

**STATE OF MICHIGAN  
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES  
FOR THE DEPARTMENT OF COMMUNITY HEALTH**

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IN THE MATTER OF:

Docket No. 2010-32444 PA  
Case No. [REDACTED]

[REDACTED],  
Appellant  
\_\_\_\_\_ /

**DECISION AND ORDER**

This matter is before the undersigned Administrative Law Judge (ALJ) pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.*, following the Appellant's request for a hearing.

After due notice, a hearing was held on [REDACTED]. The Appellant's physician, Dr. [REDACTED], represented the Appellant. [REDACTED], Appeals Review Officer, represented the Department. Dr. [REDACTED], Medical Consultant for the Office of Medical Affairs (OMA), appeared as a witness for the Department.

**ISSUE**

Did the Department properly deny the Appellant's request for prior authorization of an allogeneic stem cell transplant?

**FINDINGS OF FACT**

The Administrative Law Judge, based on the competent, material, and substantial evidence on the whole record, finds as material fact:

1. The Appellant is enrolled in both Michigan Medicaid and Children's Special Health Care Services (CSHCS). The Appellant also has primary coverage through a private insurer, Physicians Care Health Management (Exhibit 1, pages 6; 14-7; Testimony of Eggleston)
2. In [REDACTED], the Appellant's primary insurer denied coverage for the procedure because its physician reviewer concluded that the treatment was experimental/investigational. (Exhibit 1, pages 14-17)
3. On [REDACTED], Dr. [REDACTED], of the [REDACTED] Medical Center [REDACTED], requested prior authorization from Medicaid for an allogeneic stem cell transplant to treat the Appellant's condition—

Recessive Dystrophic Epidermolysis Bullosa-HS (RDEB).<sup>1</sup> (Exhibit 1, page 4)

4. On ██████████, the Department denied the prior authorization request on the basis that the treatment is investigational/experimental and, therefore, not covered by Medicaid. (Exhibit 1, pages 6-7)
5. On ██████████, the State Office of Administrative Hearings and Rules received the hearing request filed by the Appellant's mother. (Exhibit 1, page 3)

### **CONCLUSIONS OF LAW**

The Medical Assistance Program is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statute, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

Transplants are covered by Medicaid. The Medicaid Provider Manual provides as follows:

CSHCS covers services that are medically necessary, related to the client's qualifying diagnosis(es), and ordered by the client's CSHCS authorized specialist(s) or subspecialist(s). Services are covered and reimbursed according to Medicaid policy unless other stated in this chapter.

The primary CSHCS benefits may include:

\* \* \*

- Transplants and Implants.

*MDCH Medicaid Provider Manual, Children's Special Health Services Section, January 1, 2010, page 13.*

### **13.4 ORGAN TRANSPLANTS**

Medicaid covers organ transplants and related services if all requirements for these services are met.

*MDCH Medicaid Provider Manual, Practitioner Section, January 1, 2010, page 67.*

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<sup>1</sup> "Children with RDEB are unable to produce type VII collagen, resulting in extreme skin fragility. Severe RDEB usually shows generalized blistering at birth and subsequent extensive dystrophic scarring . . . [which] can produce pseudosyndactyly (mitten-hand deformity) of the hands and feet." (Exhibit 1, page 9)

However, certain procedures, including transplants, require prior authorization.

### **1.10 PRIOR AUTHORIZATION**

Medicaid requires prior authorization (PA) to cover certain services before those services are rendered to the beneficiary. The purpose of PA is to review the medical need for certain services.

*MDCH Medicaid Provider Manual, Practitioner  
Section, January 1, 2010, page 4.*

### **13.4 ORGAN TRANSPLANTS**

PA is required for all beneficiary, donor, and potential donor services related to all organ transplants except cornea and kidney transplants

*MDCH Medicaid Provider Manual, Practitioner  
Section, January 1, 2010, page 67.*

### **3.23 ORGAN TRANSPLANTS**

MDCH requires PA from the Office of Medical Affairs (OMA) for organ transplants for all beneficiaries, donors, and potential donor services related to organ transplant except for cornea and kidney.

