

MEDICARE MODERNIZATION ACT
2007 DRAFT GUIDELINES -- FORMULARIES
CMS Strategy for Affordable Access to Comprehensive Drug Coverage

Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures

1. Purpose of the Guidance

This paper is draft guidance on how CMS will review Medicare prescription drug benefit plans to assure that beneficiaries receive clinically appropriate medications at the lowest possible cost. Two key requirements in the Medicare Modernization Act (MMA) are to assure that drug plans provide access to medically necessary treatments for all and do not discriminate against any particular types of beneficiaries, and to encourage and support the use of approaches to drug benefit management that are proven and in widespread use in prescription drug plans today. The goal is for plans to provide high-quality cost-effective drug benefits by negotiating the best possible prices and using effective drug utilization management techniques. This goal can be achieved through a review by CMS that facilitates appropriate beneficiary access to all medically necessary Part D covered drugs along with plan flexibility to develop efficient benefit designs, thus bringing drug benefit strategies that are already providing effective coverage to millions of seniors and people with a disability to the Medicare population.

2. Strategic Approach

A. P & T Committee Review

We believe that current best practices for P&T committees should be applied when developing and administering P&T committees for the Medicare drug benefit. Incorporating best practice philosophies, along with inclusion of the MMA requirements, allows for a drug benefit that is clinically robust.

The requirements listed below are represented as ‘BP’ for best practice (or Industry Standard Practice) where they have been drawn from commercial best practices consistent with these nationally recognized P&T guidelines, and are represented as ‘MMA’ where the requirements support the unique provisions of the MMA.

Membership

- P&T committee members must come from various clinical specialties that adequately represent the needs of plans beneficiaries (i.e., include representation of “high volume specialists” in the standard terminology of the industry). (BP)
- A majority of the P&T committee members must be practicing physicians, practicing pharmacists or both. (BP)
- At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons. (MMA)
- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the plan and pharmaceutical manufacturers. (MMA)

Conflict of Interest

- P&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. (BP)

Meeting Administration

- P&T committee should meet on a regular basis, and not less frequently than on a quarterly basis. (BP)
- P&T committee decisions regarding formulary development or revision must be documented in writing. (BP)

Formulary Management

- P&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. (BP)
- Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe and cost effective drug therapy. (BP)
- The P&T committees will be required to establish and document procedures to assure appropriate drug review and inclusion. (BP)
- Clinical decisions by the P&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. (BP)
- Drugs' therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them into formulary tiers. (MMA)
- 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. We set this timeframe in response to public comment on our proposed guidance for 2006, but note that plans must make access to new drugs available to enrollees when medically appropriate via exceptions processes even before this deadline. (BP)
- P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis. (MMA)
- 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. (MMA)

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. (BP)

B. Formulary Review

Approach

We encourage plans to submit formularies similar to those in widespread use today. We will check the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, to satisfy the MMA requirement that a plan's categorization system does not substantially discourage enrollment to any group of beneficiaries. We also will consider the specific drugs, tiering and utilization management strategies employed in each formulary. CMS will identify outliers from common benefit management practices for further evaluation. Plans may be asked to provide written clinical justification for unusual benefit features that are identified as outliers.

Review of Categories and Classes

We will review all classification systems to assure that plans provide an appropriate breadth of categories and classes that cover all disease states. CMS will not consider a classification system in isolation from the subsequent steps in our formulary review; a classification system with a smaller number of classes may be acceptable if it nonetheless provides preferred access to a relatively broad range of widely used medicines.

As described in the MMA, plans that utilize a classification system that is consistent with the USP classification system, available at www.usp.org, will satisfy a safe harbor and thus CMS will approve their formulary classification system. For plans that choose to adopt an alternative to USP's classification structure, CMS will check the plan's proposed classification system to determine if it is similar to USP or other commonly used classification systems, such as the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification, information available at www.ashp.org/ahfs.

The minimum statutory requirement is that a formulary must include at least two drugs in each approved category and class (unless only one drug is available for a particular category or class), regardless of the classification system that is utilized. We view this requirement as a floor rather than an absolute standard. CMS may require more than two drugs per category or class in cases where additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the plan formulary may substantially discourage enrollment in the plan by beneficiaries with certain disease states.

Even though a formulary may pass the classification review and have a safe harbor for its categories and classes, it still must undergo the drug list review and benefit management tools review in order to analyze the depth and breadth of drugs and their restrictions.

Drug List Review

Regardless of the classification system chosen, CMS will review and approve drug lists that are consistent with best practice formularies currently in widespread use today. The following paragraphs describe the multiple checks that will be utilized as part of the drug list review.

