

White Paper: Formulary Development at Express Scripts

Express Scripts works with health-benefit plan sponsors and individual members of health plans to provide affordable access to clinically sound, high-quality pharmaceutical products. Drug formularies are one method of achieving this result.

From time to time, Express Scripts receives questions about how it develops formularies that are both clinically sound and cost-effective. This white paper is designed to answer those questions. The Express Scripts' formulary development process is based on the following principles:

1. *Clinical appropriateness* of the drug, not cost, is Express Scripts' foremost consideration.
2. The prescribing *physician always makes the final decision* regarding an individual patient's drug therapy.
3. Express Scripts will develop clinically sound formularies *based on evaluations of independent physicians*.

Consistent with these principles, Express Scripts offers a variety of standard formularies. Plan sponsors, based on their own unique situation, can select a formulary that is most appropriate for their members.

How Express Scripts Develops Formularies

Express Scripts has many years of formulary development expertise and an extensive clinical pharmacy department. Express Scripts develops formularies through a four-step process involving the work of three distinct committees:

1. Therapeutic Assessment Committee
2. National Pharmacy & Therapeutics Committee
3. Value Assessment Committee
4. National Pharmacy & Therapeutics Committee (annual formulary review)

Therapeutic Assessment Committee — The Therapeutic Assessment Committee (TAC) is an internal clinical review body, consisting of clinical pharmacists and physicians who are employed by Express Scripts. From a formulary development perspective, the committee is tasked to review specific medications following approval by the Food and Drug Administration (FDA). Before discussing a new drug at TAC, Express Scripts' clinical team conducts a search of the medical literature, evaluates published data from clinical trials, and develops comprehensive drug evaluation summary documents. The drug evaluation documents are developed with the aid of a wide range of resources including, but not limited to: primary literature, clinical practice guidelines, and FDA-approved package inserts. The drug evaluation documents include, at a minimum, a summary of the pharmacology, safety, efficacy, dosage, mode of administration, and the relative place in therapy of the medication under review compared to other pharmacologic alternatives. Following a review of the drug evaluation summary document, TAC ultimately provides a formulary placement recommendation which is shared with the Express Scripts' National Pharmacy and Therapeutics (P&T) Committee. TAC formulary recommendations are merely a suggestion and cannot be formally implemented without the approval of the P&T Committee.

National Pharmacy & Therapeutics Committee — The Express Scripts' National P&T Committee is a group of independent, actively practicing physicians and pharmacists who are not employed by Express Scripts. The P&T Committee is tasked to review medications from a purely clinical perspective. **The Committee does not have access to, nor does it consider, any information regarding Express Scripts' rebates/negotiated discounts, or the net cost of the drug after application of all discounts. The Committee does not use price, in any way, to make formulary placement decisions.** The Express Scripts' P&T Committee reviews a much broader range of formulary placement topics than TAC, including: new drug evaluations, new FDA-approved indications for existing drugs, new clinical line extensions, and new published or clinical practice trends that may impact previous formulary placement decisions.

For new drug evaluations, the P&T Committee reviews the relevant drug evaluation summary documents as well as the formulary placement recommendation from TAC. In addition, members of the P&T Committee provide their insight into the quality of the published literature, share their clinical practice experience, and assess the relative place in therapy of the medication and therapy class. The P&T Committee can establish one of the following four formulary placement designations: *include*, *access*, *optional*, or *exclude* from a formulary. Drugs with a designation of ***include*** are recommended for placement on all formularies. A drug may be given an *include* designation if it meets at least one of the clinical basis enumerated in the next sentence AND is anticipated, or validated via claims data, to treat a relatively large patient population. The clinical bases include: unique indication for use addressing a clinically significant unmet treatment need, efficacy superior to that of existing therapy alternatives, a safety profile superior to that of existing therapy alternatives, a unique place in therapy, and/or drugs which treat medical conditions that necessitate individualized therapy and for which there are multiple treatment options. A drug may be given an ***access*** designation if it meets the clinical basis enumerated in the sentence before AND is anticipated, or validated via claims data, to treat a relatively small patient population. Access medications are forwarded to the Value Assessment Committee (VAC) for further analysis. A drug may also be designated as ***optional*** on a formulary. A drug may be given an *optional* designation based on the conclusion that a significant proportion of its use is clinically similar to other currently available drug alternatives. Optional medications are forwarded to the VAC for further analysis. Finally, a drug may be designated as ***exclude***. Drugs may be given an *exclude* designation for one or more of the following clinical reasons: efficacy inferior to that of existing therapy alternatives, a safety profile inferior to that of existing therapy alternatives, and/or insufficient data to evaluate the drug. Medications recalled from the market for safety reasons take an automatic *exclude* status, and are formally reviewed at the next P&T Committee meeting.

