New York State Psychiatric Association, Inc.

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REPORT OF THE TASK FORCE ON PREFERRED DRUG PROGRAMS

The Task Force was charged by the NYSPA Council to review the feasibility of including psychiatric medications in the New York State Medicaid Preferred Drug Program and to identify the necessary procedural safeguards to protect patients' access to medically necessary medication if it is determined that such drugs should be included.

A Preferred Drug Program (PDP) is a program established by private insurers and government health programs (typically, Medicaid) to permit a state to secure significant reductions in expenditures for medications by limiting medication coverage to one or two medications in a therapeutic class. States use their buying power, enhanced bargaining position and the offer of PDP exclusivity to extract substantial financial concessions from drug manufacturers. In turn, a PDP will typically employ various procedures to compel or, at least encourage, physicians to limit their prescribing to those drugs on the PDP. Typically, PDPs require physicians to secure prior authorization to prescribe a non-PDP medication or require a patient to fail on the PDP medication before being able to secure a non-PDP drug (so called "fail first").

Most commentators and mental health advocacy groups have advocated for exclusion of psychiatric medications - especially atypical antipsychotics - from PDP restrictions. Many PDPs have included provisions excluding certain psychiatric medications - atypical antipsychotics and antidepressants - from PDP. Other PDPs have excluded certain psychiatric diagnoses - schizophrenia and major depressive disorder - from PDP restrictions. Often, these exclusions were necessitated because the PDP included "fail first" or "step therapy" requirements - requirements that patients fail on a PDP medication before being able to secure a non-PDP medication. "Fail first" is clinically inappropriate for psychiatric medications because clinical data indicate that psychiatric medications are not interchangeable, i.e., each psychiatric medication, even medications within the same therapeutic class, are unique and cannot be therapeutically substituted for one another. Second, there are few data demonstrating the superior efficacy of any particular psychiatric medication in certain classes of medications, e.g., atypical antipsychotics.[1] Finally, a "fail first" approach significantly increases the chances of relapse and rehospitalization of patients with chronic mental illnesses - thereby resulting in increased costs for such patients that far exceed any savings from the PDP.

FIRST TRY

The Task Force recommends an approach which it calls ***First Try***. PDP formulary restrictions should only apply to patients who are being prescribed a psychiatric medication in a given therapeutic class for the first time. ***First Try*** would also exempt patients from PDP restrictions in the following situations:

[1] NIMH is currently funding a 5 year, $47 million study entitled *Clinical Antipsychotic Trial of Intervention Effectiveness* (CATIE) to evaluate the head-to-head effectiveness of atypical antipsychotic medications based upon efficacy, side effects and outcome differences. Results from the CATIE study will likely not be available until 2006.

- Patients who are already successfully utilizing a medication in a therapeutic class will be permitted to continue on their medication regardless of whether it is on the PDP formulary.

- Patients who are not currently taking a medication if they have a prior history of a positive response to psychiatric medication not on the PDP formulary

- Patients who have a history of a negative response (poor efficacy, unacceptable side effects or adverse reactions) to a medication on the PDP formulary.

- Patients who are taking a non-psychiatric medication with which a PDP medication has an adverse drug interaction with the non-psychiatric medication the patient is already taking. In such cases, the patient's psychiatrist should be able to select a non- PDP formulary medication.

- Patients who have a ***First Try*** on PDP medication(s) and who do not respond would then be free from PDP restrictions. In essence, ***First Try*** would require limited trials on a PDP formulary medication(s).

- No restrictions should be imposed based upon off-label uses or patient diagnosis. A psychiatrist should be able to prescribe any medication on the PDP formulary (both psychiatric and non-psychiatric medications) for any mental illness or conditions as long as such treatment is consistent with generally accepted psychiatric practice.

- No restrictions should be imposed on the prescription of multiple medications consistent with generally accepted psychiatric practice.

- The PDP must include a provision for bypassing the PDP formulary in a medical emergency if necessary to secure medication on a short-term basis.

EASY PASS

Essential to the ***First Try*** approach is a simple system for psychiatrists to bypass the PDP under the eight ***First Try*** exclusions listed above. The PDP must not include a prior authorization system that impedes access to clinically appropriate medication. APA calls this approach an ***Easy Pass***. There should not be any elaborate or complicated procedures to bypass the ***First Try*** requirements when permitted. One approach would be to permit psychiatrists to check off the basis for bypassing the PDP formulary on the prescription form that is submitted to the pharmacy.

