Policy:	MA.6103
Title:	**Pharmacy and Therapeutics Committee and Formulary Management**
Department:	Medical Management
Section:	Pharmacy Management
CEO Approval:	*/s/ Michael Hunn 11/22/2024*
Effective Date:	01/01/2006
Revised Date:	11/01/2024
Applicable to:	☐ Medi-Cal ☒ OneCare ☐ PACE ☐ Administrative

I. PURPOSE

This policy defines Formulary Management for the OneCare program, and outlines CalOptima Health's Pharmacy and Therapeutics (P&T) Committee requirements.

II. POLICY

A. CalOptima Health shall meet the following Pharmacy & Therapeutics (P&T) Committee and Formulary requirements:

1. P&T Committee meeting held at least quarterly;
2. Provision of an adequate Formulary for Medicare Part D and Medicare-Medicaid Plan;
3. Transition process oversight;
4. Limitation on changes in therapeutic classification;
5. Provision of notice regarding Formulary changes;
6. Oversight of limitation of Formulary changes prior to beginning of contract year;
7. Review of materials for Provider/Member education of Formulary changes; and
8. Formulary changes, maintenance and non-maintenance, during the contract year.

B. The P&T Committee shall meet specific requirements with respect to:

1. Membership:

a. P&T Committee Members must come from various clinical specialties that adequately represent the needs of CalOptima Health Members.

b. A majority of the P&T Committee Members must:

i. Be Practicing Physicians, Practicing Pharmacists, or both;

ii. Possess a permanent, valid, active, unrestricted, and unchallenged professional license to practice in the United States, or one (1) of its Territories;

iii. Be currently practicing in the United States, or one (1) of its Territories; and

iv. Be currently employed in a work setting in which their duties and responsibilities are related to their licensure.

c. At least one (1) P&T Committee Practicing Pharmacist, and one (1) P&T Committee Practicing Physician, must be an expert in the care of elderly, or disabled, persons, evident by being:

i. Board-certified in Psychiatry;

ii. Board-certified in Geriatric Medicine;

iii. Certified in Psychiatric Pharmacy; and/or

iv. Certified in Geriatric Pharmacy.

d. At least one (1) P&T Committee Practicing Pharmacist and one (1) P&T Committee Practicing Physician, must be independent and free of conflict with respect to CalOptima Health and pharmaceutical manufacturers.

i. P&T committee Members may have certain non-employee relationships with pharmaceutical manufacturers (for example, consulting, advisory, or research relationships) and still be considered independent and free of conflict provided those relationships do not constitute significant sources of income and they do not otherwise have a conflict of interest that would compromise their independence.

ii. P&T committee Members in a staff model health maintenance organization (HMO) may be considered independent and free of conflict to the extent that any remuneration received from CalOptima Health is limited to his or her clinical responsibilities for the care of CalOptima Health Members.

e. CalOptima Health shall verify that P&T Committee Members do not appear on the Health and Human Service, Office of Inspector General's Exclusion List (LEIE), the System Award Management (SAM) Exclusion List, or the Medicare Exclusion Database (MED).

2. Conflict of Interest:

a. P&T Committee Members shall sign an annual conflict of interest statement that:

i. Reveals economic, or other relationships, with entities that may influence pharmaceutical decisions; and

ii. Discloses such conflicts to other committee Members.

b. A committee Member shall recuse him or herself from any discussions, or votes, associated with a conflict of interest issue.

3. CalOptima Health shall disclose its P&T Committee Membership to CMS annually, or when there are changes.

4. Meeting administration:

    a. CalOptima Health's P&T Committee shall meet on a regular basis, but no less than quarterly.

    b. CalOptima Health's P&T Committee decisions regarding Formulary development, or revision shall be documented, in writing.

