THE HEALTH PROFESSIONAL’S ROLE IN FORMULARY MANAGEMENT OF MEDICARE PART D BENEFITS

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INTRODUCTION

The Medicare Modernization Act (MMA) was passed in December, 2003. The MMA addressed a critical deficiency for many Medicare beneficiaries in that it established a voluntary prescription drug benefit for all Medicare beneficiaries. As approximately 85% to 90% of acute and chronic health problems are managed in both the short and long-term with prescription drug therapy, Medicare Part D addresses a significant gap in the management of disease.

The implementation of Medicare Part D was associated with more difficulty than anticipated; however, the overall design of the Medicare Part D prescription drug program is sound. The Centers for Medicare & Medicaid Services (CMS) has allowed for the application of standard drug benefit management processes that have worked adequately in the commercial sector for decades. Among these are the formulary system, the prior authorization process, step therapy, quantity limits, various drug utilization review (DUR) edits and multiple co-payment tiers.

The formulary system and the formulary serve as the cornerstone of the Medicare Part D prescription drug benefit. Many drug benefit design and drug benefit management processes and systems must interface properly with a plan formulary in order to reach their potential in fostering the safe, appropriate, effective and economical use of drugs. (See Figure 1.)

Prescription drug expenditures are expected to double over the next nine (9) years to approximately $400 billion by 2015. Millions of preventable hospital admissions and physician office visits occur each year because of poorly managed or mismanaged prescription drug use.
Optimal drug benefit management is a complex, multi-factorial process that requires a high degree of clinical and pharmacoeconomic precision and sophistication. The formulary system and plan formulary are at the core of efficient and effective drug benefit management and disease management.

**DEFINITIONS**

The formulary system and plan formulary provide foundational support for the U.S. health care system that is driven by access to care, quality of care, and health care that is provided at reasonable cost.

The formulary system is defined as a formal, organizationally sanctioned, dynamic system which utilizes an expert panel, comprised primarily of enlightened clinicians with sophisticated knowledge in applied pharmacotherapy, to continuously and objectively evaluate and select drug products considered most appropriate from an effectiveness, safety and cost perspective.\(^1\) This dynamic system is designed to address drug use issues with a minimum of external influence by special interest groups.

The formulary is best defined as an ever-changing, limited compilation of drugs selected by an expert panel of health care practitioners, predominantly physicians and pharmacists, serving as members of a Pharmacy and Therapeutics (P&T) committee with the goal of serving and maintaining the best health interests of patients.\(^1\) A plan’s P&T committee essentially serves as an objective expert system to assure patient-focused pharmacist care that places optimal health outcomes above all other considerations.

The most common formulary-type is the closed formulary with various co-payment tiers. A closed formulary contains a generous, but somewhat limited, list of drugs. Closed formularies have the most potential to foster rational and objective pharmacotherapy, achieve a high degree of prescriber compliance, foster appropriate generic drug
utilization and assist in negotiating discounts from brand name pharmaceutical manufacturers. Many Medicare Part D plans offer a formulary with a three-tiered co-payment structure in which generic drugs in tier one require a modest patient co-payment, preferred brand name drugs in tier two require an intermediate patient co-payment, and non-preferred brand name drugs in tier three require the highest patient co-payment. Some plans utilize a fourth tier that addresses specialty drug use. Drug benefit management processes such as the prior authorization (PA) process, step therapy edits and quantity limitations also serve to foster rational drug therapy while not adding unnecessary cost.

An open formulary consists of a very comprehensive list of drugs with few exclusions and very few, if any, restrictions or filters to access that encourage certain drug use. An open formulary is largely incompatible with a patient-centered formulary system focused on achieving optimal health outcomes at a reasonable cost.

A negative formulary is a list of drugs for which a plan will not pay. Elements of a negative formulary are captured in a well managed closed formulary. A negative formulary per se finds little application in modern health care.

