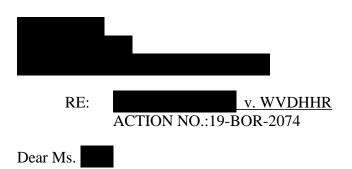


STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES OFFICE OF INSPECTOR GENERAL

Bill J. Crouch Cabinet Secretary BOARD OF REVIEW 4190 Washington Street, West Charleston, West Virginia 25313 304-746-2360 Fax – 304-558-0851 Jolynn Marra Interim Inspector General

September 25, 2019



Enclosed is a copy of the decision resulting from the hearing held in the above-referenced matter.

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.

You will find attached an explanation of possible actions you may take if you disagree with the decision reached in this matter.

Sincerely,

Danielle C. Jarrett State Hearing Officer Member, State Board of Review

Encl: Appellant's Recourse to Hearing Decision

Form IG-BR-29

cc: Lori Tyson, Department Representative

WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES BOARD OF REVIEW

Appellant,

v. BOR Action Numbers: 19-BOR-2074

WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES,

Respondent.

DECISION OF STATE HEARING OFFICER

INTRODUCTION

This is the decision of the State Hearing Officer resulting from a fair hearing for This hearing was held in accordance with the provisions found in Chapter 700 of the West Virginia Department of Health and Human Resources' Common Chapters Manual. This fair hearing was convened on August 20, 2019, on an appeal filed July 22, 2019.

The matter before the Hearing Officer arises from the July 9, 2019 decision by the Respondent to deny Medicaid prior authorization for the prescription drug Skelaxin.

At the hearing, the Respondent appeared by Lori Moles, Pharmacist for the Bureau of Medical Services (BMS). The Appellant appeared *pro se*. All witnesses were sworn and the following documents were admitted into evidence.

Department's Exhibits: D-1 Written Correspondence from , Certified Family Nurse Practitioner, , dated June 26, 2019 Customer Statement Report for Medications filled at D-2 dated June 21, 2018 through June 21, 2019 D-3 Drug Therapy Program Fax Cover Sheet, dated June 28, 2019 West Virginia Department of Health and Human Resources (DHHR) BMS Notice D-4 of Denial, dated June 27, 2019 , PC Office Note, dated April 9, 2003; and Follow-D-5 up Notes, dated June 19, 2001 Medication Log for dated May 9, 2001 through July 26, 2001; D-6 Diagnostic and Therapeutic Plan; and Office Notes, dated November 7, 2001 through May 30, 2003 DHHR Notice of Denial, dated July 3, 2019 D-7

Appellant's Exhibits:

None

After a review of the record, including testimony, exhibits, and stipulations admitted into evidence at the hearing, and after assessing the credibility of all witnesses and weighing the evidence in consideration of the same, the Hearing Officer sets forth the following Findings of Fact.

FINDINGS OF FACT

- 1) The Appellant's Certified Family Nurse Practitioner (CFNP) requested prior authorization for the prescription drug Skelaxin for degenerative disk disease on behalf of the Appellant.
- 2) The Appellant was denied the request for the prior authorization for Skelaxin.
- 3) On June 26, 2019, CFNP (Ms.), appealed the Respondent's denial and indicated the Appellant "has tried several alternatives such as Flexeril (Cyclobenzaprine), Robaxin (Methocarbamol), and Lorzone, all of which did not sufficiently manage her muscle pain." And that "a combination of Flexeril and Skelaxin have successfully eased her pain in the past." (Exhibit D-1)
- 4) On June 27, 2019, notice of denial of the appeal was issued to the Appellant indicating after a medication history review, there was no evidence that the Appellant had tried Robaxin (Methocarbamol) in the past and if the Appellant provided pharmacy records that demonstrated the dates and length of time Robaxin (Methocarbamol) was trialed then the Respondent would consider approval of Skelaxin. (Exhibit D-4)
- 5) The Appellant tried Robaxin (Methocarbamol) for several years and due to the adverse side effects, she refuses to try Robaxin (Methocarbamol) again. (Exhibit D-1)
- 6) The July 27, 2019 notice of denial further advised that Medicaid will only "cover one skeletal muscle relaxant at a time. We will not cover both Skelaxin and Cyclobenzaprine for your patient." (Exhibit D-4)
- 7) The Appellant had a history of prior prescriptions for Flexeril (Cyclobenzaprine), Robaxin (Methocarbamol), and a combination of the drugs. (Exhibits D-5 and D-6)
- 8) In August 2003, the Appellant was no longer prescribed Robaxin (Methocarbamol) and was prescribed Skelaxin. (Exhibit D-5)
- 9) The Appellant pays out-of-pocket for her prescription drug Flexeril (Cyclobenzaprine). (Exhibit D-1)
- 10) On July 3, 2019, the Respondent issued a notice advising the Appellant that her appeal for prior approval for Skelaxin was again denied. The notice further indicated that BMS "would not cover both Skelaxin and Cyclobenzaprine". (Exhibit D-7)

