

Medicare Drug Reimbursement Guide

Monthly Dispatch

FDC Reports • April 2006 • Vol. 1, No. 10

“All or Substantially All” Provision Retained for 2007

The Centers for Medicare & Medicaid Services (CMS) has issued a guideline outlining the agency’s criteria for approving Medicare Part D prescription drug formularies for the 2007 benefit year.

The March 24 guideline focuses on three areas: formulary lists, pharmacy and therapeutics committees (P&T) that develop Part D formularies, and issues related to access.

In an interview, Robert Donnelly, vice-president for government programs at MemberHealth, a national Part D prescription drug plan sponsor, and the former head of Part D at CMS, noted that “I don’t see a lot of changes,” between this draft guidance and last year’s formulary guidelines.

“I think that CMS is trying to make sure that they have a stable program. [The guidance] is just a codification of what’s going on,” Donnelly said.

For example, CMS will continue to require that formularies include “all or substantially all” drugs within six classes of drugs, including generics

See CMS, p. 2

CMS Sets \$500 Threshold for Specialty Tiers

The Centers for Medicare & Medicaid Services (CMS) has set a \$500 threshold for placing a drug in a Part D specialty tier, despite objections from the Biotechnology Industry Association (BIO). CMS set this threshold in its final guidance on formularies for the 2007 benefit year (see story above).

Drugs placed in a specialty tier may be excluded from the Part D cost-sharing exceptions process (see Ch. 7.3.2.3.2).

The guidance states that CMS will approve specialty tiers for certain “very high cost and unique items,” provided: only one tier is designated a specialty tier exempt from cost-sharing exceptions; cost sharing associated with the specialty tiers is limited to 25 percent in the initial coverage range; and only drugs with plan negotiated prices exceeding \$500 per month are placed in the specialty tier.

However, according to BIO, permitting plans to “place all therapies with negotiated prices greater than \$500 per month on the specialty tier grants plans too much discretion in setting negotiated prices and allows the inclusion of far too wide a range of therapies on the specialty tier.”

Currently, BIO estimates that drugs with monthly prices of \$2,000 to \$3,000 generally are assigned to the specialty tier.

In March 6 comments, BIO writes that “patients who need therapies that are placed in a specialty tier tend to be particularly medically vulnerable. . . . It is likely to be extremely difficult for these patients to absorb these significant out-of-pocket expenses all at once.” ♦♦

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Changes to Guide

- Ch. 1.2 has been revised to reflect a new CMS organizational chart.
- Ch. 6.1.1.2 has been changed to include new Part D bidding deadlines for the 2007 plan year.
- Ref. 5 has been updated to include USP Medicare Formulary Guidance and Formulary Key Drug Types for the 2007 plan year.

Attention Subscribers

We have added a new feature to our Web page this month to help you more easily access source documents cited in the *Medicare Drug Reimbursement Guide*. To access source documents, click on the new button that has been added to the top right-hand side of the home page at www.MedicareRxGuide.com.

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POSTMASTER: Send address changes to *Medicare Drug Reimbursement Guide*, 5635 Fishers Lane, Suite 6000, Rockville, MD 20852. ISSN 1558-5530.

The *Dispatch* newsletter for the *Medicare Drug Reimbursement Guide* includes a loose-leaf update to the *Guide*. The information provided in this publication does not constitute legal advice, which is based on specific facts. If legal advice may be needed, contact an attorney.

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CMS (continued from p. 1)

and older branded products. These include drugs in the anticonvulsant, antidepressant, antineoplastic, antipsychotic, antiretroviral, and immunosuppressant classes.

Exceptions to this requirement are multi-source brands of the same molecular structure, extended-release products when the immediate-release product is included, products that have the same active ingredient, and multiple dosage forms that do not provide a unique route of administration.

Earlier Cutoff Date

CMS' "all or substantially all" policy will not pertain to drugs that come onto the market after April 17; drugs approved after this date will be subject to an expedited P&T committee review process.

In written comments on the draft guidance, Jim Greenwood, president of the Biotechnology Organization (BIO), had objected to the cutoff date.

"BIO is concerned that the proposed April 17, 2006 date could leave patients without access to critical, life-saving therapies that come onto the market more than eight months prior to the beginning of the benefit period. . . . CMS should establish January 1, 2007 as the cut-off date, similar to its policy for last year."

