Bloomberg BNA

BNA's Medicare Report™

CMS Proposes to Eliminate Protected Class Status of Antidepressants, Immunosuppressants

By Thomas A. Gustafson, PhD and Rosemary Maxwell

On January 6, 2014, the Centers for Medicare & Medicaid Services (CMS) posted a proposed rule governing the Medicare Part D and Medicare Advantage programs for calendar year 2015.[1] Comments are due by *March 7, 2014*.

The most important proposed changes relate to the six ''protected classes'' of drugs. Under CMS' proposal, the antidepressant and immunosuppressant drug classes would no longer have ''protected'' status, which now requires that all or substantially all of these products be included on the formularies of Part D plans; the antineoplastic, anticonvulsant, and antiretroviral drug classes would retain protected status, as would antipsychotic drugs at least for 2015.

CMS proposes two criteria for identifying protected classes (*both* of which a drug class would have to satisfy to be protected):

1. ''Hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled''; AND

2. ''More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.'' [2]

CMS argues that the criteria should identify ''only those drug categories or classes for which access cannot adequately be assured by the beneficiary protections that otherwise apply''[3] to drugs outside the protected classes (hence criterion two). CMS cites a number of such protections, such as its formulary requirements for non-protected drug classes, and asserts that ''additional access safeguards [that is, pro-

[1] ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (CMS-4159-P), released January 6 and available at https://federalregister.gov/a/2013-31497.

Thomas Gustafson, PhD, is an advisor in Arnold & Porter LLP's FDA and Healthcare practice group, concentrating on Medicare reimbursement and related issues and on health policy generally. He can be reached at Thomas.Gustafson@aporter.com or (202) 942-6570. Rosemary Maxwell is Counsel in Arnold & Porter LLP's FDA and Healthcare practice group, focusing on healthcare compliance and public policy issues, Medicare and Medicaid coverage and reimbursement (including the Medicare Part D prescription drug benefit), and related regulatory issues affecting pharmaceutical and medical device manufacturers. She can be reached at Rosemary.Maxwell@aporter.com or (202) 942-6040.

[2] 79 Fed, Reg. 1918, 1942 (Jan. 10, 2014).
[3] 79 Fed. Reg. at 1938.

tected classes] are needed only in those situations where a Part D beneficiary's clinical needs cannot be more efficiently met.''[4]

CMS convened an internal clinical panel (composed of the Chief Medical Officer in CMS' Center for Medicare, and CMS pharmacists) to determine which drug classes met both of these criteria. The panel concluded that antineoplastic, anticonvulsant, and antiretroviral drugs met the criteria while the other three categories did not. The panel also evaluated drug classes that are not currently protected, but found none that met the new proposed criteria.

CMS' panel concluded that antiretroviral, antineoplastic, and anticonvulsant classes met both criteria. The panel found these classes met the second criterion because the different drugs within the classes ''are used in so many patient-, drug-, or disease-specific clinical applications that an alternative formulary requirement is not feasible.''[5] Accordingly, CMS proposes to continue the protected status of these classes.

The CMS panel concluded that immunosuppressants met the first proposed criterion but not the second. ''Because widely accepted treatment guidelines recommend sub-classes of [immunosuppressant] drugs rather than specific, individual drugs, the panel did not believe that every drug product should be required for inclusion on Part D sponsors' formularies,'' CMS explained; in addition, ''relative to the reasonably small number of transplant options available to beneficiaries (for example, stem cell, liver, lung, kidney, pancreas, heart, and intestine), the consistency and specificity of treatment guidelines, and the amount of therapeutic monitoring required for these drugs, provide us with sufficient clinical information necessary to establish additional, specific formulary requirements without needing to continue to identify [immunosuppressants] as a drug category or class of clinical concern.''[6]

The CMS panel concluded that antidepressants failed both of the two new proposed tests (although CMS seemed to hedge on the first test, stating that the panel concluded that a 7-day delay in starting therapy ''would *generally* not put the typical individual at risk of hospitalization, incapacity, disability, or death''[7]).