Value Assessment Committee — The Value Assessment Committee (VAC) considers the value of drugs by evaluating the net cost, market share, and drug utilization trends of clinically similar medications. VAC consists of Express Scripts' employees from formulary management, product management, finance, and clinical account management. No member of VAC can serve in any capacity on TAC (and vice-versa). VAC reviews drugs designated as *access* or *optional* by the P&T Committee, and develops a formulary placement recommendation. VAC is required to add medications with an *include* designation to formulary, while drugs with an *exclude* designation may not be preferred on the formulary. In both cases, economic considerations are superseded by the clinical requirements of the P&T Committee. Once complete, formulary and tier placement recommendations are then forwarded to the P&T Committee for final approval.

National Pharmacy & Therapeutics Committee (Annual Review) — On an annual basis, the National P&T Committee will review the final formulary recommendations, by drug class, for the upcoming plan year. The Committee uses this opportunity to ensure adherence to previously established formulary placement recommendations, and to validate continued alignment with best medical practices. The Committee also ensures that all Express Scripts national formularies cover a broad distribution of therapeutic classes and categories, and that the formularies neither discourage enrollment by any group of enrollees nor discriminate against certain patient populations.

National Pharmacy & Therapeutics Committee: Overview

The Express Scripts National P&T Committee consists of 14 physicians and two pharmacists from active community and academic-based practices representing a broad range of medical specialties. The Committee is chaired by an elected member. The Vice President, Office of Clinical Evaluation and Policy, TAC chair, and Express Scripts Medical Director all provide staff support to the Committee.

The following medical and pharmacy specialties are represented on Express Scripts' P&T Committee:

- Cardiology
- Dermatology
- Endocrinology
- Gastroenterology
- Geriatrics
- Internal Medicine
- Neurology
- Obstetrics & Gynecology
- Oncology
- Pediatrics
- Pharmacy (General)
- Pharmacy (Geriatrics)
- Psychiatry
- Pulmonology
- Rheumatology

Members are selected by the Committee based on:

1. contributions to the medical and pharmacy literature
2. national recognition in their specialty
3. involvement in clinical (patient care) practice (membership prerequisite)
4. previous experience with P&T committees

Members of the Express Scripts' National P&T Committee receive a stipend for preparation for and participation in the meetings. The stipend amount is based on a reasonable estimate of revenue lost by not seeing patients while out of the office for meeting attendance and preparation. New committee members are elected by current members of the Committee. Members serve for a three-year term and are eligible for re-appointment by the Committee. At the beginning of each Committee meeting, members disclose potential and actual conflicts of interest by declaring any relationships with pharmaceutical manufacturers and Part D plan sponsors, including membership on advisory boards, participation on speakers' bureaus, receipt of research grants, and stock ownership. Prior to each meeting, a subgroup of the P&T Committee or Membership Subcommittee reviews all member disclosure information and determines if a conflict of interest exists. Members who are determined to have conflicts of interest are prohibited from participating in the final discussion and voting process for medications or manufacturers where a conflict exists. In the event a conflict of interest is determined to be so significant that a member of the Committee is unable to participate in most proceedings, the member will be asked to resign from the Committee.

The P&T Committee meets at least quarterly to evaluate drugs for addition to or deletion from the formulary. If necessary, mail ballots may be used to seek committee member comments and approval for new clinical designations between meetings (e.g., following FDA approval of a therapeutic-breakthrough drug).

How Express Scripts Plan Sponsors Manage Their Formularies

Express Scripts' plan sponsors often adopt Express Scripts-developed formularies as their own or use them as the foundation for their own custom formularies. Among the more than 70 therapeutic categories, custom formularies can vary in the number of brand-name drugs per category and in the extent to which the pharmacy benefit is managed in each category.

Formulary control levels are specified through benefit design. At one end of the spectrum is the open formulary. With an open formulary, the plan sponsor pays a portion of the cost for all drugs, regardless of formulary status, although a plan sponsor may choose to exclude certain products, such as 'lifestyle' drugs, from coverage. At the other end of the spectrum is the closed formulary. With a closed formulary, non-formulary drugs are not covered unless approved via a formulary exceptions process. Between these two alternatives, a plan sponsor can implement differential copays (as with a three-tier benefit design) or other financial incentives to encourage participants to use preferred formulary drugs, but will still pay a portion of the cost of the non-preferred drug.