*MDCH Medicaid Provider Manual, Hospital Section,  
January 1, 2010, page 25.*

In addition, Medicaid will not cover transplants that are determined to be experimental or investigational in nature:

Items or services that are determined to be experimental or investigational are not covered benefits. Such determinations will be made by the Medical Services Administration, based on qualified medical advice that the items or services have not been generally accepted by the professional medical community as effective and proven treatments for the conditions for which they are being used or are to be used. This advice will originate from established sources such as Medicare, National Institutes of Health, Food and Drug Administration (FDA), the AMA's Diagnostic and Therapeutic Technology Assessment (DATTA) Program, etc. The determinations are not judgments that

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the physician's choice is inappropriate or that the patient does not need treatment.

*State Plan under Title XIX of the Social Security Act,  
Preface to Attachment 3.1-A, effective April 1, 1989*

Here, the Department witness, ██████████, testified that the Appellant's request for allogeneic stem cell transplant was denied because after review of the information submitted by ██████████, and after extensive discussion within the Department, including a consult with CSHCS, the procedure was deemed primarily investigational, but also experimental. She noted that the Appellant's private insurer had also denied the procedure on the same basis in late ██████████ (Exhibit 1, pages 14-17) and that in ██████████, the ██████████ Children's Hospital had noted that such a procedure was "very early" and that "there were potentially serious or even fatal consequences" of it. (Exhibit 1, page 39)

The Department's witness further explained that when determining if a procedure is investigational or experimental, the Department looks to see whether the procedure is within the standard of care and whether it is routinely recommended for the particular condition. In other words, the Department looks at whether doctors practicing in that area would recommend the procedure with regularity. She further noted that the University of ██████████ use of allogeneic stem cell transplant for treatment of RDEB is a clinical trial, not a regularly accepted procedure.

The Appellant's representative, ██████████, testified that he is a Pediatric Oncologist/stem cell researcher at the University of ██████████ and has been for over ██████████ years. He stated that in ██████████ the University of ██████████ performed the first ever successful stem cell transplant, and since then, has performed more transplants in children than any other center in the United States. ██████████ testified that all stem cell transplants are considered clinical trials in the United States, but that does not necessarily mean that they are experimental.

██████████ admitted that RDEB is a novel diagnosis to be considered for stem cell transplantation. However, the first one was done ██████████ years, and since then, multiple children with RDEB have been treated and with long-term success. He further testified that the procedure has been accepted by the medical community for treatment of RDEB. ██████████ stated that the New England Journal of Medicine had recently accepted the clinical trial for publication. He further testified that the FDA had approved this procedure for RDEB. Unfortunately ██████████ failed to submit any documentation, as he promised he would, to support this testimony.

Accordingly, the Department provided sufficient evidence that its denial of prior authorization for an allogeneic stem cell transplant was in accord with the Department's policy. While this Administrative Law Judge sympathizes with the Appellant's circumstances, based on the information submitted to the Department, which did not include the New England Journal of Medicine or any FDA approval, its denial was proper.

**DECISION AND ORDER**

The Administrative Law Judge, based on the above findings of fact and conclusions of law, decides that the Department properly denied the Appellant's request for prior authorization of an allogeneic stem cell transplant.

**IT IS THEREFORE ORDERED** that:

The Department's decision is AFFIRMED.

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Kristin M. Heyse  
Administrative Law Judge  
for Janet Olszewski, Director  
Michigan Department of Community Health

cc:

[REDACTED]

Date Mailed: 7/21/2010

**\*\*\* NOTICE \*\*\***

The State Office of Administrative Hearings and Rules may order a rehearing on either its own motion or at the request of a party within 30 days of the mailing date of this Decision and Order. The State Office of Administrative Hearings and Rules will not order a rehearing on the Department's motion where the final decision or rehearing cannot be implemented within 90 days of the filing of the original request. The Appellant may appeal the Decision and Order to Circuit Court within 30 days of the receipt of the Decision and Order or, if a timely request for rehearing was made, within 30 days of the receipt of the rehearing decision.