



Via U.S. Mail and Electronic Mail

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Re: Health Savings Accounts – Exception for Preventive Prescription Drugs

Dear Tom and Kevin:

Thank you for meeting with representatives from Aetna to discuss Health Savings Accounts (HSAs) and, specifically, the Internal Revenue Code section 223(c)(2)(C) exception for prescription drugs that satisfy the preventive care services safe harbor. As a follow up to our meeting with the two of you and Roy Ramthun, we wanted to provide some additional data and information on our interpretation of the preventive care safe harbor and the manner in which Aetna is implementing the published guidance that you have provided thus far. We hope that this information is helpful to you as you consider further regulations or published guidance.

Aetna is providing high deductible health plans (HDHPs) and related HSAs in both the employer group and individual markets. Aetna currently has over 50,000 members covered by HDHPs and HSAs. The guidance that Treasury and IRS have provided on HSAs has been helpful and practical as we work to expand the availability of these plans in the marketplace. One of the issues that we have addressed with clients is how to apply the preventive care safe harbor for HDHPs to ensure that the individuals covered by the HDHPs remain eligible for HSA contributions. As you know, for many employers, the HSA contribution is a significant element of the overall health plan being provided and Aetna's clients need a high level of certainty that any coverage provided to employees before the HDHP deductible has been satisfied meets one of the statutory exceptions under Code section 223, such as the preventive care exception.

This is a particular concern with respect to drugs and medications, which play a significant role in helping members living with certain chronic conditions to reduce the risk of acute illness. Understandably, employers are anxious to assure that the health plans they offer

work appropriately for these individuals, and specifically that the plan design encourages continued compliance with preventive regimens that optimize their health status and reduce the overall costs of care.

In this regard, the guidance in Notice 2004-23 and Notice 2004-50 provides a helpful framework, which we are implementing in designing HDHPs for our clients. As stated in Notice 2004-50 (Q&A 27), drugs or medications may be provided within the preventive care safe harbor and, thus, prior to the satisfaction of the HDHP deductible, where the drugs or medications are (i) taken by a person who has developed risk factors for a disease that has not yet manifested itself (*i.e.*, is asymptomatic) or (ii) to prevent the reoccurrence of a disease from which the person has recovered. Preventive care does not include drugs or medicines for treatment of an existing illness or condition. The two positive examples that are provided in the Notice are statins to prevent heart disease for those who have high cholesterol (hyperlipidemia) and “ACE” inhibitors to prevent an occurrence or reoccurrence of strokes or heart attacks for individuals with hypertension.

Beyond immunization and certain prescription vitamins (discussed below), Aetna is following the principles set forth in Notice 2004-23 and Notice 2004-50 by limiting coverage for prescription drugs below the HDHP deductible to those individuals who have been identified as having certain risk factors associated with one of five chronic conditions: hypertension, hyperlipidemia, diabetes, asthma and osteoporosis. This expands the list of conditions implied in Q&A 27 to add three other conditions for which we believe regular preventive medication serves an analogous role to statins and ACE inhibitors. In each case, individuals living with these conditions, or risk factors for these conditions, can be relatively symptom-free if the condition is managed effectively. Conversely, failure to manage these conditions can result in serious acute illnesses (or injuries, in the case of osteoporosis). Thus while it could be argued that insulin is a “treatment” for diabetes, the primary goal of regular insulin treatment is rather to prevent a diabetic from suffering acute complications of the condition such as heart attack, renal disease or circulatory failure. In our view, this therapy for a diabetic is substantially comparable to use of ACE inhibitors for hypertensives.

The attached chart indicates the specific classes of medications that we believe serve this preventive function for the conditions indicated. With respect to hypertension and hyperlipidemia we have included those medications commonly used as alternatives to ACE inhibitors and statins. For the other conditions we have specified those drugs that in our view serve the corresponding role of maintaining the individual’s health status and to avoid acute complications.

For each of these conditions it is possible that individuals will have periods in which more acute symptoms or associated illnesses are manifested. During these periods it is likely that the indicated drugs will continue to be prescribed as part of the patient’s continuing therapy. For these individuals it is not practical administratively or therapeutically to distinguish potential treatment from on-going prevention. Accordingly, for individuals at risk in one of these five categories the indicated drugs are treated consistently as preventive.

At-risk individuals are identified either by verification of the underlying condition through claims data, pre-certification, or enrollment in a related condition management program. For all alternatives the identification process is the same, based on consideration of a

combination of demographic and clinical information. In some instances preventive therapy begins after an episode of acute illness, e.g., ACE inhibitors prescribed after a heart attack, and in others it is prescribed for entirely asymptomatic individuals, e.g., calcium supplements those at risk for osteoporosis. For this reason it is not appropriate to limit (or disqualify) eligibility based on a particular diagnosis. In some cases individuals are routinely considered "at risk" following a particular health event, such as a heart attack. In others, substantial deference is given to current clinical literature and the view of the prescribing physician. The drugs identified in the attached chart were specifically selected because they are used in substantially all instances for preventive purposes. Indeed we would expect that there would be very few instances in which these drugs would be prescribed for any other purpose, however the identification process would identify outlier applications, e.g., off-label use.