**OPERATING PRINCIPLES OF THE FORMULARY SYSTEM**

Many national medical and pharmacy organizations have embraced the principles of the formulary system. The primary operating principle of the formulary system is to foster safe, appropriate and effective drug therapy. In serving this principle, clinical and patient care considerations are paramount. Managed cost should not be allowed to override critical patient care factors. A myopic view that focuses on fiscal management rather than overall disease management may allow for the lowest ingredient cost in the prescription “drug silo,” but may actually interfere with the attainment of cost-containment dividends in the “medical silo” in the form of fewer physician office visits, laboratory tests, emergency department visits and hospitalizations. Quality-of-life outcomes from effective drug therapy management can be vast.
A secondary operating principle of the formulary system is education. The formulary system represents a knowledge system of high value as a driver of quality drug therapy management. The intellectual equity that goes into the formulary drug selection process should be shared, in various forms, particularly with the network medical and pharmacy providers. These educational opportunities can take the form of clinical logic behind PA criteria, newsletters, targeted “one pagers” regarding some specific aspect of a specific drug or group of drugs, point-of-sale clinical logic for drug use review (DUR) edits, medication therapy management (MTM) services and many other educational venues. Failure to link the clinical logic behind the formulary system and formulary with prescribers and dispensers of drugs and drug information represents a substantial missed opportunity to foster rational pharmacotherapy.

A third operating principle of the formulary is cost containment. A well managed formulary system and formulary does not deprive any patient of necessary drug therapy but does selectively utilize various accountability processes to assure that drug use is medically necessary and appropriate. This process is often guided by an evidence-based, algorithmic approach to managing illness that is addressed by national treatment guidelines developed by professional organizations and associations. The objective is to use current clinical logic and not engage in overly aggressive drug therapy prematurely (see Figure 1).

**CMS GUIDELINES FOR MEDICARE PART D PLAN FORMULARIES**

**Introduction**

CMS oversees all Medicare Part D prescription drug plans to assure that all beneficiaries receive clinically appropriate medication at the lowest possible cost. In serving all beneficiaries, one must recognize that there are seven distinct groups eligible for the benefit. Medicare beneficiaries include individuals who are both elderly and people who
become permanently disabled and are below age 65. Among these two major groups are people who are low income and who reside in both the community and institutional facilities. Table 1 groups and defines eligibility status and the benefit provided.

CMS has been very attentive in assuring that no eligible beneficiary is disadvantaged in any way and has been particularly concerned by such vulnerable groups as long-term care (LTC) residents and full-benefit dual eligibles. Further, the MMA and accompanying regulations encourage and support application of value-based drug benefit design and management processes and systems that are widely utilized in the commercial market (see Figure 1).

Goal

With regard to application of the formulary system and formulary in the Medicare Part D prescription drug benefit, the CMS goal is clear. Utilizing the formulary system as a foundational element of the prescription drug benefit, CMS is seeking a high quality, cost effective drug benefit. CMS is seeking the application of drug benefit management best practices in every facet of the prescription drug benefit.

Role of the Pharmacy and Therapeutics Committee

The plan’s Pharmacy and Therapeutics (P&T) committee is vital to development and maintenance of the formulary. The P&T committee is the primary intellectual engine behind formulary development and maintenance.

P&T committee members should be chosen carefully. Superior clinical competence and demonstrated proficiency in drug therapy management among members is crucial. The drug information explosion and new drug developments require both depth and breadth of knowledge in pharmacotherapy. Clinicians who can blend clinical and pharmacoeconomic skill sets are particularly valuable human resources. P&T
committees should be encouraged to seek and utilize external experts when necessary and appropriate as advisors and consultants.

CMS has published P&T committee requirements regarding membership, conflict of interest, meeting administration, formulary management and formulary exceptions. These are included in Appendix A.

**CMS REVIEW OF PLAN FORMULARIES**

CMS periodically reviews all participating plan formularies to ensure that the formulary is designed to adequately serve clinical needs of patients. This requires breadth of drug coverage. However, CMS is also attentive to utilization management strategies that are appropriately applied while not placing any patient group at a disadvantage relative to access to medically necessary and medically justifiable drug therapy. This may involve a CMS review of plan therapeutic categories, drugs included and excluded from the plan formulary, drug tiers, and application of utilization management processes such as PA, step therapy, quantity limits, and various DUR edits.

