



State of West Virginia
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
Office of Inspector General
Board of Review
227 Third Street
Elkins, WV 26241

Joe Manchin III
Governor

Martha Yeager Walker
Secretary

November 28, 2005

Dear Mr. _____:

Attached is a copy of the findings of fact and conclusions of law on your hearing held November 22, 2005. Your hearing request was based on the Department of Health and Human Resources' denial of Medicaid coverage for a SpeechEasy fluency device.

In arriving at a decision, the State Hearing Officer is governed by the Public Welfare Laws of West Virginia and the rules and regulations established by the Department of Health and Human Resources. These same laws and regulations are used in all cases to assure that all persons are treated alike.

Eligibility for Medicaid services is based on current policy and regulations. Some of these regulations state as follows: West Virginia Medicaid will consider coverage of services not reimbursed by Medicare when the service is not experimental or investigative and is approved for use by the Federal Drug Administration (FDA). (Medicaid Regulations, Chapter 100, Section 161 and West Virginia Medicaid Program Instruction MA-99-02)

Evidence and testimony presented during the hearing revealed that the SpeechEasy fluency device cannot be covered under West Virginia Medicaid because it is considered experimental or investigative.

It is the decision of the State Hearing Officer to **uphold** the action of the Department to deny Medicaid coverage for the SpeechEasy fluency device.

Sincerely,

Pamela L. Hinzman
State Hearing Officer
Member, State Board of Review

cc: Erika H. Young, Chairman, Board of Review
Lynn Pugh, BMS

**WEST VIRGINIA DEPARTMENT OF HEALTH & HUMAN RESOURCES
BOARD OF REVIEW**

_____,
Claimant,

Action Number: 05-BOR-6071

**West Virginia Department of
Health and Human Resources,**

Respondent.

DECISION OF STATE HEARING OFFICER

I. INTRODUCTION:

This is a report of the State Hearing Officer resulting from a fair hearing concluded on November 28, 2005 for _____. This hearing was held in accordance with the provisions found in the Common Chapters Manual, Chapter 700 of the West Virginia Department of Health and Human Resources. This fair hearing was convened on November 22, 2005 on a timely appeal filed June 24, 2005. The hearing was originally scheduled for September 23, 2005, but was rescheduled at the request of the Department.

II. PROGRAM PURPOSE:

The Program entitled Medicaid is set up cooperatively between the Federal and State governments and administered by the West Virginia Department of Health & Human Resources.

The 1965 Amendments to the Social Security Act established, under Title XIX, a Federal-State medical assistance program commonly known as Medicaid. The Department of Health and Human Resources administers the Medicaid Program in West Virginia in accordance with Federal Regulations. The Bureau for Medical Services is responsible for development of regulations to implement Federal and State requirements for the program. The Department of Health and Human Resources processes claims for reimbursements to providers participating in the program.

III. PARTICIPANTS:

_____, Claimant

_____, mother of Claimant

_____, sister-in-law of Claimant

Barbara White, Program Manager II, Bureau of Medical Services (participating telephonically)

Lynn Pugh, HHR Specialist, Bureau of Medical Services (participating telephonically)

Presiding at the hearing was Pamela L. Hinzman, State Hearing Officer and a member of the State Board of Review.

IV. QUESTIONS TO BE DECIDED:

The question(s) to be decided is whether the Department was correct in its decision to deny Medicaid coverage for the SpeechEasy fluency device.

