Introduction to Magellan’s Adopted Clinical Practice Guidelines for the Treatment of Children with Autism Spectrum Disorders
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Purpose of This Document

This document is an introduction to Magellan Health Services’ (Magellan) adopted clinical practice guideline (CPG) for the treatment of children with an autistic spectrum disorder. As with all CPGs, this adopted guideline and this Introduction are intended to augment, not replace, sound clinical judgment. As a matter of good practice, clinically sound exceptions to this practice guideline should be noted in the member’s treatment record, documenting the clinical reasoning used in making the exception. Magellan periodically requests clinical files from providers in order to monitor compliance with adopted guidelines. Clear documentation of the rationale for exceptions to the guideline’s recommendations should be present in the member’s treatment record whenever there is evidence of deviation from the guideline.

Introduction

The guideline Magellan has adopted to augment providers’ clinical decision-making with members who have autism are the:

- Companion document to the guideline, **Clinical Report – Identification and Evaluation of Children With Autism Spectrum Disorders** developed by the American Academy of Pediatrics (AAP) at http://pediatrics.aappublications.org/cgi/reprint/120/5/1183 and as published in *Pediatrics* 2007: 120; 1183-1215.²

This guideline and its companion report incorporate the rapidly evolving developments in pharmacotherapy, as well as developments in other areas of educational and clinical management of children with autism. The AAP guideline and its companion report are evidence-based documents that cover all areas of management of patients with this disorder, from understanding the clinical features and screening/surveillance to medical/psychiatric treatment approaches, educational/behavioral interventions, planning and family support.

Additional Recommendations Based on Recent Literature Review

The AAP guideline and companion report are based on a literature review through 2006. Magellan conducted a further review of the clinical literature on assessment and treatment of autism spectrum disorders through May 2008. Key relevant recommendations from this more recent literature review are summarized here. Magellan encourages providers to be familiar with this information, as well as the information in both the guideline and the companion document.
Educational Interventions - Applied Behavioral Analysis

Based on an extensive review of the literature and evaluation of published research studies in peer-reviewed clinical journals, Magellan considers Applied Behavioral Analysis (ABA) used in the treatment of autism to be an investigational treatment. This determination is based on an evaluation of the research findings where the evidence did not support ABA’s effect on health outcomes, its safety and efficacy against existing alternative treatments, and its ability to demonstrate that benefits outweigh the risks.3

Only recently have controlled trials on ABA been published and one of these is a randomized controlled study.4, 5, 6, 7, 8, 9, 10 More treatment research is needed with strict empirical designs that can allow for sound inferences regarding the parameters of treatment effectiveness and can answer current questions about features of children who are most likely to respond.11 To date, most of the published literature on ABA involves studies that have several methodological problems, including lack of a clear definition of the ABA treatment and its protocols (e.g., many studies refer to using the Lovaas method manual and video), lack of control groups using established treatment alternatives, poorly chosen or poorly specified samples, outcomes measured only in limited areas (e.g., IQ), and outcome measures giving little information regarding the totality of the treatment impact. Use of a battery of assessments, both specific and global, is needed to give a comprehensive and detailed picture of treatment effects.11, 12 Additionally, most research on ABA programs has centered on preschoolers with autistic spectrum disorders and therefore research on comprehensive programs for older children and adults with autism is needed.

In addition to the limited research evidence on efficacy, there are other limitations to the use of ABA treatments in children with autism:

- ABA is very intense and intrusive in its format and delivery. Stressful reactions by the recipient of the procedure need to be carefully monitored. Sensitive and knowledgeable interventionists are essential in observing adverse outcomes.
- “Setting results” may occur with autistic individuals responding to stimuli in one environment, but unable to generalize learning to other contexts. Great care needs to be taken in selecting natural environments for instruction in order to promote skills in real world situations.
- The use of a single treatment may not be advisable – given the spectrum of difficulties, range of abilities, age of the child, culture of the family and characteristics of the patient.11, 12, 13

