

Psychotropic Medications: Addressing Costs without Restricting Access

The current economic downturn has brought with it falling State revenues and increases in Medicaid enrollments. Coupled with increasing costs for prescription pharmaceuticals, this has induced State actions to contain Medicaid drug costs. This paper describes the current budget shortfalls in the States especially with regard to medication costs, the efficacy and costs of newer psychotropic medications, and innovative medication practices adopted by States in response to budget shortfalls. These practices represent efforts to address medication cost and quality of care issues within Medicaid without restricting access to specific medications.

I. Budget Shortfalls and Medication Costs

During the 1990s, the Medicaid program benefited from the nation's economic prosperity. After a decade of growth, however, the Federal and State governments are now dealing with an economic downturn and States are facing falling revenues. In this fiscal environment, States are examining ways in which Medicaid spending increases can be reduced.

For FY 2002, States reported the costs of prescription drugs as the most significant factor contributing to higher total Medicaid spending. States reported that increasing pharmacy costs resulted from increased utilization, new and more expensive medications, price inflation for existing products, and pharmacy driven capitation rate increases for managed care organizations.¹

Because medications in general and psychotropic medications in particular were driving up Medicaid spending, a total of 24 States reported in 2002 that they had or planned in FY 2003 to take action to reduce the costs of prescription drugs.² To manage the demand for and cost of prescription drugs, States have used a variety of techniques, including mandating the use of generics, limiting the number of prescriptions that may be filled in a single month, imposing beneficiary co-payments, requiring prior authorization, and using fail-first policies (see Glossary).

II. Efficacy and Costs of Newer Psychotropic Medications

The recent development of new psychotropic medications has resulted in changes in the patterns of prescribing for individuals with mental illness. In the 1980s, selective serotonin reuptake inhibitors (SSRIs) such as Fluoxetine (Prozac) and Paroxetine (Paxil) replaced tricyclic medications such as amitriptyline and imipramine for depression.³ More recently, a new generation of antipsychotic medications has come to the fore in the treatment of schizophrenia and other psychoses. These medications, including risperidone and olanzapine, are replacing the more traditional agents.⁴ From a therapeutic perspective, these developments have been welcomed because studies have demonstrated that the medications are at least as effective as the older ones.⁵ In addition, it has been postulated that the reduction in side effects associated with these drugs would result in increased compliance with medications and improved outcomes.⁶

However, while the new medications are more efficacious (i.e., they reduce symptoms and have fewer side effects), they also are much more costly. As a result, third party payers have closely

scrutinized the unit cost of these newer medications. Cost and demand management techniques, such as prior authorization and targeted utilization review, are often implemented first. However, they can limit access to the most effective treatment for a specific individual, and have a negative effect on quality. Therefore, it is important to consider innovative alternatives that have the potential to both contain costs and improve the quality of care and outcomes.

III. Innovative Approaches

In 2001, the National Association of State Medicaid Directors (NASMD) and the National Association of State Mental Health Directors (NASMHPD) met and produced a joint report on psychiatric medications.⁷ The report concluded that restrictive measures alone were unsuccessful, and pointed to the need to manage costs in the context of appropriate usage. It also recommended that agencies develop programs to improve provider compliance with medication use guidelines, and identify educational mechanisms for providers and consumers regarding appropriate medication use.

This section describes three innovative programs – a new educational intervention and outlier management program designed to align physician prescribing practices with best practice guidelines for prescribing, treatment algorithms developed for three major psychiatric disorders, and a program to identify and reduce polypharmacy.

A. The Pennsylvania and Missouri Approach

A large Medicaid HMO in Pennsylvania elected to introduce an educational behavioral pharmacy and outlier management program for prescribers into its management systems. The intervention is built on two premises supported by data: (1) the most significant driver of growth in Medicaid expenditures is related to the volume of drugs that are prescribed; and (2) the most significant behavior problem to be addressed is the inappropriate use of medications. The intervention targets deviations from best practices, as well as cost-insensitive prescribing. It is designed to be an alternative to restrictive formularies and prior authorizations, which increase the risk of use of multiple prescriptions, reduced compliance, and poor outcomes.

This program identifies areas of concern and executes targeted expert interventions with the aim of influencing physician prescribing behavior. The targeted educational system provides direct interventions to assist high-volume physicians in obtaining the most current information on evidence-based practices.

