

ISSUE

Did Respondent properly deny Petitioner's prior authorization request for the medication Trulicity?

FINDINGS OF FACT

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

1. MMA contracts with the Department to review prior authorization requests for specified medications. (Testimony of Respondent's representative).
2. On May 29 2024, MMA received a prior authorization request for Trulicity submitted on Petitioner's behalf by Petitioner's doctor. (Exhibit A, pages 9-14).

3. Prior authorization was required because the State of Michigan had changed its policy to require such prior authorization for Trulicity beginning in February of 2024. (Testimony of Respondent's representative).
4. The prior authorization request and attached medical documentation indicated that Petitioner has been diagnosed with Type I diabetes. (Exhibit A, pages 9).
5. The documentation also indicated that Petitioner had been taking Trulicity and it was significantly decreasing his insulin resistance, morbidity, and mortality. (Exhibit A, page 11).
6. Trulicity is not covered for type 1 diabetes on the Michigan Pharmaceutical Product List (MPPL) and Michigan Medicaid Clinical and Preferred Drug List (PDL) Criteria; and could not be unilaterally approved by MMA. (Exhibit A, page 57; Testimony of Respondent's representative).
7. MMA therefore forwarded the request to the Department for a review by a Department physician. (Testimony of Respondent's representative).
8. On May 29, 2024, the Department physician reviewed the request and determined that it should be denied because it did not meet criteria for approval. (Exhibit A, page 15).
9. MMA then sent Petitioner's doctor an electronic notice of denial. (Exhibit A, page 15).
10. On May 29, 2024, MMA also sent Petitioner written notice that his prior authorization request for Trulicity had been denied because it did not meet criteria. (Exhibit A, pages 16-20).
11. On June 13, 2024, MOAHR received the request for hearing filed by Petitioner in this matter with respect to the denial of his request. (Exhibit A, pages 3-7).

CONCLUSIONS OF LAW

The Medical Assistance Program was 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.

The Social Security Act § 1927(d), 42 USC 1396r-8(d), also provides as follows:

(d) Limitations on Coverage of Drugs -

(1) Permissible Restrictions -

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if —

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restriction pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or

(iv) the State has excluded coverage of the drug from its formulary in accordance with paragraph 4.

(2) List of drugs subject to restriction—The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

- (E) Agents when used to promote smoking cessation.
- (F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- (G) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.
- (H) Covered outpatient drugs, which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- (I) Barbiturates.
- (J) Benzodiazepines.
- (K) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

- (4) Requirements for formularies - A State may establish a formulary if the formulary meets the following requirements:
 - (A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).

- (B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer, which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).
- (C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.
- (D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a Prior Authorization program that is consistent with paragraph (5),
- (E) The formulary meets such other requirements as the Secretary may impose to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

- (⁵) Requirements of Prior Authorization programs-A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug

for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval —

- (A) Provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
- (B) Except with respect to the drugs referred to in paragraph (2) provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

Exhibit A, pages 22-27

Moreover, with respect to pharmaceutical products, the applicable version of the Medicaid Provider Manual (MPM) also provides in part:

SECTION 1 — GENERAL INFORMATION

Michigan Department of Health and Human Services (MDHHS) administers the fee-for-service (FFS) programs for Medicaid, Healthy Michigan Plan, Children's Special Health Care Services (CSHCS), and Maternity Outpatient Medical Services (MOMS). This chapter, the Michigan Pharmaceutical Product List (MPPL), and the Michigan Preferred Drug List (PDL)/Single PDL comprise program policies and explain coverage and reimbursement for the services dispensed and billed by enrolled pharmacies.

* * *

1.7.A. CARVE-OUT EXCEPTIONS

Select drugs and classes may be carved-out from the respective health plan's reimbursement and paid Medicaid Fee For Service. (Refer to the PBM website listed in the Directory Appendix for a listing of these drug classes.)

Any services paid Fee For Service must follow appropriate guidelines for supporting

documentation, including attending, billing, prescribing, referring, rendering and supervising provider requirements

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SECTION 2 - PRESCRIBER REQUIREMENTS

All MDHHS-covered legend and over-the-counter drugs (OTCs), except condoms, require a prescription order by a licensed professional acting within their scope of practice as defined by state and federal laws, rules, and regulations.

Coverage of pharmaceutical products is based on limitations stated in this chapter, the MPPL, and medical necessity. Determination of medical necessity and appropriateness of service is the responsibility of the prescribing physician/provider (prescriber) within the scope of currently accepted medical practice and MDHHS limitations . . .

* * *

SECTION 7 - MICHIGAN PHARMACEUTICAL PRODUCT LIST

The Michigan Pharmaceutical Product List (MPPL) identifies the pharmaceutical products that are covered by MDHHS. The MPPL pharmaceutical product coverages may vary by MDHHS program or be limited by age, clinical parameters, and/or gender. The Point of Sale pharmacy claim adjudication also provides coverage information related to a specific beneficiary or prescription.

The MPPL is posted on the PBM's website. (Refer to the Directory Appendix for website information.) Providers must refer to the MPPL for the additions and deletions of drug products. Specific notification of changes will not be issued.

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SECTION 8 - PRIOR AUTHORIZATION

8.1 PRIOR AUTHORIZATION PROCESSOR

The MDHHS PBM processes prior authorizations (PAs). Refer to PBM's Pharmacy Claims Processing Manual for PA

procedures. (See Directory Appendix for contact information.) Authorization to override denial edits must be obtained from the PBM.

