## BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL BY THE COMMISSIONER OF HEALTH AND SOCIAL SERVICES

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In the Matter of

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OAH No. 14-2280-MDX

### DECISION

#### I. Introduction

H S (H) is a minor who is a Medicaid recipient. H's physician requested that the Medicaid program provide him with a twice daily dose of 1 mg. Intuniv. The Division of Health Care Services (Division) denied the request. H's parents, K and M S, requested a hearing on his behalf.

H's hearing was held on January 16 and 23, 2015. H's parents represented him. Ms. S testified on H's behalf. Angela Ybarra, a Medical Assistance Administrator with the Division, represented the Division. Erin Narus, a licensed pharmacist employed by the Division, testified on the Division's behalf.

The evidence shows that H should be approved to receive a twice daily 1 mg. dosage of Intuniv. The Division's decision denying prior authorization is REVERSED.

## II. Facts

The following facts were established by a preponderance of the evidence.

H is a minor with diagnoses of attention deficit hyperactivity disorder (ADHD), depressive disorder, anxiety disorder, and autistic spectrum disorder.<sup>1</sup> H was taking both Prozac and two dosages of Intuniv daily in May 2014, 1 mg. in the morning and 2 mg. in the evening.<sup>2</sup> H's medications were adjusted subsequently; he was prescribed Ritalin and Focalin. He ended up having to be placed in No Name Hospital. After his release, H's medications were adjusted again. He was first started on 1 mg. of Intuniv. Then he was placed back on his old dosage of Intuniv, 1 mg. in the morning and 2 mg. in the evening. That dosage was too high. He was then placed on a dosage of 2 mg. of Intuniv once daily. That again was too high and resulted in him being sedated.<sup>3</sup> At the end of July, 2014, he was prescribed 1 mg. of Intuniv twice daily "with

<sup>&</sup>lt;sup>1</sup> Ex. E, p. 6.

<sup>&</sup>lt;sup>2</sup> Ex. E, p. 10.

<sup>&</sup>lt;sup>3</sup> K S testimony; K S January 20, 2015 email; Ex. E, p. 7.

excellent results."<sup>4</sup> Intuniv is the extended release form of the drug guanfacine. It requires prior authorization for dosages exceeding 30 units per day.<sup>5</sup>

The Division apparently denied H's July 2014 Intuniv request for prior authorization, although the record is lacking the actual denial documents.<sup>6</sup> The Division provided interim authorization for Intuniv through November 29, 2014.<sup>7</sup> On October 2, 2014, the Division's agent Magellan notified H's doctor that the prior authorization for Intuniv ended November 29, 2014, and asked him to "consider a trial of the immediate release guanfacine for the afternoon dose prior to the expiration of the quantity limit approval" for the purposes of considering "future quantity limit overrides."<sup>8</sup> On November 10, 2014, H's doctor's office responded that he was not interested in using immediate release guanfacine and that supporting documentation would be supplied.<sup>9</sup> On November 24, 2014, H's doctor's office supplied clinical notes for August 25, 2014, September 24, 2014, and October 23, 2014, as part of a prior authorization request for the twice daily dose of Intuniv.<sup>10</sup> The October 23, 2014 notes state that H was currently stable, that it was "not in [his] best interest to change medication" and that it was "in the best interest of this patient to continue current regimen, which have been beneficial up to now."<sup>11</sup>

The record contains a subsequent "Notice of Prior Authorization Determination" dated November 27, 2014, which stating that progress was "in progress" and further stating "[if] it is necessary for this patient to exceed the established quantity of one per day for the requested medication, please give clinical justification."<sup>12</sup> On December 23, 2014, H's psychiatrist again requested that the Division prior authorize H's Intuniv twice daily 1 mg. prescription, stating that it was providing "excellent results," and that the mother reported excessive sedation at a higher dose. Copies of May 15, 2014 clinical notes were attached.<sup>13</sup> On December 24, 2014, there is a

<sup>12</sup> Ex. E, p. 40.

<sup>&</sup>lt;sup>4</sup> Ex. E, p. 5.

<sup>&</sup>lt;sup>5</sup> Intuniv is contained on the Division's list, p. 6, of prescriptions with quantity limits requiring prior authorization approval. *See <u>http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/max\_units\_all.pdf</u>. <i>Also see* Ms. Narus's testimony.

 <sup>&</sup>lt;sup>6</sup> Ms. S originally requested a hearing challenging a medication denial for Intuniv on August 8, 2014. Ex. C.
<sup>7</sup> Ex. E, p. 1.

<sup>&</sup>lt;sup>8</sup> Ex. E, p. 21.

<sup>&</sup>lt;sup>9</sup> Ex. E, p. 1.

<sup>&</sup>lt;sup>10</sup> Ex. E, pp. 22 - 38.

<sup>&</sup>lt;sup>11</sup> Ex. E, p. 26.

<sup>&</sup>lt;sup>13</sup> Ex. E, pp. 3 - 20.