The Behavioral Prescriber and Outlier Management System used as part of this intervention includes three intervention levels, and materials are continuously monitored and updated to improve quality and educational content.⁸ A basic prescription data set is used for analysis.

To provide clinically and economically meaningful data analysis, the Pharmacy Management System currently uses a health plan or State's monthly paid pharmacy claims file. The process compares 95 central nervous system medications (antipsychotics, antidepressants, sedative hypnotics and anticonvulsants) with 12 best practice prescribing behaviors. A physician prescribing profile is thus developed. Examples of best practice comparisons include therapeutic

duplications of atypical antipsychotics, cost-ineffective pill strength selection, use of two or more drugs from the same chemical class, and evidence of excessive switching of antipsychotics. This analysis tool has also produced data identifying some outlier trends in prescribing practices related to “switching”, which involves changing prescriptions from one anti-psychotic drug to another within a short timeframe. Another outlier trend is the increasing use of heavy dosages of sedatives for persons also taking atypical medications. The ability to identify emerging trends and apply educational interventions to drive prescribing practice patterns toward best practices is the major feature of this intervention.

Physician interventions are designed to be progressive in nature (there are three levels of progression), depending on size of caseload and prescribing behaviors. Level I interventions begin with prescribing practice outlier physicians receiving quality letters monthly with documentation of evidence to support best practice. The letters designed for this specific health plan are co-signed by the county health commissioner and the medical director of the health plan. These high volume outlier physicians also receive patient profile data. The letters present best practice information including an annotated bibliography, an article from a peer-reviewed journal, the Expert Consensus Guideline Series on behavioral health when applicable, and other best practice literature. Monthly reporting and on-going analysis are core features of this intervention.

Level II interventions are targeted for specific behavioral health prescribers based on the data analyses and prescribing patterns that emerge over time. These interventions include the use of Awareness/Fact sheets. Targeted prescribers receive a detailed claims data report and are requested to address the accuracy of the data and to address discontinuation/compliance issues with specified patients. A second intervention used at this level is a letter that provides detailed claims data, sorted by patient and by prescriber. The letter references clinical information relevant to a specific data issue. A final level II intervention is a benchmarking report that ranks physicians and patients against each other for type, frequency, and cost by each drug class utilized. This type of normative report has been effective in producing change in the desired direction as “outliers” make adjustments in their prescribing patterns to weigh in more toward the mean and in line with the “average” practice.

Level III interventions are customized to a specific prescriber or to a group of prescribers around a specific clinical issue. Interventions may include a targeted medical education program, peer review by the medical director for this project, or a pharmacy review of data meeting high use/high deviation criteria. All interventions are educational and consultative.

These interventions are based on the assumptions that altering physician-prescribing behaviors is critical if the desired changes are to be achieved and that the quality of prescribing practice can be significantly improved through improved education and the use of best practice treatment guidelines as opposed to more traditional control methods such as restricting formularies or prior authorization of drugs. Physicians demonstrate marked variation in their comfort level with making the recommended changes. Responses occur on a continuum from defensiveness about their practices based on real hesitations about using guidelines to acknowledgement that there is room for improvement in their prescribing practices. Others will be aware of the issues raised

and be willing to accept resources to foster improvement while another segment will pursue educational opportunities and adjust their prescribing behaviors.

On the patient side, patients with evidence of high utilization of multiple antipsychotics, extended utilization of the same, complicated or “risky” combination of medications, evidence of multiple prescribers, and repeated evidence of discontinuation may be referred for augmented case management.

Key quality and cost findings at the end of the first year of operations for the health plan include:

- Reduction in polypharmacy and associated medical risk to members,
- Reduction in multiple prescribers,
- Reduction in therapeutic duplication of atypical antipsychotics, and
- Reduction in per member/per month costs from growth trend, despite a rise in the proportion of “disabled” members in the case mix.

Missouri is the first state to adopt the BPMS for statewide Medicaid behavioral health prescribers. In March 2003, Missouri established the Missouri Mental Health Medicaid Pharmacy Partnership. The goal of the partnership is to improve the clinical quality of psychotropic medication therapies. The Missouri approach differs in its initial implementation from Pennsylvania in that Missouri has formed an Advisory Council to:

- Assist in selecting the best opportunities for improving prescribing practices,
- Assist in making the communications to physicians helpful in content and supportive in tone, and
- Assure that best practice recommendations are current and appropriate.