- 11) The July 3, 2019 notice stated "please provide literature supporting the combined long-term use of 2 centrally acting muscle relaxants for any condition and we would be willing to review the information. Otherwise, the denial for Skelaxin is considered a final decision by the Medical Director." (Exhibit D-7)
- 12) No additional documentation was received supporting the combined long-term use of two (2) centrally acting muscle relaxants for any condition.
- 13) At least since July 2018, the Appellant has paid out-of-pocket for her prescription drug Methadone. (Exhibit D-2)
- 14) The Appellant's use of prescription drugs Flexeril (Cyclobenzaprine) and Skelaxin results in therapeutic duplication.
- 15) Therapeutic duplication of prescription drugs is considered a non-covered service that is not reimbursable by Medicaid.

APPLICABLE POLICY

Bureau of Medical Services (BMS) Policy Manual § 518.1 Covered Services provides in part:

Except for certain limitations and exclusions, West Virginia Medicaid will reimburse for the following:

- outpatient legend drugs
- specific over-the-counter drugs
- compounded prescriptions
- drugs that require prior authorization when approved by the BMS
- family planning supplies including certain over-the-counter supplies
- certain diabetic supplies
- influenza, pneumonia, Hepatitis A and B, tetanus-diphtheria (Td), and tetanus-diphtheria-and-pertussis (Tdap) vaccines for adults 19 years of age and older administered by a pharmacist. Members up to 19 years of age have access to vaccines via the Vaccines for Children Program.
- Herpes zoster vaccine for adults 50 years of age and older administered by a pharmacist

Drugs covered under the Medicaid outpatient pharmacy outpatient pharmacy program are those that have been approved for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act, when used for medically accepted indications.

Medically accepted indication means any use that is supported by one or more of the following official compendia:

- The American Hospital Formulary Service Drug Information;
- The United States Pharmacopoeia Drug Information on its approved replacement;
- The DRUGEX Information System

All covered drugs, whether legend or over-the-counter, must be prescribed by a practitioner qualified under state law with the scope of his/her license and in accordance with all state and federal requirements.

BMS Policy Manual § 518.2 reads in part:

Prior authorization for Medicaid-covered drugs is required for reimbursement of certain drugs to assure the appropriateness of drug therapy. Specific prior authorization criteria are based on review of the most current clinical information, Food and Drug Administration (FDA) approved indications, and manufacturers' recommendations. These criteria are reviewed by the Medicaid Drug Utilization Review (DUR) board and recommended to the BMS. These criteria then form the basis of acceptable drug therapy for members with Medicaid pharmacy benefits. Current criteria for coverage of non-preferred drugs and other drugs requiring prior authorization is available on the BMS website. Drugs which require prior authorization and for which prior authorization criteria have not been met are considered non-reimbursable unless, upon appeal by the prescribing provider, the Medicaid Medical Director will then determine that the drug meets the appropriateness and medical necessity criteria.

BMS Policy Manual § 518.3 Non-Covered Services provides in part:

The following list of drugs, drug products, and related services are not reimbursable. Non-covered services include, but are not limited to:

- Drugs supplied by drug manufactures who have not entered into a drug rebate agreement with BMS
- Agents used for weight loss, anorexia, or weight gain
- Agents used for cosmetic purposes or hair growth
- Drugs identified by BMS as being less than effective (DESI)
- Agents used for fertility
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purposes
- Drugs used for off-label indications that are not found in official compendia or generally accepted in peer reviewed literature
- Drugs dispensed after their expiration date
- The costs of shipping or delivering a drug
- Herbal or homeopathic products
- Drugs that result in therapeutic duplication, ingredient duplication, early refills, or other DUR events that are not medically necessary

- Drugs that are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacture or its designee
- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents
- Vacation supplies
- Allergenic extracts
- Excipients except when used in compound prescriptions containing a covered legend drug.
- Excipients must be eligible for federal rebates in order to be eligible for reimbursement.
- Vaccines via the pharmacy Point of Sale (POS), except for influenza, pneumonia, Hepatitis A, Hepatitis B, tetanus, tetanus-diphtheria (Td), and tetanus-diphtheria-and-pertussis (Tdap) vaccines for adults 19 years of age and older administered by a pharmacist; and herpes vaccine for adults 50 years of age and older administered by a pharmacist.
- Methadone for the treatment of opioid addiction/dependence is not covered as a pharmacy benefit.

BMS Policy Manual § 518.4 explains that service limitations governing the provision of all West Virginia Medicaid pharmacy services will apply for eligible members as covered drugs are limited to their FDA-approved or medically accepted indications and dosing limits. Also, when appropriate, Preferred Drug List (PDL) preferred drugs must be tried before non-preferred drugs are approved.

BMS Policy Manual § 518.5 Drug Utilization Review (DUR) provides in part:

In order to meet the requirements of the statute, the DUR program must assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. The two primary objectives of DUR systems are to improve quality objectives of DUR systems are to improve quality of care and to assist in containing health care costs.

