

STATE OF MICHIGAN  
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES  
Before the Director of Insurance and Financial Services

In the matter of:

██████████  
Petitioner

v

File No. 150195-001

Alliance Health and Life Insurance Company  
Respondent

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Issued and entered  
this 10<sup>th</sup> day of November 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. BACKGROUND**

On October 5, 2015, ██████████, a registered nurse and the authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives prescription drug coverage from Alliance Health and Life Insurance Company. The Director notified Alliance of the external review request and asked for the information used to make its final adverse determination. Alliance provided its response on October 6, 2015. On October 12, 2015, after a preliminary review of the material submitted, the Director accepted the request.

Because the case involves medical issues, it was assigned to an independent medical review organization which provided its analysis and recommendation to the Director on October 30, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner is █ years old and has attention deficit hyperactivity disorder (ADHD). Her doctor prescribed the prescription drugs Adderall (15 mg in the morning) and Intuniv (2 mg in the afternoon). Alliance approved coverage for Adderall but denied coverage for Intuniv, ruling that it is not listed on its formulary and that all the formulary drugs for the treatment of ADHD had not been tried and failed.

The Petitioner appealed the denials through Alliance's internal grievance process. At the conclusion of that process, on August 10, 2015, Alliance issued a final adverse determination upholding the denial. The Petitioner now seeks from the Director a review of the denial.

### III. ISSUE

Did Alliance properly deny prescription drug coverage for Intuniv?

### IV. ANALYSIS

#### Respondent's Argument

In the final adverse determination issued to the Petitioner's father Alliance wrote:

We upheld the denial for the prescription drug Intuniv, because all the formulary agents for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) has not been tried and failed.

\* \* \*

The criteria for coverage of a DAW [dispense as written] medication are that all generic and preferred brand name formulary medications must be found to cause adverse effects or lack efficacy. A formulary drug that has not been tried includes: Clonidine, Methylphenidate, Dexmethylphenidate, and Concerta which do not require prior authorization. The prescription drugs Daytrana, Focalin ER, and Vyvanse are also available for members that meet prior authorization criteria. Therefore, we recommend upholding the denial of Intuniv brand name because the information provided does not support the medical necessity for receiving Intuniv instead of all the formulary options listed above.

#### Petitioner's Argument

In an October 5, 2015 letter filed with the request for an external review, the Petitioner's doctor stated:

I have found that the best combination of medications to treat [Petitioner's] ADHD symptoms is Adderall 15mg in am and then Intuniv 2 mg in the afternoon. [Petitioner] has trialed several medications: Strattera, Clonidine, Ritalin, Focallin, and Focallin XR.

[Petitioner] was initially started on Adderall (7/20/14), this caused her to be emotional and irritable in the afternoon as it wears off. She then tried Strattera, this caused GI upset and headaches. The Strattera was then stopped and Adderall restarted with Intuniv in the afternoon. This combination allowed [Petitioner] to focus throughout the day and she

stopped having bladder accidents. Generic Intuniv was trialed but was not effective. At this point [Petitioner] was denied coverage for Intuniv. [Petitioner] has since tried Clonidine, which caused excessive drowsiness to the point that she is having bladder accidents again and Ritalin which has not helped with her focus or emotional outbursts in the afternoon. [Petitioner] then switched to Focalin XR in am, which did not provide her with the same level of focus as Adderall and [Petitioner] continued to have urinary accidents and angry outbursts in the afternoon. A regular Focalin dose was then added at noon. [Petitioner] is still experiencing bladder accidents in the afternoon, she is irritable and has emotional outbursts. These behaviors are negatively affecting her afternoons at school and her family time at home in the evening.

The 2015-2016 school year has started. Adderall and Intuniv in combination was very helpful for last school year. We have attempted to trial other medications on the preferred drug list without success. I find it necessary that [Petitioner] use Intuniv for her ADHD....

#### Director's Review

Alliance argues that, because the Petitioner had not tried all seven of its approved ADHD drugs, Intuniv was not medically necessary. (Although according to the Petitioner's doctor, she had tried, without success, two of those approved drugs, Clonidine and Focalin.) The question of whether Intuniv is medically necessary for treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is a physician who is board certified in neurology, child neurology, pediatrics and neurodevelopmental disabilities and has been active practice for more than 20 years. The IRO reviewer's report included the following analysis and recommendation:

The member's treating child neurologist had utilized multiple psychotropic medications to maintain her in the school classroom including Strattera, Ritalin, Focalin, clonidine and Focalin XR....[T]he member had significant side effects on these medications. By multiple trials of single drugs and various combinations, the member's child neurologist has placed her on Foclalin XR 15 mg in the morning, Focalin 5mg at noon and Intuniv 2mg at 2:30 PM. The member's mother and apparently her teachers have reported significant improvement in her attentiveness and attention span with this combination of medications with minimal or no significant side effects.

As the Intuniv was not a covered medication on the health plan's formulary, generic guanfacine was substituted. According to the information provided, the

member's behavior deteriorated with reoccurrence of her attention deficit hyperactivity symptoms. When Intuniv, a long-acting guanfacine formulation was reintroduced in combination with the Focalin, the member returned to her improved state according to her mother and her teachers. The member is also maintained on Singular 4mg for chronic asthma.

[T]he utilization of brand-name Intuniv is a medically necessary component of the member's medications. The member's treating child neurologist did clinical trials of multiple medications, including Strattera, Ritalin, clonidine and Focalin....[I]t is well known among child neurologists that individual responses vary markedly between patients and that multiple trials of somewhat similar psychostimulant drugs may be necessary to be effective in controlling the symptoms of attention deficit hyperactivity disorder....[T]he substitution of generic guanfacine for Intuniv was not an equivalent substitution. Intuniv is a sustained release medication and guanfacine is not....[S]ustained release Intuniv has a clinical record of effectiveness in controlling the symptoms of attention deficit hyperactivity disorder....[T]he metabolic effects of the co-metabolism of Singular may have reduced the circulating levels of guanfacine far more than the sustained release Intuniv. The member's child neurologist did the cross-over experiment of substituting generic guanfacine for Intuniv and then crossed back over to demonstrate the superiority of Intuniv for her....[I]t has been well established that generic medications may have dissimilar bioequivalencies when compared with long-established brand-name drugs. [Citations omitted]

Pursuant to the information set forth above and available documentation...brand name Intuniv is medically necessary and appropriate for treatment of the member's condition.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination, the Director must cite "the principal reason or reasons why the [Director] did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive experience, expertise and professional judgment.

The Director can discern no reason why the IRO's recommendation should be rejected in the present case, finds that Intuniv is medically necessary and appropriate for treatment of the Petitioner's condition and therefore, must be covered.

#### V. ORDER

The Director reverses Alliance Health and Life Insurance Company's August 10, 2015 final adverse determination. Alliance shall immediately provide prescription drug coverage for

brand-name Intuniv. See MCL 550.1911(17). Alliance shall, within seven days of providing coverage, furnish the Director with proof it implemented this order.

To enforce this order, the Petitioner may report any complaint regarding the implementation to the Department of Insurance and Financial Services, Health Care Appeals Sections, at this toll free telephone number: (877) 999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than sixty days from the date of this order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin  
Director

For the Director



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Randall S. Gregg  
Special Deputy Director