The Advisory Council includes broad representation from the practice community. Among its members are three representatives from in-state psychiatric societies, four medical school psychiatry clinics, a representative from the Community Mental Health Coalition and Group Practices, advocacy organizations, and from Medicaid and the Department of Mental Health. Psychiatrists are heavily represented on this advisory council. The intent is to obtain buy-in to the project, its goals, findings, and recommendations from the groups representing psychiatrists across the state. This newly launched project is using an inclusionary strategy in its effort to improve physician prescribing practices.

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B. The Texas Approach

The Texas Medication Algorithm Project (TMAP) is a collaborative effort that has led to the development of evidence-based treatment guidelines for three major psychiatric disorders – schizophrenia, major depressive disorder, and bipolar disorder. TMAP began in 1996 and involves a consortium (government and academic) including the Texas Department of Mental Health and Mental Retardation (MHMR). TMAP was designed to “develop, implement, and evaluate an algorithm-driven treatment philosophy for major adult psychiatric disorders treated

in the Texas public mental health sector.”⁹ The target population for TMAP is persons with serious and chronic mental illness who are served by public programs.

The goals of TMAP are twofold: 1) to improve the quality of care and achieve the best possible patient outcomes for the resources expended; and 2) to develop and continuously update treatment algorithms and use them to reduce the immediate and long-term emotional, physical and financial burdens of mental disorders for clients, their families, and their health care systems.¹⁰ The components of TMAP include:

- 1) Evidence-based, consensually agreed upon medication treatment algorithms,
- 2) Clinical and technical support necessary to allow clinicians to implement the algorithms,
- 3) Patient and family education programs (which describe the nature of the illness and the effects of various medications) that allow the patient to be an active partner in care, and
- 4) Uniform documentation of care provided and resulting patient outcomes.

In addition, TMAP involves 1) a prospective comparison of the clinical outcomes and economic costs of using these medication guidelines with "treatment as usual" within the Texas MHMR system, and 2) implementation of these algorithms in the "real world" of the clinics and hospitals of the Texas Department of MHMR.¹¹

