



STATE OF WISCONSIN  
Division of Hearings and Appeals

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In the Matter of

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

DECISION

CWA/151573

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**PRELIMINARY RECITALS**

Pursuant to a petition filed August 23, 2013, under Wis. Admin. Code § HA 3.03, to review a decision by the Bureau of Long-Term Support in regard to Medical Assistance, a hearing was held on November 07, 2013, at Waukesha, Wisconsin.

This case is related to cases CWA-151569, CWA-151570, CWA-151574 and CWA-151579.

On November 7, 2013, Ms. Speer submitted an Individual Support and Service Plan dated August 10, 2012, a letter to Petitioner summarizing changes made to the plan, an Individual Support and Service Plan dated September 28, 2012, and a letter to Petitioner summarizing changes made to that plan. These documents have been marked as Exhibits 33, 34, 35 and 36, respectively.

On November 11, 2013, Petitioner's mother submitted Letters of Guardianship of the Person, an Individual Support and Service Plan – Financial and Service Summary by Goal, a receipt from Natural Health Ministry dated November 13, 2010, one page from an Individual Support and Service Plan dated May 10, 2010 and an Expense Report dated November 2010. The documents have been marked as Exhibits 37, 38, 39, 40 and 41, respectively.

The issue for determination is whether Wisconsin IRIS (the agency) correctly discontinued Petitioner's sublingual treatment of seasonal allergies.

There appeared at that time and place the following persons:

**PARTIES IN INTEREST:**

Petitioner:

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

Respondent:

Department of Health Services  
1 West Wilson Street  
Madison, Wisconsin 53703

By: Jill Speer, Participant Services Specialist  
IRIS Consultant Agency  
1 South Pickney Street

Suite 320  
Madison, WI 53703-2887

ADMINISTRATIVE LAW JUDGE:  
Mayumi M. Ishii  
Division of Hearings and Appeals

### **FINDINGS OF FACT**

1. Petitioner is a resident of Waukesha County.
2. Petitioner is 24 years old and is diagnosed with autism, communication disorder, neurological/cognitive deficit, seizure disorder, asthma and allergies. (Exhibit 29) In 2012, Petitioner was also diagnosed with gastrointestinal mal-absorption, abdominal pain, constipation, immune mechanism disorder, metabolic disorder, toxic encephalopathy, and sleep disturbances. (Exhibit 1)
3. Petitioner has is very afraid of needles and has never received subcutaneous immunotherapy a.k.a. allergy shots. (Testimony of Petitioner's mother) Petitioner's allergist has deemed Petitioner, "not an ideal candidate for injection immunotherapy". (Exhibit 16)
4. Petitioner receives sublingual immunotherapy to treat allergic rhinitis, hay fever, and "asthma like episodes". He is treated by Dr. Vijay K. Sabnis of Allergy Associates of La Crosse. (Exhibit 16) Petitioner's condition is further monitored, by his primary care physician, Dr. Bartel. (Exhibit 17)
5. Sublingual immunotherapy involves administering antigens in drops under the tongue, in lieu of more traditional allergy shots. (Exhibit 25)
6. Petitioner receives the antigen drops from Allergy Associates of La Crosse. (Exhibits 18 and 35)
7. Sublingual use of antigens is considered an off-label use and is not approved by the Food and Drug Administration. (Exhibit 25)
8. Sublingual immunotherapy is not covered by Medicaid. (Exhibit 22, Letter from Dr. Lora Wiggins)
9. Petitioner's last Individual Support and Service Plan dated September 28, 2012, indicated that allergy therapy with Allergy Associates of La Crosse was approved at a cost of \$60.00 per unit, 12 times per year. (Exhibit 35, pg. 9)
10. Treatment with Allergy Associates of La Crosse was also approved in a July 14, 2011 Individual Support and Service Plan. (Exhibit 38)
11. In July 2013, Petitioner requested sublingual drops for his seasonal allergies, \$113 per item, four times per year. (Testimony of Ms. Speer)
12. On July 17, 2013, Wisconsin IRIS (the agency) sent Petitioner a notice of action denying the requested service because the agency deemed the service to be experimental in nature and because, "There is insufficient evidence to deem the above requests medically necessarily [sic], therapeutically valuable, or even a safe means to support the participant." (Exhibit 30, pg. 4)
13. Petitioner filed a request for fair hearing that was received by the Division of Hearings and Appeals on August 23, 2013.

### **DISCUSSION**

The petitioner receives medical benefits under IRIS, which stands for Include, Respect, I Self-Direct. This program is a fee-for-service alternative to Family Care, PACE, or Partnership for individuals requesting a long-term care support program in Family Care counties. *Medicaid Eligibility Handbook*, § 37.1.1.

The IRIS program, as an MA Waiver service, may include the following services:

- (1) Case management services.
- (2) Homemaker services.

- (3) Home health aide services.
- (4) Personal care services.
- (5) Adult day health services.
- (6) Habilitation services.
- (7) Respite care services.
- (8) Day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services (whether or not furnished in a facility) for individuals with chronic mental illness, subject to the conditions specified in paragraph (d) of this section.
- (9) Other services requested by the agency and approved by CMS as cost effective and necessary to avoid institutionalization.