The majority of plans participating in the Medicare Part D prescription drug benefit have chosen to utilize the CMS sanctioned United States Pharmacopeia (USP) Classification System (available at [www.usp.org/healthcareInfo/mmgs](http://www.usp.org/healthcareInfo/mmgs)). Other classification systems may be used, but they are reviewed by CMS to assure that breadth of drug coverage reflected in the formulary is consistent with that achieved utilizing the USP Classification System.

It is a statutory requirement that a plan formulary must contain at least two drugs in each approved therapeutic grouping unless only one drug is available in a particular category. CMS may require more than two drugs in a therapeutic category or class when additional drugs present unique and important advantages relative to efficacy and/or safety. CMS monitors for the absence of essential drugs that could substantially discourage enrollment by a patient with a particular disease.
CMS monitors formularies for inclusion of at least one drug in what is identified by the USP Classification System as a Formulary Key Drug Type (FKDT). Plans may present clinical justification for not including at least one FKDT. For example, if a FKDT is a drug that is typically covered under Medicare Part B, the drug is not considered a Part D FKDT.

CMS also conducts a periodic review of the placement of drugs into the formulary co-payment tier structure. Plans are given substantial leeway in assigning drugs to various co-payment tiers. Typically tier one with the lowest co-payment addresses generic drugs, tier two, with an intermediate co-payment, addresses preferred formulary brand name drugs and tier three, with the highest co-payment, addresses non-preferred brand name drugs. Additional tiers may be included in a plan design to address various aspects of drug utilization. CMS will monitor placement of drugs into the tier co-payments structures to assure that plan enrollment is not discouraged because widely utilized drugs are placed in tier three (or a higher, more restrictive tier) when commonly utilized, therapeutically similar drugs are not included in the more preferred tier one and/or tier two positions.

CMS also monitors formularies to assure that appropriate access is provided to drugs or drug classes addressed in widely accepted treatment guidelines that reflect state-of-the-art clinical practice. This monitoring process maximizes access to critical therapies to treat a variety of highly prevalent diseases associated with profound morbidity and mortality (e.g., diabetes, hypertension, lipid disorders, coronary artery disease, heart failure, asthma, obstructive lung disease, seizure disorders, cardiac rhythm disturbances, depression, dementia, stroke, myocardial infarction, migraine, osteoporosis, gastroesophageal reflux disease, infectious diseases, Parkinson’s disease, osteoarthritis, rheumatoid arthritis, multiple sclerosis, HIV/AIDS, cancer).
CMS Review of Drug Benefit Management Processes

CMS is expected to ultimately address and monitor a wide spectrum of drug benefit management processes and systems (see Figure 1). At this time, CMS formally monitors the PA process, step therapy and quantity limitations to assure that plans utilize these drug benefit management “tools” in a manner consistent with existing best practices. Application of one or more of these management processes that falls outside the CMS interpretation of current best practices requires reasonable justification by the plan.

A brief description of how these three drug benefit management processes complement the goals and objectives of the formulary system are included below:

**prior authorization**

The prior authorization (PA) process permeates contemporary health care and encompasses medical procedures, surgery, dental procedures, organ transplants, drug therapy and so forth. The universality of application of the PA process is evidenced by over 200,000 Internet entries on “prior authorization – drug.” Virtually all entities that have the responsibility of administering/managing a drug benefit endorse and utilize the PA process.

In the context of drug benefit management, PA is defined as …. “The process of obtaining prior approval as to the clinical and/or economic appropriateness of a prescribed medication before the medication is authorized for payment and dispensed to the patient.” The PA process is typically selectively applied to relatively few drugs with the goal of maximizing their safe, appropriate, effective and economical use.

