



September 17, 2004

United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852-1790

Attention: Lynn Lang

Comments to the Draft Model Medicare Guidelines

Ladies and Gentlemen:

I am pleased today to submit the following written comments on behalf of the National Alliance for the Mentally Ill (NAMI) on the U.S. Pharmacopeia Draft Model Guidelines on the Medicare Modernization Act (MMA).

Who is NAMI?

NAMI is the nation's largest organization representing individuals with mental illnesses and their families. With 210,000 members and 1,200 affiliates in all 50 states, NAMI is engaged in education, advocacy and support on behalf of people living with mental illness across the life spectrum. Illnesses such as schizophrenia, bipolar disorder, major depression and severe anxiety disorders are associated with enormous disease burden on our nation in terms of medical treatment costs, disability and lost productivity. These major mental illnesses are also an enormous share of the burden within programs such as Social Security and Medicare, both in terms of treatment cost and income support payments.

As a result, the Medicare Modernization Act (MMA) is an enormous priority for NAMI. NAMI's consumer and family membership was extremely pleased when Congress enacted this important legislation in 2003. For years, NAMI grew frustrated as partisan bickering resulted in lack of an outpatient prescription drug benefit in the Medicare program. Since January, NAMI has been working hard to ensure that the new drug benefit meets the special needs of vulnerable Medicare beneficiaries living with mental illnesses. This is especially the case with low-income beneficiaries with severe disabilities who are dually eligible for both Medicare and Medicaid. This includes both frail elderly beneficiaries and non-elderly people with disabilities who qualify for Medicare through eligibility for SSDI. In both cases, NAMI feels strongly special accommodations need to be made to ensure that they made a smooth transition to the new Part D program.

USP Model Guidelines are Critical for Ensuring Access to Treatment for all Medicare Beneficiaries

NAMI believes that the USP Medicare Model Guidelines Project is a critically important step in the implementation of the MMA. As you know, adoption of the Model Guidelines by Part D plans will grant a “safe harbor” and deemed approval from the Centers for Medicare and Medicaid Services (CMS) with respect to the range of therapeutic classes they offer coverage for. This is important for several reasons. First, since the law requires coverage of two medications within each therapeutic class, the range of classes becomes a critical benchmark for range of drugs that enrollees and their doctors will have access to.

More importantly, the “safe harbor,” and deemed approval from CMS, will allow plans that adopt the USP guidelines to avoid scrutiny from CMS on a very important issue – is the breadth of coverage offered by the plan sufficient to meet the non-discrimination standard set forth by Congress in the MMA. This important standard allows CMS to disapprove (or later sanction) plans that use formularies or benefit design to discourage enrollment of certain beneficiaries, i.e. Medicare beneficiaries with severe disabilities or chronic illnesses who have higher treatment costs. NAMI’s concern is that adoption of the USP guidelines should in no way allow a plan to use an abbreviated list of therapeutic classes to discourage enrollment of beneficiaries with chronic illnesses. Doing so would, in NAMI’s view, allow the USP guidelines to, in effect, trump the very strong non-discrimination standard set forth by Congress in the MMA.

In NAMI’s view the relatively short list of therapeutic categories raises significant concerns about the ability of Part D plans to pick two older medications within a number of the broad classifications. NAMI’s overriding concern is that this would allow plans to avoid covering newer more effective medications with superior side effect profiles and a stronger support among treating physicians. If CMS were to adopt this recommended draft, millions of Medicare beneficiaries would likely find their treatment disrupted in January 2006 when the new Part D program goes into effect. The impact would be enormous, not only on the well-being of elderly and disabled beneficiaries, but also on the Medicare program as a whole as costs are shifted to other parts of the Medicare program, particularly inpatient care as patient care is disrupted.

This is of particular concern to beneficiaries living with mental illness and their families. Medicare beneficiaries with severe mental illness are particularly vulnerable, because most have important disease-related cognitive impairments as well as limited social and financial support. Anti-psychotics, anti-depressants, and bipolar medications are critically important in controlling acute episodes and preventing recurrence. In accordance with multiple studies, NAMI strongly supports open, unrestricted access to medications to treat mental illness to maximize both quality health outcomes for individual patients, as well as to provide the most cost-effective total healthcare strategy.

