

 	<b>Policy Number:</b> PTC-8500
	<b>Subject:</b> Prescription Drug Program
	<b>Impact:</b> Membership with a Prescription Drug Benefit
<b>Primary Authors:</b> On File	<b>Origination Date:</b> June 6, 2005
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**Policy:**

The Health Plan will offer a comprehensive prescription drug program including a suitable array of products to allow practitioners to appropriately manage their patients.

**Purpose:**

To mitigate the impact of disease on our customers for covered conditions.

**Regulatory References:**

**29 CFR § 2560-503-1; 29 § CFR 2590.715-2719; 45 CFR § 147.136; 45 CFR § 156.122**

**Requirements**

1. Pharmacy Management Program

- A. The Pharmacy Management Program will be reviewed annually and updated as needed when new pharmacy information is available.
- B. The Health Plan’s Pharmacy Benefit Manager (PBM) will maintain a preferred list of drugs, or formulary, that practitioners may consider when treating our customers. Drugs considered for the formulary are evaluated by the PBM’s Pharmacy and Therapeutics (P&T) Committee.
- C. P&T Committee
  - i. P&T membership will include physicians and pharmacists, and may include other ancillary health care professionals such as nurse practitioners and/or physician assistants. The Committee meets at least quarterly.
  - ii. Information is primarily obtained from peer-reviewed journals, pharmaceutical companies, and the FDA.
  - iii. Clinical appropriateness compared to other available treatments is the key consideration in the evaluation process.
    - a. P&T designates a drug as “include,” “exclude,” or “optional.” “Include” means the drug is automatically added to the formulary; “exclude” means it is not added. “Optional” drugs undergo a financial analysis and then are returned to the P&T Committee for a final decision.
    - b. Drugs evaluated by the P&T Committee will be designated one of the following statuses:

- Preferred generic drug: practitioners may prescribe without restriction.
- Generic drug: practitioners may prescribe without restriction.
- Preferred brand drug: practitioners may prescribe without restriction.
- Preferred brand drug/prior authorization required: coverage will be granted if customer meets certain established criteria (see section 2A).
- Brand drug: practitioners may prescribe without restriction, but customer financial responsibility may be greater.
- Brand drug/prior authorization required: coverage will be granted if customer meets certain established criteria (see section 2A); customer financial responsibility may be greater.

- iv. Formulary decisions are available to providers throughout the year by accessing the PBM's website: <http://www.express-scripts.com/aboutus/formularyinformation> (available to practitioners in hard copy, by request)

#### D. Other important coverage considerations

- i. There is one health plan formulary. Different versions may be compiled and displayed for certain segments of our customers (e.g., Marketplace). Most groups subject to the formulary have a tiered drug benefit. Other groups offer a qualified high-deductible health plan with a combined medical/pharmacy deductible and coinsurance after the deductible is met.

##### a. Tiered Formulary (increasing customer cost share)

- Preferred generic drug
- Generic drug
- Preferred brand drug or preferred brand drug/prior authorization required
- Brand drug or brand drug/prior authorization required

Note: Some plans offer a unique tier for specialty drugs. Specialty drugs are high-cost brand and generic drugs that require closer monitoring and/or special handling. Specialty drug tiers are generally the customer's highest financial responsibility tier.

"Biosimilar" is a new classification of specialty drug. Depending on its FDA designation, individual biosimilars may be handled as brands or generics based upon their interchangeability.

##### b. High-Deductible Health Plan (Combined medical/pharmacy deductibles)

- a. All covered drugs are subject to deductible/coinsurance up to an annual maximum out of pocket.
- b. If prior authorization is required—deductible/coinsurance up to an annual maximum out of pocket applies if coverage is granted, otherwise, the customer pays entire cost.

