EVOLENT HEALTH LLC
POLICY AND PROCEDURE

POLICY TITLE: **Preferred Drug List Decision Making Process**
DEPARTMENT: **Pharmacy**
ORIGINAL DATE: **July 2016**

Approver(s): David Stackhouse, Managing Director, Pharmacy Operations

Policy Review Committee Approval Date: September 6, 2019

Product Applicability:

COMMERCIAL	[ ] HMO [ ] PPO *Products:* [ ] Small [ ] Indiv. [ ] Large *Exchange:* [ ] Shop [ ] Indiv. [ ] All
	States: [ ] GA [ ] MD [ ] OH [ ] TX [ ] _____
GOVERNMENT PROGRAMS	[ ] MA HMO [ ] MA C-SNP [ ] MA D-SNP [ ] MSSP [ ] Next Gen ACO [ ] MA All
	[X] Medicaid *States:* [ ] DC [X] KY [ ] MD [ ] _____
OTHER	[ ] Self-funded/ASO

Regulatory Requirements: Kentucky Department for Medicaid Services Contract Section 32.0 and 32.5

Related Documents RX.051.KY Pharmacy and Therapeutics Advisory Committee

PURPOSE

The purpose of this policy is to describe the process for developing and implementing the Preferred Drug List (PDL) including any restrictions. To describe the types and categories of drugs comprised in the drug list. To outline the process used to make changes (additions and deletions) to the drug list and the communication of these changes. To describe the process used for posting and distribution of the preferred drug list to members and providers.

DEFINITIONS

AB-RATED GENERIC: A pharmaceutical product rated in the FDA Orange Book as being equivalent to the innovator brand product.

BIOSIMILAR DRUG: Highly similar to an already approved biological product except for minor differences in the inactive components. They must lack clinically meaningful differences relative to the safety, purity, and potency of the reference biological product.

BIOSIMILAR SUBSTITUTION: Dispensing a biological product that is similar to an originator biological which is expected to produce the same clinical benefit.

GENERIC DRUG: Chemically equivalent copy designed from a brand name drug whose patent has expired.

GENERIC SUBSTITUTION: Dispensing a generic drug in place of a brand name medication.

NARROW THERAPEUTIC INDEX DRUGS: Drugs that have a very small, above or below, therapeutic dose range which could cause significant toxicity or sub-therapeutic levels; and also bear an increased risk of causing injury when they are misused (i.e. digoxin, phenytoin, warfarin, etc.).

Over-the Counter Drugs (OTC): Medications that do not require a prescription.

OTC DRUG LIST: A list of clinically efficacious and cost-effective OTC drug products identified and selected by a group of knowledgeable and duly licensed clinicians, to be utilized in order to deliver a high quality of care to members while containing costs.

PHARMACY & THERAPEUTICS ADVISORY COMMITTEE (P&T): The P&T advisory committee advises on the establishment, and maintenance of a preferred drug list which promotes clinically appropriate cost-effective drug therapy. The committee also serves in an advisory capacity on matters pertaining to the utilization, prescribing, dispensing and administration of drugs, medicinal, and medication-related supplies for patient care and treatment.

Pharmacy Benefits Manager (PBM): an entity contracted to provide pharmacy services, which may include prior authorization evaluations.

Preferred Drug List (PDL): means a list of prescriptions drugs, both generic and brand name, used to identify drugs with status (preferred or non-preferred) that offer the greatest overall value based on efficacy, safety and cost-effectiveness. The Preferred Drug List shall be maintained by a group of clinicians

Prior Authorization (PA): obtaining approval for a particular service or medication before it is provided.

STEP-THERAPY PROTOCOL: A step-by-step set of directions that identifies the

progression of drug therapy from first line therapy to the second line drug therapy.

THERAPEUTIC INTERCHANGE: The dispensing of a drug product different from that which is prescribed, but which is deemed to be therapeutically equivalent to the original product prescribed.

