2001 COLORADO BEST PRACTICE WORK GROUP

ATYPICAL ANTIPSYCHOTIC MEDICATIONS

REPORT AND GUIDELINES

January 31, 2002

Executive Summary/Introduction

In 2000, Colorado's Health Care Policy and Finance (HCPF) and Mental Health Services (MHS) jointly developed best practice guidelines for atypical antipsychotic medications. Since then, new scientific findings have been reported, new products and indications have been approved, and medication costs have continued to rise in all sectors of the health care system. Scientific studies and evolving clinical practices continue to demonstrate the outstanding efficacy and tolerability of atypical antipsychotic medications in the treatment of many serious mental disorders, leading to expanded use. The Colorado Best Practice Work Group on Atypical Antipsychotic Medications was re-convened in February 2001 to update Colorado's guidelines regarding the appropriate and cost-effective use of these medications.

The work group included HCPF and MHS representatives, medical directors of mental health centers and Mental Health Assessment and Service Agencies (MHASA's), Medicaid health maintenance organization representatives, pharmacists, consumers, and advocates. [1] The goals included updating Colorado's previous (2000) guidelines and developing recommendations for the Medicaid Pharmacy Program regarding clozapine. In addition, the 2001 work group attempted to address the use of atypical antipsychotic medications in a growing range of conditions beyond the major psychotic mental disorders.

The term "best practice," as used by the work group, refers to a process or treatment guideline that promotes improvements in care. The group's charge was to focus on one specific aspect of care, the use of atypical antipsychotic medications. The group made use of scientific studies, existing guidelines and algorithms, local experts, prevailing community practices, and input from consumers, advocates, and stakeholders. The 2001 guidelines outline the conditions that are appropriately treated with atypical antipsychotic medications, dose ranges, and strategies to maximize cost effectiveness. The guidelines are general recommendations and are not intended to be final program directives, end-user educational materials, or a substitute for individualized clinical judgement. Implementation requires interpretation and adaptation based on the setting in which they are being used and the development of specific protocols and educational processes involving providers, consumers, and family members within that system.

[1] See Appendix I.

I. Background Information

The group surveyed Colorado's **values and ethics** regarding medications in the treatment of mental disorders, summarized below:

- Consumers, including Medicaid consumers, should have access to technological advances for the treatment of mental disorders on parity with other medical disorders.
- Consumer choice is related to medication receptivity and enhanced outcome.
- Informed consent is an important aspect of medication treatment, and includes educating consumers about available treatment options, potential benefits, and risks.
- Clinical practice should be based on scientific evidence, expert consensus guidelines, and prevailing community standards.
- Colorado's public mental health system is committed to using all medications appropriately and responsibly.
- Consumers' quality of life should be considered in medication treatment decisions.
- The cost-effectiveness of medications should take into account not only medication acquisition costs but also the total costs of care and the personal and social burden of mental disorders.
- Inadequate medication regimens/response can result in hospitalizations, out-of-home placements, institutionalization, and in some cases, suicide. Ethical considerations should promote the use of interventions, such as atypical antipsychotic medications, that are associated with decreasing these outcomes.

The **scientific basis** for the use of atypical antipsychotic medications has grown since the 2000 guidelines were developed, as follows:

- The biologic basis of serious mental disorders is well established.
- Medications are essential in the treatment of most serious mental disorders.
- Atypical antipsychotic medications are superior to conventional antipsychotic medications in the treatment of schizophrenia, mood disorders with psychosis, and some other serious, disabling mental disorders.
- Conventional antipsychotic medications carry a high risk of tardive dyskinesia, a serious, disabling, and permanent movement disorder resembling Huntington's chorea. This risk is greatly reduced with atypical antipsychotic medications.
- Atypical antipsychotic medications have been shown in research studies to significantly decrease the risk of suicide in persons with certain mental disorders.
- The National Institute for Mental Health has strongly recommended atypical antipsychotic medications as the treatment of first choice for certain serious mental disorders.
- Atypical antipsychotic medications have been shown in research studies to decrease costs associated with psychiatric hospitalization, and potentially indirect costs of untreated mental disorders in public systems (e.g., criminal justice, general medical care). While psychiatric hospitalization costs may decline, outpatient mental health treatment costs may rise due to improved participation and ability to benefit from treatment. The net impact of atypical antipsychotic medications on total mental health treatment costs is not clear.