Finally, I would note that the attached chart also identifies certain prescription pediatric and prenatal vitamins (with iron and folic acid), which we also treat as preventive medications. We believe these compounds inherently satisfy the safe harbor for preventive care since they are prescribed only for well baby and pregnancy, both of which are within the standard for preventive care outlined in Notice 2004-23.

In developing this chart our physicians and pharmacists have put a great deal of effort into maintaining consistency with the principle of preventive drugs as articulated in Q&A 27 of Notice 2004-50. This is a very selective list, and again we believe that there will be very few instances in which these drugs are not prescribed for preventive purposes in the manner we understand the guidance.

Again, thank you for meeting with us. We hope that this information is helpful to you. As always, we would be happy to discuss issues related to HSAs with you at your convenience. Should you have any questions about the chart or the information in this letter, please do not hesitate to call me.

Sincerely yours,



Charles H. Klippel
Senior Vice President & Deputy General Counsel

Attachment

c: Roy Ramthun (White House)
Andrew Baskin, M.D. (Aetna)
Jeffrey Taylor R.Ph. (Aetna)
Charlyn Iovino (Aetna)
Catherine L. Creech (Davis & Harman LLP)

Preventive Medication Classes - First Dollar Coverage			
Medical Condition	[Therapeutic Category], {Pharmacologic Drug Class} & (Formulary Drug Type) defined by USP (United States Pharmacopia) NOTE: Only <u>Bolded & Underlined</u> categories/classes/drug types are included. Other Therapeutic Category and Pharmacologic Class information is included for reference only.	Generic Product Indicator (Medispan® Drug Class Number)	Drug Class defined by Medispan®
Associated with hypertension and prevention of various conditions related to hypertension:	[Cardiovascular Agents], <u>{Beta-adrenergic Blocking Agents}</u>	33----	BETA BLOCKERS
	[Cardiovascular Agents], <u>{Calcium Channel Blocking Agents}</u>	34----	CALCIUM CHANNEL BLOCKERS
	[Cardiovascular Agents], <u>{Renin-angiotensin- aldosterone System Inhibitors}</u>	36----	ANTI-HYPERTENSIVES e.g., ACE Inhibitors, Angiotensin Receptor Blockers
	[Cardiovascular Agents], <u>{Diuretics}</u>	37----	DIURETICS
Associated with hyperlipidemia and prevention of heart disease, etc.:	[Cardiovascular Agents], <u>{Dyslipidemics}</u>	39----	ANTI-HYPERLIPIDEMICS e.g., Statins
Associated with diabetes and prevention of various diabetic complications:	<u>{Blood Glucose Regulators}</u>	27----	ANTI-DIABETICS
Associated with asthma and prevention of asthmatic episodes:	[Respiratory Tract Agents], <u>{Antileukotrienes}, {Bronchodilators, Anticholinergic}, {Bronchodilators, Anti-inflammatories}, {Bronchodilators, Phosphodiesterase 2 Inhibitors}</u> .	44----	ANTI-ASTHMATIC AGENTS
Associated with osteoporosis and prevention of conditions stemming from osteoporosis:	[Hormonal Agents, Stimulant/Replacement/Modifying], {Parathyroid/Metabolic Bone Disease Agents}, <u>{Bisphosphonates}, {Calcium Regulating Hormones}, {Vitamin D-related Agents/Metabolic Bone Disease Agents}</u>	30-04----	ANTI-OSTEOPOROSIS MEDICATIONS
Associated with prevention of stroke:	[Blood Products/Modifiers/Volume Expanders], <u>{Anticoagulants}</u>	83----	ANTICOAGULANTS
	[Blood Products/Modifiers/Volume Expanders], <u>{Platelet Aggregation Inhibitors}</u>	85-15----	PLATELET AGGREGATION INHIBITORS
Associated with prevention of a variety of pediatric conditions	[Therapeutic Nutrients/Minerals/Electrolytes], {Electrolytes/Minerals}, <u>{Folate}, {Flouride}</u>	78440500----	PEDIATRIC VITAMINS w/FLOURIDE
Associated with prevention of maternal and fetal problems:	[Therapeutic Nutrients/Minerals/Electrolytes], {Vitamins}, <u>{Prenatal Vitamins}</u>	78512000----	PRENATAL MULTIVITAMIN w/Fe-FA