POLICY

It is the policy of Evolent Health (Evolent) to provide coverage for all medically necessary legend and non-legend drugs which are FDA approved and where the manufacturer has entered into a national rebate agreement with the Secretary of the U.S. Department for Health and Human Resources. However, Evolent may choose to apply utilization management techniques through prior authorization (PA), step therapy (ST) or quantity limits (QL) to any drug or therapeutic category on this list. A hard copy of the preferred drug list must be provided when requested by members. Additions or deletions are based upon clinical review of the drug and cost-effectiveness of the treatment in relation to similarly used agents already on the drug list. Providers are notified in writing via Pharmacy News Bulletin of all drug list changes.

PROCEDURE

A. **Pharmacy & Therapeutics (P&T) Advisory Committee**
   a. Refer to Policy & Procedure RX.051.KY Pharmacy and Therapeutics Advisory Committee
   b. The P&T Committee is comprised of actively practicing physicians and pharmacists who can contribute clinical expertise. The role of the committee is to advise on the establishment and maintenance of a preferred drug list which promotes clinically appropriate cost-effective drug therapy. The committee shall represent the enrollees including those with special needs.

B. Drug Selection Process
   a. Formulary coverage is considered for all medically necessary legend and non-legend drugs which are Food and Drug Administration (FDA) approved and where the manufacturer has entered into a national rebate agreement with the Secretary of the U.S. Department for Health and Human Resources.
   b. The P&T committee makes a recommendation on covered medications in accordance with RX.051.KY P&T Advisory Committee.

c. The PDL will be reviewed on a rolling basis so that all represented drug classes are reviewed within at least a three (3) year period.

C. **Drug classification:** drugs on the PDL are divided into 5 categories
   a. Preferred drugs – Drugs that are covered without additional limitations and do not require approval from Evolent before they are provided to members.
   b. Preferred drugs with limitations – Drugs that are covered with additional limitations, such as quantity per month or year limits, limitations specific to certain drug or therapeutic categories, age or gender. Exceptions to these limits require prior authorization.
   c. Non-Preferred drugs – Drugs that require a prior authorization. Certain additional quantity limits may also apply.
   d. OTC drugs – A limited number of OTC products are covered and may only be dispensed when accompanied by a valid prescription.
   e. Non-Formulary drugs – drugs that are not currently coded but may process once approved through an exceptions process.
   f. Excluded drugs – Drugs that are not a covered benefit by the DMS and thus, not covered by Evolent.

D. Newly FDA-Approved Medications, Technology and Pharmaceutical Information
   a. Evolent Health Plan pharmacy staff in collaboration with the PBM will identify new drug products or formulations as they become available in the marketplace.
   b. Prior to committee review, the drug will be assigned as non-preferred status with PA.
   c. The health plan client's Pharmacy and Therapeutics Advisory Committee will review new drugs in accordance with RX.051.KY Pharmacy and Therapeutics Advisory Committees
   d. Existing policies and procedures are updated as needed upon release of new pharmaceutical information
   e. In order to provide timely care for our members, a request for coverage of a new technology or a new application of an existing technology may occur before a formal policy has been developed.

E. Medical Literature References
   a. Formulary decisions including therapeutic interchange and step therapy protocols are developed using the following references:
      i. CMS Compendia: Gold Standard Clinical Pharmacology, Thompson Micromedex DrugDex, and AHFS–DI
      ii. Peer reviewed journals, such as the Journal of American Medical Association (JAMA), American Journal of Health-System Pharmacy (AJHP), Drug Intelligence and Clinical Pharmacy (DICP) or similar

publication;
iii. Trade publication or non-peer review journal, such as Pharmacy Times, Pharmacy Practice News, Drug Topics, or similar publication;
iv. Pharmacy references including Facts and comparisons (Facts), The Physicians' Desk Reference (PDR), Remington, or similar pharmacy or pharmacology reference;
v. Non-promotional materials from drug manufacturers, including drug inserts and advice for proper use;
vi. Recommendations from professionals serving on advisory committees such as the Pharmacy Committee; and
vii. Other materials or the recommendations of advisory professionals as deemed appropriate by the pharmacy director and/or adjunctive professional staff.
viii. Other recognized scientific based technology assessment reports.