Medical Management - Psychopharmacology

The Magellan-approved AAP Practice Guideline on the Management of Children With Autism Spectrum Disorders indicates that the Food and Drug Administration (FDA)-approved atypical antipsychotic risperidone is now widely used to treat symptomatic irritability, aggressive behavior, deliberate self-injury and temper tantrums in children and adolescents with autism.1 The atypical or second-generation antipsychotic (SGA) drugs aripiprazole, olanzapine, quetiapine and ziprasidone currently are being investigated for use in treating such behaviors as hyperactivity, impulsivity, inattention, aggression and explosive outburst and self-injury.1 In a recently published review of antipsychotic treatment of autism, Posey et al. note that with the widespread use of SGA agents, the use of conventional antipsychotics, like haloperidol, became and continue to become less frequent,
although prior randomized controlled trials have shown that they too are efficacious in young children with autism.\textsuperscript{14}

Most of the clinical studies on the use of conventional antipsychotics occurred in the decade spanning 1965-1975. These studies were well-designed controlled studies of haloperidol in doses of 1 to 2 mg/day, where the drug was found to be more efficacious than placebo for withdrawal, stereotypy, hyperactivity, affective lability, anger and temper outbursts.\textsuperscript{14, 15} Posey concludes that while multiple studies found haloperidol efficacious for improving a variety of behavioral symptoms in young children with autism, there was less robust evidence for the efficacy of other conventional antipsychotics. Posey concludes that since haloperidol treatment frequently leads to acute dystonic reactions, withdrawal dyskinesias and tardive dyskinesia, this high risk of extrapyramidal symptoms has limited the use of these medications to only the most treatment-refractory patients.\textsuperscript{14}

Along with other studies comparing SGAs to placebo in the treatment of autism, in 2001 Malone et al. conducted an open-label trial of 12 children with autistic disorders who were randomly assigned to treatment with either olanzapine or haloperidol for six weeks following a one-week period with no treatment.\textsuperscript{16} The children studied ranged in age from 4.9 to 11.8 years. The primary outcome measure used was the Clinical Global Impressions Improvement (CGI-I) scale; secondary measure was the Children’s Psychiatric Rating Scale (CPRS) with four factors (autism, anger/uncooperativeness, hyperactivity and speech deviance).\textsuperscript{16}

Researchers found no significant difference in CGI-I scores between the two treatment groups. For CGI-Severity of Illness (CGI-S) scores, both treatments resulted in non-significant improvement from baseline. Both olanzapine and haloperidol were associated with significant improvement from baseline in CPRS autism factor scores (hyperactivity, anger/uncooperativeness). No significant effect of treatment was seen for CPRS speech deviance factor. Drowsiness and weight gain were the most common adverse events reported, with patients given olanzapine reporting a higher weight gain compared with those who received haloperidol.\textsuperscript{16, 17}

**Obtaining Copies of the American Academy of Pediatrics (AAP) Guideline**

Copies of the *Practice Guideline for the Management of Children With Autism Spectrum Disorders* may be obtained through the AAP at [http://www.pediatrics.org/cgi/content/full/120/5/1162](http://www.pediatrics.org/cgi/content/full/120/5/1162) or by obtaining this article as published in *Pediatrics* 2007: 120; 1162-1182. (doi:10.1542/peds.2007-2362)

Copies of the companion document to the guideline, *Clinical Report – Identification and Evaluation of Children With Autism Spectrum Disorders*, may be obtained through the AAP at [http://pediatrics.aappublications.org/cgi/reprint/120/5/1183](http://pediatrics.aappublications.org/cgi/reprint/120/5/1183) or by obtaining this article as published in *Pediatrics* 2007: 120; 1183-1215.
Provider Feedback

Magellan welcomes feedback on our clinical practice guidelines. All suggestions and recommendations are taken into consideration in our ongoing review of the guidelines. Comments may be submitted to:

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References


**Additional Sources Reviewed But Not Cited**