42 CFR § 440.180(b)

When determining whether a service is necessary, the Division must review, among other things, the medical necessity of the service, the appropriateness of the service, the cost of the service, the extent to which less expensive alternative services are available, and whether the service is an effective and appropriate use of available services. Wis. Admin. Code, § DHS 107.02(3)(e)1.,2.,3.,6. and 7.

"Medically necessary" means a medical assistance service under ch. DHS 107 that is:

- (a) Required to prevent, identify or treat a recipient's illness, injury or disability; and
- (b) Meets the following standards:
  1. Is consistent with the recipient's symptoms or with prevention, diagnosis or treatment of the recipient's illness, injury or disability;
  2. Is provided consistent with standards of acceptable quality of care applicable to the type of service, the type of provider, and the setting in which the service is provided;
  3. Is appropriate with regard to generally accepted standards of medical practice;
  4. Is not medically contraindicated with regard to the recipient's diagnoses, the recipient's symptoms or other medically necessary services being provided to the recipient;
  5. Is of proven medical value or usefulness and, consistent with s. DHS 107.035, is not experimental in nature;
  6. Is not duplicative with respect to other services being provided to the recipient;
  7. Is not solely for the convenience of the recipient, the recipient's family, or a provider;
  8. With respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient; and
  9. Is the most appropriate supply or level of service that can safely and effectively be provided to the recipient.

Wis. Admin. Code, § DHS 101.03(96m).

In furtherance of implementing this law, the IRIS program has developed various policies regarding funding of goods and services. See *Policy: SC 16.1, IRIS Funding for Goods, Supports and Services (September 1, 2010 – September 30, 2011)* and the *Medicaid Services and Summaries Definitions* manual.

### BURDEN OF PROOF

It is a well-established principle that a moving party generally has the burden of proof, especially in administrative proceedings. State v. Hanson, 295 N.W.2d 209, 98 Wis. 2d 80 (Wis. App. 1980). In a case involving a request for services from IRIS, the applicant has the initial burden to show that the requested services meet the program's guidelines for approval. However, where the agency discontinues a service, the initial burden falls upon the agency to show that it acted correctly.

In the case at hand, Wisconsin IRIS has been paying for some form of sublingual immunotherapy since at least 2011. It is unclear whether this was for seasonal allergies or for food/environmental allergies, because the Individual Service and Support Plan did not specify what type of allergy was being treated. It only indicated that

what was approved in 2012 cost \$60.00 per item, 12 times per year. In developing the most current Individual Service and Support Plan, Petitioner made separate requests for sublingual immunotherapy to treat seasonal allergies at \$113 per item, 4 times a year and for sublingual treatment of food/environmental allergies at \$60.00 per item, 12 times per year.

Regardless of the type of allergy being treated, the fact remains that until the most recent denial, the agency was approving sublingual treatment of Petitioner's allergies. Thus, its current denial of the treatment is a termination of services and the burden of proof falls upon the agency to show that it correctly terminated the service.

#### WHAT TYPE OF SERVICE DOES SUBLINGUAL IMMUNOTHERAPY FALL UNDER?

When asked this question, the agency representative indicated that she did not know under what category of service Sublingual Immunotherapy would fall under. However, in order to determine what rules or laws apply to the requested service, one needs to know what category the service falls into.

The Individual Support and Service Plans listed treatment with Allergy Associates of La Crosse as "Counseling and Therapeutic Resources" in 2011 and as, "Physical or Manipulative Therapy for Maintenance" in 2012.

I can find no category of services entitled "Physical or Manipulative Therapy" in either the policy memo submitted by the agency, *Policy: SC 16.1, IRIS Funding for Goods, Supports and Services (September 1, 2010-September 30, 2011)* or in the *Medicaid Waiver Services Summary Definitions* manual. However, "Counseling and Therapeutic Services" is in the *Medicaid Waiver Services Summary Definitions* manual and is an appropriate categorization. Such services include, "the provision of professional treatment-oriented to participant's identified needs for physical, medical, personal, social behavior, cognitive, developmental, emotional, or substance abuse treatment. The goal of treatment is to maintain or improve participant health, welfare, or functioning in the community." *Medicaid Waiver Services Summary Definitions, pg. 9*

Given that sublingual immunotherapy is a medical treatment for allergies overseen by a medical doctor, it is reasonable to conclude that sublingual immunotherapy falls under "Counseling and Therapeutic Services".

#### IS SUBLINGUAL IMMUNOTHERAPY COVERED THROUGH IRIS?

Wisconsin IRIS previously paid for sublingual immunotherapy. As such, someone at Wisconsin IRIS determined that the therapy was a covered service. It appears that it is now the agency's contention that the sublingual immunotherapy was previously approved in error.

In the *Medicaid Waiver Services Summary Definitions*, it states that "Counseling and Therapeutic Services" excludes 1) In-patient services, 2) Services provided by a physician and 3) Services available through the Medicaid State Plan. Although the sublingual drops are administered at home, the therapy is being provided by and overseen by a physician. Consequently, it is excluded from covered Counseling and Therapeutic Services.

