Appendix C-2

Summary Report Effect of Second Opinion Review on ADHD Prescribing in a Medicaid Insured Population

SUMMARY REPORT
EFFECT OF SECOND OPINION REVIEW ON ADHD PRESCRIBING IN A MEDICAID INSURED POPULATION

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This report details record review activity and outcomes of a second opinion review process on Psychotropic medications in Washington State Medicaid insured children and adolescents. This report is a responsibility of the contract between Seattle Children's Hospital and the Washington State Department of Social and Health Services and reports on the period from December 2008 to May 2009.

Washington State Medicaid has developed safety parameters for ADHD medications based on a process which began in 2004, when the state Medicaid convened a mental health drug work group to discuss issues related to implementation of a preferred drug program, and make recommendations to improve quality and safety. The group developed a set of safety guidelines based on published scientific literature and utilization data such that when thresholds were exceeded, a second opinion record review would be required. The thresholds included age (< 5 years old), combination medication use greater than 30 days (≥2 ADHD drugs), and high doses (amphetamines or dexmethylphenidate >60 mg/day, methylphenidate or atomoxetine > 120 mg/day; for newer brand named preparations Daytrana >30 mg/day or Vyvanse >70 mg/day).

Members of the Seattle Children's Hospital review group were instrumental in the development of the next phase of the psychotropic medication practice for Medicaid insured children and adolescents in the state of Washington with the extension of the review process to include all other psychotropic medications including atypical antipsychotic medications, mood stabilizers, antidepressant medications and anxiolytic medications. As described above with regard to the process employed to set standards with regard to ADHD medication this was an iterative process which reviewed best practices in each of the medication groups to identify optimal dosing strategies stratified by age. Decisions were made with regard to how many psychotropic medications could be prescribed concomitantly before a review was put into a place. The following criteria were established as a result:

Reviews would occur:

(1) If established maximum daily doses of atypical antipsychotic medications (AAPs), stratified by age, were exceeded

(2) If two or more antipsychotic medications were concomitantly prescribed for longer than 60 days

(3) If three or more concomitant mood stabilizers were prescribed for a mental health diagnosis after 60 days

(4) If five or more psychotropic medications were prescribed concomitantly after 60 days

The next phase of Medicaid insured psychotropic medication practice began on February 1, 2009 with review of criterion 1 above. During the period of February 1, 2009 through May 15, 2009 there were 90 reviews of the use of AAPs. Of those, 82 were approved; 7 were denied; and 1 was referred for a direct exam/clinical assessment. All of these reviews were provoked by virtue of exceeding criterion 1 of the AAPs of exceeding the maximum dose of an atypical antipsychotic medication by age. In addition, 8 of these cases also had two or more concomitant antipsychotic or ADHD medications being prescribed for periods longer than 60 days, and 5 were being treated with 5 or more psychotropic medications concomitantly for more than 60 days. The latter 2 were not part of the initial roll-out of the second phase of this review process, but were noted by the reviewers. Of the 131 ADHD reviews in this period, 122 were approved and 9 were denied. (Table I)

The following are descriptions of two cases which illustrate the significant safety concerns being addressed in the next phase of review process**:**

Case 1

Sixteen year old female with a reported diagnosis of bipolar disorder and anxiety. She is currently on Geodon 320 mg/day and Seroquel 1000/mg/day. She was adopted and currently lives with her parents and 10 year old sister. She reports a history of 1-2 week episodes of 1-2 hours/night of sleep, impulsive behavior, increased irritability, getting high and having sex with a stranger. She has reportedly been on almost every medication including lithium. They are usually discontinued because of a side effect she experiences. There is a long history of suicidal thoughts from age 10 and remote history of self harm. She also has a history of marijuana use; other substance use is not clear although her provider says she is pretty sure the patient isn't doing anything else. She plans to get a urine drug screen through a CD evaluation that has not been completed yet. This patient has never been in inpatient treatment and she is no longer in therapy. Despite her difficulties she is able to maintain a job according to her provider and has been more stable in the last year. She was initially on Lamictal and Seroquel when she came to this provider. After the Seroquel was increased and they felt there was no response, Geodon was started. She says that there was no response to Geodon until it got to the 320 mg dose. Her provider is now planning to decrease the Seroquel .