Finally, a PDP must always include a mechanism to permit a psychiatrist to secure prior authorization in those cases not otherwise covered by the ***First Try*** exceptions. While the Task Force believes that the exceptions listed above should address most clinical situations, there must be a mechanism to permit a treating psychiatrist to prescribe any medication consistent with generally accepted psychiatric practice as deemed necessary and without regard to the PDP formulary based upon the patient's individual clinical circumstances.

THERAPEUTIC CLASSES

Critical to the clinical appropriateness of a PDP for psychiatric medication is the identification of the appropriate therapeutic classes and subclasses of psychiatric medications. In each therapeutic class and subclass, the Task Force recommends that a PDP include at least two medications. In addition, the Task Force recommends that certain specific medications be included in addition to the two designated medications. In these cases, the Task Force has concluded that because of the unique properties of a specific medication, inclusion in the PDP is clinically mandated. Of course, these classifications, the drugs placed on the formulary, and the mandatory drugs must all be subject to regular review, reconsideration and revision if necessary based upon clinical data and findings regarding efficacy, side effects, adverse reactions and possible drug interactions (e.g. CATIE study) and the availability and uses of new medications. Based upon current generally accepted psychiatric practice, the Task Force recommends the following classes, subclasses and clinically mandated medications:

Antipsychotics
- 1st Generation (Typical)
- 2nd Generation (Atypical)
- Clozapine (mandatory inclusion)

Antidepressants
- MAO Inhibitors
- Tricyclics
- SSRIs
- Effexor (venlafaxine) or Cymbalta (duloxetine) (at least one must be a mandatory inclusion)
- Remeron (mirtazapine)(mandatory inclusion)
- Bupropion SR or XL (mandatory inclusion)

Bipolar Disorder Medications
- Lithium (mandatory inclusion)
- Anticonvulsants

Dementia Medications
- Cholinesterase inhibitors
- Namenda (memantine) (mandatory inclusion)

ADHD Medications
- Stimulants, regular and long acting
- Strattera (mandatory inclusion)
- Beta blockers
- Alpha 2 adrenergic agonists

Anxiolytics
- Long acting benzodiazapines
- Short acting benzodiazapines
- Buspar (mandatory inclusion)

Hypnotics
- Benzodiazapine agents
- Non-benzodiazapine non-barbiturate agents

THE NEW YORK STATE MEDICAID PREFERRED DRUG PROGRAM

New York State has adopted a PDP for its Medicaid program and other public health plans that include coverage for medications. The program includes many of the protections recommended by the Task Force. The prior authorization process for non-formulary drugs recognizes an exception where the preferred drug has been tried and failed, the patient has tried the preferred drug and has experienced unacceptable side effects, and the patient has been stabilized on a non-preferred drug and transition to a preferred drug would be contraindicated. The program also permits the use of non-preferred drugs based upon consideration of medical needs of special populations including patients with mental illness. Finally, the state PDP provides that, if a patient does not meet any of the above exceptions, a treating physician may, after providing additional information regarding the need for a non-preferred drug, override the PDP formulary restrictions and the non-preferred drug must be approved. In additional to the patient protections above, no prior authorization is required for atypical antipsychotics or antidepressants as a therapeutic class or subclass.

RECOMMENDATIONS

The Task Force concluded that it would be feasible to include psychiatric medications including atypical antipsychotics and antidepressants in a PDP provided that the plan included the protections recommended by the Task Force: a ***First Try*** approach with the eight listed exceptions, an ***Easy Pass*** for bypassing the PDP formulary, a treating psychiatrist exception to permit patients to secure any medication based upon their individual clinical circumstances, at least two medications included in the PDP formulary in each therapeutic class and subclass, and inclusion of mandatory medications. The Task Force concluded that with these protections, psychiatric medications in all classes and subclasses could be included in a Preferred Drug Plan. Because the NYS Medicaid PDP includes substantially all the patient protections recommended by the Task Force, with additional statutory changes to meet the Task Force recommendations regarding minimum number of preferred medications in every class or subclass of psychiatric medications, atypical antipsychotics and antidepressants could be included in the Medicaid PDP.

Respectfully submitted,

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