- ii. Classes of drugs to treat the following conditions are generally excluded from coverage by contract language:

- Weight loss
- Cosmetic conditions, such as wrinkles or hair loss
- Infertility
- Sexual dysfunction

- iii. Drugs that can be obtained without a prescription, with few exceptions, are excluded from coverage and not considered for the formulary.
- iv. With the exception of certain oncology agents and applicable government mandates, approved drugs used for experimental purposes are excluded from coverage.
- v. All other drugs and drug classes can be considered for the formulary.
- vi. Generic drugs, not specifically excluded by benefit design, are considered formulary.
- vii. Brand drugs that have at least one FDA-approved substitutable generic are covered but the customer pays the difference in cost between the brand and generic plus the non-preferred brand copay. The cost difference is considered a non-covered benefit.

E. The Pharmacy Program policy will be posted on the plan’s website (available to practitioners in hard copy, by request).

F. The Drug Formulary document is reviewed and updated at least quarterly and can be accessed by customers and practitioners on the plan’s website (available in hard copy, by request).

G. Certain formulary and non-formulary drugs require a practitioner to supply medical information before coverage is determined. Our PBM or other designee will establish parameters on which to base coverage of these specific drugs. See “Prior Authorization” (section 2A) of this policy for details.

H. All drugs that are new to the market are initially given nonformulary status.

2. Pharmaceutical Restrictions and Preferences

A. Prior Authorization

- i. Drugs that are determined to have medical utility, but also require a higher degree of review to determine appropriateness, are required to undergo prior authorization.
  - a. The Pharmacy and Therapeutics Committee (or similar body) develops authorization criteria after considering clinical data, reference materials, expert physician opinion, FDA-approved labeling, and/or cost-benefit information.
    - Step therapy (i.e., encouraging the use of certain drugs prior to using others) may be incorporated into these parameters at the discretion of the plan.
  - b. Practitioners can identify drugs requiring prior authorization via our website.
  - c. Practitioners may request the criteria for their review.
  - d. Determinations will be made by the either the health plan or its designee.
  - e. Both brand and generic drugs may require prior authorization.

ii. Processing of Practitioner Prior Authorization Requests

a. Timeliness of decision making

	24 hours	1 day	72 hours	3 days	15 days	30 days
urgent concurrent review	X					
urgent prior authorization			X			
nonurgent prior authorization					X	
post service decision						X
exigent step therapy review		X				
nonurgent step therapy review				X		
urgent formulary exception	X					
nonurgent formulary exception			X			

- b. Extending decision time frames—practitioners will be notified if their request requires additional information.

	48 hours	72 hours	14 days	15 days	30 days
urgent concurrent review*	X				
urgent prior authorization**	X				
nonurgent prior authorization***				X	
post-service decision***				X	

\*At least one attempt to obtain the information will be made within 24 hours of the request.

\*\*At least one attempt to obtain the information from the customer or his/her representative will be made within 24 hours of the request.

\*\*\*At least one attempt to obtain the information from the customer or his/her representative will be made within the decision time frame; 45 days will be allowed for submission of additional information.

The plan will deny the request if additional information is not received within the required time frame. The customer may appeal the denial.

- c. The plan and/or its delegates will have processes in place to address urgent requests after normal business hours within the appropriate time frames.
- d. Information submitted by the practitioner will be compared to the coverage criteria to render a decision on each request. Once a decision has been rendered, notification of the approval or denial will be sent to the practitioner and customer. For a denial, the customer and practitioner will be informed about how to contact the reviewer to discuss the case.
- Notification may be verbal, electronic, or in writing.
  - Notification will follow the time frames identified in “a” above.
  - A denial can only be made by a pharmacist or physician.
- e. If the request is denied for medical necessity or as experimental/investigational treatment, the notification letter will include information about the reason for the denial as well as the appeal and independent review processes. If the request is denied as a plan exclusion, or for any other reason, the notification letter will include information about the reason for the denial and the appeal and independent review processes.
- f. Timeliness reports will be prepared and reviewed by the Quality Committee twice annually.
- iii. Creation of Prior Authorization (PA) and Step Therapy (ST) Criteria
- a. When establishing a prior authorization or step therapy protocol, clinical review criteria that are based on clinical practice guidelines that are derived from peer-reviewed publications, evidence-based research, and widely accepted medical practice shall be used.
- In order to be used in the development of a prior authorization or step therapy protocol, a clinical practice guideline must be developed by a nationally or internationally recognized medical organization or group of organizations and must use evidence-based research that includes a systematic review of peer-reviewed scientific literature, widely accepted medical practice, and an assessment of likely benefits and harms of a particular treatment.