The PA process is simply an accountability system. The process is a non-punitive, high-ground drug therapy management process supported by a knowledge system driven by scientific objectivity and medical evidence. The PA process is in no
way designed to usurp the physician’s prescribing prerogatives or deprive patients of necessary drug therapy. It should be designed, however, to determine whether certain non-preferred or non-formulary drug use is medically justifiable and/or high prices are not paid when therapeutically equivalent or safer and/or more effective but less expensive therapeutic agents are available.

A few physicians may express resistance to PA requirements involving drug therapy because it takes time, intellectually challenges prescribing practices and requires medical justification and accountability. These are not defensible reasons to not utilize PA as a drug benefit management process to the limits of its value.

When PA criteria are met and medical justification is provided, payment is authorized and the prescription is dispensed. Approval of PA requests may be for weeks, several months, a year or indefinitely.

Failure to appropriately utilize the PA process in drug therapy management can result in less than optimal clinical outcomes, safety issues and unnecessary drug expenditures. Evidence supports the fact that the PA process, selectively applied, fosters safe, appropriate, effective and economical drug use. There is virtually no objective evidence that wise application of the PA process adversely affects quality of health care.

**step therapy**

A step therapy program is highly complementary to the formulary management process. In some cases step therapy may allow avoidance of the more laborious PA process. Step therapy edits are selectively employed, add an element of precision to drug therapy management and are totally consistent with the value quest that addresses both quality of care and avoidance of unnecessary drug therapy expenditures.
Step therapy is defined as a logical process that takes an evidence-based, algorithmic approach to drug utilization. Step therapy contributes to drug safety, cost-effectiveness and optimal therapeutic outcomes by…

- Minimizing the premature use of drug therapies that should be held in reserve for more serious and advanced stages of illness,

- Avoiding premature use of drug therapies that have high risk (e.g., contraindications, warnings, precautions, adverse effects, drug interactions, special dosing considerations) until they are absolutely essential,

- Fostering cost avoidance by discouraging the premature or inappropriate prescribing of drugs that offer no significant clinical/therapeutic advantage over equally effective, but less expensive, therapies.

Clinical consideration of drug safety and effectiveness are primary in evolving step therapy. Cost considerations are secondary. Application of the step therapy process is best suited for chronic maintenance therapies (e.g., pain management, depression, degenerative joint disease, diabetes, dyslipidemias, hypertension, acid-secretory disorders, asthma, COPD, sleep disorders).

If there is evidence in the electronic file that a patient has been on a step one drug, a prescription for a step two drug will adjudicate automatically. If a step two drug is prescribed before a step one drug is utilized, the dispensing pharmacist will receive an electronic message that will require an intervention. In such cases, the pharmacist will typically contact the prescriber and request a new prescription for a step one agent. If the prescriber feels a step two drug is the only appropriate drug for a specific patient, the physician will be required to provide evidence of medical necessity for the step two drug. Patients who choose to receive an unauthorized step two drug are typically liable for the full prescription cost.
Responsibility to ultimate purchasers/payers of prescription drugs requires clinical and fiscal responsibility and accountability. Step therapy offers an effective, minimally intrusive management dimension to this responsibility.

**quantity limitations**

Quantity limitation is an edit program measured against time. Some plans refer to quantity limits as “Quantity vs. Time” or QVT limits. This prospective process sets dosage unit limits per unit of time in a scientific manner consistent with administration and dosage guidelines of the drug manufacturers’ product labeling approved by the U.S. Food and Drug Administration (FDA) or standard U.S. pharmaceutical compendia.

Quantity limits complement the formulary system by focusing on drug use that is safe and appropriate. In many instances, quantity limits are selectively established to monitor drugs and/or drug classes (therapeutic groups) that are widely recognized as having relatively high potential for overuse, misuse, abuse and/or diversion into illicit channels of drug distribution.

In a genuine effort to accommodate prescriber preference and patient need, quantity vs. time limits are usually set at the upper limit of the FDA-approved daily dosage range. If a drug has multiple indications, these quantity limits are typically established for the indication/diagnosis that is most prevalent in society. For chronic maintenance medications, the quantity limits will usually be set for a 30-day supply. For certain self-limited conditions, quantity limits may be established for a shorter period (e.g., seven days, 10 days, 14 days).