We discussed the concern about the patient's high doses of Seroquel and Geodon and the potential interaction because of the same metabolic pathway (CYP3A3). The provider recently sent an EKG that was completed on

3/31/09 by the patient. The QTc was 439 msec. This is a borderline reading of possible prolongation. Therefore, we discussed the safety concerns and necessary follow at this juncture.

Recommendation: Decrease in Seroquel dose by 200 mg, then repeat the EKG in a week. At that point we will have another phone appointment to discuss the case. If there is improvement in the EKG we will likely continue the Seroquel taper (200 mg every 2 weeks). If the EKG remains the same or worse, we will discuss possible discontinuation of Geodon or Seroquel more rapidly if necessary. Therefore at this time Seroquel will be tapered and Geodon will remain the same for now

Case 2

Per prior stimulant review with MD, pt is a 4 1/2 year-old initially transferred to Dr. X from Oregon on Adderall (short-acting) 30mg four times a day, Risperdal 1mg am and noon, and 2 mg qhs, and clonidine 0.2mg qhs. Although Dr. X did not observe any overt concerns for cardiac problems (child was extremely active in the room), he was concerned about this dose. He prescribed Vyvanse at 50mg to provide longer action and decreased Amphetamine from 120mg total daily dose to 30mg for the afternoon. He also decreased Risperdal from 4 to 2mg, and prescribed Abilify 5mg. Clonidine remained unchanged at 0.2mg qhs.

Upon our first discussion, I authorized Vyvanse to 30mg qam and reduced the afternoon amphetamine dose to 15mg with an estimated total dose of amphetamines near 1mg/kg. I also strongly recommended obtaining an EKG and continuing to follow vital signs. Subsequently, Dr. X left word that this child's Vyvanse prescription had been denied and was now prescribed a daily total of 4mg of Risperdal spread throughout the day and 5mg Abilify tid in addition to clonidine 0.2mg qhs. I contacted Dr. X's office and recommended limiting stimulants to Adderall XR 15mg am and short-acting Adderall of 5-10mg in the afternoon, Risperdal to a maximum of 2mg per day, no Abilify, and hospitalization if this child decompensated in any way.

Since our first consulation, pt's Vyvanse has been approved. He is currently prescribed Vyvanse 50mg am and Adderall (short acting) 30mg in the afternoon. He also takes Risperdal 2mg at bedtime, Abilify 5mg am and noon, and clonidine 0.3mg qhs. MD reports pt seems better in office today and vitals remain reassuring, although mother was not able to obtain a recommended EKG. Mom reports Abilify doesn't seem to help. She notes continued problems with sleep and only through the combination of 2mg of Risperdal and 0.3mg of clonidine does he fall asleep and then only for about 4 hours. MD has arranged for pt to enter BEST program in September and also reports pt will be in preschool.

We discussed that I am still concerned at overall dose of stimulants (still 2-3 times recommended maximum) which may be provoking agitation, aggression, and insomnia. I am also concerned at total dose of atypicals.

AUTHORIZATION:

1. Reduce stimulants to Vyvanse 30mg am and Adderall short acting 5mg in afternoon which results in a total dose of amphetamines between 0.5mg and 1mg/kg/day. It is my hope that this reduction will also reduce agitation, aggression, and insomnia.
2. Discontinue Abilify. This has not helped per mother and we have little evidence to support its use in a child this age.
3. MD may continue Risperdal at no more than 2mg total per day. This may be given in divided doses.
4. While I would like to decrease clonidine (at 0.3mg qhs), this will need to be done more slowly owing to risk of rebound hypertension. It will also be important to monitor pt's vitals
5. If pt decompensates at all, including being unable to sleep, I would hospitalize to facilitate medication reduction to safer levels and assist with diagnosis.

