



CMA WEEKLY ALERT – JULY 21, 2005

## DO YOU SPEAK MEDICARE PART D?

In the next few months the older people and people with disabilities who rely on Medicare, along with their families, friends, and advocates, will be asked to make choices concerning Medicare Part D, the new Medicare prescription drug benefit. Individuals will have to decide whether to enroll in a drug plan and, if they decide to enroll, which drug plan to choose. The initial enrollment period for Part D begins November 15, 2005 and ends May 15, 2006.

Right now, efforts to educate beneficiaries focus on general information about the new drug benefit. The Centers for Medicare & Medicaid Services (CMS) will provide information about the specific drug plan choices that will be available in each region of the country in the *Medicare & You Handbook 2006*, which will be mailed to all Medicare beneficiaries in mid-October. They will also post information about available drug plans on their web site, [www.medicare.gov](http://www.medicare.gov). Drug plan sponsors will begin marketing their drug plans in October as well.

In order to evaluate which drug plan provides the best benefit, beneficiaries and those who assist them must understand the terminology used to describe the benefits under the plan. For example, a beneficiary must check each plan's formulary to see whether it includes her drugs, but what's a formulary? And how is it arranged? What's a category or class of drugs? If the drug is on the formulary, what co-payment tier is the drug on? Will the beneficiary need prior authorization before the plan will pay for the drug? Will she be required to go through step therapy? Does the plan authorize generic substitution? Can she ask for an exception?

The Center for Medicare Advocacy has developed a fact sheet, **Definitions of Selected Health Insurance Terminology Under Medicare Part D**, that answers these and other questions about terms used under Part D. The fact sheet is below. We thank our medical student, Marisa Cevasco, for putting together the definitions.

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## **DEFINITIONS OF SELECTED HEALTH INSURANCE TERMINOLOGY UNDER MEDICARE PART D**

### **Co-insurance**

In medical insurance, the insured person and the insurer share the covered procedures under a policy in a specified ratio. For example, the insurer may pay 80% of a procedure's cost and the insured must pay the remaining 20%.

### **Co-pay**

An arrangement where the insured pays a specified amount for various drugs or services and the health carrier pays the remaining charge. Again, varies depending on health plan or drug formulary and type of service or drug used.

### **Drug Categories, Drug Classes and examples**

In 2004, the United States Pharmacopeia (USP), a non-profit non-governmental organization, received directive from the Medicare Modernization Act to publish guidelines on drug categories and classes. These guidelines are to be used by prescription drug plans (PDPs) in developing their formularies for the Medicare population.

**Categories** are groupings that reflect therapeutic uses of drugs based on the International Classification of Diseases (ICD-9) diagnostic codes. For example, drugs may belong to the analgesic category or the antiparkinson category. Categories may also be based on an organ system, such as the cardiovascular category.

**Classes** are subcomponents of drug categories and are based either on the chemical structure of the drug or on its "mechanism of action," i.e., how it works to achieve its results. For example, the analgesic category, or drugs which treat pain, is broken down into two classes—opioids (such as codeine or morphine) and non-opioids (such as ibuprofen or aspirin).

Certain classes are subdivided into an additional level of specificity. For example, the beta-adrenergic blocking agent class of the cardiovascular category, or drugs used to treat hypertension, is subdivided into alpha-beta-adrenergic blocking agents (such as Normodyne), cardioselective beta-adrenergic blocking agents (such as Brevibloc), and nonselective beta-adrenergic blocking agents (such as Inderal).

The USP defined 41 therapeutic categories, 32 of which are further divided into pharmacologic classes. Overall, the draft model includes 137 classes and 9 categories that have no classes, for a total of 146 unique therapeutic categories and pharmacologic classes. PDPs that adopt the guidelines are required to include at least two drugs from each class in a category. If a category is not broken into classes, the PDP must include at least two drugs from the category. For classes that have additional subdivisions, PDPs are required to cover 1 drug from each such subdivision.

### **Exceptions process**

A course of action that allows patients to challenge the placement of a drug on a higher-cost tier or the exclusion of a particular drug from their formulary. Under the Prescription Drug Benefit, an exceptions process must be incorporated into both stand-alone prescription drug plans (PDP) and those that are part of a Medicare Advantage plan (MA-PD). Enrollees are able to request that a formulary drug be provided at a lower tier for cost-sharing (thereby reducing the patient's co-pay) or that a non-formulary drug be provided by the plan. Because exceptions requests are coverage determinations, the plan must act within the time frame for standard coverage determinations (within 72 hours) or expedited coverage determinations (within 24 hours).