5. Formulary Management:

    a. The P&T Committee must review, for clinical appropriateness, the practices and policies for Formulary Management activities Utilization Management edits such as Prior Authorizations, step therapies, quantity limitations, generic substitutions, and other drug utilization activities that affect access. P&T Committee recommendations regarding these activities are advisory only, and not binding.

    b. Formulary Management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost-effective drug therapy.

    c. The P&T Committee will be required to establish and document procedures to ensure appropriate drug review and inclusion. This includes documentation of decisions regarding Formulary development, revision, and Utilization Management activities (Title 42, Code of Federal Regulations, Section 423.120(b)(1)(viii)). P&T Committee recommendations regarding which Covered Part D Drugs) are placed on the OneCare Formulary are binding.

    d. Clinical decisions by the P&T Committee should be Evidence Based, CMS recognized compendia (American Hospital Formulary System Drug Information, MicroMedex, Clinical Pharmacology, National Comprehensive Cancer Network Drugs and Biologicals compendium) and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines, and pharmacoeconomic studies, as well as other sources of appropriate information.

    e. Drug therapeutic advantages in terms of safety and efficacy must be considered when selecting Formulary drugs and placing them on Formulary tiers.

    f. The P&T Committee will:

        i. Make a reasonable effort to review a new Federal and Drug Administration (FDA) approved drug product (or new FDA approved indication) within ninety (90) calendar days of its release onto the market, and will make a decision on each new FDA approved drug product (or new FDA approved indication) within one hundred eighty (180) calendar days of its release onto the market, or a clinical justification will be provided if this time frame is not met.

        ii. Perform expedited reviews of new drugs or newly approved uses for drugs within the six (6) protected classes within ninety (90) calendar days, and add substantially all these drugs to the Formulary as described in this Policy.

g. At least annually, the P&T Committee will evaluate and analyze treatment protocols and procedures related to the Formulary.

h. On an annual basis, the P&T Committee will approve inclusion, or exclusion, of the therapeutic classes in the Formulary.

6. Formulary exceptions

a. CalOptima Health's P&T Committee must review, for clinical appropriateness, protocols and procedures for the timely use of, and access to, both Formulary and non-Formulary drug products.

7. P&T Committee's Role in Transition

a. CalOptima Health's P&T Committee shall, in accordance with CalOptima Health Policy MA.6110: Transition Process:

i. Address procedures for medical review of non-Formulary drug requests, and, when appropriate, a process for switching new Members, or continuing Members whose treatment setting has changed or is affected by Formulary changes, to therapeutically appropriate Formulary alternatives;

ii. Review and provide recommendations regarding the procedures for medical review of non-Formulary drug requests; and

iii. Ensure that transition decisions appropriately address situations involving Members stabilized on drugs that are not on the Formulary (or that are on the Formulary but require Prior Authorization or Step Therapy under OneCare's Utilization Management requirements), and which are known to have risks associated with any changes in the prescribed regimen.

C. The P&T Committee shall review and provide recommendations regarding Utilization Management edits. These Utilization Management edits include the following safety edits applied at the point-of-sale or point-of-distribution to prevent dispensing of unsafe dosing of drugs and assist the Pharmacist in identifying and/or preventing inappropriate drug therapy:

1. Screening for potential drug therapy problems due to therapeutic duplication;

2. Age/gender-related contraindications;

3. Over-Utilization (e.g., early refill) and Under-Utilization;

4. Drug-drug interactions;

5. Incorrect drug dosage, or duration of drug therapy (e.g., doses above FDA maximum approved dosing);

6. Drug-allergy contraindications;

7. Clinical Abuse/Misuse Screening for potential drug;

8. Cumulative acetaminophen (APAP) content of combination opioid analgesics;

9. Cumulative morphine equivalent dose (MED) across the opioid class.

D. If CalOptima Health changes Pharmacy Benefit Management (PBM) mid-year, it is required to continue the existing Formulary.

E. The Pharmacy Management Department shall delegate daily Formulary administrative functions to the Pharmacy Benefit Manager (PBM), and shall ensure that these activities are conducted pursuant to CalOptima Health policies and procedures through oversight and monitoring of the PBM's Formulary administrative process.

III. PROCEDURE

A. The P&T Committee shall develop and review the OneCare Formulary.

1. The P&T Committee shall appropriately review and recommend revisions to the Formulary, to adapt the Formulary to both the number and types of drugs on the market.