Since March 1, 2008 the review group has met monthly to promote quality control in the review process. To improve the specificity of the review process and to enhance relationships with providers a decision was made to

have direct discussion by phone between providers and reviewers for every review if possible. Case reviews conducted by one of the reviewing child and adolescent psychiatrist were brought to the group discussion for purposes of promoting optimal, uniform and reliable review of cases. In these monthly meetings there also were several recommendations to streamline the review process and to respond to comments and concerns expressed by community providers. Refinements were made in some of the individual standards which led to reviews. For example, in the case in which a provider chose to prescribe more than one ADHD medication class a process was developed whereby a provider could provide in writing a rationale for that clinical recommendation including documenting that a child had individual monotherapy trials of each of the two stimulant classes (amphetamine and methylphenidate) as well as atomoxetine, which were not of benefit to the child. In those instances the request would be authorized without a formal review.

Other recommendations from the second opinion review group to DSHS were to be as responsive in timely a fashion as possible to provider and patient concerns implementing as quickly as possible the recommendations of the review process.

To promote internal consistency and reliability by the review group, we conducted blinded reviews of evaluations done by other second opinions reviews in May, 2009. Each of the five child and adolescent psychiatrists involved in the review process rated reviews done by other reviewers. In all 10 of the secondary reviews there was agreement of the conclusions with the initial evaluation (correlation 1.0).

An anonymous questionnaire to consider provider experience with the review process was sent by mail to each of 156 prescribers who had a second opinion review conducted in the period of March 2008 to December 2008 asking whether the ADHD medication second opinion program had a clear purpose, if the reviewers were clear in their opinions, and if customer services timely and convenient. The respondents between March 2008 and December 2008 indicated that the second opinion program had a clear purpose (87%), the reviewers were clear in their opinions (95%), and customer services timely and convenient (87%). No untoward patient outcomes were reported.

The practice of distributing anonymous questionnaires to providers continued in the period of December 2008 through May 2009 during which time there was the extension of the review process from the ADHD medications to the next phase of all psychotropic medications specifically including AAPs. In this period there were 160 questionnaires sent to prescribers who had ADHD medications reviewed and 30 responses were received. Also, during this period there were 84 questionnaires related to atypical antipsychotic medications with 24 provider responses. As to the new atypical antipsychotic review process, the responses were very similar to the prior ADHD provider responses. Eighty-three percent of respondents felt that the purpose of the review was clear. For the 4 of 24 for whom it was not initially clear, 3 felt that it was made clearer in the review process. Eighty-three percent felt the review was timely and convenient, and 100% felt that the reviewers' final opinion was clearly explained. (Table II)

Respondents in general felt that the process was useful, that the second opinion process promoted here is the best practice parameter and that it was important to undertake efforts to reduce variance in prescriptive practice for psychotropic medications in Washington State. This was done on the basis of a Likert scale, grouped value responses (attached).

The ADHD reviews in this period were similar to the prior ADHD provider response characteristics. Ninety-three percent of the respondents felt that the review process was clear prior to the review and 100% said that for those that it was not clear was made clear by the reviewer, 87% felt that the reviews scheduled in a timely and convenient fashion and 100% of the respondents felt that the reviewers' final opinion was clearly explained. (Table III)

As to how useful the process was, the majority felt that based upon grouped values on a Likert scale the majority felt that the review process was useful. However, there was less agreement that it was important for the second opinion review process to be conducted to promote adherence to the best practice parameters or that it was important to undertake efforts to reduce variance in prescribing practices for mental health medications.

Providers were also given opportunity to provide narrative comments about the process. There was a broad range in the comments from providers from appreciating the "second set of eyes and opinions" regarding a patient to other

providers feeling that this was an unnecessary process which was a waste of their time. It should be commented that the response rates were quite low and possibly not representative of the views of the entire provider group.

SUMMARY

The institution of the next phase of the review progress is well underway. The reviews have been scheduled in a timely fashion. In this period there was a lower rate of denial (AAP 9%; ADHD 7%) as compared to the first 8 months (ADHD 17%) of the review program. Providers have generally been satisfied with the process, but some have questioned the value. The review group has been ready to extend the second phase of the review to all issues for some time.