1. CMS will review formularies for at least one drug in each of the Formulary Key Drug Types identified by USP. Best practice formularies commonly include at least one drug in each of the Formulary Key Drug Types as a minimum on their formulary. Plans may present a reasonable clinical justification for formularies that do not contain at least one drug for each of the USP Formulary Key Drug Types. If a USP Formulary Key Drug Type only includes drugs that are primarily covered under Part B, it is not CMS' expectation that these Key Drug Types be represented on formularies. Similarly, if only over-the-counter (OTC) or statutorily excluded drugs, or drugs that were determined by the FDA to be less than effective (LTE), comprise a Key Drug Type, plans do not need to include representative drugs on the formulary.
2. CMS will review tier placement to provide an assurance that the formulary does not substantially discourage enrollment of certain beneficiaries. When developing their formulary tier structure, plans should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers within the formulary structure will be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 will have a higher cost-share for beneficiaries than drugs in Tier 2. Best practices in existing formularies and preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary. The CMS review will focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.
3. CMS will analyze formularies to determine whether appropriate access is afforded to drugs or drug classes addressed in widely accepted treatment guidelines which are indicative of general best practice. Examples of these may include asthma, diabetes, chronic stable angina, atrial fibrillation, heart failure, thrombosis, lipid disorders, hypertension, chronic obstructive pulmonary disease, dementia, depression, bipolar disorder, schizophrenia, benign prostatic hyperplasia, osteoporosis, migraine, gastroesophageal reflux disease, epilepsy, Parkinson's disease, end stage renal disease, hepatitis, tuberculosis, community acquired pneumonia, rheumatoid arthritis, multiple sclerosis and HIV. This list of conditions does not represent an exhaustive list, but merely serves as another check in the review process. Drugs or drug classes included within these widely accepted guidelines will not place undue burden on

plans since these drugs are usually placed in favorable positions on commonly used, best practice formularies.

4. CMS will analyze the availability and tier position of the most commonly prescribed drug classes for the general Medicare and the dually eligible population (Appendix A). This list is derived from the Medicare Current Beneficiary Survey (MCBS) data from 2002 and the Department of Health and Human Services Office of Inspector General (OIG) study: *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*. As with the MCBS data, the drugs identified by the OIG will be expanded to the class level, not the specific drug identified by the report. CMS understands that plans will not provide identical coverage of these drug classes, and our review will focus on assuring that plans present a balanced formulary. These drug classes will cover common diseases and conditions, and will allow us to ensure that plans are covering the most widely used medications, or therapeutically similar medications, for the most common conditions.

C. Review of Benefit Management Tools that Affect Access

Approach

Prior Authorization, Step Therapy, and Quantity Limitations

CMS will look to existing best practices to check that plans' use of these utilization management tools is consistent with such practices. We will look to current industry standards as well as appropriate guidelines that might be found from expert organizations such as NCQA, AMCP, and NAIC, and to the use of such standards in existing drug plans that are widely used by seniors and people with disabilities. CMS will assure that plans' use of such tools is consistent with best practices. CMS will also compare formularies amongst the applicants to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits. Our expectation is that these techniques will be used in Part D formularies consistently with the way they are applied in existing formulary systems. In cases where a plan may fall outside of best practices, the plan will be asked to provide a reasonable justification for their practices.

All formularies will be evaluated using the criteria outlined above. Outliers for each area of review will be further evaluated by CMS to determine if the outlier is deemed potentially discriminatory. Examples of this may include a lack of appropriate drug classes to treat certain diseases, a lack of sufficient drugs in a therapeutic class, inappropriate tier placement that would discriminate against a group of beneficiaries, or missing drugs that would cause discrimination. If any of the outliers appear to create problems of access, plans will have the opportunity to present reasonable clinical justifications.

3. Other Formulary Considerations

A. Long-term Care Accessibility

Part D plans will be required to provide medically necessary prescription drug treatments for the general Medicare population, as well as those beneficiaries who reside in long-term care (LTC) facilities. For example, it is CMS' expectation that plans provide coverage of dosage forms of drugs that are widely utilized in the LTC setting such as unit dose products, liquid, chewable, and parenteral preparations. Further, while nebulized solutions may not be required on all formularies, we would expect plans to also cover these dosage forms under circumstances in which Part B coverage does not exist. When determining days supplies for residents in LTC facilities, Part D plans should follow industry best practices and allow for at least 31 days per fill.