F. Generic Equivalents

a. Evolent recognizes that generic substitution of drug products is mandated in the Commonwealth of Kentucky and that generic products provide high quality pharmaceutical care at a potentially lower cost. Evolent requires dispensing of high-quality generic drug products.
b. When the FDA approves a new generic drug, the PBM is permitted to remove the corresponding brand and subsequently place the newly approved generic drug onto the Preferred Drug List (PDL) without prior approval of the P&T Committee.
    i. Note: Narrow therapeutic index drugs are excluded from this policy.
c. When a generic agent is approved by the FDA for a non-preferred product, the newly available generic is not automatically added to the PDL. A value assessment is conducted to determine the cost benefit of the new generic compared to current PDL products in the corresponding drug class. If a cost benefit is found, the generic can be added to the PDL if there are no clinical and/or safety issues that would render the drug less desirable than current PDL medications in the class. Medications that have any clinical/ safety issues are presented to the P&T Advisory Committee prior to any decision on PDL status.
d. Evolent notifies the health plan client P&T Advisory Committee in writing before their next meeting of any changes to the Preferred Drug List.
e. If a valid prescription(s) for a brand name drug(s) having an AB-rated generic equivalent product is presented to a network pharmacy, it is filled with the generic product.
f. If the prescribing practitioner requests the dispensing of a brand-named product when AB-rated generic products are available, a prior

authorization request must be submitted (see RX.060.E.KY: Prior Authorization of Pharmaceuticals Policy).

i. As available, biosimilar drugs will be dispensed in accordance with state and federal regulations.

G. Therapeutic Equivalent Interchange

a. Evolent may use methods such as therapeutic interchange to assure appropriate utilization of certain medications. Pharmacists, unless participating in a collaborative care agreement with an individual practitioner, are not allowed according to Kentucky State statues to substitute one agent for another therapeutically equivalent drug without the prescribing practitioners' authorization
b. The PBM and/or Evolent identifies the need for therapeutic interchange for a particular disease state through the health plan client's Pharmacy & Therapeutics Committee evaluations, Evolent utilization data, provider drug profiling, and cost-benefit analysis of pharmacy claims.
c. Interchange recommendations are developed jointly by the PBM and Evolent based upon review of the medical literature evaluating the differences and similarities of products within a therapeutic or chemical class. References that shall be used for documentation and development of interchange recommendations are listed under Medical Literature References (section E).
d. Therapeutic interchange recommendations are geared toward optimal therapy within each drug class. The protocols are integrated into the authorization criteria used by the PBM.

H. Step Therapy Protocol

a. The PBM and/or Evolent identifies the need for step-therapy protocols for a particular disease state through the health plan client's Pharmacy and Therapeutics Advisory Committee evaluations, utilization data, provider drug profiling, and cost-benefit analysis of pharmacy claims.
b. Step-therapy protocol recommendations are developed jointly by the PBM and Evolent based upon review of the medical literature evaluating the differences and similarities of products within a therapeutic or chemical class. References that shall be used for documentation and development of step-therapy protocol are listed under Medical Literature References (section E).
c. Step-therapy protocol recommendations are geared toward optimal therapy within each drug class. The step-therapy protocols are integrated into the authorization criteria used by the PBM.
d. The preferred drug list which includes step-therapy protocols is made available to practitioners annually or whenever changes are made via the the Health Plan website and/or Pharmacy News Bulletin.

e. Step-therapy protocols are evaluated and updated as necessary based upon changes in the medical literature and product availability. The Pharmacy and Therapeutics Advisory Committee reviews all step-therapy protocols at least annually, or more often as changes in medical care dictate.

I. OTC Medications

a. Evolent recognizes the therapeutic value of a limited number of over-the-counter (OTC) products and that members may not be able to afford to purchase such products. Evolent provides coverage for certain OTC products if the criteria outlined in this policy are met.
b. The health plan client's Pharmacy and Therapeutics Advisory Committee shall review and maintain a limited list of covered OTC medications.
c. OTC products may only be dispensed if accompanied by a prescription written by a licensed practitioner. Generic substitution is required; if the brand name product is medically necessary, prior authorization is required.
d. OTC products not on the covered list may be excluded from coverage.
e. A copy of the OTC drug list is available on the internet at the Health Plan's website for both practitioner and members. The member newsletter also states a hard copy of the OTC drug list is available upon request. Digital copies of the member newsletter can be found at passporthealthplan.com/members/my-health-my-life-member-newsletter/.