2. The P&T Committee shall consider whether or not the inclusion of a particular Drug on the Formulary, or on a particular Formulary tier, has any therapeutic advantages in safety and efficacy. The P&T Committee shall consider the therapeutic advantages in relation to the interaction of a drug therapy regimen and the use of other health care services.

3. The P&T Committee shall perform an initial review of drugs that are clinically effective. If two (2) or more drugs have the same therapeutic advantages in regard to safety and efficacy, the P&T Committee may consider total health care costs to achieve appropriate, safe, and cost-effective drug therapy.

4. The P&T Committee shall review policies that guide Exceptions and other Utilization Management processes, including:

a. Drug utilization review;

b. Quantity limits;

c. Generic substitution; and

d. Therapeutic interchange.

B. The P&T Committee shall evaluate, analyze, and recommend treatment protocols and procedures for the timely use of, and access to the OneCare Formulary and non-Formulary drug products at least annually, and consistent with CalOptima Health policy guidelines and instructions from the CMS.

C. The P&T Committee shall base clinical decisions on the strength of scientific evidence, CMS recognized compendia, standards of practice, and safety and efficacy considerations. The P&T Committee may use the following to assist in decision-making:

1. Peer-reviewed medical literature;

2. Randomized clinical trials;

3. Well-established clinical practice guidelines;

4. Pharmacoeconomic studies;

5. Outcomes research data; and

6. Other information, as it determines appropriate.

D. The P&T Committee shall ensure the OneCare Formulary includes:

1. At least two (2) chemically distinct Covered Part D Drugs that are not therapeutically equivalent and bioequivalent in each therapeutic category and class of Covered Part D Drug, except where a particular category or class includes only one (1) Part D drug, or only two (2) drugs are available but one (1) drug is clinically superior to the other;

2. Drugs may be included in the Formulary if they present unique and important therapeutic advantages in terms of safety and efficacy, and their absence would substantially discourage enrollment by beneficiaries with certain disease states.

3. All or substantially all drugs and unique dosage forms within the six (6) protected classes:

a. Immunosuppressant (for prophylaxis of organ transplant rejection);

b. Antidepressant;

c. Antipsychotic;

d. Anticonvulsant;

e. Antiretroviral; and

f. Antineoplastic.

4. Dosage forms of drugs that are widely utilized in long term care (LTC) facilities and home infusion, such as unit dose products and liquid, chewable, parenteral preparations, and nebulized solutions for situations when Part B coverage is not available.

5. All commercially available vaccines.

a. Commercially available vaccines shall be excluded if:

i. Reimbursement is available under Part B, e.g., influenza or pneumococcal vaccines; or

ii. The manufacturer does not participate in the coverage gap discount program.

b. Drug Utilization Management tools shall only be used to:

i. Assess the necessity of vaccines that are less commonly administered in the Medicare population, such as anthrax and yellow fever vaccines;

ii. Facilitate use of vaccines in line with Advisory Committee on Immunization Practices (ACIP) recommendations; and

iii. Evaluate potential reimbursement of those vaccines that could be covered under Part B when directly related to the treatment of an injury or direct exposure to a disease or condition (e.g., tetanus).

E. CalOptima Health shall ensure that the P&T Committee uses appropriate scientific and economic criteria when considering Utilization Management activities that affect access to drugs, including, but not limited to:

1. Access to non-Formulary drugs;

2. Prior authorization;

3. Step Therapy;

4. Quantity limit;

5. Generic substitution; and

6. Therapeutic interchange protocols.

F. CalOptima Health shall adopt all P&T Committee recommendations regarding the drugs placed on the OneCare Formulary.

G. CalOptima Health shall consider recommendations from the P&T Committee in the following areas as advisory, and not binding:

1. Review of practices and policies that guide Utilization Management:

a. Prior Authorizations;

b. Step Therapies;

c. Quantity limitations;

d. Generic substitutions; and

e. Other drug utilization activities that affect access.

2. Evaluation and analysis of treatment protocols and procedures.

H. CalOptima Health shall maintain written documentation of P&T Committee decisions regarding Formulary development and revision, and Utilization Management activities, as described in Title 42, Code of Federal Regulations, Section 423.120(b)(1)(viii) and meeting minutes.

