ISSUE

Did the Department properly deny Petitioner's request for prior authorization of the medication Repatha Sureclick?

FINDINGS OF FACT

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

1. Petitioner is a Medicaid beneficiary who has been diagnosed with pure hypercholesterolemia. (Exhibit A, pp 2, 6; Testimony.)

2. On September 3, 2024, Petitioner's provider sought prior authorization for the medication Repatha Sureclick for Petitioner. (Exhibit A, p 6; Testimony.) The provider did not submit any supporting documentation with the request. *(Id.)*

3. Per Michigan Medicaid Clinical and PDL Criteria, Repatha Sureclick can only be approved for a diagnosis of atherosclerotic cardiovascular disease (ASCVD), heterozygous familiar hypercholesterolemia (HeFH), or homozygous familiar hypercholesterolemia (HoFH). (Exhibit A, pp 6, 13; Testimony.)

In addition, there must also be a treatment failure despite high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin) for at least 8 weeks and a treatment failure of ezetimibe, alone or with either a high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin). *(Id.)*

4. Because Repatha Sureclick could not be approved with the clinical information submitted, the PA request was referred to a physician reviewer at the State of Michigan, who upheld the denial, stating, "Denied; does not meet criteria for approval, no supportive documentation submitted." (Exhibit A, p 7; Testimony.)

5. On September 4, 2024, an Adequate Action Notice of denial was sent to Petitioner and his provider. (Exhibit A, pp 8-12; Testimony.)

6. On May 9, 2024, Petitioner's request for hearing was received by the Michigan Office of Administrative Hearings and Rules. (Exhibit A, pp 3-5.)

CONCLUSIONS OF LAW

The Medical Assistance Program is 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),* provides as follows:

> 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).
>
> 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.

(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 in order 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).

42 USC 1396r-8(k)(6) **MEDICALLY ACCEPTED** INDICATION -

The term **"medically accepted** indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

The Medicaid Provider Manual indicates, in relevant part:

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.

8.4 DOCUMENTATION REQUIREMENTS

For all requests for PA, the following documentation is required:

- Pharmacy name and phone number;
- Beneficiary diagnosis and medical reason(s) why another covered drug cannot be used;
- Drug name, strength, and form;
- Other pharmaceutical products prescribed;
- Results of therapeutic alternative medications tried; and
- MedWatch Form or other clinical information may be required.

* * * *

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.

Medicaid Provider Manual Pharmacy Section July 1, 2024, pp 15-18 Emphasis added

Michigan Medicaid Clinical Criteria for Repatha Sureclick indicates as follows:

CARDIAC MEDICATIONS: LIPID LOWERING AGENTS: PCSK9 INHIBITORS

(PDL Class - see MICHIGAN PREFERRED DRUG LIST)

Length of Authorization: 1 year

CRITERIA TO APPROVE

CLINICAL PA CRITERIA FOR PCSK-9 INHIBITORS

- Diagnosis of atherosclerotic cardiovascular disease (ASCVD); OR
- Diagnosis of heterozygous familial hypercholesterolemia (HeFH); OR
- Diagnosis of homozygous familial hypercholesterolemia (HoFH); AND
- A treatment failure despite high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin) for at least 8 weeks. If intolerant to statins, this must be supported by submitted chart notes/labs.; AND
- A treatment failure of ezetimibe, alone or with either a high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin); AND
- Patient has failed to reach target LDL-C levels (document lab values):
    - o ASCVD at very high risk (including those with FH), LDL-C goal <55 mg/dL.

- ASCVD not at very high risk (not including FH), LDL-C goal <70 mg/dL with the option to target <55 mg/dL.
- HeFH or HoFH: No LDL-C value required

* * * *

Exhibit A, p 13

The Department's Sr. Clinical Pharmacist testified that on September 3, 2024, Petitioner's provider sought prior authorization for the medication Repatha Sureclick for Petitioner but did not submit any supporting documentation with the request. The Department's Sr. Clinical Pharmacist indicated that per Michigan Medicaid Clinical and PDL Criteria, Repatha Sureclick can only be approved for a diagnosis of atherosclerotic cardiovascular disease (ASCVD), heterozygous familiar hypercholesterolemia (HeFH), or homozygous familiar hypercholesterolemia (HoFH). The Department's Sr. Clinical Pharmacist also indicated that there must also be a treatment failure despite high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin) for at least 8 weeks and a treatment failure of ezetimibe, alone or with either a high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin). The Department's Sr. Clinical Pharmacist testified that because Repatha Sureclick could not be approved with the clinical information submitted, the PA request was referred to a physician reviewer at the State of Michigan, who upheld the denial, stating, "Denied; does not meet criteria for approval, no supportive documentation submitted." The Department's Sr. Clinical Pharmacist indicated that based on the above, an Adequate Action Notice of denial was sent to Petitioner and his provider.

Petitioner testified that he had Blue Cross Blue Shield until September and this medication was approved and he had been taking it since May 2024. Petitioner indicated that he was taking this medication because rosuvastatin caused him terrible leg pain. Petitioner testified that Repatha was working well and he wished to remain on it. Petitioner noted that he recently had a lipid test and his numbers were fantastic. Petitioner testified that both his grandfathers died of heart attacks and his dad suffered a heart attack but is still alive. Petitioner indicated that he knows he is destined to have heart disease unless he takes very good care of the situation. Petitioner testified that he had a CT calcium test in January which came back at 24.9, which does indicate disease. Petitioner noted that his left side had quite a bit of calcium buildup.

In response, the Department's Sr. Clinical Pharmacist indicated that Petitioner's provider did not submit any supporting documentation whatsoever, so none of the information Petitioner testified to was known. The Department's Sr. Clinical Pharmacist indicated that the fact Petitioner was already on the medication and had the leg pain with rosuvastatin might sway the medical reviewer. The Department's Sr. Clinical Pharmacist suggested that Petitioner revisit his provider and see if he/she will resubmit the request with more documentation.

Based on the evidence presented, Petitioner has failed to prove, by a preponderance of the evidence, that the Department improperly denied the prior authorization request for the medication Repatha Sureclick. As indicated above, Repatha Sureclick can only be approved for a diagnosis of atherosclerotic cardiovascular disease (ASCVD), heterozygous familiar hypercholesterolemia (HeFH), or homozygous familiar hypercholesterolemia (HoFH). The Department's Sr. Clinical Pharmacist also indicated that there must also be a treatment failure despite high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin) for at least 8 weeks and a treatment failure of ezetimibe, alone or with either a high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin). Here, Petitioner's provider submitted no documentation with the request so it was impossible for the Department to determine if Petitioner met any of the criteria. Also, as indicated Petitioner can and should resubmit the request with supporting documentation. However, based on the lack of documentation submitted, the Department's denial was proper.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, finds that the Department properly denied coverage for the medication Repatha Sureclick.

IT IS THEREFORE ORDERED that:

The Department's decision is **AFFIRMED.**