



Safe Harbor Preventative Drugs for High Deductible Health Plans White Paper

Safe Harbor: Preventative Drugs for High Deductible Health Plans

Summary of 2Q21 Safe Harbor No Deductible Table Additions (effective 7/1/2021)			
Therapeutic Category	Drug Class	Drug	Rationale
Cardiovascular disease	HMG CoA-reductase inhibitor & a cholesterol absorption inhibitor	Roszet	Both components of Roszet are already included in Safe Harbor table.

Background

The Safe Harbor Preventive Drug List is an optional and highly customizable offering that high-deductible health plans (HDHP) may provide for members to access preventative care medications at plan-specified tiered copays prior to the member fulfilling to the deductible.

A typical key feature of a HDHP is a higher annual deductible compared to traditional health plans. While a high deductible is designed for members to assume greater financial responsibility for non-catastrophic healthcare expenses, it can also incentivize patients to forgo preventive care including delaying or skipping physician-recommended tests or treatments and medications. However, neglecting preventive care would be counterproductive, as it is crucial for controlling chronic conditions and avoiding costly hospitalizations and/or treatments.

A HDHP, often used in conjunction with a Health Savings Account (HSA), is regulated by the Internal Revenue Service (IRS), a Department of Treasury bureau, due its tax-sheltering benefits. Generally, a HDHP may not provide benefits until the deductible has been satisfied for that year; however, an exemption (i.e., “safe harbor”) from meeting the deductible is permitted for preventive care benefits.

The IRS released Notice 2004-23 to allow this exemption and this notice functioned to provide general guidance on the definitions of primary and secondary prevention, though it did not provide discrete direction on which specific preventative medications should or could be included in the benefit. The IRS Notice 2019-45 expanded the existing preventative care benefits that could be provided under the Safe Harbor and classified certain chronic conditions as preventative care due to the strong likelihood that the service would prevent an exacerbation of the chronic condition. This 2019 guidance also provided some clarity as to which medications may be considered as eligible for this benefit, but it did not supersede or replace older existing IRS guidance. While the IRS has provided guidance statements and select examples, there remains no clear and comprehensive definition of “preventive care.”

The MedImpact Safe Harbor Table incorporates medications from eleven therapeutic areas noted in the table below.

Standard Therapeutic Categories of MedImpact Safe Harbor Program

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Anaphylaxis Therapy	Hypertension
Anticoagulation/Antiplatelet	Diabetes
Asthma/COPD	Human immunodeficiency virus prophylaxis
Cancer Prevention	Osteoporosis
Cardiovascular Disease (includes hypertension and hyperlipidemia)	Vitamins (pediatric and prenatal)
Selective Serotonin Reuptake Inhibitors	Blood Glucose Meters

These therapeutic categories were selected based on the following factors:

- An established role of medication therapy in the primary or secondary prevention of morbidity and mortality (e.g., prevention of cancer, HIV, deep vein thrombosis/pulmonary embolism, stroke, myocardial infarction, reduction of the risk for anaphylaxis)
- A condition listed on the National Center for Health Statistics Leading Causes of Death (e.g., heart disease, chronic lower respiratory disease, diabetes)
- Listed in the appendix of IRS Notice 2019-45
- Therapeutic categories are further subdivided into pharmacological drug classes. These drug classes were selected on recommendations from major treatment guidelines and FDA approved indications.

Disclaimers

This list includes medications identified as those most likely to qualify as “preventive” based on IRS guidance and may not include all medications considered preventive nor every health condition for which a preventive drug may be prescribed. At this time, neither MedImpact nor the health plan can guarantee which medications will satisfy U.S. Treasury Department definition for preventative safe harbor medications.

Furthermore:

- Utilization management strategies such as prior authorization, step therapy, and quantity limits may still apply to listed medications based on the plan’s benefit design
- Use of generics may be required depending on plan design
- Some strengths/dosage forms and certain products/therapeutic categories may not be included
- This list is subject to change without prior notice
- Regardless of their appearance in this document, patients should contact member services at the number on the prescription benefits card should they have any questions regarding coverage

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