As with other drug benefit management processes, quantity limit protocols typically accommodate legitimate, medically justifiable, exceptions. Plans will, however, explore the clinical circumstances which might warrant variations in pre-established quantity limits. Off-label use that is not supported by evidence and is significantly
inconsistent with package labeling (which is a legal document) is the area of greatest controversy with quantity limit edits.

Other Formulary Considerations

**long-term care accessibility**

Plans are expected to not only address formulary needs of the general Medicare population but also the Part D beneficiary residing in a long-term care (LTC) facility. CMS expects participating Medicare Part D plans to cover drugs and dosage forms of drugs that are widely utilized in the LTC environment. These include a variety of injectable medications, products available in unit dose packages, liquids, chewables, and other dosage forms. However, confusion has occurred as some drugs and supplies in LTC facilities are covered under Medicare Part B. CMS regulations are reasonably clear on Part B vs. Part D coverage, although some ambiguities have occurred. Such ambiguities are being clarified to assure that there are no gaps or lapses in patient drug therapy.

**specialty drug tier**

Specialty drugs are generally defined as "a variety of biologicals, immunologic, hematologic, chemotherapeutic and traditional molecular entities where a constellation of special considerations converge that require higher levels of clinical and pharmacoeconomic oversight, safeguards and health care provider accountability to assure safe, appropriate, effective and economical drug use."

Medicare allows a specialty drug tier. Most Part D plans with a specialty drug tier designate specialty drugs as fourth tier pharmaceuticals. CMS will only approve formularies and benefit designs with a specialty tier that complies with the following requirements:²
• Only one tier can carry the designation of "specialty drug tier."

• Cost sharing associated with the specialty tier is limited to 25% in the initial coverage range (or actuarial equivalent for plans with decreased or no deductible basic alternative benefit design).

• Only Part D drugs with plan negotiated prices that exceed $500 per month may be placed in the specialty tier.

If all drugs within a therapeutic category or class meet the criteria for inclusion in a specialty tier, a Part D plan is not required to identify a preferred drug for that therapeutic category or class. Standard drug benefit management processes (e.g., prior authorization, step therapy) may be applied, and frequently are, to specialty drug use to assure appropriateness of therapy.

six therapeutic classes of particular clinical concern

CMS identified six therapeutic classes of drugs in which "all or substantially all" drugs in the class are required to be on the plan formulary. These therapeutic classes are the immunosuppressants, antidepressants, antipsychotic agents, anticonvulsants, antiretrovirals and antineoplastics. CMS developed this policy to ensure that Medicare Part D beneficiaries reliant upon one or more drugs in these therapeutic classes not be discouraged from enrolling in any Part D plan. This policy was also designed to decrease risk from any significant disruption of drug therapy in these vulnerable populations.

"Substantially all" is interpreted as all drugs and unique dosage forms in these categories with the following exceptions:²

• Multi-source brands of the identical molecular structure.
• Extended-release products when the immediate-release product is included.

• Products that have the same active ingredient.

• Multiple dosage forms that do not provide a unique route of administration (e.g., tablets and capsules).

For calendar year 2007, CMS will continue to require Part D plan formularies to include all or substantially all drugs in these six therapeutic groups. New drugs or newly approved drugs in these six therapeutic groups that enter the market after April 17, 2006 will be subject to an expedited P&T Committee review. The expedited review process requires the P&T Committee to make decisions within 90 days rather than the normally required 180 days for all other therapeutic groups. CMS is receptive to feedback from plans and providers about managed care strategies that could be implemented, within the context of the current policy, to manage these drug classes when appropriate.

Part D plan sponsors may not implement PA or step therapy requirements that could steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug. If a plan cannot determine at the point-of-sale that an enrollee is currently taking a drug (i.e., new enrollee filling a prescription for the first time) plans must treat the enrollee as "currently taking the drug." For beneficiaries who begin treatment with drugs in these categories other than HIV/AIDS drugs, plans may use these processes to manage therapy. Plans may consult with prescribers regarding treatment options and clinical outcomes at any time.

