STATE OF RHODE ISLAND
EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES APPEALS OFFICE

[redacted]
FOR
[redacted]

v. DOCKET No. 21-784

EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES

DECISION

I. INTRODUCTION

A telephonic hearing on the above-entitled matter was conducted by an Appeals Officer on May 20, 2021, with the Executive Office of Health and Human Services (hereinafter "Agency") and Neighborhood Health Plan of Rhode Island (hereinafter "NHP"). The Appellant's mother, on behalf of her minor child [redacted] initiated this matter to appeal an action taken by NHP and upheld by the Agency. This matter arose from the Appellant's denial of Relizorb, medically necessary, in conjunction with his enteral feedings to treat his exocrine pancreatic insufficiency (EPI) due to a history of cystic fibrosis (CF), malabsorption, poor weight gain and G tube dependency. NHP denied the Appellants request based on the Access Members Handbook that does not list Relizorb as a covered benefit and experimental procedures are a non-covered service. NHP considers Relizorb as an experimental procedure. The Agency concurred as NHP followed the contractual steps required for Medicaid.

This Appeals Officer completed a thorough review of the evidence and testimony presented in this case. For the reasons discussed in more detail below, the decision bas been decided in favor of the Appellant.

II. JURISDICTION

The Executive Office of Health and Human Services is authorized and designated by R.I.G.L. §42-7.2-6.1 and regulation 210-RICR-10-05-2 to be the entity responsible for appeals and hearings related to Medicaid.

III. ISSUE

The issue before this Appeals Officer is whether the Appellant's request for coverage of Relizorb be approved in accordance with the Departmental Regulations as set forth below.

IV. PARTIES AND EXHIBITS

Agency representative, John Neubauer, EOHHS Interdepartmental Project Manager for Medicaid managed care contracts, attended the telephonic hearing and provided testimony on behalf of the Agency. Also, in attendance Christopher Ottiano, Medical Director for NHP, Attorney Robert D. Fine, outside council for NHP from Chace Ruttenberg & Freedman, LLP, Mary M. Eldridge, Assistant General Counsel for NHP, and Jacqueline Bigbee, Senior Manager NHP, provided testimony and evidence relevant to the Appellant's request for coverage of Relizorb. The Agency offered the following into evidence: NHP Member Handbook, marked as Agency Exhibit 1.

The Appellant's mother, [redacted] attended the telephonic hearing and testified on her son's behalf. Also, in attendance Angela Dziok, Cystic Fibrosis Nurse Practitioner & Program Coordinator at Hasbro Children's Hospital, and Donna Moore, Relizorb RN Case Manager, provided testimony and evidence relevant to the Appellant's request for Relizorb. The Appellant offered the following into evidence: An evidence packet that supports their request, marked as Appellant Exhibit 1.

V. RELEVANT LAW

The Rhode Island Code of Rules ("RICR") for the EOHHS in effect at the time of the Agency action, 210-RICR-10-00-1, entitled "Overview of the Rhode Island Medicaid and Children's Health Insurance", provides established guidance pertaining to Medicaid. NHP Access Trust Member Handbook, provides established guidance pertaining to all covered benefits and non-covered services. A copy is attached.

VI. FINDINGS OF FACT

1. The Appellant is an active recipient of Rhode Island Medicaid with NHP as his Managed Care Organization (MCO).

2. On December 31, 2020, NHP upheld the denial of the Appellant's request for Relizorb because it is not listed as a covered benefit, therefore excluded form coverage.

3. The Appellant's mother filed an appeal on his behalf on March 8, 2021, based on NHP's denial of Relizorb.

4. A telephonic hearing was scheduled on May 4, 2021 and rescheduled at the request of the Appellant.

5. The telephonic hearing was held on May 20, 2021. It was agreed by all parties that the hearing would be held open until close of business on June 1, 2021, for submission and review additional evidence.

6. At hearing, the Agency representative upheld the NHP for denial of Relizorb because they followed the Medicaid regulations and contractual steps required.

7. Relizorb is an FDA approved, single use digestive enzyme cartridge designed to hydrolyze fats in enteral tube feeding formula.