- Medications should be used in conjunction with other services (e.g., psychotherapy, family interventions, rehabilitation programs, case management) that address the totality of the consumer's needs, enhance medication adherence, and improve outcomes.
- Clinical practice guideline use is increasing nationwide. Guidelines are generally intended to promote proven therapeutic interventions and reduce inappropriate variation in clinical practice, but are not cost containment mechanisms per se. Guideline implementation is expected to improve outcomes and facilitate cost management. Guidelines are usually based on a combination of scientific evidence and expert consensus. Algorithms are a subset of practice guidelines and give step-by-step input to clinical decisions.
- The Texas Medication Algorithm Project (TMAP) has developed specific protocols for the medication management of schizophrenia/schizoaffective disorder, bipolar disorder, and major depression. These algorithms are based on scientific evidence and expert consensus and address all medications (not just atypical antipsychotic medications) used to treat these disorders.
- Practice guidelines are not a substitute for clinical judgement based on assessment of individual consumers' needs. Policies that are based on practice guidelines should incorporate that understanding.
- Ziprasidone is a newly available atypical antipsychotic medication.
- Clozapine is currently available in generic preparations that are significantly lower in cost and have an FDA "AB" rating.
- New atypical antipsychotic medications are expected to be available within 3-5 years.

II. Clinical Guidelines for Use of Atypical Antipsychotic Medications

Indications:

- Atypical antipsychotic medications are generally the preferred (first-line) treatment for psychotic mental disorders (e.g., schizophrenia) and other conditions with psychotic symptoms. When an antipsychotic medication is needed, they are almost always preferred over the conventional antipsychotic medications.
- In children and adolescents, atypical antipsychotic medications are generally preferred over conventional antipsychotic medications because they have a greatly reduced risk of tardive dyskinesia and improve rather than impair cognitive functioning.
- Some consumers have unique or treatment-resistant conditions that may not be well characterized by existing diagnostic categories or respond to standard treatments. In these cases, a thorough re-evaluation should occur periodically to review the diagnosis, assessment, and treatment plan. A trial of atypical antipsychotic medications may be warranted in this situation, even not generally indicated for the condition. The target symptoms for the atypical antipsychotic medication should be delineated and systematically monitored to determine therapeutic response.
- The use of atypical antipsychotic medications in consumers with non-psychotic conditions/disorders is generally short term and should be periodically reviewed to determine if tapering/discontinuing the medication is appropriate. This is particularly recommended for children and adolescents.

Medication selection and evaluation:

- The lowest-cost indicated antipsychotic medication should be used first unless there are substantial scientific or clinical reasons to the contrary[2]. The five currently available atypical antipsychotic medications are distinct and have different indications and side effect profiles; all should be available for consumers when indicated. If available, lower cost generic products should be prescribed first, unless there are substantial clinical reasons to the contrary.
- Individual clinical factors such as co-occurring medical conditions should be considered in medication selection and may represent a substantial clinical reason to use a higher-cost medication.
- The availability of medication samples should not influence medication selection. However, samples may be appropriate to facilitate medication initiation.
- Adequate medication trials of sufficient duration and dose should be attempted before changing atypical antipsychotic medications. Changing to another medication is indicated if there is inadequate therapeutic response and/or unacceptable side effect(s).
- In the long-term treatment of psychotic disorders such as schizophrenia, the therapeutic response to atypical antipsychotic medications may take longer develop, compared to conventional antipsychotic medications. In order to minimize premature medication changes, excessive doses, and side effects, medication response should be assessed at intervals of approximately 4-6 weeks.
- Concurrent use of more than one atypical antipsychotic medication is not supported by scientific studies and should be avoided unless there is a clear and substantial clinical rationale.

Medication dosing:

- Atypical antipsychotic medications should be prescribed in doses consistent with product packaging and/or established practice guidelines[3]. Higher doses should only be used if there is a clear and substantial clinical rationale.
- Prescribers should use clinically appropriate schedules and tablet sizes that result in the lowest cost for a particular medication dose.
- To reduce waste, small quantities of medication should be prescribed when initiating therapy and when short-term treatment is anticipated.

Clozapine:

- Clozapine is generally not considered a first-line atypical antipsychotic medication because of safety considerations and the need for laboratory monitoring.
- Clozapine is FDA indicated for schizophrenia. Substantial evidence suggests that clozapine is also effective in treatment-resistant schizophrenia, and may be useful in psychogenic water intoxication, tardive dyskinesia, and bipolar disorder.
- New prescriptions for clozapine should be filled with the generic product unless there is a substantial clinical contraindication.

