurance coverage⁴ to provide benefits for certain preventive services without imposing cost-sharing requirements. Notice 2013-57, 2013-40 IRB 293, provides that any item or service that is a preventive service under section 2713 of the PHS Act will also be treated as preventive care under section 223(c)(2)(C) of the Code. With respect to women,⁵ preventive services under section 2713 of the PHS Act include those provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA-Supported Guidelines).

Notice 2004-23, 2004-15 IRB 725, provides that preventive care under section 223(c)(2)(C) includes, among other types of care, “Breast Cancer (e.g., Mammogram)” screening services.

Notice 2018-12, 2018-12 IRB 441, states that, absent further guidance to the contrary, benefits for male sterilization or male contraceptives would not be considered preventive care. The notice bases its reasoning on the fact that, at the time of publication of the notice: (1) male sterilization and male contraceptives were not preventive care under the SSA; (2) HRSA-Supported Guidelines did not provide for coverage of benefits or services relating to a man’s reproductive capacity, such as vasectomies and condoms; and (3) no applicable guidance issued by the Treasury

⁴ The Department of Health and Human Services, the Department of Labor, and the Treasury Department (collectively, the Departments) share interpretive jurisdiction over section 1251 of the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010) (ACA), as amended, which generally provides that certain group health plans and health insurance coverage existing as of March 23, 2010, the date of enactment of ACA (referred to collectively in the statute as grandfathered health plans), are subject to only certain provisions of ACA.

⁵ The references to “women” in this notice are not limited based on sex assigned at birth, gender identity, or gender of the individual otherwise recorded by the plan or issuer in accordance with FAQs about Affordable Care Act implementation Part XXVI (May 11, 2015), Q5, available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

Department or the IRS provided for the treatment of male sterilization or male contraceptives as preventive care within the meaning of section 223(c)(2)(C).

B. Oral Contraceptives

The HRSA-Supported Guidelines include the full range of U.S. Food and Drug Administration (FDA)-approved, -granted, or -cleared contraceptives, including those currently listed in the FDA's Birth Control Guide, such as "oral contraceptives (progestin only)" and "emergency contraception (levonorgestrel)."⁶ An OTC progestin-only daily oral contraceptive was recently approved by the Food and Drug Administration (FDA) and is currently available.⁷ Some emergency contraceptives also are available as OTC products (e.g., levonorgestrel). Additional recommended preventive products may also become available as OTC products in the future. The HRSA-Supported Guidelines relating to contraceptives have been updated and no longer contain the "as prescribed" restriction they once did.

C. Male Condoms

Notice 2024-71, 2024-44 IRB 1026, provides a safe harbor, under which the Treasury Department and the IRS will treat amounts paid for condoms as amounts paid for medical care under section 213(d). While the HRSA-Supported Guidelines previously included only female condoms, the HRSA-Supported Guidelines were expanded in 2021 after Notice 2018-12 was published to encompass contraceptives

⁶ <https://www.hrsa.gov/womens-guidelines>.

⁷ On July 13, 2023, the FDA announced that it had approved a progestin-only birth control pill as the first daily oral contraceptive for use in the United States available without a prescription by a health care provider. See FDA Approves First Nonprescription Daily Oral Contraceptive, July 13, 2023, <https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive>. Progestin-only oral contraceptives are a product that is already available in a prescription form and are a category of contraceptives listed in the HRSA-Supported Guidelines.

that are not female-controlled, such as male condoms.⁸ However, the expanded HRSA-Supported Guidelines made no changes to the recommendations regarding male sterilization and continue not to include male sterilization.

D. Breast Cancer Screening

Notice 2004-23 provides that breast cancer screening is treated as preventive care under section 223(c)(2)(C) but provides a “mammogram” as the only listed example of such screenings. Breast cancer screening recommended with an “A” or “B” rating by the United States Preventive Services Task Force (USPSTF), which must be covered without cost-sharing for certain individuals under section 2713 of the PHS Act, generally is limited to mammography.⁹

E. Continuous Glucose Monitors and Insulin

Notice 2019-45 provides that specified services and items, including glucometers and insulin, are treated as preventive care under section 223(c)(2)(C). However, the notice also provides that specified services and items are treated as preventive care only when prescribed to treat an individual diagnosed with the specified associated chronic condition (diabetes in the case of glucometers and insulin), and only when

⁸ HRSA made this change to allow women to purchase male condoms for pregnancy prevention. See 86 FR 59741, 59742 (Oct. 28, 2021).