I. When removing a Covered Part D Drug from the OneCare Formulary, making any changes to the preferred or tiered cost-sharing status of a Covered Part D Drug, or adding Utilization Management edits, CalOptima Health shall submit requests to CMS for approval and provide notice in accordance with the timeframes set forth by CMS:

1. To immediately remove a brand-name drug (or to make a change in the preferred or tiered cost-sharing status) and replace the brand-name drug with (or add to the Formulary) a newly approved generic rated therapeutically equivalent by the FDA to the brand-name drug:

a. CalOptima Health shall provide advance general notice to Members, and

b. CalOptima Health shall provide retrospective direct notice to Members, and

c. CalOptima Health shall provide retrospective direct notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and Pharmacists.

2. To make mid-year Formulary changes when (aside from expedited generic substitutions, interchangeable and unbranded biological product substitutions, and drugs deemed unsafe or withdrawn from the market) drug removal or changes in cost-sharing would affect Members:

   a. CalOptima Health shall provide direct written notice to affected Members at least thirty (30) calendar days prior to the date the change becomes effective, and

   b. CalOptima Health shall provide at least thirty (30) calendar days direct notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and Pharmacists

3. To make direct written notice to Members:

   a. CalOptima Health shall inform Members of a Formulary change in the Explanation of Benefits (EOB) that is sent to a Member on a monthly basis, in accordance with CalOptima Health Policies : Member Disclosures and MA.4007: Member Disclosures.

   b. CalOptima Health shall send the Notice of Formulary or Cost-sharing Change, or similar CMS-approved notice, to inform Members of a Formulary change when no EOB is sent to such Members in a given month because they have not received prescription drugs during the prior month.

   c. The EOB and Notice of Formulary or Cost-sharing Change shall contain the following information:

      i. The name of the affected Covered Part D Drug;

      ii. Whether CalOptima Health is removing the affected drug from the OneCare Formulary, or changing its preferred or tiered cost-sharing status;

      iii. The effective date of change;

      iv. The reason for the change;

      v. Alternative drugs in the same therapeutic category or class or cost-sharing tier, and expected cost-sharing for those drugs; and

      vi. The means by which a Member may obtain a Coverage Determination, as set forth in CalOptima Health Policy MA.6101: Medicare Part D Coverage Determination.

   d. If CalOptima Health fails to notify a Member of mid-year Formulary changes (aside from expedited generic substitutions and drugs deemed unsafe or withdrawn from the market), in accordance with this section, the Member shall be provided with a thirty (30) calendar day supply of the affected drug and the Notice of Formulary or Cost-sharing Change at the time the Member requests a refill of the drug.

4. CalOptima Health shall provide annual notice to State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, Participating Pharmacies, and Pharmacists with information on OneCare change policy and the CalOptima Health website where these entities can verify the Formulary status of particular drugs. All changes are posted on the CalOptima Health website.

J. If CalOptima Health changes a Formulary due to the immediate removal of a Covered Part D Drug deemed unsafe by the Food and Drug Administration (FDA), or removed from the market by the manufacturer, CalOptima Health shall provide retrospective notice to Members, CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, Participating Pharmacies, and Pharmacists.

K. CalOptima Health shall submit to CMS a Negative Formulary Change Request when proposing to remove a drug from the OneCare Formulary in accordance with the timeframes set forth by CMS.

L. OneCare shall use one or more of the following modes of communication to notify authorized prescribers, Participating Pharmacies, and Pharmacists of changes in the OneCare Formulary, including addition or removal of a drug as approved by the P&T Committee, and in accordance with the timeframes set forth by CMS:

1. Facsimile;

2. OneCare Website; and

3. CalOptima Health Provider Bulletin.

M. The P&T Committee shall help ensure that transition decisions appropriately address situations involving Members stabilized on drugs that are not on the OneCare Formulary (or that are on the Formulary require Prior Authorization or Step Therapy under OneCare's Utilization Management requirements) and which are known to have risks associated with any changes in the prescribed regimen, in accordance with CalOptima Health Policy MA.6110: Transition Process.