**submission of multiple formularies**

CMS acknowledges the fact that an organization (i.e. individual plans) may wish to submit more than one formulary in order to offer enhanced access to Part D drugs. CMS reviews different formularies of single plans to assure that meaningful differences
between plan formularies exist and confusion among beneficiaries is minimal. CMS reserves the option to request that a plan withdraw a formulary if no meaningful differences exist.

**drugs excluded from Medicare Part D coverage**

Drugs excluded from Medicare Part D coverage are included in Table 2. In some cases, drugs are excluded because they are or can be covered under Medicare Part B. The most controversial exclusion is the benzodiazepines (BZDs). BZDs with active metabolites and/or those possessing a long half-life, are generally appropriate for exclusion. However, BZDs used as anxiolytics that possess a short half-life and duration of action with no active metabolite(s) (e.g., lorazepam, oxazepam) are considered standard anxiolytics and are recommended as primary therapy in national guidelines in the management of a variety of anxiety disorders. Many national professional organizations have developed formal statements calling for coverage of selected BZDs. Some plans are providing enhanced coverage of selected BZDs to assure access to clinically necessary, reasonably priced anxiolytics.

Non-coverage of nonprescription drugs is also controversial, particularly when recent switches of certain drugs (e.g., Prilosec OTC®, Claritin®, Zantac 150®, Pepcid AC Maximum Strength®) occurred at the most commonly prescribed strength. A recent study revealed that coverage of omeprazole 20 mg (as Prilosec OTC®) produced a 38% reduction in plan costs for all proton pump inhibitor (PPI) use.³ In this 127,495 member plan, this reduction in plan cost for PPIs translated into an annualized saving of $3,365,880 despite a 6% increase in PPI utilization. More and more commercial plans are selectively adding nonprescription drug coverage to plan designs to avoid unnecessary drug expenditures at virtually no risk to quality of care and clinical outcomes. Some Medicare Part D plans are considering the provision of selected nonprescription drugs to beneficiaries. In this case, the plan would be responsible for paying for the nonprescription drugs. CMS is expected to continue to evaluate coverage issues with nonprescription drugs.
CONCLUSION

The formulary system and the intellectual equity that goes into the development and maintenance of a formulary is a valuable process that yields significant quality of care and cost of care dividends. When the formulary system and formulary interface appropriately with other drug benefit management processes (see Figure 1), the synergies achieved can be highly significant. A patient-focused, quality-of-care driven formulary system and formulary is foundational to the contemporary drug benefit management process and should receive a high priority resource commitment by all plans.
BIBLIOGRAPHY


Table 1. Eligibility Groupings for the Medicare Part D Prescription Drug Benefit

<table>
<thead>
<tr>
<th>Federal Poverty Level (FPL) &amp; Assets</th>
<th>Percentage of Premium Subsidy Amount</th>
<th>Deductible</th>
<th>Copayment up to out-of-pocket limit</th>
<th>Copayment above out-of-pocket limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full-benefit dual eligible—Institutionalized individual</td>
<td>100%</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Full-benefit dual eligible—Income at or below 100% FPL (non-institutionalized individual)</td>
<td>100%</td>
<td>$0</td>
<td>The lesser of: (1) an amount that does not exceed $1 generic/preferred multiple source and $3– other drugs, or (2) the amount charged to other full subsidy eligible individuals who are not full-benefit dual eligible individuals or whose incomes exceed 100% of the FPL</td>
<td>$0</td>
</tr>
<tr>
<td>Full-benefit dual eligible—Income above 100% FPL (non-institutionalized individual)</td>
<td>100%</td>
<td>$0</td>
<td>An amount that does not exceed $2-generic/preferred multiple source and $5–other drugs</td>
<td>$0</td>
</tr>
<tr>
<td>Non-full benefit dual eligible beneficiary—Income below 135% FPL and with assets that do not exceed $6,000 (individuals) or $9,000 (couples)</td>
<td>100%</td>
<td>$0</td>
<td>An amount that does not exceed $2–generic/preferred multiple source and $5–other drugs</td>
<td>$0</td>
</tr>
<tr>
<td>Non-full benefit dual eligible beneficiary—Income below 135% FPL and with assets that exceed $6,000 but do not exceed $10,000 (individuals) or with assets that exceed $9,000 but do not exceed $20,000 (couples)</td>
<td>100%</td>
<td>$50</td>
<td>15% coinsurance</td>
<td>An amount that does not exceed $2–generic/preferred multiple source drug or $5–other drugs</td>
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</table>
| Non-full benefit dual eligible beneficiary—  
*Income at or above 135% FPL but below 150% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)* | Sliding scale premium subsidy (100%-0%) | $50 | 15% coinsurance | An amount that does not exceed $2–generic/preferred multiple source drug or $5–other drugs |
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<tbody>
<tr>
<td>Standard Benefit</td>
<td>0%</td>
<td>$250</td>
<td>25% of drug costs until $2,250 in drug spending (not including monthly premium) then 100% of drug costs until $3,600 true out-of-pocket costs</td>
<td>An amount that does not exceed $2–generic/preferred multiple source drug or $5–other drugs</td>
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Table 2. Drugs and Products Currently Excluded from Medicare Part D Coverage