### **Formulary**

List of prescription drugs covered by a particular drug benefit plan. Formularies are based on evaluations of efficacy, safety, and cost-effectiveness of drugs. Patients pay varying co-pays for drugs that are on formulary. For drugs that are not on formulary, patients must pay the entire cost of the drug. Formularies vary between drug plans and differ in the breadth of drugs covered and costs of co-pay and premiums. Most formularies cover at least one drug in each drug class, and encourage generic substitution. Also known as a preferred drug list.

### **Formulation substitution and therapeutic equivalency**

As patients and prescription benefit plans seek to lower their healthcare costs, they may substitute a less expensive therapeutically equivalent drug for a more costly drug. This is known as formulation substitution. Formulation substitution can include switching from a brand-name drug to a generic drug, switching from one generic drug to another generic drug, or (rather uncommonly) switching from a generic drug to a brand-name drug.

In most states, formulation substitution is allowed and encouraged, provided that the replacement formulation is deemed to be "therapeutically equivalent" to the innovator formulation by the Food and Drug Administration (FDA). The FDA publishes a list of drug products and equivalents entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*; this is commonly referred to as the "Orange Book." The FDA's designation of "therapeutic equivalence" indicates that the generic formulation is bioequivalent to the innovator formulation. This means that drug products are considered to be therapeutic equivalents only if they have identical active ingredients and if they can

be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

### **Generic drugs**

A drug which is exactly the same as a brand name drug and which may be manufactured and marketed after the brand name drug's patent expires (approximately 9-10 years after the brand-name drug entered the market). Generic drugs cost significantly less than brand name drugs, and are identical in terms of efficacy, safety, side effect profile, and dosing. Important exceptions to this may include drugs such as immunosuppressants or drugs with a "narrow therapeutic index" such as anti-arrhythmics. "Narrow therapeutic index" refers to drugs that have a high rate of side effects at commonly administered dosages. Also known as a "generic equivalent."

### **Generic substitution**

Substituting a generic drug for an identical brand-name drug that has lost its patent protection. Generic substitution lowers drug costs for both consumers and prescription benefit managers while providing equal efficacy, safety, side effect profile and dosing (with a few important exceptions. For more information on exceptions to generic substitution see therapeutic equivalency.)

### **Premium**

A periodic payment by the insured to the health insurance company or prescription benefit manager in exchange for insurance coverage. Varies depending on health plan or drug formulary.

### **Prescription Benefit Managers (PBMs)**

Firms that contract with health plans or plan sponsors (such as employers) and specialize in claims processing and administrative functions involved with operating a prescription drug program. PBMs negotiate with pharmaceutical companies and prescription drug wholesalers to obtain a discount on bulk orders of prescription drugs. PBMs may also attempt to influence doctors' prescribing behavior or patients' drug utilization by manipulating the cost of certain prescription drugs to influence the use of alternative and comparable drug therapies.

### **Prior approval**

The process for obtaining approval from a health insurer before a specific treatment, procedure, service or supply has been provided. Completing this process ensures that the patient receives full benefits for the specified services. Health insurers may require prior approval for specific services or products, including home health assistance, durable medical equipment, surgery, or skilled nursing facility stays. Typically, prior approvals

are valid for a set length of time as long as the patient's benefits do not change between the date the approval is given and the date the service or product is provided.

### **Prior authorization**

The process for obtaining drug coverage from a prescription benefit manager. If a physician feels that, for medically necessary reasons, a patient needs a certain medication that is not on the patient's drug formulary or requires prior authorization, the prescribing physician may request an exception by contacting the patient's prescription benefit manager. Prior authorization may be required for a number of reasons, such as the potential toxicity or the potential abuse of the drug. Prior authorization is similar to prior approval but typically used only in reference to drug benefits. Prior authorization is designed to encourage appropriate drug use and to assist in reducing drug benefit costs.

### **Step therapy and "fail first" requirements**

The process of beginning drug therapy for a medical condition with the most cost-effective and safest drug therapy and progressing to other more costly or risky therapy. Progression to a new medication is predicated on the former medication failing to provide symptomatic relief or cure; hence "fail first." Step therapy aims to control costs and minimize risks. Drug plans may require an enrollee to try one drug before the plan will pay for another drug. Also called "step protocol."

### **Tiered formularies**

List of preferred prescription drugs in which different drugs have different co-pays. Each drug is assigned to a specific 'tier' within the formulary. The most cost-effective drugs, often generic drugs, belong to the most preferred tier and typically have the lowest co-pay, whereas the least cost effective drugs belong to the least preferred tier and have the highest co-pay. Tiered formularies encourage consumers to be cost-conscious in choosing their medications, and reward consumers for choosing generic medications by requiring a lower co-pay. Tiered formularies may also provide some level of coverage for prescriptions that might not otherwise be covered.