II. Medical Necessity

a. Refer to RX.008.2.KY Exceptions Due to Medical Necessity. This policy explains how specific coverage exception requests are handled. The processes of the operational issues, timeliness of response, and member and provider notification as a result of the request are addressed in Policy and Procedure RX.060.KY Prior Authorization of Pharmaceuticals
b. A clinical pharmacist and/or Evolent Health medical director reviews all requests received for medical exception.

III. Changes to the Preferred Drug List:

a. The PBM and/or Evolent identifies the need for changes to the drug list through Pharmacy and Therapeutics Advisory Committee evaluations, utilization data, provider drug profiling, cost-benefit analysis of pharmacy claims, and upon participating practitioner request.
b. Requests from participating practitioners for changes to the drug list must be made in writing. See the Health Plan Client Committee Request for Drug List Review located on the internet at the Health Plan's website.
c. Evolent Pharmacy department staff, in collaboration with the PBM, reviews the request and submitted materials and supplements the

information provided with additional clinical and financial analysis as outlined in RX.051.KY Pharmacy and Therapeutics Advisory Committee.

d. The Pharmacy and Therapeutics Advisory Committee advises to add/remove drugs from the drug list based on the clinical review of the drug in relation to similar drugs on the drug list and optimal therapy.
e. Evolent may elect to make changes to the Preferred Drug List without review from Pharmacy and Therapeutics Advisory Committee if the change presents a significant financial impact to the plan and/or a significant safety concern for the membership. Any changes made will be communicated to the committee at the next meeting. Evolent is responsible for maintaining the Preferred Drug List, evaluating additions and deletions to the list, and communicating changes to the PBM and providers.

L. Alignment with Department for Medicaid Services (DMS) Initiatives:

a. When directed by DMS, the PDL and/or any associated utilization management edits and programs will be updated to align with DMS sponsored clinical criteria, pharmacy-based programs, and other initiatives.
b. Necessary updates to policies, systems, and processes will be made within ninety (90) calendar days after written notification is sent from DMS and will be made at no cost to DMS

M. Distribution of the Preferred Drug List and notification of changes:

1. The PBM provides to Pharmacy Management an updated printable preferred drug list (PDL) annually or as needed. The PDL includes notations of any drugs that have restrictions such as prior authorization, step therapy, and/or quantity limit.
2. Following review of the preferred drug list, Pharmacy Management initiates a project request form to Marketing and Community Engagement to post the PDL on the Health Plan client's website.
3. Pharmacy Management provides notification to plan staff when updates to the PDL have been posted.
4. The Evolent pharmacy department provides providers and members, in writing, with other requirements, restrictions or limitations that apply to the use of certain pharmaceuticals
    a. Notices are sent to members at least 30 days prior to any negative changes
    b. Providers are notified via eNews and the provider newsletter
5. Provider and pharmacy notification: The preferred drug list which includes step therapy protocol and therapeutic interchange, if applicable, is made available to practitioners annually or whenever changes are made via the Health Plan website and/or Pharmacy News

Bulletin published quarterly by mail and email. Updates to the PDL shall be distributed in the formats herein mentioned no later than the effective date of changes.

6. Member notification: The information on how to view the drug list on the web site is communicated to the member in the member newsletter that is published three times a year. The member newsletter also states a hard copy of the drug list is available upon request. Digital copies of the member newsletter can be found at passporthealthplan.com/members/my-health-my-life-member-newsletter/.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	11/16
Annual Review	12/17, 12/18
Policy renamed PDL Decision Making Process Merged and retired the following policies: - RX.053.KY Review of New Drug for the Drug List - RX.054.KY Substitution of Drug Products - RX.055.KY Coverage of OTC Products - RX.057.KY Design and Implementation of Step-Therapy Drug Protocols - RX.058.KY Design and Implementation of Drug Therapeutic Interchange Protocols - RX.063.KY Communicate Pharmacy Procedure and Changes - RX.065.KY Addition of New Generic Entities to the PDL	05/19
DMS Section update	09/2019