VII. DISCUSSION

EOHHS is responsible for administering the State's Medicaid program, which provides health care services and supports to a significant number of Rhode Islanders on an annual basis. The Rhode Island Medicaid program provides health coverage to low-income individuals and families, adults without dependent children age 19 to 64, elders and persons with disabilities who otherwise cannot afford or obtain the services and supports they need to live safe and healthy lives. In this case, the Appellant is in the Medicaid Affordable Care Coverage (MACC) group, under Modified Adjusted Gross Income (MAGI) and eligible for the full scope of services and supports authorized. There are certain limits and restrictions for services and supports financed and administered through the Medicaid program. The record consists of the evidence and testimony submitted by the Agency, as well as the Appellant.

The Agency representative, John Neubauer testified that the documentation received for this case were reviewed. It was determined that NHP followed their contractual requirements regarding the internal appeal process, providing the Appellant the opportunity to appeal to the state for a fair hearing. The Agency is not making any clinical recommendation of the treatment. The Agency feels NHP followed the procedural steps required to issue a denial of coverage for Relizorb and the right to appeal thereafter. The Agency refers to the NHP representatives to explain the specific reasons for the denial.

NHP Medical Director, Christopher Ottiano, noted the Agency's testimony and has closely followed the policies for authorization for coverage of new products or services. The process involves a thorough review of data, papers or references and research indicating that a product or service has become standard of care or widely accepted and a determination is then made if the product should be moved from non-covered to covered status. Approximately 2 to 2

½ years ago, the company who produces the product Relizorb requested that it be moved to covered status. At that time, NHP one of the two largest MCO's, the other MCO, and the states fee for service Medicaid all agreed that the Relizorb was investigational and there was not enough data to indicate it was a benefit to patients who receive it. It was decided that the product would remain at non-covered status. The company continues to provide Relizorb to patients in the community in coordination with providers to accumulate more data and research. NHP is always willing to review new data, research, and patient experience with any product for possible coverage in the future. Based on the NHP contract as a MCO with RI Medicaid, it is recognized we need to be careful allocating Medicaid dollars to products considered as experimental or investigational.

Medical Director Ottiano further testified in preparation for this hearing, NHP reviewed all the documents received. With respect to Nurse Practitioner, Dziok and Dr. Daigle, NHP contacted them to verify that they had all the documents and references for review. In the current review, it is noted that the State Fee-for-Service Medicaid program and the other large MCO in the State still has this product as non-covered. In further review of the references provided, there is a lot of research being done on the product. NHP understands BMI is a very important factor in the care of CF patients. Almost all the references, data, and studies prior to the most recent study in January-February 2021, were looking at fatty acids and other metrics related to BMI, but not strictly BMI. A small study in January-February 2021 showed optimistic findings regarding BMI.

Medical Director Ottiano concluded that the hearing evidence submitted also requested a modification to policy stating that CF patients on enteral feedings be allowed to use Relizorb. The most promising study is small with only 93 participants of which 88 were pediatric. The

modification requests a broad change to the policy to include all CF cases on enteral feedings. NHP's position remains that they encourage further development and data, but to date Relizorb does not meet the states "medical necessity" requirement so it remains non-covered. Both Nurse Practitioner Dziok and Dr. Daigle are respected members in our network, we value their judgement and will continue discussions on Relizorb for the development and evaluation for coverage as long as the data shows significant improvement for patients prescribed it. Although there was a request to modify the policy, he agreed the Appeal Officer's decision will be based solely on [redacted] need for Relizorb.

Attorney Fine noted that a copy of the NHP Member Handbook will be provided to all parties. Additionally, Medical Director Ottiano clarified that in the handbook, if it is a covered service it is listed, anything else is non-covered.

