STATE OF FLORIDA
DEPARTMENT OF CHILDREN AND FAMILIES
OFFICE OF APPEAL HEARINGS

APPEAL NO. 09F-04843

PETITIONER,

Vs.

AGENCY FOR HEALTH
CARE ADMINISTRATION
CIRCUIT: 02 Leon
UNIT: AHCA

RESPONDENT.
_____/

FINAL ORDER

Pursuant to notice, an administrative hearing was convened before the undersigned hearing officer on November 12, 2009, at 2:45 p.m., in Tallahassee, Florida. The petitioner was present. He was represented by his mother, (..id. Testifying on behalf of the petitioner was his step-father, . The respondent was represented by Harold Walker, program administrator, Agency for Health Care Administration (AHCA). Testifying on behalf of the respondent was Dan Gabrick, Medicaid health care program analyst.

The hearing was originally scheduled to be held on September 7, 2009 but was rescheduled for October 6, 2009 at the petitioner's request. A further request for continuance was granted and the hearing was convened on November 12, 2009.

ISSUE

At issue is whether or not state plan Medicaid denial of coverage of durable medical equipment and supplies was correct based on the contention that the service is not a covered service under that plan as it is considered experimental or investigational in nature and does not meet the definition of medical necessity.

FINDINGS OF FACT

1. The petitioner is 31 years old. He has cerebral palsy and is developmentally delayed. The petitioner lives with his mother and stepfather and receives state plan Medicaid services as a recipient of Supplemental Security Income (SSI).
2. The petitioner was born prematurely and contracted spinal meningitis shortly after his birth. He is severely retarded, is hydrocephalic, and has seizures. At the age of 12, the petitioner began experiencing problems with bowel movements. His treating physician, ..., provided a letter indicating that "due to his very limited physical activity, he has been plagued with chronic constipation and near fecal obstruction."
3. The petitioner's family has tried several alternate methods to provide relief to the petitioner including the use of ducolax (laxatives), stool softeners and enemas but have not found them to be effective. The petitioner has required manual disimpactions and hospital visits for this affliction.

4. The petitioner's mother received literature regarding durable medical equipment, specifically a pulsed irrigated evacuation (PIE) system that could help alleviate the constipation. The PIE is an automated enema in which small pulses of warm tap water are delivered into the rectum, serving to rehydrate feces and promote peristalsis. The petitioner purchased the PIE system privately. The PIE requires a disposable collection container, tubing and a speculum which are medical supplies.
5. The respondent explained that HCPCS codes, (billing codes) are alphanumeric codes in the Common Procedure Coding System used by the Centers for Medicare and Medicaid Services to report services provided to Medicare and Medicaid beneficiaries. Medicaid uses these codes for non-physician procedures, such as ambulance services, durable medical equipment and medical supplies.
6. HCPCS code E0350 is defined as "control unit for electronic bowel irrigation/evacuation system. This code is not open and is not covered by Florida Medicaid (Respondent's Exhibit 2).
7. HCPCS code E0352 is defined as "disposable pack (water reservoir bag, speculum, valving mechanism and collection bag/box) for use with the electronic bowel irrigation/evacuation system". This code is not open and is not covered by Florida Medicaid

8. HCPCS code E1399 is defined as "Miscellaneous, durable Medical Equipment". Code E1399 requires prior authorization and requests must be submitted to the Agency for review by staff.
9. HCPCS code A9900 is defined as "Miscellaneous DME supply, accessory, and/or service component of another HCPC code". A9900 does not require prior authorization, but providers must submit paper claims for manual pricing and medical necessity review.
10. The respondent explained the term medical necessity as defined in the DME and Medical Supply Services coverage and Limitations Handbook (2-9). Medicaid reimburses for services that do not duplicate another provider's service and are determined to be medically necessary as outlined in 59G-1.010, Florida Administrative Code. In addition, the respondent explained that there is a list of items and services not reimbursed through the Medicaid DME and Medical supply Services Program. One of the non-covered items pertinent to the denial is experimental or investigational equipment of any type. Some of the DME and supplies may be reimbursed through other Medicaid programs, such as Home and Community-Based Waiver Programs or other state-operated programs.
11. On March 14, 2005, the respondent denied an "E1399" prior authorization request for disposable pack supplies for use with the electronic

bowel/evacuation system. It was denied for submitting under the improper procedure code for review.

12. On January 20, 2006, the respondent did approve an "A9900" prior authorization request for disposable pack supplies for use with the electronic bowel irrigation/evacuation system. The respondent acknowledged that the approval was made in error and should have been denied based on Agency policy and protocol. Further, only two claims have been approved, the claim associated with the erroneous prior authorization approval and a second claim as a result of the fair hearing proceedings. All other claims were reviewed and denied.

13. The respondent presented an example of Aetna's policy bulletin categorizing the PIE device as experimental and investigational because its clinical value for persons with chronic constipation has not been established along with a listing of HCPCS codes not covered, including code E0350 and E0352 (Respondent's Exhibit 6).

