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May 28, 2010

Susan Parker, Pharm D
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, IA 50315

Dear Ms. Parker:

The Iowa Psychiatric Society (IPS) is writing to share our concerns about the proposed prior authorization (PA) for Intuniv. IPS has agreed to support the restriction of some medications if decisions are based on sound clinical evidence.

A work group composed of child psychiatrists of the Iowa Psychiatric Society has reviewed the proposed PA for Intuniv. This work group agreed that it would be acceptable to have a PA for this long acting drug but they have serious concerns about the prior authorization criteria.

Concerns about the proposed PA:

- The biggest concern we have is that in order for a patient to receive approval for Intuniv they would have to fail 5 different medications. With the length of trial for each medication it could take 6 months for a patient to meet the criteria.
- The use of stimulants is not always an appropriate medication to use and is a different class of medication.
- Strattera is also a different class of medication and costs approximately the same as Intuniv.
- Limiting the diagnosis to ADHD does not take into account patients with autism and tourette's that can benefit by the use of guanfacine as stated in the attached research papers. If a patient would benefit by using the generic short term medication there could be cases that because of compliance issues or inadequate response might benefit from Intuniv.
- The age limit of 6-17 does not take into account that children as young as 4 with autism who benefit from guanfacine (Standard of Care).

With these concerns in mind, the Iowa Psychiatric Society is requesting a change in this prior authorization to read as follows:

- Must be between 4 and 17 years of age.
- Must successfully establish appropriate dose using immediate release guanfacine and have significant compliance issues or inadequate response necessitating the extended release product.
- Limited to once daily dosing.
- Maximum dose authorized is 4 mg/day.

Susan Parker, Pharm D
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While IPS is willing to implement strategies to reduce medication costs in Medicaid, our first and foremost concern is that the process will not negatively impact our patients by being restricted from receiving the necessary medications for their recovery in a timely manner. Treatment delayed is treatment denied.

Again, we appreciate the opportunity to be part of this critical decision making process and would be more than willing to meet with you.

Sincerely,



Karen Loihl
Executive Director

cc: Pam Smith R.PH. - Iowa DUR Coordinator
cc: Thomas Kline, D.O. — Medical Director, Iowa Medicaid Enterprise
cc: Jennifer Vermeer, Medicaid Director

Attachments:

A Placebo-Controlled Study of Guanfacine in the Treatment of Children with Tic Disorders and Attention Deficit Hyperactivity
Am J Psychiatry, 2001 Jul; 158(7): 1067-74

Guanfacine in Children with Autism and/or Intellectual Disabilities
J Dev Behav Pediatr, 2008 Aug; 29(4): 303-8

A Prospective Open Trial of Guanfacine in Children with Pervasive Developmental Disorders
J Child Adolesc Psychopharmacol. 2006 Oct; 16(5): 589-98

Guanfacine Treatment of Hyperactivity and Inattention in Pervasive Developmental Disorders: A Retrospective Analysis of 80 Cases.
J Child Adolesc Psychopharmacol, 2004 Summer; 14(2): 233-41

Guanfacine in children with autism and/or intellectual disabilities.

Handen BL, Sahl R, Hardan AY.

University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, USA.

Abstract

OBJECTIVE: Attention-deficit/hyperactivity disorder (ADHD) affects 3%-5% of typical school-age children. However, considerably higher rates of ADHD (15%-25%) are observed in children with intellectual disability and autism. Studies of psychostimulants in the latter two populations have found poorer response rates compared to typically developing children. In addition, evidence suggests that children with developmental disabilities experience higher rates of adverse events. Guanfacine, an alpha2-adrenergic receptor agonist, has shown some promise as an alternative to psychostimulants. **METHODS:** The present study involved a double-blind, placebo-controlled, crossover trial of guanfacine in 11 children (ages 5-9 years) with developmental disabilities and symptoms of inattention/overactivity. The 6-week trial involved a maximum dose of 3 mg/day of guanfacine. **RESULTS:** Significant benefits were observed on the Hyperactivity subscale of the parent and teacher Aberrant Behavior Checklist (ABC) and Global Improvement Ratings. No gains were noted on other ABC subscales. Five of the 11 subjects (45%) were judged to be responders based on a 50% decrease in the ABC Hyperactivity subscale score between the placebo and guanfacine conditions. Several side effects were reported, including drowsiness and irritability. **CONCLUSION:** While guanfacine appears to be an alternative to psychostimulants among children with developmental disabilities, clinicians need to remain vigilant to the possibility of side effects.

PMID: 18552703 [PubMed - indexed for MEDLINE]

Am J Psychiatry. 2001 Jul;158(7):1067-74.

A placebo-controlled study of guanfacine in the treatment of children with tic disorders and attention deficit hyperactivity disorder.

Scahill L, Chappell PB, Kim YS, Schultz RT, Katsovich L, Shepherd E, Arnsten AF, Cohen DJ, Leckman JF.