⁹ <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening-and> <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening-2002> (in effect until January 1, 2026). FAQs about Affordable Care Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 59 (July 28, 2022), Q7, available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-59> and <https://www.cms.gov/files/document/faqs-part-59.pdf>, provides that items and services recommended with an “A” or “B” rating by the USPSTF on or after March 23, 2010, will be treated as preventive care for purposes of Code section 223(c)(2)(C), regardless of whether these items and services must be covered, without cost sharing, under PHS Act section 2713. The HRSA-Supported Guidelines likewise mention only “mammography screening.”

prescribed for the purpose of preventing the exacerbation of the chronic condition or the development of a secondary condition.

While Notice 2019-45 provides that glucometers are treated as preventive care, it does not directly refer to continuous glucose monitors, which similarly measure glucose levels.

Section 11408 of the Inflation Reduction Act of 2022¹⁰ amended section 223 of the Code with respect to insulin products effective for plan years beginning after December 31, 2022, by adding a new section 223(c)(2)(G) to provide that a plan shall not fail to be treated as an HDHP by reason of failing to have a deductible for selected insulin products described in that section.

III. QUESTIONS AND ANSWERS

A. Oral Contraceptives

Q-1. Will a health plan fail to qualify as an HDHP under section 223(c)(2) of the Code merely because it provides benefits for OTC oral or emergency contraceptives without a prescription before an individual satisfies the minimum annual deductible for an HDHP under section 223(c)(2)(A)?

A-1. No. Regardless of whether OTC contraceptives without a prescription are preventive care required to be covered without cost sharing under section 2713 of the PHS Act, the Treasury Department and the IRS have determined that it is not appropriate to distinguish OTC oral contraceptives that are now available from other types of contraceptives that are considered to be preventive care for purposes of the safe harbor for the absence of a preventive care deductible under section 223(c)(2)(C).

¹⁰ Pub. L. 117-169, § 11408, 136 Stat. 1818, 1905 (Aug. 16, 2022).

Consequently, preventive care for purposes of section 223(c)(2)(C) includes all benefits for OTC oral contraceptives for a covered individual potentially capable of becoming pregnant, including, but not limited to, OTC birth control pills and emergency contraception, regardless of whether they are purchased with a prescription. Accordingly, a health plan will not fail to qualify as an HDHP under section 223(c)(2) merely because it provides benefits for those contraceptives before such an individual satisfies the minimum annual deductible for an HDHP under section 223(c)(2)(A). This guidance is effective for plan years (in the individual market, policy years) that begin on or after December 30, 2022.

B. Male Condoms

Q-2. Will a health plan fail to qualify as an HDHP under section 223(c)(2) of the Code merely because it provides benefits for male condoms (with or without a prescription) before an individual satisfies the minimum annual deductible for an HDHP under section 223(c)(2)(A)?

A-2. No. Notice 2024-71, as well as the expansion of the HRSA-Supported Guidelines to encompass male condoms as described above in paragraph II.C. of the Background section of this notice, has caused the Treasury Department and the IRS to revisit the position on male contraceptives as set forth in Notice 2018-12.

Upon reconsideration, the Treasury Department and the IRS have determined that preventive care for purposes of section 223(c)(2)(C) includes all benefits for male condoms, regardless of whether they are purchased with a prescription and regardless of the gender of the individual covered under the HDHP who purchases them. Accordingly, a health plan will not fail to qualify as an HDHP under section 223(c)(2)

merely because it provides benefits for male condoms (with or without a prescription) before an individual satisfies the minimum deductible for an HDHP under section 223(c)(2)(A).¹¹ This guidance is effective for plan years (in the individual market, policy years) that begin on or after December 30, 2022.

C. Breast Cancer Screening

Q-3. Will a health plan fail to qualify as an HDHP under section 223(c)(2) of the Code merely because it provides benefits for breast cancer screening other than mammograms before an individual satisfies the minimum annual deductible for an HDHP under section 223(c)(2)(A)?

A-3. No. The Treasury Department and the IRS have determined that, because breast cancer screening may include imaging other than mammograms,¹² the reference in Notice 2004-23 to breast cancer screening should be changed to “Breast Cancer (e.g., Mammograms, Magnetic Resonance Imaging (MRIs), Ultrasounds, and similar breast cancer screening services).” This language change is effective as of the date of publication of Notice 2004-23 (April 12, 2004).