CF Nurse Practitioner, Angela Dziok testified on behalf of Jericho and has been caring for him for a long time, along with the CF team at Hasbro Children's Hospital. [redacted] is a 12-year-old male with a history of CF, EPI, malabsorption, poor weight gain and G tube dependency. The G tube was placed approximately 7 years ago due to poor weight gain for supplemental enteral nutrition. The G tube delivers the supplements at night when he is at rest, to the appropriate intestinal places. This gives [redacted] the energy to sustain normal activities, fight lung infection, breathe normally and compensate for the missed calories that he doesn't receive during the day. [redacted] is woken up to take the oral enzymes, pancreatic enzyme replacement therapy (PERT) before and after his overnight tube feedings. PERT is not always effective for [redacted] because he may not have a good appetite in the morning and may vomit the whole feed due to malabsorption. [redacted] additionally suffers from diarrhea, fatty stools, abdominal pain, bloating and flatulence. Despite the G tube and low BMI, PERT is a failed attempt with his

enteral nutrition feedings. The CF foundation guidelines recommend that children 2 to 20 years old have a BMI of at least in the 50th percentile based on improved pulmonary function, but at [redacted] last appointment his BMI was in the 23rd percentile. Furthermore, [redacted] is an active 12-year old child who tries to keep up with his family and friends, but living with these symptoms daily, slows him down.

Nurse Practitioner Dziok further testified that they are very supportive that [redacted] is given the Relizorb and it has the opportunity to work for him as proven in the multiple studies, including the most recent January 2021 study out of the Journal of Pediatrics Gastroenterol and Nutrition. It has been noted that the inline cartridge that holds the enzymes is delivered in the G tube feeding system, not invasive, easy to use and an FDA approved way to deliver the pancreatic enzyme and the patient does not have to be disturbed. Additionally, 90 percent of fats are broken down, which allows the body to absorb resulting in gained weight, better nutrition, and lung health. The CF guidelines show patients are seen approximately 4 times a year for normal preventative care that include taking cultures for pulmonary lung functioning. [redacted] has been seen in the clinic over 7 times in the past year, not including emergency room visits for abdominal pain and pulmonary exacerbations. This shows he would benefit from steady increase in weight gain which occurs with the Relizorb cartridge. On the other hand, crushed PERT is not endorsed by the manufacturer due to issues of clogging the feeding system that would contribute to increased health care costs that include but not limited to emergency room visits and repairing the feeding system. The benefits of Relizorb for [redacted] are that he would be able to manage his enteral feeds, better his mental health and be more actively engaged in everyday life with friends

and family. Finally, the diagnosis of EPI, necessitates the G tube for optimal nutrition and Relizorb is the only FDA approved treatment that is safe and can be used with the enteral feeds.

[redacted] mom, Ms. [redacted] disputed Mr. Ottiano's testimony, this is not a standard of care product for CF because there is no standard of care. CF is different in every patient based on their individual needs, so is treatment, unlike a cancer patient where most need chemotherapy and radiation. She argued the use of Relizorb is for her son to assist with his treatment and not to change policy for all, as not all CF patients have feeding tubes or have the same malabsorption rates as [redacted] needs supplements in his overnight feeds for nutrition, extra calories and fat due to his severe malabsorption because he can't keep weight on. Another problem [redacted] has is severe stomach issues, sometimes common is CF patients. When [redacted] receives his overnight tube feeding and gets his PERT before and after, he wakes up in the morning with vomiting and diarrhea he loses most if not all the supplemental feeding that he received in the 8-hour period. [redacted] remains in the 23rd percentile for weight but sometimes has been as low as 5th percentile. [redacted] is active 12-year old involved in Lacrosse and Soccer, but he doesn't always have the energy or muscle mass needed for these sports because of his poor nutrition.

Ms. [redacted] concluded that the Relizorb cartridge provides [redacted] not the whole CF population, a constant flow of pancreatic enzymes, so his body at rest does not have to work excessively to break down the nutrition he needs, it does it for him. [redacted] can rest, not lose energy, fat, calories and nutritional needs to boost his health. She understands NHP reviewed Relizorb as a product for enteral feeding, weight and BMI but argues BMI in CF patients are related to their lung health. CF patients live longer with better lung health and that's what she wants for [redacted] and Relizorb can do that for her son. Furthermore, CF centers do not provide Relizorb, it is provided through bridge programs which is only for a period. [redacted] received

Relizorb through 3 separate bridge programs in the last 2 years. This involves numerous documents to be submitted by his doctors each time he applies for a program.