[2] See Appendix II
[3] See Appendix III

- Prescribers who are re-starting clozapine after an interval of discontinuation should prescribe the generic product. Brand name clozapine should be used on re-starts only if there is evidence that the consumer has had a significant prior problem (e.g., inadequate response, non-tolerance) with the generic product.
- Prescribers at psychiatric hospitals should switch consumers to generic clozapine during inpatient admissions. Upon discharge, consumers should be continued on the generic product unless there is a substantial clinical contraindication.
- Prescribers should evaluate consumers who are stable in the community on brand name clozapine to determine the possible risks and appropriate timing of switching to the generic product. Prescribers should switch these consumers to generic clozapine unless there is a substantial clinical contraindication; this will require planning, education of the consumer and family, and careful monitoring. The appropriate process and timeline should be determined by individual consumers' needs. Serum clozapine levels may need to be monitored more closely during this transition.

Risperidone:

- Risperidone is FDA indicated for the management of the manifestations of psychotic disorders. Its effectiveness for short-term management of schizophrenia has been established.
- Risperidone does not have FDA approval for bipolar disorder. However, a substantial amount of scientific evidence supports its use in bipolar disorder with psychosis, acute mania, and as an adjunctive mood stabilizer.
- Risperidone has been shown in scientific studies to be effective in the treatment of severe physical agitation and aggression across a wide range of diagnostic categories.

Olanzapine:

- Olanzapine is FDA indicated for the treatment of schizophrenia, including long-term maintenance, and for the short-term treatment of acute mania associated with bipolar disorder. A substantial amount of scientific evidence supports its use in bipolar disorder with psychosis and in other phases of bipolar disorder.
- Olanzapine has been shown in scientific studies to be effective in the treatment of severe physical agitation and aggression across a wide range of diagnostic categories.

Quetiapine:

- Quetiapine is FDA indicated for the management of the symptoms of psychotic disorders. A substantial amount of scientific evidence supports its use as an alternative treatment in bipolar disorder.

Ziprasidone:

- Ziprasidone is FDA indicated for the treatment of schizophrenia.

Summary of clinical use:

- Below is a table summarizing the recommended use of atypical antipsychotic medications. In all situations where an antipsychotic medication is indicated, the atypical agents are considered first line and preferred over the conventional agents.

When atypical agents are listed as second line or lower, it is relative to other classes of medications also used to treat that disorder.

- More detailed information can be found in The Expert Consensus Guideline Series, The American Psychiatric Association Practice Guidelines, The Texas Medication Algorithm Project, and other guidelines listed in the bibliography[4]. Implementation of these guidelines should incorporate awareness of the expanded information and recommendations detailed within those reports.

Disorder	**Recommended Use of Atypical Antipsychotic Medications**	**Recommended Doses/duration**
Schizophrenia and schizoaffective disorder	1st line Children/adolescents and adults	Long-term
Psychosis not otherwise specified	1st line Children/adolescents and adults	Short-term May be long-term if need clearly established; evaluate periodically
Bipolar disorder	1st line in all ages and stages of illness if psychotic symptoms are present 1st or 2nd line for adults in acute mania 1st or 2nd line for children/adolescents in acute mania and maintenance Adjunctive role in adults for maintenance, especially if treatment resistant	Short-term May be long-term if need clearly established; evaluate periodically
Major depression with psychosis	1st line, usually adjunct to antidepressant(s) Children/adolescents and adults	Short-term May be long-term if need clearly established; evaluate periodically
Major depression without psychosis	Not 1st line May have adjunctive role if treatment resistant Adults	Short-term May be long-term if need clearly established; evaluate periodically
Borderline personality disorder	Not generally indicated for this disorder 1st line if psychosis or another indicated disorder is present	Short-term Low-dose May be long-term if

[4] See Appendix IV.