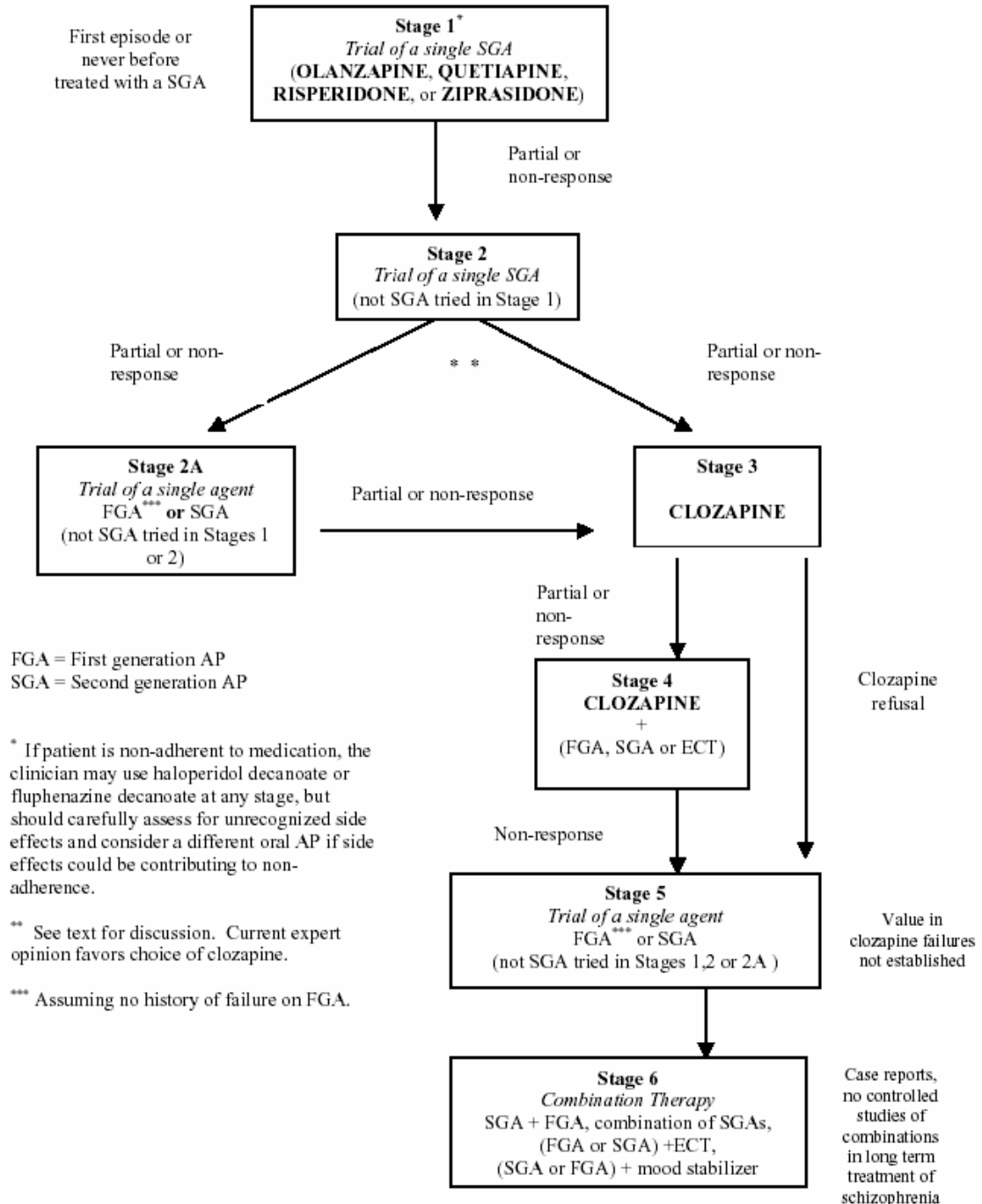
The TMAP model uses algorithms (or step-by-step procedures) in the form of flow charts to help physicians deliver quality care based on making the best choice of medications and an assessment of their effectiveness. While algorithms do not dictate clinical answers, they provide a framework that clinicians use and which should yield similar treatment approaches in similar clinical situations.¹² The algorithms provide guidance regarding treatment regimens, including issues such as choice of “initial medication(s), initial dosage, dosage changes, methods to assess response to treatment, frequency of assessment and re-evaluation, and minimum and maximum treatment periods in order to assess adequacy of therapeutic response.”¹³ The algorithms were developed by systematically obtaining input from groups of clinicians, consultants, and consumers. Each algorithm was initially tested in five sites within the Texas public mental health system. The algorithm package consists of multiple components – patient education, frequent medical visits, medication availability, and consultation. The algorithm basically provides a framework for clinical decision making, with multiple options given (if possible) at each stage so that the patient’s treatment plan can be altered to obtain optimal outcomes. There are a series of treatment steps that are determined by the patient’s clinical response to the preceding step.

As an example, for schizophrenia, there are six stages of treatment in the current version of the algorithm (see Figure on next page and details in the TIMA schizophrenia physician’s manual at <http://www.mhmr.state.tx.us/centraloffice/medicaldirector/timasczman.pdf>).¹⁴ For patients experiencing their first episode of schizophrenia or who have never before been treated with a second generation anti-psychotic (e.g., olanzapine, quetiapine, risperidone, or ziprasidone), the first stage involves use of one of four different types of these second-generation anti-psychotic medications. If the patient responds favorably to the medication, the drug is continued and moved into a maintenance phase where indicated. If the patient does not respond favorably to the drug given at stage 1, he or she moves to stage 2, where a different one of the four types of

anti-psychotic medications (from stage 1) is given. Stage 2a involves trial of a single first generation or second generation (other than the ones tried in Stages 1 and 2) anti-psychotic. In

Choice of antipsychotic (AP) should be guided by considering the clinical characteristics of the patient and the efficacy and side effect profiles of the medication

Any stage(s) can be skipped depending on the clinical picture or history of antipsychotic failures



stage 3, clozapine is used. Stage 4 involves the use of clozapine and a first generation or second generation anti-psychotic or electroconvulsive therapy (ECT). The final stage involves combination therapy – a first generation anti-psychotic and a second generation anti-psychotic, or a combination of second generation anti-psychotics, or a first generation or second generation anti-psychotic plus ECT, or a first generation or second generation anti-psychotic plus a mood stabilizer.