In explaining why the panel felt antidepressants did not satisfy the second test, CMS quoted a statement in the American Psychiatric Association's 2010 treatment guideline that ''the effectiveness of antidepressant medications is generally comparable between classes and within classes of medications.''

CMS indicated that antipsychotics also failed to meet the proposed criteria (because the CMS panel concluded that they failed the second test); however, CMS proposed to keep protecting antipsychotics for CY 2015 (and until further rulemaking) to ''make certain we have not overlooked a need for any transitional considerations'' that might be associated with removing antipsychotics from the protected classes.

Throughout the discussion, CMS expressed concern that protected class status increases plans' drug costs (partly by reducing manufacturers' incentive to offer high rebates) and may lead to overutilization because in some instances plans are precluded from using otherwise-permitted utilization management techniques. CMS also alluded to safety concerns (especially in relation to antipsychotics) that could be mitigated by narrowing the protected classes.

Estimated Savings from the Proposal

CMS' impact statement indicates that removing antidepressants, immunosuppressants, and antipsychotics from protected class status would save Medicare about $720 million in 2015-2019 — but ''most of these savings [are] generated by the antipsychotics class'' that CMS proposes to continue protecting.

CMS does not present an estimate of the savings from the policy it actually proposes. CMS notes that it expects Part D plans' negotiating power to increase, likely leading to reduced drug costs and hence lower bids to Medicare. [8]

Proposed ''Exceptions'' to the Protected Classes Policy

CMS proposes some refinements and revisions to the existing set of ''exceptions'' to the requirement to cover all or substantially all protected class drugs. Currently some of these exceptions are in regulations (42 C.F.R. § 423.120) and most are in subregulatory guidance.

CMS proposes the following (which would only be relevant to drugs that ultimately retain protected class status in CMS' final rule):

- To retain an existing exception for drugs that are rated as therapeutically equivalent in FDA's Orange Book, and to make an amended exception described in the preamble as being ''for point-of-sale utilization management safety edits . . . based on maximum daily doses and black-box warnings . . ., potential drug interactions, or duplication of therapy.''
- To create a new exception for drugs that are ''almost always'' covered by Medicare Parts A or B.
- To create a new exception to permit prior authorization in order to determine whether a drug is being used for a medically-accepted indication (as defined in the Part D statute) or to verify that the drug is not covered under Medicare Parts A or B for the patient.
- To create a new exception for compounded products and a new exception for FDA-approved fixed dose combination products containing at least one protected class drug (but with a carve-out for antiretroviral products that are fixed-dose combination or co-packaged, due to the risks from nonadherence with antiretrovirals).
- To retain exceptions in current sub-regulatory guidance for certain types of Part D drugs, including multi-source brands with the identical molecu-

[4] 79 Fed. Reg. at 1941.
[5] 79 Fed. Reg. at 1944.
[6] 79 Fed. Reg. at 1945.
[7] 79 Fed. Reg. at 1945 (emphasis added).

[8] The proposed regulatory text refers to ″point-of-sale utilization management safety edits consistent with the FDA approved label.″ 79 Fed. Reg. at 2063 (proposed 42 C.F.R. § 423.120(b)(2)((vi)(F)). The existing regulatory text refers to ″utilization management processes that limit the quantity of drugs due to safety.″ 42 C.F.R. § 423.120(b)(2)(vi)(B).

  MCR ISSN 1049-7986

lar structure; extended-release products when an immediate release product is included on the plan's formulary; products with the same active ingredient or moiety; and dosage forms that do not provide a unique route of administration (*e.g.*, tablets and capsules).

CMS also requests comments on a possible regulatory exception allowing plans to impose prior authorization requirements on enrollees who are ''new starts'' on a protected class drug, consistent with a current subregulatory exception.

Even though allowing prior authorization for ''new starts'' on a protected class drug ''has been our policy since the start of the Part D program,'' CMS stated, it ''raises the potential for a delay in access to initial therapy . . . and could . . . conflict with our first proposed criterion.''[9] Therefore CMS requests comments on this issue without making a specific proposal.

[9] 79 Fed. Reg. at 1944.