Ms. Dziok agreed with Ms. [redacted] that the treatment is different for each CF patient using Relizorb based on caloric intake. CF is a very complex disease that is still being studied. BMI is the best tracker for good lung health throughout the patient's lifespan especially during a growth spurt, but also good bone health is based on the nutrient's patients take in.

Donna Moore, Relizorb Support Services Case Manager added that the bridge programs were offered by the manufacturer that supplied Relizorb to patients while they were in the process of obtaining authorization for the product. Unfortunately, it was a challenging program to sustain and ended.

In this case, there is no dispute an appeal was filed on the Appellant's behalf based on the NHP denial of Relizorb because it is considered experimental procedure which is non-covered benefit. There is further no dispute that the Agency upheld NHP's denial because NHP followed the Medicaid regulations and contract as a MCO to issue a denial of coverage. The argument is whether the product Relizorb met the policy criteria to be moved from a non-covered to covered status as NHP considers it to be experimental or investigational and does not meet the "medically necessary" requirement.

In review of the regulation 210-RICR-10-00-1, "Overview of the Rhode Island Medicaid and Children's Health Insurance Programs", the Appellant is enrolled in RI Medicaid and his MCO is NHP. In section 1.3 "Purposes and Scope of the Medicaid Program" provides policy on the eligible benefits covered by Medicaid. In further review, the Agency referred to NHP representatives who provided testimony and the NHP Member Handbook as evidence that details all covered benefits and non-covered services. In review of the handbook, NHP stated Relizorb is

a non-covered service because it is considered an experimental procedure as listed on Page 20. Also, NHP explained the process for authorization for coverage of products or services that included through review of data, papers, references, and research to determine if it has become a standard of care or widely accepted. NHP discussed the research and stated it showed optimism but Relizorb doesn't meet the "medically necessary" requirement at this time. The Agency and NHP failed to provide regulations, guidance, or clinical evidence to prove why Relizorb is experimental and remains a non-covered procedure.

In further review of all the evidence and testimony in this case, Relizorb is an FDA approved treatment option for [redacted] as PERT therapy has failed. [redacted] has been involved in 3 bridge programs to receive Relizorb in the past 2 years. According to the NHP Member Handbook, the definition of "Medically Necessary" states, "Direct care, services or supplies that are needed for the diagnosis or treatment of your medical condition, behavioral health, or prevention of worsening of your condition. They must meet the standards of good medical practice and aren't for the convenience of you or your doctor." In [redacted] case this would not be a convenience to use Relizorb, it is needed to treat his EPI, malabsorption, poor weight gain, due to a history of CF. In addition, the [redacted] mom and medical representatives detailed the benefits Relizorb has with his supplemental G tube feedings, that include not but not limited to weight gain, better mental health, nutrition, and better lung health.

VIII. CONCLUSIONS OF LAW

This decision is based solely on whether the Appellant, [redacted] needs Relizorb for his treatment not all NHP members. The Appellant's mom and medical representatives provided credible testimony and evidence to prove Relizorb is FDA approved, safe and is a medically necessary for [redacted] treatment and optimal better health.

After careful and considerate review of the Agency's Rules and Regulations, as well as the evidence and testimony provided, this Appeals Officer concludes that the denial for Relizorb is reversed and the Appellant's request for coverage is granted.

IX. DECISION

Based on the foregoing Findings of Fact, Conclusions of Law and by a preponderance of evidence it is found that a final order be entered that the Appellants request for is granted.

APPEAL GRANTED

/s/ Louanne Marcello

Louanne Marcello
Appeals Officer

CERTIFICATION

I hereby certify that I mailed, via regular mail, postage prepaid, a true copy of the foregoing to [redacted], copies were sent via email to Agency representatives John Neubauer, Kristin Souza, Jane Morgan, Esq., NHP representatives Mary Eldridge and Douglas Byrd and Attorney Robert D. Fine @ rfine@crfllp.com, on this 12 day of JULY, 2021.