#### FOR FUTURE REFERENCE

As a side note to the parties, I note that the agency also contended that the requested service is experimental in nature, but did not provide any documentation substantiating that assertion. Although Petitioner submitted documentation that seems to suggest that sublingual use of antigens is experimental, I need not reach that question here, because of the basis for denial discussed above. However, Petitioner should note that the Department of Health Services engages a committee that determines whether a service is experimental in nature and that such determinations are governed under Wis. Admin. Code DHS§107.035:

#### **DHS 107.035 Definition and identification of experimental services.**

- (1) DEFINITION. "Experimental in nature," as used in s. [DHS 107.03 \(4\)](#) and this section, means a service, procedure or treatment provided by a particular provider which the department has

determined under sub. (2) not to be a proven and effective treatment for the condition for which it is intended or used.

- (2) DEPARTMENTAL REVIEW. In assessing whether a service provided by a particular provider is experimental in nature, the department shall consider whether the service is a proven and effective treatment for the condition which it is intended or used, as evidenced by:
- (a) The current and historical judgment of the medical community as evidenced by medical research, studies, journals or treatises;
  - (b) The extent to which medicare and private health insurers recognize and provide coverage for the service;
  - (c) The current judgment of experts and specialists in the medical specialty area or areas in which the service is applicable or used; and
  - (d) The judgment of the MA medical audit committee of the state medical society of Wisconsin or the judgment of any other committee which may be under contract with the department to perform health care services review within the meaning of s. [146.37](#), Stats.
- (3) EXCLUSION OF COVERAGE. If on the basis of its review the department determines that a particular service provided by a particular provider is experimental in nature and should therefore be denied MA coverage in whole or in part, the department shall send written notice to physicians or other affected certified providers who have requested reimbursement for the provision of the experimental service. The notice shall identify the service, the basis for its exclusion from MA coverage and the specific circumstances, if any, under which coverage will or may be provided.
- (4) REVIEW OF EXCLUSION FROM COVERAGE. At least once a year following a determination under sub. (3), the department shall reassess services previously designated as experimental to ascertain whether the services have advanced through the research and experimental stage to become established as proven and effective means of treatment for the particular condition or conditions for which they are designed. If the department concludes that a service should no longer be considered experimental, written notice of that determination shall be given to the affected providers. That notice shall identify the extent to which MA coverage will be recognized.

The agency should note that the policy memo *Policy: SC 16.1, IRIS Funding for Goods, Supports and Services (September 1, 2010-September 30, 2011)* is somewhat in conflict with the *Medicaid Waiver Services Summary Definitions* manual. The former states that experimental goods and/or treatment are not covered by IRIS, but the latter, under “Counseling and Therapeutic Services” only excludes 1) in-patient services, 2) Services provided by a physician and 3) Services available through the Medicaid State Plan. It might behoove IRIS/Department of Health Services to update its memo or to create some consistency between its published policies, should this issue arise again.

### **CONCLUSIONS OF LAW**

The agency correctly discontinued Petitioner’s sublingual treatment of seasonal allergies.

**THEREFORE, it is**

**ORDERED**

That the petition be dismissed.

### **REQUEST FOR A REHEARING**

This is a final administrative decision. If you think this decision is based on a serious mistake in the facts or the law, you may request a rehearing. You may also ask for a rehearing if you have found new evidence which would change the decision. Your request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and tell why you did not have it at your first hearing. If you do not explain these things, your request will have to be denied.

To ask for a rehearing, send a written request to the Division of Hearings and Appeals, P.O. Box 7875, Madison, WI 53707-7875. Send a copy of your request to the other people named in this decision as "PARTIES IN INTEREST." Your request for a rehearing must be received no later than 20 days after the date of the decision. Late requests cannot be granted.

The process for asking for a rehearing is in Wis. Stat. § 227.49. A copy of the statutes can be found at your local library or courthouse.

### **APPEAL TO COURT**

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be served and filed with the appropriate court no more than 30 days after the date of this hearing decision (or 30 days after a denial of rehearing, if you ask for one).

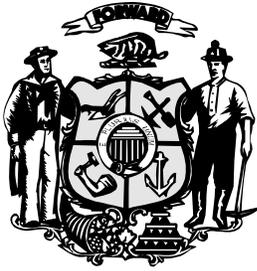
For purposes of appeal to circuit court, the Respondent in this matter is the Department of Health Services. After filing the appeal with the appropriate court, it must be served on the Secretary of that Department, either personally or by certified mail. The address of the Department is: 1 West Wilson Street, Madison, Wisconsin 53703. A copy should also be sent to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400.

The appeal must also be served on the other "PARTIES IN INTEREST" named in this decision. The process for appeals to the Circuit Court is in Wis. Stat. §§ 227.52 and 227.53.

Given under my hand at the City of Milwaukee,  
Wisconsin, this 14th day of November, 2013.

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\sMayumi M. Ishii  
Administrative Law Judge  
Division of Hearings and Appeals



**State of Wisconsin\DIVISION OF HEARINGS AND APPEALS**

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The preceding decision was sent to the following parties on November 14, 2013.

Bureau of Long-Term Support