V. APPLICABLE POLICY:

Medicaid Regulations, Chapter 100, Section 161

West Virginia Medicaid Program Instruction MA-99-02

VI. LISTING OF DOCUMENTARY EVIDENCE ADMITTED:

Department's Exhibits:

- D-1 Prior authorization request forms submitted to West Virginia Medical Institute and denial letter
- D-2 Medicaid Regulations, Chapter 100, Section 161
- D-3 West Virginia Medicaid Program Instruction MA-99-02
- D-4 Electronic mail transmission from Dr. [REDACTED]
- D-5 Information from [REDACTED] regarding SpeechEasy device
- D-6 Information from insurance companies and National Stuttering Association

VII. FINDINGS OF FACT:

- 1) The Claimant's physician submitted a Certificate of Necessity dated April 18, 2005 (D-1) to the West Virginia Medical Institute (WVMI) requesting Medicaid authorization for the purchase of a SpeechEasy fluency device.
- 2) The Claimant was sent a Notice of Denial (D-1) on May 17, 2005 which indicated that coverage of the device was denied by the Bureau of Medical Services because the fluency prosthesis is a non-covered Medicaid service.
- 3) Ms. White testified that Medicaid coverage was denied because the SpeechEasy device is considered experimental, investigational and unproven. She provided evidence from

the National Stuttering Association internet site (D-6) printed on November 21, 2005 which states:

Unfortunately, at present, there are no published, independent studies that show what percentage of the population of people who stutter are likely to benefit from the SpeechEasy.

- 4) Ms. White also provided evidence from [REDACTED] Health Care, Cigna Healthcare and Aetna insurance (D-6) regarding their positions on insurance coverage for speech fluency devices.

Information from [REDACTED] states:

The SpeechEasy Device for stuttering is not covered due to insufficient clinical evidence in support of the effectiveness of the device.

Evidence from Cigna Healthcare states:

Cigna Healthcare does not cover the use of stuttering treatment devices because they are considered experimental, investigational or unproven. Based on a review of the published peer-reviewed scientific literature, there is insufficient evidence to conclude that stuttering devices are effective in the treatment of stuttering or dysfluency. The results of very small, uncontrolled case reports suggest that some individuals experience a decrease in stuttering while using AAF devices. However, well-designed prospective randomized, controlled clinical trials are needed to establish the long-term efficacy of these devices and to define their role in the treatment of stuttering when compared to standard or no treatment.

The information reveals that Aetna also considers the SpeechEasy device “experimental and investigational.”

- 5) _____ testified that her nephew’s speech is limited and he cannot express himself, which hinders his development of life skills. She explained how the SpeechEasy operates and discussed a videotape she had viewed showing remarkable improvements in the communication of those utilizing the SpeechEasy device. Ms. White responded that she does not dispute the potential benefit of the device, but explained that Medicaid cannot cover experimental equipment.
- 6) Medicaid Regulations, Chapter 100, Section 161 (D-2) state that the West Virginia Medicaid Program does not cover certain services and items regardless of medical necessity. The list of non-covered services/items includes experimental or investigational/research services or drugs.
- 7) West Virginia Medicaid Program Instruction MA-99-02 (D-3) states that West Virginia Medicaid will consider coverage of services not reimbursed by Medicare under the following criteria:

The service must not be experimental or investigative and must be FDA (Federal Drug Administration) approved for this use.

VIII. CONCLUSIONS OF LAW:

- 1) The Claimant requested Medicaid coverage for a SpeechEasy fluency device to improve communication problems caused by stuttering
- 2) The Department provided evidence to indicate that the SpeechEasy and other fluency devices are considered experimental and their effectiveness is unproven by clinical trials.
- 3) Policy reveals that West Virginia Medicaid prohibits payment for experimental or investigational/research services or drugs.
- 4) While the Claimant's need for improved communication is unquestionable, the Department took the correct action in denying the Claimant's request for payment of a SpeechEasy fluency device.

IX. DECISION:

It is the ruling of the State Hearing Officer to **uphold** the Department's decision to deny Medicaid payment of a SpeechEasy fluency device.

X. RIGHT OF APPEAL:

See Attachment

XI. ATTACHMENTS:

The Claimant's Recourse to Hearing Decision

Form IG-BR-29

ENTERED this 28th Day of November, 2005.

Pamela L. Hinzman
State Hearing Officer