APPENDIX

210-RICR-10-00-1
TITLE 210 – EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES
CHAPTER 10 – EOHHS GENERAL PROVISIONS
SUBCHAPTER 00 - GENERAL PROVISIONS
Part 1 - Overview of the Rhode Island Medicaid and Children's Health Insurance Programs
1.1 Statutory Authority of the State Agency

A. R.I. Gen. Laws § 42-7.2-2 created the Rhode Island Executive Office of Health and Human Services (EOHHS) in 2006. EOHHS serves "as the principal agency of the executive branch of state government for managing the departments of children, youth and families, health, human services, and behavioral healthcare, developmental disabilities and hospitals."

B. EOHHS is responsible for administering the State's Medicaid program, which provides health care services and supports to a significant number of Rhode Islanders on an annual basis.

C. The statutory foundations of the Rhode Island Medicaid program are Title XIX of the Social Security Act (42 U.S.C. § 1396a et seq.), R.I. Gen. Laws Chapter 40-8, and R.I. Gen. Laws Chapter 42-7.2. Statutory authority for health care coverage funded in whole or in part by the federal Children's Health Insurance Program (CHIP) is derived from 42 U.S.C. § 1397aa et seq., of the U.S. Social Security Act, which establishes that program and provides the legal basis for providing health coverage, services and supports to certain targeted low-income children and pregnant women through Medicaid.

D. EOHHS is designated as the "single state agency", authorized under Title XIX and, as such, is legally responsible for the fiscal management and administration of the Medicaid program. As health care coverage funded by CHIP is administered through the State's Medicaid program, EOHHS also serves as the CHIP State Agency under federal and State laws and regulations.

E. The Medicaid and CHIP State Plans and the Rhode Island's Medicaid Section 1115 demonstration waiver provide the necessary authorities for the health care administered through the Medicaid program and establish the respective roles and responsibilities of beneficiaries, providers, and the State.

1.2 Definitions

A. As used herein, these definitions have the following meaning:

1. "CHIP State Plan" means the State of Rhode Island's State Plan identifying the eligibility categories and services authorized for federal financial participation

under Title XIX of the federal Social Security Act establishing the Children's Health Insurance Program (CHIP).

2. "Executive Office of Health and Human Services" or "EOHHS" means the state agency established in 2006 under the provisions of R.I. Gen. Laws Chapter 42-7.2 within the executive branch of state government and serves as the principal agency for the purposes of managing the Departments of Children, Youth, and Families (DCYF); Health (RIDOH); Human Services (DHS); and Behavioral Healthcare, Developmental Disabilities, and Hospitals (BHDDH). EOHHS is designated as the "single state agency," authorized under Title XIX of the U.S. Social Security Act (42 U.S.C. § 1396a et seq.) and, as such, is legally responsible for the program / fiscal management and administration of the Medicaid Program.
3. "Medicaid State Plan" means State of Rhode Island's State Plan identifying the eligibility categories and services authorized for federal financial participation under Title XIX of the federal Social Security Act establishing the Medicaid program.

4. "State agency" means EOHHS.

1.3 Purposes and Scope of the Medicaid Program

A. The Rhode Island Medicaid program is the joint federal/state health care program that provides publicly funded health coverage to low-income individuals and families, adults without dependent children age nineteen (19) to sixty-four (64), elders, and persons with disabilities who otherwise cannot afford or obtain the services and supports they need to live safe and healthy lives.

B. Eligibility -- Coverage Groups. A coverage group is a classification of individuals eligible to receive Medicaid benefits based on a shared characteristic such as age, income, health status, and level of need criteria. Pursuant to the authority provided under the Medicaid and CHIP State Plans and the State's Section 1115 demonstration waiver, health coverage, services, and supports are available to individuals and families who meet the eligibility requirements for the following coverage groups:

1. Medicaid Affordable Care Coverage (MACC) Groups –A single income standard – Modified Adjusted Gross Income or "MAGI" – must be used to determine the eligibility of all applicants under the Medicaid affordable care coverage groups, which are as follows:

a. Families with children and young adults, pregnant women, infants and parents/caretakers with income up to the levels sets forth in Part 30-00-3 of this Title; …

C. Benefits. Medicaid beneficiaries are eligible for the full scope of services and supports authorized by the Medicaid State Plan and the Section 1115 demonstration waiver.