The DUR Board is charged with making recommendations for educational interventions to prescribers and pharmacists to identify and reduce, for both providers and patients, the frequency of patterns of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care. The DUR Board also assists BMS in defining criteria for coverage of drugs that require prior authorization. Specific drugs or classes of drugs may be targeted in regard to:

- Therapeutic appropriateness
- Overutilization
- Under utilization
- Appropriate use of generic products

- Therapeutic duplication (same or different prescriber)
- Drug-disease contraindications
- Drug-drug interactions
- Incorrect drug dosage
- Incorrect duration of drug treatment
- Drug-allergy interactions
- Clinical abuse/misuse

DISCUSSION

The Appellant's CFNP, submitted a request for the prior authorization for the prescription drug Skelaxin for degenerative disk disease on behalf of the Appellant. On June 26, 2019, Ms. appealed the Respondent's denial of the Appellant's request for Skelaxin and advised that the Appellant tried several alternatives to Skelaxin, such as Flexeril (Cyclobenzaprine), Robaxin (Methocarbamol), and Lorzone, all of which did not sufficiently manage her pain. The Appellant's medical records indicated that a combination of Flexeril (Cyclobenzaprine) and Skelaxin successfully eased the Appellant's pain in the past.

On June 27, 2019, notice of denial was issued to the Appellant indicating after a medication history review, there was no evidence that the Appellant had tried Robaxin (Methocarbamol) in the past. The June 27, 2019 notice indicated that if the Appellant provided pharmacy records which demonstrated the dates and length of time Robaxin (Methocarbamol) was trialed, the Respondent would reconsider the denial. The notice further advised that Medicaid will only "cover one skeletal muscle relaxant at a time. We will not cover both Skelaxin and Cyclobenzaprine for your patient."

The Appellant provided documentation from Previously prescribed Flexeril (Cyclobenzaprine), Robaxin (Methocarbamol), and Skelaxin. Pharmacy records indicate the Appellant paid out-of-pocket for Flexeril (Cyclobenzaprine) and Methadone.

On July 3, 2019, the Respondent issued a notice to the Appellant advising her appeal for prior authorization for Skelaxin was denied. The notice indicated that Medicaid would not reimburse both Skelaxin and Flexeril (Cyclobenzaprine). The notice further indicated the Appellant's physician could provide literature supporting the combined long-term use of two (2) centrally acting muscle relaxants and the Respondent would be willing to review the information. Otherwise, the denial for Skelaxin was considered a final decision by the Medical Director. It is noted that no additional documentation was received supporting the combined long-term use of two (2) centrally acting muscle relaxants for any condition.

The Appellant argued that she should be eligible for the prior authorization of the prescription drug Skelaxin. The Appellant testified that when she resided in she was prescribed Robaxin (Methocarbamol) and because it did not manage her pain, she would never take it again. The Appellant further argued that the only way she can manage her pain is with a combination of Flexeril (Cyclobenzaprine) during nighttime hours because it makes her drowsy and Skelaxin during the daytime hours. While it may be true the Appellant was able to successfully manage her

pain with the combination of drugs, policy does not permit the approval of two (2) muscle relaxants.

The Respondent expressed concerns because the Appellant paid out-of-pocket for Methadone and failed to disclose the use of Methadone at the time of request for prior authorization or her subsequent appeals for denial. The Respondent indicated that the Appellant's initial prior authorization for Skelaxin would have been denied if the Medical Director knew the Appellant was prescribed Methadone due to drug-to-drug interaction between Flexeril (Cyclobenzaprine) and Methadone. The Respondent further indicated that the drug-to-drug interaction with the use of muscle relaxants in conjunction with a narcotic pain medication can lead to serious side effects, including death.

The Respondent testified that even if the Appellant was not prescribed Methadone, West Virginia Medicaid would only approve prior authorization for one (1) muscle relaxant. The Respondent explained that West Virginia Medicaid would pay for the Appellant's prescription of Flexeril (Cyclobenzaprine) but would not give the prior authorization for Skelaxin because of therapeutic duplication. Therapeutic duplication exists between Flexeril (Cyclobenzaprine) and Skelaxin because they are both prescribed for muscle relaxation. Furthermore, policy states that prescription drugs which result in therapeutic duplication are not reimbursable services of Medicaid.

CONCLUSIONS OF LAW

- 1) The combination of prescription drugs Flexeril (Cyclobenzaprine) and Skelaxin is defined as therapeutic duplication.
- 2) Because the Appellant is prescribed Flexeril (Cyclobenzaprine), the Appellant is not eligible for the prior authorization of prescription drug Skelaxin due to therapeutic duplication.

DECISION

It is the decision of the State Hearing Officer to **UPHOLD** the Respondent's decision to deny the Appellant's appeal for prior authorization of the prescription drug Skelaxin.

ENTERED this day of September 2019.	
	Danielle C. Jarrett
	State Hearing Officer