"Notice of Prior Authorization Determination" stating prior authorization was denied because the "patient does not meet the AK Medicaid criteria for approval of this medication."<sup>14</sup>

#### **III.** Discussion

The Alaska Medicaid program has a number of medications which require prior authorization.<sup>15</sup> In determining whether to grant prior authorization for a medication (or any service), regulation 7 AAC 105.130 states the "factors that the department will consider include the service's medical necessity, clinical effectiveness, cost-effectiveness, and likelihood of adverse effects . . ."<sup>16</sup> That same regulation allows the department to limit quantities of a service in order to address waste, fraud, and abuse.<sup>17</sup> A more specific regulation states that the department "[a]s necessary to prevent waste or to address fraud and abuse . . . may limit its payment to minimum or maximum quantities allowed of a specific prescribed drug."<sup>18</sup> Any dosage of Intuniv exceeding more than one unit per day is one of those limited quantity medications.<sup>19</sup>

The Division's pharmacist, Ms. Narus', testimony argued that in order to go beyond the prior authorization limits, there must be peer reviewed literature or compendia supporting the requested use, and that there was no compendia on Intuniv, merely on the immediate release form of guanfacine. She referred to federal Medicaid statute 42 USC 1396r-8(g)(1)(b), which references compendia and peer reviewed literature. However, that statute refers to the drug review process, not the limitation on drug prescription amounts. That limitation is contained in 42 USC 1396r-8(d)(6), which, as with the Alaska regulations, allows quantity limitations to address waste, fraud, and abuse. The Division's only specific inquiries contained in the record are the October 2, 2014 request to consider a clinical trial of guanfacine immediate release instead of Intuniv, which was declined by the physician, and the November 27, 2014 inquiry asking for clinical justification. Given that the Division inquiry appeared to be focused on clinical justification, and given what appears to be the inapplicability of the general standards for

<sup>&</sup>lt;sup>14</sup> Ex. E, p. 41.

 $<sup>^{15}</sup>$  7 AAC 105.130(a)(13); 7 AAC 120.130(a)(1).

<sup>&</sup>lt;sup>16</sup> 7 AAC 105.130(c). When the words "include" or "including" are part of the text of a law, they are "construed as though followed by the phrase 'but not limited to." AS 01.10.040(b).

 $<sup>\</sup>begin{array}{ccc} 17 & 7 \text{ AAC } 105.130(c)(2). \\ 18 & 7 \text{ AAC } 120, 120(d) \end{array}$ 

<sup>&</sup>lt;sup>18</sup> 7 AAC 120.130(d).

<sup>&</sup>lt;sup>19</sup> Intuniv is contained on the Division's list, p. 6, of prescriptions with quantity limits requiring prior authorization approval. *See <u>http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/max\_units\_all.pdf</u>*.

setting up a drug review process (compendia and peer reviewed literature), to the specific question in this case, the Division's argument is not persuasive.

This decision will therefore focus on the grounds for prior authorization contained in the applicable regulations, being medical necessity, clinical effectiveness, cost-effectiveness, and likelihood of adverse effects, waste, fraud, and abuse.<sup>20</sup> There is no evidence of any type showing waste, fraud, and abuse. Instead, there is clinical evidence, consisting of H's doctor's clinical notes showing that H was excessively sedated when he received Intuniv twice daily, a 1 mg. and a 2 mg. dose, that when his medication was adjusted he had adverse effects, and that when his medications were again adjusted in late July 2014 to 1 mg. of Intuniv twice daily, he was stable and experienced "excellent results."

"The Medicaid statute and regulatory scheme create a presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment."<sup>21</sup> An administrative law judge must provide "clear and convincing" reasons for rejecting the uncontradicted opinion of either a treating or examining physician.<sup>22</sup> The facts do not provide "clear and convincing" reasons for rejecting the pediatrician's medical necessity opinion. Instead, given that H is taking the twice daily dose of Intuniv with "excellent results," the facts corroborate the physician's medical necessity opinion. Based upon the evidence as a whole, it is more likely true than not true that H should receive 1 mg. of Intuniv twice daily.

## IV. Conclusion

The Division's decision to deny H's prior authorization request is REVERSED. DATED this 17<sup>th</sup> day of March, 2015.

<u>Signed</u> Lawrence A. Pederson

Administrative Law Judge

<sup>&</sup>lt;sup>20</sup> 7 AAC 105.130(c), 7 AAC 120.130(d).

<sup>&</sup>lt;sup>21</sup> Weaver v. Reagan, 886 F.2d 194, 200 (8<sup>th</sup> Cir. 1989).

<sup>&</sup>lt;sup>22</sup> Lester v. Chater, 81 F.3d 821, 830 (9<sup>th</sup> Cir. 1996).

# Adoption

The undersigned, by delegation from of the Commissioner of Health and Social Services, adopts this Decision, under the authority of AS 44.64.060(e)(1), as the final administrative determination in this matter.

Judicial review of this decision may be obtained by filing an appeal in the Alaska Superior Court in accordance with Alaska R. App. P. 602(a)(2) within 30 days after the date of this decision.

DATED this 30<sup>th</sup> day of April, 2015.

By: <u>Signed</u> Name: Jared Kosin Title: Executive Director, ORR, DHSS

[This document has been modified to conform to the technical standards for publication.]