1. General scope of coverage. Although there is variation in benefits by coverage group, in general Medicaid health coverage includes the following:

Doctor's office visits	Home health care
Immunizations	Skilled nursing care
Prescription and over-the-counter medications	Nutrition services
Lab tests	Interpreter Services
Residential treatment	Childbirth education program
Behavioral health services	Prenatal and post-partum care
Drug or alcohol treatment	Parenting classes
Early and Periodic, Screening, Detection and Treatment (EPSDT)	Smoking cessation programs
Referral to specialists	Transportation services
Hospital care	Dental care
Emergency care	Expedited LTSS
Urgent Care	Organ transplants
Long-term Services and Supports (LTSS) in home and community-based and health care institutional settings such as nursing homes	Durable Medical Equipment

2. EPSDT. Title XIX authorizes Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) for all Medicaid beneficiaries who are under age twenty-one (21) for the purposes of identifying and treating behavioral health illnesses and conditions. Medically necessary EPSDT services must be provided irrespective of whether they are within the scope of Medicaid State Plan covered services.

3. Limits. Certain benefits covered by the Medicaid State Plan or the State's Section 1115 waiver are subject to limits under federal and/or State law. Program-wide benefit limits are set forth in § 1.5 of this Part. Limits and restrictions applicable to specific coverage groups are located in the rules describing the coverage group and service delivery.

1.4 Program Administration

B. Eligibility Agent -- DHS. The Medicaid State Agency is authorized under Title XIX and federal implementing regulations to enter into agreements with other State agencies for the purposes of determining Medicaid eligibility. EOHHS has entered into a cooperative agreement with tbe Rhode Island Department of Human Services (DHS) that authorizes the DHS to conduct certain eligibility functions. In accordance with 42 C.F.R. § 431.10 (c)(3), the DHS has agreed to carry out these functions in accordance with the Medicaid State Plan, the State's Section 1115 demonstration waiver, and the rules promulgated by EOHHS.

D. Mandatory Managed Care Service Delivery. To ensure that all Medicaid beneficiaries have access to quality and affordable health care, EOHHS is authorized to implement mandatory managed care delivery systems. Managed care is a health care delivery system that integrates an efficient financing mechanism with quality service delivery, provides a medical home to assure appropriate care and deter unnecessary services, and places emphasis on preventive and primary care. Managed care systems also include a primary care case management model in which ancillary services are provided under the direction of a physician in a practice that meets standards established by the Medicaid agency. Managed care systems include the Medicaid program's integrated care options such as long-term services and supports and primary care health coverage for eligible beneficiaries. The managed care options for Medicaid beneficiaries vary on the basis of eligibility as follows:

1. Families with children eligible under the Part 30-00-1 of this Title are enrolled in a RIte Care managed care plan in accordance with the Part 30- 05-2 of this Title or, as applicable, an employer health plan approved by EOHHS for the RIte Share Premium Assistance Program in accordance with the Part 30-05-3 of this Title unless specifically exempted;

1.5 Program-wide Limits and Restrictions

A. Both federal and State law impose certain limits and restrictions on the scope, amount, and duration of the health care coverage, services, and supports financed and administered through the Medicaid program.

NOTICE OF APPELLATE RIGHTS

This Final Order constitutes a final order of the Department of Human Services pursuant to RI General Laws §42-35-12. Pursuant to RI General Laws §42-35-15, a final order may be appealed to the Superior Court sitting in and for the County of Providence within thirty (30) days of the mailing date of this decision. Such appeal, if taken, must be completed by filing a petition for review in Superior Court. The filing of the complaint does not itself stay enforcement of this order. The agency may grant, or the reviewing court may order, a stay upon the appropriate terms.