N. The P&T Committee shall report decisions and recommendations to the CalOptima Health Utilization Management Committee (UMC).

O. If the P&T Committee fails to meet timeframes set forth in this Policy, CalOptima Health shall provide a clinical justification for such delay to CMS.

P. OneCare Formulary Management shall be administered as follows:

1. The Pharmacy Management Department shall be responsible for the overall administration of the Formulary Management process. The Pharmacy Management Department shall coordinate activities with other internal departments, as needed, to carry out its administrative responsibilities. Specific responsibilities include, but are not limited to, the following:

a. Ensure compliance with CMS Formulary requirements;

b. Track and report pharmacy utilization;

c. Assess Formulary compliance;

d. Oversight the PBM in the performance of the online administration of the Formulary;

e. Communicate with the PBM regarding Formulary changes;

f. Publish the Formulary and monthly updates to the Formulary on the CalOptima Health website: www.CalOptima Health.org;

g. Coordinate the P&T Committee scheduling, agenda, actions, and minutes;

h. Update information published in the Evidence of Coverage/Member Handbook.

2. All FDA-approved tobacco cessation medications shall be available without requiring Prior Authorization.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

A. CalOptima Health Contract with the Centers for Medicare and Medicaid Services (CMS) for Medicare Advantage
B. CalOptima Health Policy MA.4007: Member Disclosures
C. CalOptima Health Policy MA.6101: Medicare Part D Coverage Determination
D. CalOptima Health Policy MA.6110: Transition Process
E. Federal Register, January 28, 2005, Vol. 70, No. 18
F. Formulary/Pharmacy and Therapeutics (P&T) Committee Affordable Care Act, Section 3307 Guidance: P&T Committee Integrity and Certification of Such by Part D Applicant Sponsor Medicare Modernization Act, Section 1860D-4(b)(3)(A)
G. Guidance for California Requirements for Non-Part D Drug Coverage (CY 2015)
H. Medicare Prescription Drug Benefit Manual, Chapter 6: Revised January 15, 2016
I. Title 42, Code of Federal Regulations (C.F.R.), §§ 423.100, 423.104, 423.120(b), 423.128, 423.4, 423.578(d), and 423.272(b)(2)
J. CY 2019 Medicare Communications and Marketing Guidelines (MCMG). September 5, 2018.
K. Applications from Medicare Advantage Prescription Drug Plans (MA-PD) Sponsors
L. Federal Register, April 16, 2018, Vol 85, No. 73
M. Federal Register, April 23, 2024, Vol 89, No. 79

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD ACTION(S)

None to Date

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	01/01/2006	MA.6103	Pharmacy and Therapeutics Committee	OneCare
Revised	07/01/2007	MA.6103	Pharmacy and Therapeutics Committee	OneCare
Revised	08/01/2008	MA.6103	Pharmacy and Therapeutics Committee	OneCare
Revised	10/01/2012	MA.6103	Pharmacy and Therapeutics Committee	OneCare

Action	Date	Policy	Policy Title	Program(s)
Revised	03/01/2013	MA.6103	Pharmacy and Therapeutics Committee	OneCare
Revised	06/01/2015	MA.6103	Pharmacy and Therapeutics Committee	OneCare OneCare Connect
Revised	04/01/2016	MA.6103	Pharmacy and Therapeutics Committee	OneCare OneCare Connect
Revised	11/01/2016	MA.6103	Pharmacy and Therapeutics Committee and Formulary Management	OneCare OneCare Connect
Revised	02/01/2018	MA.6103	Pharmacy and Therapeutics Committee and Formulary Management	OneCare OneCare Connect
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Revised	07/01/2020	MA.6103	Pharmacy and Therapeutics Committee and Formulary Management	OneCare OneCare Connect
Revised	09/01/2021	MA.6103	Pharmacy and Therapeutics Committee and Formulary Management	OneCare OneCare Connect
Revised	12/31/2022	MA.6103	Pharmacy and Therapeutics Committee and Formulary Management	OneCare
Revised	09/01/2023	MA.6103	Pharmacy and Therapeutics Committee and Formulary Management	OneCare
Revised	11/01/2024	MA.6103	Pharmacy and Therapeutics Committee and Formulary Management	OneCare