The Association of Community Cancer Centers, (ACCC) also had urged CMS to extend the cutoff date. "The standard of care for patients receiving Part D coverage effective January 1, 2007, should not be determined more than six months earlier," ACCC wrote in comments submitted March 6.

Because the new guidance does not make significant changes to CMS' criteria for formulary placement, Donnelly predicted that many plans will choose to submit similar formularies for 2007.

"I wouldn't expect that plans want to make wholesale changes. If you propose a formulary, there is not much difference between the old and new. Maybe there will be some tweaks here and there," Donnelly said.

The American Society of Consultant Pharmacists (ASCP), in written comments, had suggested that the "all or substantially all" requirement should be expanded to include drugs for the treatment of Parkinson's disease and Alzheimer's disease.

ASCP also had argued that extended-release products should not be granted an exception from the "all or substantially all" policy. Neither of these suggestions were adopted in the final guideline.

Formulary Reviews

The guidance notes that the minimum statutory requirement is that formularies include "at least two drugs in each approved category and class." Part D plans that follow U.S. Pharmacopeia (USP) voluntary guidelines are deemed in compliance with nondiscrimination requirements related to category and class (see "Revised USP Guidelines Kick Off 2007 Bid Cycle," March 2006 *Dispatch*, p. 1).

Similar to last year's guidelines, CMS again made clear that including two drugs in each category and class will not always be sufficient for agency approval (see Ch. 7.3.2.2).

“We view this requirement as a floor rather than an absolute standard,” the guidance states. “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.”

The formulary guidance lists four criteria that CMS will examine in evaluating formularies:

- CMS will review formularies for at least one drug in each of the formulary key drug types identified by USP;
- CMS will review tier placement to ensure that the formulary does not discourage enrollment of certain beneficiaries;
- CMS will evaluate formularies to determine whether appropriate access is afforded to drugs or drug classes addressed in widely accepted treatment guidelines; and
- CMS will analyze the availability and tier position of the most commonly prescribed drug classes for the general Medicare and dual eligible populations.

Under the guidance, CMS will no longer review Medicare risk adjustment data to determine whether formularies include drugs that are most commonly used by the Medicare population. Last year’s guidelines included this data in CMS’ formulary evaluation.

Newly Approved Drugs

The guidance specifies that P&T committees make a “reasonable effort” to review a new chemical entity within 90 days and make a formulary decision within 180 days of its release onto the market, or to provide a clinical justification if this timeframe is not met (see Ch. 7.3.4). However, under a new expedited review

process, P&T committees must make a formulary decision within 90 days if the newly approved drug belongs to an “all or substantially all” category.

CMS also noted that “plans must make access to new drugs available to enrollees when medically appropriate via the exceptions process even before” the 90-day or 180-day deadlines (see Ch. 8). In maintaining the 180-day deadline for most new therapies, CMS rejected a suggestion by BIO to shorten this requirement to 90 days. The agency also failed to follow BIO’s recommendation regarding specialty tiers (see related story, p. 1).

Access Issues

The guidance aims to promote patient access by barring plans from imposing prior authorization or step therapy requirements for patients who are just starting on drugs covered under the “all or substantially all” policy (see Ch. 7.3.2.2).

Prior authorization and step therapy generally will not be permitted at all for HIV/AIDS drugs, “consistent with the 2006 policy.”

The guidance also requires that plans cover dosage forms of drugs that are “widely used” in the long-term care (LTC) setting. These include unit dose products, liquid, chewable and parenteral preparations. Part D plans should follow “industry best practices” and allow for at least 31 days per fill” for LTC residents, the guidance states.

Plan sponsors must submit 2007 formulary files for CMS review by April 17. The agency will allow sponsors one opportunity to update formularies prior to the start of the 2007 contract year. The open period for these changes will be Aug. 1 to Aug. 7. [Editor’s Note: See this month’s update to Ch. 6.1.1.2 for details on 2007 bid deadlines.] ♦♦

News Briefs

New Rebate Disclosures Proposed

The Centers for Medicare & Medicaid Services (CMS) has issued a draft “call letter” proposing major policy changes for the 2007 Part D benefit year.