	Indicated for severe aggression/ self-injurious behaviors, after 1st line medications have been tried Adults	need clearly established; evaluate periodically
Other personality disorders	Not generally indicated for these disorders 1st line if psychosis or another indicated disorder is present	N/A
Dissociative disorders	Not generally indicated for these disorders 1st line if psychosis or another indicated disorder is present	N/A
Post traumatic stress disorder	Not generally indicated for this disorder 1st line if psychosis or another indicated disorder is present in adults Indicated in children/adolescents for rage/aggression or dissociative/psychotic symptoms, after 1st line medications have been tried	Short-term May be long-term if need clearly established; evaluate periodically
Obsessive compulsive disorder	1st line if psychotic symptoms are present, usually adjunct to other medication(s) Indicated for lack of insight or treatment-resistance, after 1st line medications have been tried Children/adolescents and adults	Short-term May be long-term if need clearly established; evaluate periodically
Other anxiety disorders	Not indicated	N/A
Developmental disorders and mental retardation	1st line for severe self-injurious behaviors, if not due to another treatable disorder 1st line for severe aggression to others/property, if not due to another treatable disorder 1st line for severe motor stereotypies, if not due to another treatable disorder Indicated for pervasive developmental disorders with severe dysphoria, tactile defensiveness, and anxiety after psychosocial/environmental interventions and 1st line medications have been tried Children/adolescents and adults	Short-term May be long-term if need clearly established; evaluate periodically

Attention deficit disorder	Not indicated	N/A
Tourette's disorder	1st line for motor and vocal tics	Short-term or long-term
Conduct disorder of childhood	Not generally indicated for this disorder. Psychosocial interventions are generally 1st line, rather than medications 1st line for severe aggressive behaviors, if not due to another treatable disorder and/or after psychosocial interventions have been tried Not indicated for antisocial behaviors	Short-term
Pica	Not indicated	N/A
Oppositional defiant disorder	Not indicated	N/A
Delirium	Medications are not generally indicated for this disorder 1st line for psychotic symptoms and severe physical agitation/aggression Adults	Short-term Low-dose
Dementia	1st line if psychotic symptoms are present Indicated for severe physical agitation/aggression, after 1st line medications have been tried Adults	Short-term Low-dose
Stroke	1st line if psychotic symptoms are present Indicated for severe physical agitation/aggression, after 1st line medications have been tried Adults	Short-term Low-dose
Tardive dyskinesia treatment	1st line	Long-term
Traumatic brain injury	1st line if psychotic symptoms are present Indicated for severe physical agitation/aggression, after mood stabilizing anticonvulsants and psychostimulants have been tried	Short-term May be long-term if need clearly established; evaluate periodically

Insomnia, sleep disorders	Not indicated	N/A
Pain symptoms, headaches	Not indicated	N/A

III. Implementation/Monitoring Guidelines for Atypical Antipsychotic Medications

- Development of specific policies/protocols for implementation of these guidelines requires input from consumers, family members, advocates, and providers in the system in which they will be used.
- Successful implementation of specific protocols requires education of consumers, providers, and family members, as well as active medical/clinical leadership, in the system in which they will be used.
- Prescribers and pharmacists should be educated about medication costs and strategies to maximize cost effectiveness. This process should be ongoing, taking into account new developments and provider turnover.
- All clinical service providers should be educated about medication guidelines/protocols and be able to provide education and support.
- Prior authorization requirements for all atypical antipsychotic medication prescriptions may be unduly burdensome and is unlikely to be cost-effective.
- Prior authorization requirements may be appropriate for the use of atypical antipsychotic medication outside the guidelines' recommendations.
- Atypical antipsychotic medications prescribed outside of specialty mental health care settings/providers may require closer monitoring to ensure appropriate use.
- Concurrent review should facilitate intervention at the time of medication dispensing. Prescriptions that fall outside the guidelines (e.g., dosing schedules that increase costs, excessive doses) should be reviewed at this point; automated pharmacy systems are needed to facilitate this process.
- Post-hoc review of practice patterns should facilitate ongoing provider education and identification of outliers (e.g., use of atypical antipsychotic medications for non-indicated conditions). Prescriber profiling should be used to characterize and compare the practices of individuals or systems, to promote best practices, and to reduce inappropriate variation in care.
- Guideline implementation monitoring should evaluate performance and outcomes, as well as adherence.
- Processes used to implement guidelines or monitor adherence to them should not cause undue burdens for consumers trying to obtain medications, as medication non-compliance and adverse outcomes can result.

APPENDIX I

2001 COLORADO BEST PRACTICE WORK GROUP

ATYPICAL ANTIPSYCHOTIC MEDICATIONS

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Columbia University and New York State Office of Mental Health, The Center for the Advancement of Children's Mental Health-- Treatment Recommendations for the Use of Antipsychotics for Children and Adolescents with Behavioral Disorders (unpublished manuscript).