For example, a plan sponsor using a three-tier benefit design may elect to manage a particular therapeutic category by making all generics in that category available at the first-tier copay level and preferred branded products available at the second-tier copay level. Non-preferred products could be placed on the third tier — available, but at a higher copay.

After first taking into account clinical considerations, plan sponsors consider cost in making their formulary choices. Generally, the fewer the drugs offered on the formulary and the greater the incentives to use the formulary's preferred drugs, the higher the discounts available from manufacturers and, therefore, the lower the cost to the plan sponsor. Most formularies offer generics at the lowest copay and typically include the vast majority of available generic products.

Express Scripts is able to administer lower-cost prescription drug benefits for plan sponsors in part because of the rebates that ESI receives from manufacturers. A rebate is simply a retrospective payment that is paid to ESI pursuant to rebate contracts negotiated independently by ESI with pharmaceutical manufacturers and directly attributable to the utilization of certain pharmaceuticals by our client's members. Many factors can affect the amount of the rebate, but in general, higher rebates are achieved when a plan sponsor adopts a formulary and plan design that provides greater incentives to its participants to use a formulary (preferred) drug.

Accessing Non-Formulary Medications

Express Scripts encourages plan sponsors to develop formulary systems that enable individual patient needs to be met with non-formulary drug products when demonstrated to be clinically justified by the physician or other prescriber. Generally speaking, plan sponsors should offer an efficient process for the timely procurement of non-formulary drug products, impose minimal administrative burdens, and provide access to a formal appeal process if request for a non-formulary drug is denied.

Due to the variability in plan sponsor benefit design, Express Scripts encourages individual patients who are attempting to access a non-formulary medication for clinical purposes to contact the phone number, mailing address or website outlined on their prescription drug card. The decision to cover non-formulary medications, as well as the mechanism by which it is administered, is entirely determined by the plan sponsor; not Express Scripts.

Express Scripts Formulary Compliance Programs

Express Scripts' plan sponsors also achieve formulary management through participation in one of Express Scripts' Formulary Compliance programs. These programs help plan sponsors reduce overall prescription drug costs by encouraging utilization of preferred drugs (generics and formulary brand name medications) through intervention strategies.

Express Scripts never recommends changing to a higher-cost drug, but it may suggest an equally-effective, lower-cost drug (typically, a generic) before a more expensive brand name alternative. The Express Scripts formulary compliance programs provide clear information about formulary drugs to all of the participants in the prescription-dispensing process. For example, when a prescription for a drug that is not on the member's formulary is taken to a retail pharmacy in our network, the **claims processing system** notifies the pharmacist of comparable drugs that are covered by the member's plan. The pharmacist can then work with the member and the prescriber to replace the originally-prescribed drug with an appropriate formulary product, if possible. A second example is our **formulary notification program**. The formulary notification program sends targeted letters to members who are taking a maintenance medication that will soon become non-formulary. These notifications frequently include a list of clinically similar, formulary alternatives. The member can take this type of communication to their physician, and determine if a formulary alternative is right for them. The third type of formulary support tool includes Express Scripts' **web-based tools**. Express Scripts and/or the members' plan sponsor provides a suite of online resources including: copies of the formulary, relative price comparisons of therapeutic alternatives, and information about which drugs have a generic equivalent.

Conclusion

Prescription drug costs continue to increase for a variety of complex reasons. As a result, the job of managing the pharmacy benefit has become an essential element of the overall healthcare management equation. Left unmanaged, plan sponsors' costs would rise at faster rates, with the likely ultimate result of reduced benefits and higher costs to consumers.

Affordable access to a clinically sound, high-quality pharmacy benefit depends on sophisticated, carefully constructed cost-control strategies — strategies that always place patients and their physicians first. The processes Express Scripts uses to develop formularies have been constructed to ensure that clinical considerations are paramount and fully taken into account *before* cost considerations. Express Scripts has also implemented one of the industry's most unique cost-lowering rebate policies — one which ensures that each drug is considered individually on its own merits with the active involvement of our plan sponsors. Finally, Express Scripts' has a number of tools (formulary, plan design, and clinical programs) to ensure that plan sponsors maximize the use of lower cost, clinically-equivalent generic medications. By combining the solutions above, plan sponsors can continue to offer a fair, clinically appropriate, and financially responsible pharmacy benefit.

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