Significantly, CMS proposes that Part D prescription drug plan (PDP) sponsors disclose all drug manufacturer rebates paid to pharmacy benefit managers and long-term care pharmacies. The draft call letter was issued Feb. 21.

CMS states that “we have significant concerns about the continued payment of . . . rebates to LTC pharmacies that are providing covered Part D drugs and LTC pharmacy services as part of a Part D plan’s network.”

CMS proposes that for 2007, PDPs must report 100 percent of all manufacturer rebates (see Ch. 7.4). This provision was not included in contracts for the 2006 benefit year.

See *News Briefs*, p. 4

News Briefs (continued from p. 3)

To simplify PDP offerings and reduce confusion among beneficiaries, CMS also proposes to limit the number of stand-alone PDP options per geographic region to two in the 2007 contract year.

“We are looking at the feasibility of limiting submissions to one basic benefit . . . and one enhanced alternative benefit within each region per contract,” CMS states.

The agency will issue renewal notices to existing sponsors May 1. June 5 is the deadline for submitting bids for the 2007 contract year.

A separate CMS draft call letter addresses Medicare Advantage prescription drug plans. ♦♦

Transition Guidances Revised

In the wake of widespread problems experienced during the Part D launch, CMS has proposed to strengthen transition requirements related to temporary first-fill prescriptions for new Part D plan enrollees (see “Part D Transition Period Extended,” March 2006 *Dispatch*, p. 3).

In a Feb. 23 draft guidance, CMS said that for the 2007 benefit year “plans will be required to provide a temporary supply fill anytime during the first 90 days of a beneficiary’s enrollment in a plan.” During this transition period, plans will be required to provide a temporary 30-day fill for the drug.

Last year’s guidance gave plan sponsors more discretion in deciding the “appropriate” time frame for a one-time transition supply.

To promote continuity of care, the final Part D rule requires that plans establish a “transition process” for new enrollees whose current drug therapies are not on a PDP’s formulary (see Ch. 7.3.5).

CMS’ revised transition standard also would apply to residents in (LTC) facilities. However, the draft guidance states that “unlike in the retail setting, plans must honor multiple fills of non-formulary Part D drugs, including Part D drugs that are on a plan’s formulary but require prior authorization or step therapy . . . during the entire length of the 90-day transition period.”

The draft guidance also specifies that Part D plans must provide an emergency supply of non-formulary Part D drugs for LTC residents; this supply must be provided even for enrollees outside of the 90-day transition period.

Plan sponsors must submit transition plans for 2007 by May 1. ♦♦

UPDATE SPOTLIGHT

This month we have updated the *Guide* to include Part D bidding deadlines for the 2007 plan year – see Ch. 6.1.1.2.

Guide Covers Pharmaceutical Fraud

CMS has issued a draft guidance to assist Part D plan sponsors in designing compliance programs for detecting fraud, waste and abuse.

The draft, released for comment on Feb. 8, incorporates many elements of the “Office of the Inspector General’s Compliance Program Guidance for Pharmaceutical Manufacturers” issued in May 2003.

For example, pharmaceutical manufacturers may be liable under the False Claims Act or the anti-kickback statute if government reimbursement for the manufacturer’s product depends on information generated by or reported by the manufacturer, and the manufacturer has “knowingly failed to generate or report such information completely and accurately.”

The anti-kickback act also may be invoked by “inappropriate marketing or promotion of products reimbursable by federal healthcare programs” or inducements offered if the purchased products are reimbursable by any federal health programs.

CMS’ draft guidance also advises plan sponsors that potentially fraudulent schemes could be perpetrated due to the “cross-over” between Part B and Part D drugs (see Ch. 7.2).

Examples of potential fraud schemes involving cross-over products include:

- Home infusion products: Home infusion pharmacies are often paid delivery and dispensing fees for certain self-injectable medications, even if the beneficiary self-administers these products. The draft guidance notes that “as home infusion pharmacies will be part of both Part B and Part D networks, these pharmacies might inappropriately submit the claim for coverage under [an] inappropriate benefit.”
- Duplicate billing: Claims could be submitted by a provider under both Part B and Part D. The guidance notes that “control mechanisms may include prior authorization processes that identify by diagnosis and other qualifying factors if a drug is covered under Part B or Part D and prevents the claim from being paid by the non-covered component.” ♦♦