In drafting the MMA, the House-Senate Conference Committee was explicit in their expectation of pharmaceutical coverage for patients with mental illness:

“It is the intent of the Conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness and neurological diseases resulting in severe epileptic episodes under the new provisions of Part D. To fulfill this purpose the Administrator of the Center for Medicare Choices shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriated access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention deficit disorder/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes.” H.Rpt. 108-39, p 769

NAMI’s Concerns with the USP Draft Model Guidelines

NAMI has particular concerns about how the draft Model Guidelines deal with several therapeutic categories most relevant to psychiatric illnesses. This is a matter discussed in greater detail below. Before discussing those specific concerns, I would like to cover a few issues relevant across the entire Model Guidelines, as well as a few issues related to the process by which the USP Expert Committee developed this draft.

1. NAMI recommends that the preamble to the Model Guidelines be expanded and clarified to ensure that they are not used by Medicare Part D plans in the future to restrict access to new medications within a given classification or new classes of medications developed in the future.

Specifically, NAMI recommends that the USP add the following requirements and qualifications on the use of the Model Guidelines to ensure that:

- all recommended subdivisions in the draft Guidelines be required classes with at least two drugs per class,
- physicians should be able to prescribe any available drug regardless of diagnosis or category,
- a requirement for a timely review process and framework for the introduction of new drugs and new classes should be included,
- disease category listings should be expanded to include all diseases in the population of elderly and disabled Medicare beneficiaries, and
- the draft classification system should be expanded to accommodate for combination products.

2. NAMI is pleased that the draft Guidelines include a distinct class for atypical antipsychotic medications

NAMI would like to express appreciation and support for inclusion of a specific therapeutic class for “non-phenothiazines/atypical antipsychotics,” class number 56 in the draft. Equally as important, NAMI is grateful that there are separate classes for “phenothiazines” (#54) and “non-phenothiazines” (#55). NAMI is very encouraged that inclusion of these separate distinct classes in the final USP guidelines will be an enormous step forward in protecting access to the newer and more effective class of

atypical antipsychotic medications to treat schizophrenia and other psychotic disorders. In NAMI's view, there is overwhelming scientific evidence demonstrating that atypical antipsychotics are superior in treating this complicated illness, in terms of both the positive and negative symptoms associated with schizophrenia and side effect profiles that have such a profound impact on treatment adherence. **NAMI strongly urges that these separate and distinct classifications be retained in the final version of the Model Guidelines.**

3. The grouping of a single classification for "bipolar agents" (category number 76) is likely to create enormous confusion

Classification number 76 contains a single listing for "bipolar agents" without specifying whether or not this includes the broad array of treatments for the serious and complicated illness of manic-depression, also known as bipolar disorder. While there are a few medications that have received FDA approval for treatment of core symptoms of bipolar disorder, there is no single medication that has proven successful in treating the varied and complicated symptoms of this illness.

Typically, individuals with bipolar disorder are taking a range of medications that often include an anticonvulsant, an anti-depressant and an anti-anxiety drug to manage the mood swings associated with episodes of mania, depression and (in some cases) mixed states. Further, most of these treatments are "off-label." However, despite the fact that they are not generally FDA approved, it does not mean that there is not a substantial amount of scientific evidence (and clinical experience) demonstrating their efficacy. To limit their use as part of the new Medicare drug benefit would be disastrous for beneficiaries living with this serious illness.

The absence of recommended subdivisions in the draft Guidelines would likely create enormous confusion among Part D plans and beneficiaries alike. Does this classification include agents from other classes when prescribed to treat bipolar disorder, i.e. anticonvulsants, antidepressants and antipsychotics? Is this category open-ended and able to accommodate medications that may in the future receive FDA approval? NAMI urges the Expert Committee to further develop this category and consult with experienced researchers to ensure that this category is further refined to create greater clarity.

4. NAMI is strongly opposed to the USP's decision to collapse four separate therapeutic categories of antidepressants into a single therapeutic classification – identified in the draft Guidelines as "Antidepressants – Reuptake Inhibitors"

NAMI believes that the decision to combine such a vast array treatments for depression is a serious mistake that will have enormous negative consequences for elderly and disabled Medicare beneficiaries who experience symptoms of depression – both as a distinct illness, and as a co-morbid condition with other serious health conditions such as heart disease and stroke.