14. The Agency determined the PIE equipment, supplies, and procedure are non-covered services as those services have been deemed as experimental and investigational. The existing HCPCS codes are not open and are classified as non-covered services. Finally, the agency acknowledges that the services using A9900 prior authorization request does not require prior authorization

and claims for the PIE/Pak (supplies) would have been reviewed and then denied as a non-covered service.

15. The petitioner's representative believes the PIE/Pak system has decreased episodes of chronic constipation and that as a result of using this system, the petitioner is more comfortable, healthier and requires fewer hospitalizations. In support of her argument, the representative submitted a letter from the petitioner's treating physician, Temple Robinson, MD stating in part. "Over the past few years the family, has found that the use of the PIE PAK colon irrigation system" has decreased episodes of chronic constipation and near fecal obstruction and prevented hospitalization. " requires fewer manual disimpactions by his parents and overall, has a better disposition...This system, though cumbersome, has been shown to prevent many surgical bowel obstructions and is as effective as more costly inpatient bowel evacuation procedures. Any consideration you can offer his family would be greatly appreciated." (Petitioner's Exhibit 1)

16. The PIE/Pak supplies have been sent to the petitioner on a monthly basis but there is no indication how these supplies were paid or if there will be a bill submitted to the petitioner. The representative indicated that there is a waiver support coordinator but is unsure under which program the petitioner is receiving the coordination of benefits. Further, the representative has explored other alternative sources to help with the chronic constipation

including a colostomy. The representative believes that a colostomy and supplies would be an expensive alternative.

CONCLUSIONS OF LAW

The Florida Administrative Code Rule 59G-1.010 addresses relevant definitions within the Medicaid Program, which apply to this Medicaid decision on the requested equipment and services at issue. Subsection (166) of the Florida Administrative Code Rule defines "medically necessary" care, goods or services, as follows:

> ...means that the medical or allied care, goods, or services furnished or ordered must:
>
> (a) Meet the following conditions:
>
> 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
> 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
> 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available; statewide; and
> 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

Paragraph 3 of the above rule shows that defined services must be consistent with generally accepted professional medical standards as determined by the Medicaid program and not experimental or investigational. Further, medically necessary services must be effective, but must reflect the more conservative or least costly level of services, per paragraph 4.

Findings show that the petitioner's treating physician requested consideration be offered to the petitioner based on how well he tolerated the procedure as treatment to relieve chronic constipation. The Aetna, clinical policy bulletin reviewing the PIE devise indicates generally accepted standard treatments for chronic constipation include: minimization of use of any medications know to cause constipation; correction of metabolic abnormalities that may contribute to constipation; exercise; increased fluid intake; increase dietary fiber; and bulk fiber forming laxatives. In addition, hyperosmotic laxatives (e.g., lactulose, sorbitol and magnesium hydroxide), enemas, and emollient laxatives (docusate sodium) are used in selected cases. The PIE system was cleared by the FDA but there is no clinical efficacy date provided to the FDA. The only comparative study of PIE compared the device to a standard per-oral colonic lavage in patients undergoing colonscopy preparation. The study found PIE equivalent to, but not superior to, standard per-oral lavage. Based on the evidence of the efficacy of PIE and comparative study of PIE compared to standard treatments for chronic constipation, the PIE devise was determined to be experimental and investigational because its clinical value for persons with chronic constipation has not been established. The respondent does not believe that this treatment is as effective as the more conservative generally accepted standard treatment options. There is no rebuttal physician opinion that the use of the PIE/Pak system and supplies would be more effective than the generally accepted standard less costly treatment available to the petitioner.

The DME and Medical Supply Services Coverage and Limitations Handbook p. 2-96 lists non-covered items:

> Non-Covered Items: The following list of items and services are not reimbursed through the Medicaid DME and Medical Supply Services Program; however some of these items may be reimbursed through other Medicaid programs, such as the Medicaid State plan, Home and Community-Based Waiver Programs, or other state-operated programs:...
> - Experimental or investigational equipment of any type.

According to the above authorities, equipment deemed as experimental or investigational are non-covered items by state plan Medicaid. Based on the evidence and testimony provided and a review of the controlling authorities, the undersigned authority concludes the respondent acted correctly to deny coverage for the requested durable medical equipment and supplies under state plan Medicaid.

DECISION

The appeal is denied and the Agency action affirmed.

NOTICE OF RIGHT TO APPEAL

This decision is final and binding on the part of the agency. If the petitioner disagrees with this decision, the petitioner may seek a judicial review. To begin the judicial review, the petitioner must file one copy of a "Notice of Appeal" with the Agency Clerk, Agency for Health Care Administration, 2727 Mahan Drive, Tallahassee, FL 32308-5403. The petitioner must also file another copy of the "Notice of Appeal" with the appropriate District Court of Appeal. The Notices must be filed within thirty (30) days of the date stamped on the first page of the final order. The petitioner must either pay the court fees required by law or seek an order of indigency to waive those fees. The agency has no funds to assist in this review, and any financial obligations incurred will be the petitioner's responsibility.

DONE and ORDERED this 24th day of November, 2009,

in Tallahassee, Florida.

Linda Garton
Hearing Officer
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850-488-1429

Copies Furnished To:
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