- All medications/products covered under Part B including:
  - Immunosuppressants following organ transplantation
  - Diabetic testing supplies such as test strips, lancets, and monitoring devices
- Weight loss or weight gain medications
- Fertility agents
- Hair growth products used for cosmetic purposes
- Cough and cold medications
- Prescription vitamin and mineral products (except prenatal vitamins and fluoride preparations)
- Nonprescription drugs
- Barbiturates
- Benzodiazepines
- Agents for erectile dysfunction (effective in 2007)
### APPENDIX A. CMS Requirements for P&T Committee Activity

<table>
<thead>
<tr>
<th>Membership</th>
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<tbody>
<tr>
<td>• P&amp;T committee members must come from various clinical specialties that adequately represent the needs of plans beneficiaries.</td>
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<tr>
<td>• A majority of the P&amp;T Committee member must be practicing physicians, practicing pharmacists or both.</td>
</tr>
<tr>
<td>• At least one P&amp;T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons.</td>
</tr>
<tr>
<td>• At least one P&amp;T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the plan and pharmaceutical manufacturers.</td>
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<tr>
<th>Conflict of Interest</th>
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<tr>
<td>• P&amp;T Committee members should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions.</td>
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<tr>
<th>Meeting Administration</th>
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<tr>
<td>• P&amp;T committee should meet on a regular basis, and not less frequently than on a quarterly basis.</td>
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<tr>
<td>• P&amp;T committee decisions regarding formulary development or revision must be documented in writing.</td>
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<tr>
<th>Formulary Management</th>
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<tr>
<td>• P&amp;T committee must review for clinical appropriateness, the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions and other drug utilization activities that affect access.</td>
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<tr>
<td>• Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve an appropriate, safe and cost effective drug therapy.</td>
</tr>
<tr>
<td>• The P&amp;T committees will be required to establish and document procedures to assure appropriate drug review and inclusion.</td>
</tr>
<tr>
<td>• Clinical decisions by the P&amp;T committee should be based on scientific evidence and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines and pharmacoeconomic studies as well as other sources of appropriate information.</td>
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</table>
Formulary Management (cont’d)
- Drugs’ therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them into formulary tiers.
- The P&T committee will make a reasonable effort to review a new chemical entity within 90 days, and will make a decision on each new chemical entity within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. These timeframes also include the review of products for which new FDA indications have been approved.
- P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.
- Formulary therapeutic categories and classes may be changed only at the beginning of each plan year or when new drugs or new drug therapeutic uses appear.

Formulary Exceptions
- P&T committees must review for clinical appropriateness protocols and procedures for the timely use of and access to both formulary and non-formulary drug products. A non-formulary drug may be needed, for example, when the formulary drug would cause adverse effects or would not be as effective or both, based on scientific evidence or medical necessity.