Yale Child Study Center, New Haven, CT 06520, USA. lawrence.scahill@yale.edu

Abstract

OBJECTIVE: This study evaluated the efficacy and safety of guanfacine in treating children with tic disorders and attention deficit hyperactivity disorder (ADHD). **METHOD:** Subjects from a specialty tic disorders clinic were randomly assigned to receive 8 weeks of treatment with guanfacine or placebo under double-blind conditions. Follow-up visits occurred every 2 weeks for safety monitoring and dose adjustment. **RESULTS:** Thirty-four medication-free subjects (31 boys and three girls with a mean age of 10.4 years) with ADHD, combined type, and a tic disorder participated. After 8 weeks of treatment, guanfacine was associated with a mean improvement of 37% in the total score on the teacher-rated ADHD Rating Scale, compared to 8% improvement for placebo. Nine of 17 subjects who received guanfacine were blindly rated on the Clinical Global Improvement scale as either much improved or very much improved, compared with none of 17 subjects who received placebo. The mean score on the parent-rated hyperactivity index improved by 27% in the guanfacine group and 21% in the placebo group, not a significant difference. On the Continuous Performance Test, commission errors decreased by 22% and omission errors by 17% in the guanfacine group, compared with increases of 29% in commission errors and of 31% in omission errors in the placebo group. Tic severity decreased by 31% in the guanfacine group, compared to 0% in the placebo group. One guanfacine subject with sedation withdrew at week 4. Guanfacine was associated with insignificant decreases in blood pressure and pulse. **CONCLUSIONS:** Guanfacine appears to be a safe and effective treatment for children with tic disorders and ADHD.

PMID: 11431228 [PubMed - indexed for MEDLINE]Free Article

J Child Adolesc Psychopharmacol. 2006 Oct;16(5):589-98.

A prospective open trial of guanfacine in children with pervasive developmental disorders.

Scahill L, Aman MG, McDougle CJ, McCracken JT, Tierney E, Dziura J, Arnold LE, Posey D, Young C, Shah B, Ghuman J, Ritz L, Vitiello B.

Yale Child Study Center, P.O. Box 207900, New Haven, CT 06520, USA. lawrence.scahill@yale.edu

Abstract

OBJECTIVE: A common complaint for children with pervasive developmental disorder (PDD) is hyperactivity. The purpose of this pilot study was to gather preliminary information on the efficacy of guanfacine in children with PDD and hyperactivity. **METHODS:** Children with PDD accompanied by hyperactivity entered the open-label trial if there was a recent history of failed treatment with methylphenidate or the child did not improve on methylphenidate in a multisite, placebo-controlled trial. **RESULTS:** Children (23 boys and 2 girls) with a mean age of 9.03 (+/-3.14) years entered the open-label trial. After 8 weeks of treatment, the parent-rated Hyperactivity subscale of the Aberrant Behavior Checklist (ABC) went from a mean of 31.3 (+/-8.89) at baseline to 18.9 (+/-10.37) (effect size = 1.4; $p < 0.001$). The teacher-rated Hyperactivity subscale decreased from a mean of 29.9 (+/-9.12) at baseline to 22.3 (+/-9.44) (effect size = 0.83; $p < 0.01$). Twelve children (48%) were rated as Much Improved or Very Much Improved on the Clinical Global Impressions-Improvement. Doses ranged from 1.0 to 3.0 mg/day in two or three divided doses. Common adverse effects included irritability, sedation, sleep disturbance (insomnia or midsleep awakening), and constipation. Irritability led to discontinuation in 3 subjects. There were no significant changes in pulse, blood pressure, or electrocardiogram. **CONCLUSIONS:** Guanfacine may be useful for the treatment of hyperactivity in children with PDD. Placebo-controlled studies are needed to guide clinical practice.

PMID: 17069547 [PubMed - indexed for MEDLINE]

Guanfacine treatment of hyperactivity and inattention in pervasive developmental disorders: a retrospective analysis of 80 cases.

Posey DJ, Puntney JI, Sasher TM, Kem DL, McDougle CJ.

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Abstract

OBJECTIVE: The aim of this study was to retrospectively review a large sample of children and adolescents with pervasive developmental disorders (PDDs) treated with open-label guanfacine in order to gather preliminary data as to its effectiveness and safety. **METHOD:** Eighty (80) subjects with PDDs (10 females, 70 males) (mean +/- SD age = 7.7 +/- 3.5 years, range 3-18 years) were treated with guanfacine within an academic specialty clinic. Charts were reviewed to determine the response of specific target symptoms, including hyperactivity, inattention, and impulsivity. The relationship between treatment response and age, diagnosis, level of cognitive impairment, and symptom severity was determined. Adverse effects were also evaluated. **RESULTS:** Guanfacine (mean daily dose = 2.6 +/- 1.7 mg, range 0.25-9 mg; mean duration of treatment = 334 +/- 374 days, range 7-1776 days) treatment was effective in 19 of 80 (23.8%) subjects. Subjects with PDD not otherwise specified (11 of 28 responders; 39.3%) and Asperger's disorder (2 of 6 responders; 33.3%) showed a greater rate of global response than those with autistic disorder (6 of 46 responders; 13.0%). There was a trend for subjects without comorbid mental retardation (9 of 24 subjects; 37.5%) to respond at a greater rate than those with mental retardation (10 of 56 subjects; 17.9%). Symptom improvement was seen in hyperactivity, inattention, insomnia, and tics. Guanfacine was well tolerated, and did not lead to significant changes in blood pressure or heart rate. **CONCLUSIONS:** Guanfacine may have a role in the treatment of hyperactivity and inattention occurring in some persons with PDDs. Further studies are needed to determine its efficacy in this population.

PMID: 15319020 [PubMed - indexed for MEDLINE]