- If such clinical practice guidelines are unavailable, the clinical review criteria shall be derived from peer-reviewed publications, evidence-based research, and widely accepted medical practice.
- b. The clinical review criteria shall be continually updated based on updates to the clinical practice guidelines or a review of new evidence and research and newly developed treatments.
- c. Any individual involved in establishing a step therapy protocol under this subsection shall disclose any potential conflict of interest due to a financial or other relationship or payment from a pharmaceutical manufacturer and shall recuse himself or herself from voting on a decision regarding the step therapy protocol if he or she has a conflict of interest.

## B. Exceptions

- i. A customer, customer's representative, or customer's prescribing physician may request and gain access to clinically appropriate drugs not otherwise covered by the plan. Exceptions can be requested by calling 800-417-8164 for drugs managed by the PBM or 888-515-1357 for specialty drugs. The key pieces of information needed to process an exception request include:
  - a. Patient Name, date of birth, and ID number.
  - b. Drug requested, reason for use, and duration of treatment.
  - c. Drug(s) customer has previously tried for this condition and reason for failure.
  - d. Practitioner name, specialty, telephone, and fax number.
- ii. Timeliness of decision making. The organization must make and provide notice of its determination within:
  - 72 hours of receiving a standard request.
  - 24 hours of receiving an expedited request based on exigent circumstances. Exigent circumstances exist when a patient is suffering from a health condition that may seriously jeopardize the patient's life, health, or ability to regain maximum function or when a patient is undergoing a current course of treatment using a nonformulary drug.

## C. Decisions

- i. Approval
  - a. If a standard or expedited prior authorization is approved, the plan must provide coverage for the duration specified in the prior authorization criteria (e.g., three months for an initial approval and 12 months for continuation).
  - b. If a standard or expedited step therapy review is approved, the plan must provide coverage for at least one year from the date of the approval.
  - c. If a standard exception request is approved, the plan must provide coverage for the duration of the prescription, including refills.
  - d. If an expedited exception request is approved, the plan must provide coverage for the duration of the exigency.
- ii. Denial
  - a. If the request for a prior authorization, step therapy review, or exception is denied, the customer, customer's representative, or customer's prescribing physician may request to have the request reviewed by an independent review organization. The internal

appeal process does not need to be exhausted prior to requesting an independent review.

### 3. Other Management Policies

- A. The plan contracts for claims processing with its PBM. As part of this process, the PBM communicates relevant drug interaction information to pharmacies as part of the claim adjudication process using standardized NCPDP messaging (this includes the severity level of the interaction as defined by First Database or MediSpan). PBM will regularly review and approve the severity level messaging. Drug interaction information is advisory to the pharmacist and does not preclude the prescription from being dispensed.
- B. When the manufacturer recalls a drug for a Class 1 recall or a voluntary market withdrawal, our PBM notifies all affected members within 25 calendar days who received that drug in the past three months. The PBM also sends an informational letter to the prescribing physician.

For Class II drug recalls and voluntary withdrawals due to drug safety concerns—affected customers and providers are notified within 30 calendar days.

- C. Generic substitution will be promoted when A-rated generic drugs are available and when interchangeable biosimilars are FDA approved. The practitioner or customer will always have the choice to select the brand, however, greater customer financial responsibility may apply. This financial responsibility is not considered a covered benefit and does not accrue toward a customer's out-of-pocket limit.
- D. Quantity limits may be placed on drugs to ensure the appropriate quantity is dispensed. These are established by the PBM's Pharmacy and Therapeutics Committee and represent the typical amounts used in relation to the parameters of the pharmacy benefit (e.g., up to a 30-day supply at retail; up to a 90-day supply via mail order). If for reasons of medical necessity a greater quantity is required, the practitioner may request an exception as described in section 2A.
- E. Therapeutic substitution is not a component of the plan's pharmacy management activities as it is not permitted by law for health plans.

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**Approved By:**



**Director of Pharmacy**

**Date:** 9/23/2019