APPENDIX II

Atypical Antipsychotic Medication Cost Comparison

Risperidone (Risperdal)	Daily Dose		Regimen	Cost per Month	Drug cost AWP*	Cost per Mg
	0.25	mg	0.25mgx1	$78.49	$2.79	$11.16
	0.5	mg	0.5mgx1	$78.49	$2.79	$5.58
	1	mg	1mgx1	$78.49	$2.79	$2.79
	2	mg	2mgx1	$127.89	$4.64	$2.32
	3	mg	3mgx1	$150.32	$5.48	$1.83
	4	mg	4mgx1	$196.77	$7.22	$1.81
	6	mg	3mg/2	$296.63	$10.96	$1.83
Olanzapine (Zyprexa)						
	2.5	mg	2.5mgx1	$137.50	$5.00	$2.00
	5	mg	5mgx1	$161.80	$5.91	$1.18
	7.5	mg	7.5mgx1	$169.54	$6.20	$0.83
	10	mg	10mgx1	$243.77	$8.98	$0.90
	15	mg	15mgx1	$362.58	$13.43	$0.90
	20	mg	20mgx1	$483.27	$17.95	$0.90
Quetiapine (Seroquel)						
	25	mg	25mgx1	$43.25	$1.47	$0.06
	100	mg	50mgx2	$75.56	$2.68	$0.03
	200	mg	100mgx2	$139.10	$5.06	$0.03
	300	mg	100mgx3	$196.77	$7.22	$0.02
	600	mg	200mgx3	$409.31	$15.18	$0.02
	900	mg	300mgx3	$582.32	$21.66	$0.02
Ziprasidon (Geodon)						
	20	mg		$112.40	$4.06	$0.20
	40	mg	20mgX2	$220.80	$8.12	$0.20
	60	mg	30mgx2	$220.80	$8.12	$0.14
	80	mg	40mgX2	$220.80	$8.12	$0.10
	160	mg	80mgx2	$220.80	$8.12	$0.05
Clozapine				**Generic cost per month**	**Brand cost per month**	
	300	mg	100mgx3	$163.30	$297.17	
	500	mg	100mgx5	$269.50	$492.61	
	700	mg	100mgx7	$375.70	$688.05	
	900	mg	100mgx9	$481.90	$883.50	

*Based on Colorado fee schedule November 2001

APPENDIX III

Atypical Antipsychotic Medication Dosage Recommendations

(May need to be adjusted for age, co-medications, co-morbidities, etc.)

A. Schizophrenia

Adapted from Texas Medication Algorithm. See TMAP algorithm or prescribing information for dose titration recommendations.

Medication	Target Daily Dose Range	Preferred Dosing Schedule
Clozapine	300-900 mg (check serum level for doses > 600 mg)	BID (1/3 in am, 2/3 in pm)
Olanzapine	5-20 mg	HS
Quetiapine	250-800 mg	BID or HS
Risperidone	2-6 mg	HS or AM
Ziprasidone	80-160 mg	BID (½ in am, ½ in pm)

B. Major Depression

Adapted from Texas Medication Algorithm. See TMAP algorithm or prescribing information for dose titration recommendations. N/A = no specific dosage information available for major depression.

Medication	Target Daily Dose Range	Preferred Dosing Schedule
Clozapine	N/A	N/A
Olanzapine	10-20 mg	HS
Quetiapine	N/A	N/A
Risperidone	2-8 mg	HS or AM
Ziprasidone	N/A	N/A

C. Bipolar Disorder

Adapted from Texas Medication Algorithm. See TMAP algorithm or prescribing information for dose titration recommendations. Most information is available on bipolar mania. Doses are not well established for other phases of bipolar disorder. N/A = no specific dosage information available for bipolar disorder.

Medication	Target Daily Dose Range	Preferred Dosing Schedule
Clozapine	100-900 mg	BID (1/3 in a.m., 2/3 in p.m.)
Olanzapine	10-20 mg	HS
Quetiapine	300-700 mg	BID or HS
Risperidone	2-6 mg	HS or AM
Ziprasidone	N/A	N/A

APPENDIX IV

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Texas Medication Algorithm Project (TMAP) and Texas Implementation of the Medication Algorithms (TIMA)

www.mhmr.state.tx.us/centraloffice/medicaldirector/tmapover.html

www.mhmr.state.tx.us/centraloffice/medicaldirector/timaover.html

The Pyschopharmacology Algorithm Project

www.mhc.com/Algorithms