In terms of providing clinicians with information to help guide their decisions about which medication to use, the appropriate dose, and the duration of treatment, the TIMA Schizophrenia Physician's Manual includes information to guide decision making at critical decision points (CDPs), which are “the point in the course of the medication trial when the clinician decides whether to continue the present medication regimen, adjust the medication dose, or move on to another medication.” At each CDP, clinicians evaluate the patient's level of response to the antipsychotic. As an example, for schizophrenia, clinicians initially choose between one of the second-generation antipsychotics, a therapeutic dose of the drug is determined during the first week, and then the patient is seen for each of the next four weeks to evaluate drug tolerability and the need for dosage adjustments, as well as to monitor for symptom improvement or deterioration, side effects, etc. The clinician then determines if the patient has improved adequately (i.e., an improvement in symptoms), such that the dosage can be maintained; otherwise, adjustments to dosage or movement to the next stage of the algorithm are recommended. Subsequent CDPs occur at 8 and 12 weeks. If a patient has not achieved positive symptom reduction goals as specified in the user's manual by 12 weeks, it is recommended that treatment move to the next stage of the algorithm. Separate CDPs are specified for the use of clozapine. The Physician's Manual also includes information on average doses for each drug, with recommended adjustments (e.g., average daily dose of risperidone is 4-5 mg/day, which is adjusted in 1-2 mg increments every 3-7 days).

One of the main areas of focus in the TMAP program is to ensure that people with any of the three disorders are receiving the clinically appropriate and most effective medications for their disorders. TMAP tries to provide ongoing information about the research on medications, as well as how to measure their effectiveness. Key recommendations include:

- Multiple same therapeutic-class medications should *only* be a last resort, and
- When working to find an appropriate medication, make sure that the person receives an appropriate dose and tests the medication for an adequate time period.¹⁵

Evaluations of TMAP have shown that it is more effective than standard treatment for the three major psychiatric disorders addressed by the treatment algorithms.¹⁶ Positive clinical outcomes include 1) a faster response to treatment than for persons not in the program, 2) a greater improvement in cognition, and 3) positive clinical outcomes being maintained more effectively over time.

There are specific outcomes measures for the each of the three diagnoses. For schizophrenia, TMAP has resulted in a higher level of cognitive functioning and a more rapid reduction in the positive symptoms of the disorder.¹⁷ Cognitive functioning is viewed as a critical feature in reducing both positive symptoms (e.g., suspiciousness, unusual thought content, hallucinations)

and negative symptoms (e.g., prolonged time to respond, reduced social drive, poor grooming and hygiene) of the disorder.¹⁸

For bipolar disorder, manic symptoms for individuals in TMAP decreased more significantly than for those not in TMAP, and the difference in symptoms was maintained over time.¹⁹ For individuals with major depression, both groups improved with treatment, but individuals in TMAP had a markedly better response, which was maintained over time.²⁰

The TMAP team is analyzing the effects on service use and health care costs with results to be submitted for publication during 2004. Based on its success in Texas, the TMAP approach has been adopted to varying degrees by health organizations in 11 other states plus the District of Columbia.²¹

TMAP has also developed medication algorithms for two common children's mental disorders: attention deficit hyperactivity disorder (ADHD)²² and childhood depression. Successful feasibility testing has been completed with both of these, and the algorithms are currently under revision. Implementation of these algorithms in the Texas public mental health system will occur during 2005. Algorithms for the treatment of substance use disorders co-occurring with major depression, bipolar disorder, and schizophrenia are in the final stages of development.

From TMAP's experience to date, there are several key components of the program: 1) all medications in the algorithm must be available in the formulary and all formulary decisions must be based on overall effectiveness of treatment, not just drug cost; 2) it is vital to allow enough time for medications to work and consumer visits with clinicians should be as frequent as clinically necessary; 3) consumers and families must be educated and work in partnership with physicians to choose the medications used; and 4) when clinicians reach a decision point on the algorithm, such as whether to change medication or increase dosage, the best guide to making that decision is to rate the patient's actual symptoms.

C. The Massachusetts Approach

Polypharmacy is defined as the "use of two or more medications to treat the same condition, use of two or more drugs of the same chemical class, or use of two or more drugs with the same or similar pharmacologic action to treat different conditions."²³ There are both cost and quality of care issues related to the use of multiple prescription drugs, particularly multiple drugs within the same therapeutic class. Quality of care can be compromised by potential drug interactions, both through increased side effects and decreased efficacy of one or more drugs.²⁴ Further, multiple prescriptions within the same therapeutic class rarely represent best practices.