IX. GLOSSARY

Term	Definition
Coverage Determination (CD)	Any decision made by CalOptima Health regarding: 1. Receipt of, or payment for, a prescription drug that a Member believes may be covered; 2. A tiering or Formulary Exception request; 3. The amount that the plan sponsor requires a Member to pay for a Part D prescription drug and the Member disagrees with the plan sponsor; 4. A limit on the quantity (or dose) of a requested drug and the Member disagrees with the requirement or dosage limitation; 5. A requirement that a Member try another drug before the plan sponsor will pay for the requested drug and the Member disagrees with the requirement; and 6. A decision whether a Member has, or has not, satisfied a Prior Authorization or other Utilization Management requirement.
Covered Part D Drug	A Covered Part D Drug includes: 1. A drug that may be dispensed only upon a Prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication as set forth in Section 1927(k)(2)(A) of the Social Security Act; 2. A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Social Security Act; 3. Insulin described in section 1927(k)(2)(C) of the Social Security Act; 4. Medical supplies associated with the delivery of insulin; and 5. A vaccine licensed under section 351 of the Public Health Service Act and its administration.
Evidence-Based	A document or recommendation created using an unbiased and transparent process of systematically reviewing, appraising, and using the best clinical research findings of the highest value to aid in the delivery of optimum clinical care to patients.
Formulary	The approved list of outpatient medications, medical supplies and devices, and the Utilization and Contingent Therapy Protocols as approved by the CalOptima Health Pharmacy & Therapeutics (P&T) Committee for prescribing to Members without the need for Prior Authorization.
Formulary Management	Refers to the overall management of Medicare prescription drug formularies through Utilization Management activities and Evidence-Based reviews carried out by Pharmacy and Therapeutics (P&T) Committees with oversight from the Centers for Medicare & Medicaid Services (CMS) as outlined in the Medicare Modernization Act.
Member	A beneficiary enrolled in a CalOptima Health program.
Over-Utilization	Unnecessary health care provided with a higher volume or cost than is appropriate in delivering quality health care services.
Participating Pharmacy	Any pharmacy that is credentialed by and subcontracted to the Pharmacy Benefit Manager (PBM) for the specific purpose of providing pharmacy services to Members.
Pharmacist	A person to whom the State Board of Pharmacy has issued a license, authorizing the person to practice pharmacy.

Term	Definition
Pharmacy and Therapeutics (P&T) Committee	A committee, the majority of whose Members shall consist of individuals who are Practicing Physicians or Practicing Pharmacists (or both), that is charged with developing and reviewing a Formulary. Such committee shall include at least one Practicing Physician and at least one (1) Practicing Pharmacist, each of whom is independent and free of conflict with respect to the Part D Sponsor and pharmaceutical manufacturers. At least one (1) Practicing Physician and at least one (1) Practicing Pharmacist must have expertise in the care of elderly or disabled persons. (*See* Title 42 C.F.R. § 423.120(b)(1)).
Prior Authorization (Pharmacy)	The Formulary restriction which requires approval from CalOptima Health before the requested medication is covered.
Practicing Physician or Practicing Pharmacist	A Practicing Physician or Pharmacist is an individual who has an active professional license to practice in the United States or one of its Territories and is currently practicing in the U.S. or one of its Territories.
Protected Class Drugs	Drugs classified within: immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes.
Provider (Part D)	All contracted Providers including physicians, Non-physician Medical Practitioners, ancillary providers, and facilities or institutions who are licensed to furnish Covered Services.
Step Therapy	The Formulary restriction which requires an enrollee to first try certain drugs to treat a medical condition before the requested medication is covered.
Under Utilization	A condition wherein the optimal healthcare resources are not being delivered in the appropriate volume to provide quality health care services.
Utilization Management	Requirements or limits on coverage. Utilization Management may include, but is not limited to, prior authorization, quantity limit, or Step Therapy restrictions.