NAMI's principal concern with this USP draft is that Selective Serotonin Reuptake Inhibitors (SSRIs) and Selective Norepinephrine Reuptake Inhibitors (SNRIs) are collapsed into a single category with the older tricyclic medications that are now widely recognized as outdated and antiquated treatment options. Because of the way in which Medicare Part D plans can use the USP guidelines to restrict access – as a “safe harbor” from CMS scrutiny – it is reasonable to assume that many plans will choose to offer two older tricyclic medications as the only treatment option for depression for their plan enrollees.

In NAMI's view, there is a mountain of evidence demonstrating why SSRIs as a class are a superior therapeutic option when measured against the older tricyclics. In preparing these comments, the NAMI staff conferred with NAMI's Medical Director Ken Duckworth, MD, Assistant Professor of Psychiatry at Harvard Medical School and formerly Medical Director of the Department of Mental Health for the Commonwealth of Massachusetts. Dr. Duckworth offered the following points in urging the USP to reject this overly broad and discriminatory classification for antidepressant medications.

- SSRIs have a superior safety profile in terms of overdose – Individuals with depression are often more suicidal and use of medications as a method of suicide is well documented. Overdose is significantly more lethal when older tricyclics are involved.
- SSRIs are much more likely to be taken correctly over the prescribed course of treatment given their superior side effect profile – adherence is critical in achieving desired clinical outcomes.
- SSRIs do not have the complex interactions with cardiac rhythms that the older tricyclics do and as a result are the first choice in patients who have cardiac conduction concerns or a recent heart attack. As cardiovascular disease is the number one killer in America and the condition disproportionately impacts the elderly, to restrict use of SSRIs is potentially dangerous to this population.
- SSRIs and tricyclics are not interchangeable – they differ in molecular structure, affinities to neurotransmitter receptors and pharmaceutical mechanics and action,
- SSRIs and tricyclics do not offer the same symptom relief – they differ in terms of neurotransmitter targets. SSRIs target serotonin, while others target other neurotransmitters. Further, different patients may respond preferentially to antidepressants acting norepinephrine, serotonin or other neurotransmitters. Symptoms of depression in some patients may be relieved by serotonin (e.g. impulsivity, aggression, etc.) or norepinephrine (e.g. difficulty in concentration). Both serotonin and norepinephrine are believed to mediate common symptoms of depression such as sadness and physical pain.

Dr. Duckworth further noted that the older tricyclics have fallen out of favor as a treatment for depression, precisely because their risk/benefit ratio is simply not as good as the SSRIs. NAMI shares his view that to exclude a class of medications with better safety profile is dangerous and will be disastrous for Medicare beneficiaries experiencing the devastating symptoms of depression.

The reality is that physicians must weigh many factors in prescribing anti-depressants including the individual patient's current symptoms, past treatment history, likelihood of side effects, likely response to side effects, other medications currently being taken, any co-morbid illnesses and risk of overdose. This process is complex and requires that the full array of anti-depressants be available for beneficiaries under the new Medicare drug benefit. **NAMI therefore strongly urges the USP to reject this shortsighted definition and segregate SSRIs as a distinct therapeutic category in the final version of the Model Guidelines. It is critically important that Medicare beneficiaries have access to the full array of treatments for depression.**

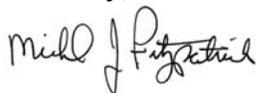
5. NAMI is very concerned about the proposal to establish a single class for all anti-convulsants.

A broad range of anti-convulsants have proven effective as off-label treatments for bipolar disorder, also known as manic depression. As noted above, bipolar disorder is a complex illness that involves a high degree of second line and off-label treatment from other therapeutic classifications, including anti-convulsants which are commonly prescribed as mood stabilizers. The Draft Guidelines establish only a single class for all anti-convulsants (category number 14), of which there are over twenty. In doing so, the Draft Guidelines would encourage Medicare drug plans offering the drug benefit to cover only the older, less efficacious medications.

In NAMI's view, these older drugs are more dangerous and cannot be used when consumers have certain medical conditions. Further, it is likely that nearly all of the anti-convulsants that are prescribed as mood stabilizers, and all of the drugs approved after 1978, would fall under a classification of "other anticonvulsants." At a minimum, USP should create additional classes based on mechanisms of action for the anti-convulsants beyond the current recommended subdivisions. Anti-convulsants are not interchangeable and physicians need to have access to the broad array of medications in order to choose what medication will work best for the individual patient.

Thank you for the opportunity to offer NAMI's views on the USP Draft Model Guidelines for the Medicare drug benefit.

Sincerely,



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