Do **not** call the PBM's Call Centers for:

- Supplies billed by Medical Suppliers, including enteral formula and Total Parenteral Nutrition (TPN), since these are only reimbursed to a Medical Supplier provider. Contact the MDHHS Program Review Division for PA. (Refer to the Directory Appendix for contact information.)
- Information about the member's MHP. The provider must contact the MHP to obtain their policies.

8.2 PRIOR AUTHORIZATION REQUIREMENTS

PA is required for:

- Products as specified in the MPPL. Pharmacies should review the information in the Remarks as certain drugs may have PA only for selected age groups, gender, etc. (e.g., over 17 years).
- Payment above the Maximum Allowable Cost (MAC) rate.
- Prescriptions that exceed MDHHS quantity or dosage limits.
- Medical exception for drugs not listed in the MPPL.
- Medical exception for noncovered drug categories.
- Acute dosage prescriptions beyond MDHHS coverage limits for H2 Antagonists and Proton Pump Inhibitor medications.
- Dispensing a 100-day supply of maintenance medications that are beneficiary-specific and not on the maintenance list.
- Pharmaceutical products included in selected therapeutic classes. These classes include those with products that have minimal clinical differences, the

same or similar therapeutic actions, the same or similar outcomes, or have multiple effective generics available.

* * *

8.6 PRIOR AUTHORIZATION DENIALS

PA denials are conveyed to the requester. PA is denied if:

- The medical necessity is not established.
- Alternative medications are not ruled out.
- Evidence-based research and compendia do not support it.
- It is contraindicated, inappropriate standard of care.
- It does not fall within MDHHS clinical review criteria.
- Documentation required was not provided.

The PBM reviews the information submitted to determine whether the clinical criteria have been met. If the submitted information does not indicate that the criteria have been met, the PA is then sent to the Office of Medical Affairs in MDHHS for final determination on whether the clinical criteria have been met.

*MPM, April 1, 2024 version
Pharmacy Chapter, pages 1, 6, 8, 15-16, 18*

The Department is therefore authorized by federal law to develop both a formulary of approved or limited prescriptions and a prior authorization process.

It has done so and, with respect to incretin mimetics and combinations like Trulicity, the MPPL and Michigan Medicaid Clinical and PDL Criteria require both prior authorization and a diagnosis of type 2 diabetes. (Exhibit A, page 21), with an initial review conducted by MMA and any secondary, final review conducted by MDHHS.¹

Here, MMA received a prior authorization request for Trulicity submitted on Petitioner's behalf by his doctor which indicated that Petitioner has been diagnosed with type 1 diabetes.

¹ See also [MI Medicaid Clinical and PDL PA Criteria \(magellanrx.com\)](http://MI.Medicaid.Clinical.and.PDL.PA.Criteria.(magellanrx.com))

Respondent's representative testified that, pursuant to the above criteria, the request could not be approved by MMA given the non-covered diagnosis, and that it had to be reviewed by a Department physician for a final determination on whether the clinical criteria had been met. She also testified that the Department physician reviewed the request and determined that it should be denied as it did not meet clinical criteria.

In response, Petitioner's representative testified that Petitioner has been successfully receiving Trulicity for years and that, when she called MMA about the denial, she was told it was because Petitioner had not tried other, preferred drugs first. She also testified that Petitioner's doctor twice wrote letters in support of the request and that the medical necessity for the medication is clear. She further testified that it is not being used as a weight loss drug.

Respondent's representative then testified that, while she does not know who Petitioner's representative spoke to at MMA, the denial in this case was based on Petitioner's diagnosis and not on whether he had to try preferred drugs first, with Trulicity also being a preferred drug. She also testified that, while the notice of denial does not give specifics on what criteria was not met, she can see the diagnosis and clear-cut reason for the denial.

Petitioner bears the burden of proving by a preponderance of the evidence that Respondent erred in denying his prior authorization request. Moreover, the undersigned Administrative Law Judge is limited to reviewing Respondent's decision in light of the information that was available at the time the decision was made.

Given the available information and applicable policies in this case, Petitioner has failed to meet that burden of proof and the Respondent's decision must be affirmed.

As discussed above, the Department has been authorized by federal law to develop both a formulary of approved prescriptions and a prior authorization process; it has done so; and, with respect to Trulicity, it has restricted approval to cases where a beneficiary has been diagnosed with type 2 diabetes.

Respondent's representative credibly testified that the requirement for prior authorization and restriction on approval for Trulicity have only been in place since February of 2024, rendering any past receipt of the medication moot. However, even if there had been no policy change and Petitioner had still received Trulicity in the past under the current policy, the past approval would not be dispositive and the undersigned ALJ must still review the request at issue in this case pursuant to the policy in place at the time.

With respect to the current request, it is undisputed that Petitioner does not meet the applicable criteria as he is diagnosed with type 1 diabetes; and, while the undersigned ALJ agrees that Respondent could have been clearer as to the reason for the denial in the notice sent to Petitioner, the denial was proper as Petitioner did not meet clinical

criteria for approval. Petitioner may disagree with the clinical criteria, but Respondent and the undersigned ALJ are bound by it.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that Respondent properly denied Petitioner's prior authorization request.

IT IS, THEREFORE, ORDERED that:

Respondent's decision is **AFFIRMED**.