B. Specialty Tiers

Section 423.578(a)(7) of the Title I regulations allows Part D plans to exempt a formulary tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. In order to ensure that a Part D plan does not substantially discourage enrollment by specific patient populations reliant upon these medications, CMS will only approve formularies and benefit designs that include a specialty tier that complies with the following:

1. Only 1 tier is designated a specialty tier exempt from cost-sharing exceptions.
2. Cost-sharing associated with the specialty tier is limited to 25% in the initial coverage range (or actuarially equivalent for plans with decreased or no deductible basic alternative benefit designs).
3. 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 category or class meet the criteria for inclusion in the specialty tier, then a plan does not need to identify a preferred drug for that category or class.

C. Six Classes of Clinical Concern

For CY 2006, CMS required Part D plan formularies to include “all or substantially all” drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling with Part D plans and to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.

For CY 2007, CMS will continue to require Part D plan formularies to include all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes in order to maintain the level of protection that is currently being provided to beneficiaries who are being treated with drugs from these six classes of clinical concern. CMS is interested in obtaining industry feedback related to current managed care strategies that could be implemented within the context of this policy that would allow plan sponsors the flexibility to manage these drug classes where appropriate.

We expect formularies to include substantially all drugs in these six categories that are available on April 17, 2006. Drugs that come onto the market after April 17, 2006 will be subject to the normal Pharmacy and Therapeutic committee review process.

“Substantially all” in this context means that all drugs and unique dosage forms in these categories are expected to be included in plan formularies, with the following exceptions:

- 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)

Part D plan sponsors may not implement prior authorization or step therapy requirements that are intended to 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 not currently taking a drug (e.g. new enrollee filling a prescription for the first time), plans shall treat such enrollees as currently taking the drug. For beneficiaries who begin treatment with drugs in these categories other than HIV/AIDS drugs, plans may use these techniques to manage therapy. For HIV/AIDS drugs, the use of utilization management tools such as prior authorization and step therapy should be consistent with the 2006 policy. Plans may, of course, conduct consultations with physicians regarding treatment options and outcomes in all cases.

D. Submission of Multiple Formularies

CMS recognizes that plans may wish to submit more than one formulary in order to offer enhanced access to Part D drugs. We have the responsibility to ensure that there are meaningful differences between multiple formulary submissions from one organization to reduce confusion amongst beneficiaries. CMS may request that plans withdraw a formulary in which no meaningful differences can be demonstrated.

4. Formulary Submission Requirements

In support of the Medicare Modernization Act (MMA), CMS has established a systems interface within the Health Plan Management System (HPMS) to enable plans to submit their formularies electronically. This functionality provides for the upload and receipt of the formulary file, prior authorization, and step therapy supplemental data, as defined by CMS. It will also allow CMS to provide more timely, systematic, and consistent feedback to plans regarding their formulary practices.

Using the HPMS formulary upload module, the user will submit one or more formulary files for the plans offered under a contract. This submission must occur between March 27, 2006 and April 17, 2006, 5:00pm EDT. Detailed technical user instructions will be forthcoming.

Appendix A

Top Drug Classes

ACE inhibitors	Macrolides
Alpha-2 adrenergic agonists	Nitrates
Alpha blockers	Non-opioid analgesics
Angiotensin receptor blockers	Non-sedating antihistamines
Anticholinergic bronchodilators	Ophthalmic prostaglandins
Anticoagulants	Opioid analgesics
Antidyskinetics	Penicillins
Antiemetics	Platelet aggregation inhibitors
Antigout agents	Potassium sparing diuretics
Atypical antipsychotics	Potassium supplements
Beta-blockers	Proton pump inhibitors
Biguanides	Quinolones
Bisphosphonates	Sedatives
Calcium channel blockers	Selective estrogen receptor modifiers
Cardiac inotropes	Serotonin modifiers
Cephalosporins	Short-acting and intermediate-acting insulin mixtures
Cholesterol absorption inhibitors	Short-acting beta agonists
Cholinesterase inhibitors	Short-acting insulins
Corticosteroids	Skeletal muscle relaxants
Cox-2 inhibitors	Sodium channel inhibitors
Estrogens	SSRIs
GABA agents	Statins
Inhaled corticosteroid	Sulfonylureas
Intermediate-acting insulins	Thiazide diuretics
Intranasal corticosteroids	Thiazolidinediones
Laxatives	Thyroid replacements
Leukotriene modifiers	Tricyclic antidepressants
Long-acting beta agonists	Urinary Antispasmodics
Loop diuretics	