Table I

ADHD Medication Reviews Completed from March 1, 2008 – December, 1 2008
Total Reviews=199

Reviews resulting in a recommendation for no change in drug therapy	Reviews resulting in a recommendation for a change in drug therapy	Reviews completed resulting in a recommendation for a clinical consultation
165	30	4

ADHD Medication Reviews Completed from December 2, 2008– May, 15 2009
Total Reviews=131

Reviews resulting in a recommendation for no change in drug therapy	Reviews resulting in a recommendation for a change in drug therapy	Reviews completed resulting in a recommendation for a clinical consultation
122	9	0

AAP Medication Reviews Completed from February 1, 2009– May, 15 2009
Total Reviews=90

Reviews resulting in a recommendation for no change in drug therapy	Reviews resulting in a recommendation for a change in drug therapy	Reviews completed resulting in a recommendation for a clinical consultation
82	7	1

Table II

AAP Drug Utilization Review Program Survey Results
February 1, 2009 – April 30, 2009

APP Drug Utilization Review Program Survey Results			
Question	Yes	No	No Response
Was the purpose of the review clear prior to the review?	20	4	0
If no, was it made clear by the reviewer?	3	1	21
Was scheduling the review timely and convenient?	20	4	0
Was the reviewer's final opinion explained clearly?	24	0	0

Likert Scale Grouped Values			
Likert item	**1-3**	**4**	**5-7**
How useful was the review process?	4	7	13
To what extent do you agree with the following statements:			
It is important for 2nd opinion reviews to be conducted to promote adherence to the best practice parameters	2	5	17
It is important that efforts are taken to reduce variance in prescribing practices for mental health medications in WA	6	4	13

Table III

ADHD Drug Utilization Review Survey Results

October 1, 2008 – April 30, 2009

ADHD Drug Utilization Review Program Survey Results

Question	Yes	No	No Response
Was the purpose of the review clear prior to the review?	28	2	0
If no, was it made clear by the reviewer?	3	0	27
Was scheduling the review timely and convenient?	26	4	0
Was the reviewer's final opinion explained clearly?	30	0	0

Likert Scale Grouped Values			
Likert item	**1-3**	**4**	**5-7**
How useful was the review process?	9	4	17
To what extent do you agree with the following statements:			
It is important for 2nd opinion reviews to be conducted to promote adherence to the best practice parameters	11	9	10
It is important that efforts are taken to reduce variance in prescribing practices for mental health medications in WA	12	4	14

PCP Questionnaire: ADHD Drug Utilization Review Program

http://maa.dshs.wa.gov/Pharmacy/

1. Was the purpose of the review clear to you prior to the review? ☐ Yes ☐ No

   If no, was it made clear by the reviewer? ☐ Yes ☐ No

2. Was the scheduling of the review timely and convenient? ☐ Yes ☐ No

3. Was the reviewer's final opinion explained clearly? ☐ Yes ☐ No

4. How useful was this review process (please circle a number 1-7)?

Not at all useful			**Neutral**			**Very useful**
1	2	3	4	5	6	7

5. To what extent do you agree with the following statements (please circle a number 1-7)?

   a. It is important that second opinion reviews be conducted to promote adherence to the best practice parameters.

Strongly Disagree			**Neutral**			**Completely Agree**
1	2	3	4	5	6	7

   b. It is important that efforts are taken to reduce variance in prescribing practices for mental health medications in Washington.

Strongly Disagree			**Neutral**			**Completely Agree**
1	2	3	4	5	6	7

6. What suggestions do you have to improve the process?

   _____

   _____

   _____

☐ Provider chooses not to participate in survey.

Please fax completed survey to DSHS 2nd Opinion Reviews, Fax: (206)985-3109 in a timely manner. If you wish to share your comments about the review process by phone, you may contact Chris Varley, MD at (206)987-3236