The state of Massachusetts has a clinical work group to address polypharmacy, including psychopharmacologists, members of the Massachusetts Psychiatric Society, and representatives of the Department of Mental Health, the Division of Medical Assistance, the state Pharmacy Program, and the Alliance for the Mentally Ill. The workgroup's analysis of Massachusetts Medicaid drug data showed that "more than 2,200 adults received more than one atypical antipsychotic at a time for more than 60 days, at a cost of \$24 million; that almost 5,000 Medicaid recipients were taking more than one selective serotonin reuptake inhibitor for more

than 60 days, at a cost of more than \$4.5 million; and that more than 1,100 MassHealth recipients were receiving five or more psychiatric medications in January 2002, often from multiple prescribers.”²⁵ In response to these findings, the Massachusetts Medicaid program has begun to educate prescribers about the costs of various prescribing patterns as well as the threat escalating prescription drug costs pose to enrollee access to these drugs. While acknowledging that polypharmacy is essential for some patients, the Medicaid program also has identified the physicians who are outliers (i.e., those who routinely use polypharmacy approaches) and will work to educate them about their “prescribing practices and the evidence base as it relates to the type of patients they treat.”²⁶

While the overall costs associated with polypharmacy are unknown, one pharmacy benefits manager, Prescription Solutions, reported that unneeded prescriptions can cost up to \$50 billion annually. An estimate of savings in psychiatric drug costs for the state of Massachusetts, by implementing the program described above, is \$10 million. This projected savings represents about 2% of the state’s current spending on psychiatric drugs.²⁷

Glossary

Dispensing or Prescribing Limits - Restrictions on the number of prescriptions per month, or the amount of medication that may be prescribed in a given time frame (e.g., a 90-day limit at each pharmacy).

Drug Formulary - A list of medications that consumers may readily access through their health plans. Non-formulary medications may not be accessible or may be accessible only if prior authorization is obtained.

Drug Utilization Review (DUR) - Efforts to control drug utilization and costs by a facility or a health plan. Common methods include the use of a formulary (see above), substitution of generic products for more expensive name brands and encouraging use of drugs that will trigger rebates or discounts.

Fail-First Policies – Requirement that as a prerequisite for authorization of a specific, often non-formulary medication, the patient fail on at least one other medication (often involves multiple tries).

Generic Substitution – The practice of substituting a cheaper, generic medication for a brand-name medication. This can be mandated by the state to occur at the point of sale or can occur at consumer request.

Pharmacy and Therapeutics Committee (P&T Committee) – A committee, usually made up of physicians, pharmacists, and other medical staff, that develops the list of medications that are on the prescription drug formulary and/or require prior approval.

Pharmaceutical Benefits Manager (PBM) - An entity that is responsible for managing prescription benefits.

Prior Authorization/Approval - A cost-control procedure in which a payer requires a service to be approved for coverage in advance of delivery.

Reference-based formulary – Identifies categories of drugs that are similar in effectiveness, but with a range of cost. The most cost-effective drug would become the reference drug and set the maximum price paid by the State for that category.

Therapeutic Class Substitution – A different medication from the same therapeutic class is substituted. Often a formulary will list one or two medications from each therapeutic class, rather than allowing access to a full array of medications.

Tiered Co-payment Structure – Different co-payments are set for brand and generic medications.

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 - ⁸ Comprehensive NeuroScience, Inc. White Plains, NY. Patent pending. 2002.
 - ⁹ <http://www.mhmr.state.tx.us/centraloffice/medicalsector/TMAPover.html>
 - ¹⁰ Ibid.
 - ¹¹ Ibid.
 - ¹² TIMA Schizophrenia Physician’s Manual, p. 6, January 8, 2003.
 - ¹³ Ibid.
 - ¹⁴ Two other widely reference treatment guidelines for schizophrenia are available at www.psychguides.com/gl-treatment_of_schizophrenia_1999.html and www.psych.org/clin_res/pg_schizo.cfm
 - ¹⁵ Many physicians and patients, in an effort to find an effective medication right away, do not wait long enough to determine if a medication is effective. Research is now finding that it often takes up to four months to see the full impact of certain antidepressants. TMAP is now recommending staying with one type of medication and treating symptoms with other medications for that test period.
 - ¹⁶ Personal communication with Steven Shon, March 2003.
 - ¹⁷ TIMA Schizophrenia Physician’s Manual, p. 2, January 8, 2003.
 - ¹⁸ TMAP. NorthSTAR Implementation Planning Team Presentation (12-13-2002).
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