



November 30, 2010

Dr. Jami Earnest
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852

Dear Dr. Earnest,

MAPRx brings together beneficiary, family caregiver and health professional organizations committed to improving access to prescription medications and safeguarding the well-being of beneficiaries with chronic diseases and disabilities who are enrolled in the Medicare prescription drug program (Part D).

MAPRx appreciates the United States Pharmacopeia's (USP) work on the Medicare Model Guidelines Version 5.0 (Model Guidelines) and is grateful for the opportunity to submit this comment letter. As noted above, MAPRx's sole concern is for patient access to needed medications under Medicare Part D, and it is from this perspective that these comments are offered.

Our specific concerns related to the newly released Model Guidelines focus broadly on the process and the resulting classification, and how they may impact patient access. Particular issues of concern include the following:

- The triennial review process that presents significant challenges and may have the unintended consequence of denying beneficiaries access to effective new treatments.
- For those drugs with multiple uses/indications, changes that eliminate multiple listings of the drug and limit placement to one category or class.
- The need for greater coordination of policy between USP and the Centers for Medicare and Medicaid Services (CMS) regarding the use of Formulary Key Drug Types (FKDT).

Three-Year Review Process

In the materials released with the Draft Model Guidelines, USP notes concerns regarding the triennial review process. USP refers to the challenge of reviewing in a

short timeframe all drugs newly approved by the Food and Drug Administration (FDA) over the past three years. MAPRx shares this concern, noting the possibility for vital new drugs to be overlooked, insufficiently considered, or inappropriately categorized.

Most importantly, MAPRx is concerned about the potential lag time between FDA approval and USP review. Following the release of the Final Model Guidelines, the next review will not take place until 2013, with the next iteration of the Guidelines going into effect for Plan Year 2015. During this time, vital new therapies may receive FDA approval but, due to the lack of USP review and inclusion on updated Model Guidelines, patients may have limited or no access to them. If a drug does not fit into an existing category or class or is a newly approved combination therapy, Part D plans and Medicare Advantage prescription drug plans may not offer coverage. This is particularly worrisome for those patients living with conditions for which there are few or no treatments. While CMS has given direction to Part D plans for how to include drugs approved in off years, we are concerned that plans may inadvertently miscategorize new drugs and, as a result, may restrict patient access to essential, innovative therapies.

Given the necessity of ensuring that patients can obtain the drugs needed to treat their condition from their Part D plans, we urge CMS and USP to consider the implications of limiting the review to a three-year cycle and implement guidelines for timely consideration of newly approved drugs.

Listing of Drugs in a Single Category or Class

Another challenge cited by USP involves consideration of drugs with multiple FDA-approved indications and the correct placement of such therapies within the USP model. In the Draft Version 5.0, drugs that were previously listed under multiple categories or classes have been limited to a single placement. This has the potential to significantly impact coverage decisions by Part D plans, ultimately affecting patients' ability to obtain prescribed treatments.

USP noted that the number of classes was expanded in the Draft Model Guidelines, although the number of categories was slightly reduced. With plans required to cover at least two drugs under each category and class, USP presented this as greatly expanding the number of drugs eligible for coverage. In addition, the guidelines include a substantial number of newly added drugs in an effort to coordinate with CMS' Formulary Reference File, as well as those newly approved by the FDA since the previous review.

However, the placement of a drug in a single category or class may have the effect of blunting the above steps toward expansion of drugs included in the Model Guidelines. Although plans have to cover at least two drugs in each category or class, limiting a drug to only one placement presents a greater chance for the drug to be left off plan formularies than when listed multiple times. If a drug is placed into a

category or class with multiple therapies, a plan will likely choose to cover some but not all of the eligible medications. If listed multiple times, a drug has a greater chance of being covered. When listed only once, however, a drug faces a greater likelihood of being overlooked or excluded by Part D plans. If this happens, patients will pay the price, both in terms of financial and health outcomes.

MAPRx, in the interest of Part D beneficiaries, asks that USP reconsider this policy of eliminating duplicate placements. At a minimum, we ask that USP make clear that this change was done to achieve simplification of the Model Guidelines but that drugs with multiple indications may fit in many categories or classes and are therefore recommended for inclusion on plan formularies.

Improved Coordination Regarding Formulary Key Drug Types

In 2008, CMS guidance changed the use of the FKDT in the CMS formulary review process to an “outlier test,” as opposed to the earlier CMS requirement that Part D plans cover at least one medication from each FKDT. According to the Prescription Drug Benefit Manual (Chapter 6), CMS still uses the FKDT as part of its review process. However, USP’s recent comments indicate that CMS has once again minimized or entirely eliminated the importance of the FKDT in formulary reviews.

MAPRx is concerned about this development because use of the FKDT as part of the outlier test ensures that plans have a formulary that is appropriately granular to meet the needs of their beneficiaries. While we praise USP for retaining the FKDT classification in the Model Guidelines, we encourage USP and CMS to clarify the real use of this component of the classification system.

The draft Model Guidelines reduce the number of FKDTs and, per USP’s statement, this review was done in light of the revised CMS policy. Several FKDTs were raised to the level of a class in the Model Guidelines Version 5.0. As a result, the plans may face additional coverage requirements due to the necessity of including two drugs per class rather than one per FKDT. This has the potential to be a positive development for patients and, as such, would be viewed in a favorable light by MAPRx.

Conclusion

Several MAPRx members, who represent a wide range of Part D beneficiaries, will be submitting separate comments specifically delineating any issues related to inclusion and/or classification of particular therapies. Although not mentioned in this comment letter, MAPRx supports its members in their efforts to raise these issues and urges USP to carefully consider any and all such comments.

Once again, MAPRx would like to express its gratitude for the work of USP and the opportunity to submit comments on the Model Guidelines Version 5.0. If there are

any questions about these comments, please do not hesitate to contact Mary Beth Buchholz, MAPRx convener, or Tim McKenna. Mary Beth can be reached at (202) 637-9732 ext 229 or by email at Marybeth@maprxinfo.org. Tim can be reached at (202) 637-9732 ext 227 or by email at tim@maprxinfo.org.

Thank you for your consideration of MAPRx's comments.

Sincerely,

Alzheimer's Association

National Health Council

American Society of Consultant
Pharmacists

National Kidney Foundation

Arthritis Foundation

National Organization for Rare
Disorders (NORD)

Center for Medicare Advocacy, Inc.

National Osteoporosis Foundation

Easter Seals

National Spinal Cord Injury
Association

Epilepsy Foundation

RetireSafe

Mental Health America

The AIDS Institute

National Alliance for Caregiving

The ALS Association

National Alliance on Mental Illness
(NAMI)

The Lupus Foundation of America

National Council for Community
Behavioral Healthcare

The National Psoriasis Foundation

National Grange of the Order of
Patrons of Husbandry

United Spinal Association