D. Continuous Glucose Monitors and Insulin

Q-4. Will a health plan fail to qualify as an HDHP under section 223(c)(2) of the Code merely because it provides benefits for continuous glucose monitors before an

¹¹ While this guidance applies to male condoms, it does not apply to any other male contraceptives, such as male sterilization.

¹² According to the American Cancer Society, individuals who are at high risk for breast cancer based on certain factors should get a breast MRI in addition to a mammogram. See <https://www.cancer.org/cancer/types/breast-cancer/screening-tests-and-early-detection/american-cancer-society-recommendations-for-the-early-detection-of-breast-cancer.html>. Also, ultrasound can be helpful in individuals with dense breast tissue, which can make it hard to see abnormal areas on mammograms. See <https://www.cancer.org/cancer/types/breast-cancer/screening-tests-and-early-detection/breast-ultrasound.html>.

individual satisfies the minimum annual deductible for an HDHP under section 223(c)(2)(A)?

A-4. Generally, no. This notice clarifies that in accordance with Notice 2019-45 continuous glucose monitors are preventive care for purposes of section 223(c)(2)(C) in the same circumstances as other glucometers if the continuous glucose monitor is measuring glucose levels using a similar detection method or mechanism to other glucometers (*i.e.*, piercing the skin).¹³

Consequently, this notice clarifies that preventive care for purposes of section 223(c)(2)(C) includes all benefits for continuous glucose monitors subject to the conditions in the preceding paragraph. Accordingly, a health plan will not fail to qualify as an HDHP under section 223(c)(2) merely because it provides such benefits before an individual satisfies the minimum annual deductible for an HDHP under section 223(c)(2)(A). This guidance is effective as of the effective date of Notice 2019-45 (July 17, 2019).

Some continuous glucose monitors may have additional medical functions, such as insulin delivery, or non-medical functions. If so, those functions also would need to be preventive care in order for an HDHP to cover any benefits for the continuous glucose monitor before an individual satisfies the minimum annual deductible for an HDHP under section 223(c)(2)(A). A continuous glucose monitor that both monitors and

¹³ The FDA has warned consumers, patients, caregivers, and health care providers of risks related to using smartwatches or smart rings that claim to measure blood glucose levels without piercing the skin. These devices are different than smartwatch applications that display data from FDA-authorized blood glucose measuring devices that pierce the skin, like continuous glucose monitoring devices. The FDA has not authorized, cleared, or approved any smartwatch or smart ring that is intended to measure or estimate blood glucose values on its own. See <https://www.fda.gov/medical-devices/safety-communications/do-not-use-smartwatches-or-smart-rings-measure-blood-glucose-levels-fda-safety-communication>.

provides insulin may be treated as preventive care as explained in Q&A-5 of this notice because it is a device for delivering insulin. If a continuous glucose monitor provides additional medical or non-medical functions that are not preventive care (other than minor functions, such as clock and date functions), however, then the HDHP may not cover the continuous glucose monitor before an individual satisfies the minimum annual deductible for an HDHP.

Q-5. May an HDHP provide benefits for the selected insulin products described in section 223(c)(2)(G) of the Code, as added by section 11408 of the Inflation Reduction Act of 2022, prior to satisfying the minimum annual deductible for an HDHP under section 223(c)(2)(A), effective for plan years after December 31, 2022?

A-5. Yes. This notice clarifies that an HDHP may provide benefits for the selected insulin products described in section 223(c)(2)(G) before an individual satisfies the minimum annual deductible for an HDHP under section 223(c)(2)(A) without regard to whether the insulin product is prescribed to treat an individual diagnosed with diabetes or prescribed for the purpose of preventing the exacerbation of diabetes or the development of a secondary condition. The Treasury Department and the IRS interpret section 223(c)(2)(G) to include any devices used to administer or deliver the selected insulin products described in that section. This guidance is effective for plan years (in the individual market, policy years) beginning after December 31, 2022.

IV. EFFECT ON OTHER DOCUMENTS

Notice 2004-23 is clarified by noting the safe harbor for absence of a deductible for breast cancer screening.

Notice 2018-12 is superseded with respect to the guidance regarding male condoms.

Notice 2019-45 is clarified and expanded by noting the safe harbor for absence of a deductible for continuous glucose monitors and for certain insulin products pursuant to the Inflation Reduction Act of 2022.

V. DRAFTING INFORMATION

The principal authors of this notice are Jennifer Friedman and William Fischer of the Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes), though other Treasury Department and IRS officials participated in its development. For further information on the provisions of this notice, contact William Fischer at (202) 317-5500 (not a toll-free number).