

White Paper: Formulary Development at Express Scripts

Express Scripts acts on behalf of 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. Most important are the principles that guide all our actions in this area:

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 recommends formularies tailored to meet the needs of its many plan sponsors.

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 three-step process involving the work of the following committees:

1. Therapeutic Assessment Committee
2. Value Assessment Committee
3. National Pharmacy & Therapeutics (P&T) Committee

Therapeutic Assessment Committee — Composed of Express Scripts' clinical pharmacists and medical director, the Therapeutic Assessment Committee (TAC) focuses on primary drug review. This committee evaluates a drug after its approval by the Food and Drug Administration (FDA). Pharmacists conduct a search of medical literature, review published data from clinical trials and the FDA-approved package insert. Pharmacists typically contact the pharmaceutical manufacturer in order to obtain and evaluate additional safety and efficacy information that led to the product's FDA approval. The pharmacists may also contact physician specialists to obtain additional information and review medical practice guidelines relevant to the drug's approved indication. A thorough clinical review is conducted, including medication pharmacology, safety, efficacy, and dosage. The clinical information on the drug under review is then compared to clinical information on pharmacologic and non-pharmacologic therapy alternatives. After clinical evaluation, the TAC forwards to the Value Assessment Committee (VAC), and subsequently to the Express Scripts National P&T Committee, its recommended clinical designation (e.g., whether the drug should be included on or excluded from the Express Scripts National Formularies, whether it is optional for formulary inclusion, or whether it should be given a conditional include designation to meet the specific therapeutic needs of an identifiable subset of patients with a given condition).

Drugs with a designation of **include** are recommended for placement on all formularies. Drugs may be given an **include** designation for one or more of the following clinical reasons: unique indication for use, efficacy superior to that of existing therapy alternatives, a safety profile superior to that of existing therapy alternatives, and/or a unique place in therapy. Drugs with an **exclude** designation are not recommended for formulary inclusion. Drugs are 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. Drugs designated as **optional** are forwarded to the Value Assessment Committee for formulary consideration. Drugs are given an **optional** designation based on the assessment that they are clinically equivalent to currently available formulary alternatives and do not demonstrate a clinical reason for an “exclude” designation. Drugs in the **conditional include** category are recommended for inclusion on all ESI National Formularies after meeting a conditional qualification. Drugs in this category have a unique indication or place in therapy in an *identifiable* subgroup of patients within a broader set of less unique medical indications where more clinical choices are available. The ranking of conditional include is based on a case by case assessment which determines the need for a formulary exception override process or prior authorization program (e.g. an individual patient meets the defined criteria for access to the drug).

Value Assessment Committee — The Value Assessment Committee (VAC) considers the value of drugs by comparing the cost of clinically equivalent products. The VAC committee is comprised of Express Scripts' staff formulary management, research and product management, finance, and clinical account management. No members of the Value Assessment Committee serve in any capacity on the Therapeutic Assessment Committee. The VAC reviews drugs designated as **optional** by the TAC and develops a formulary-placement recommendation that is forwarded to the Express Scripts National P&T Committee. For products that are designated by the P&T Committee as **exclude** or **include** VAC updates the formulary status to reflect non-formulary for excludes and formulary for includes. For products that are designated by the P&T Committee as **conditional include** VAC considers the operational and financial impact of a prior authorization program and may make the decision to place the drug on the formulary and generally available to all patients for whom it is prescribed, or not place the drug on the formulary, but making it available to the identifiable sub-group of patients who require the drug. For all clinical parameters a financial value assessment is made.

In addition to providing formulary placement recommendations to the Express Scripts P&T Committee, the VAC provides its evaluations to the P&T committees for plans with custom formularies, for their review and final approval

National Pharmacy & Therapeutics Committee — The formulary recommendations from TAC and VAC are then presented to the Express Scripts National Pharmacy & Therapeutics (P&T) Committee. The P&T Committee approves or disapproves the recommended clinical designations of TAC (e.g., whether the drug should be included on or excluded from the formulary, whether it is optional for inclusion, or whether it meets the criteria for a conditional include designation). **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 and does not use price information in making a decision about the inclusion or exclusion of a drug from the formulary.** If the P&T Committee does not approve TAC's recommended clinical designation for a drug, the designation is changed to reflect the P&T Committee's decision. Drugs with an **include** designation are then placed on the formulary and those with an **exclude** designation are not placed on the formulary. Drugs given an **optional** or **conditional include** designation are referred back to the VAC for final formulary placement. If a conditional include drug is not placed on the formulary, a formulary exception override process or prior authorization program designating the clinical situations for which an individual patient may get the drug will be put in place.

The Express Scripts National P&T Committee consists of 19 non-employee physician members and one pharmacist member from active community and academic-based practices and represents a broad range of medical specialties. The Committee is chaired by an elected physician member. Two Express Scripts registered pharmacists, an Express Scripts Medical Director, and the Chief Medical Officer offer staff support to the Committee. Although members receive reimbursement for travel costs and a stipend, their involvement on the P&T Committee reflects their desire to foster better patient care on a national level.

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

- Allergy & Asthma
- Cardiology
- Dermatology
- Endocrinology
- Family Practice
- Gastroenterology
- Geriatrics
- Geriatric Pharmacy
- Infectious Disease
- Internal Medicine
- Neurology (Parkinson's & Dementia)
- Neurology (Seizures & Headaches)
- Obstetrics & Gynecology
- Oncology
- Ophthalmology
- Pediatrics
- 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 for a maximum of three consecutive three-year terms. At the beginning of each Committee meeting, members disclose potential conflicts of interest by declaring any relationships with pharmaceutical manufacturers, including membership on advisory boards, research grants, and stock ownership. The Committee members vote to determine whether disclosures present a conflict of interest. Members who are determined to have conflicts of interest are prohibited from participation in the discussion and voting process. 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 its 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).

In addition, the P&T Committee reviews and approves therapeutic categories to be included in the formulary compliance programs. For example, based on the P&T Committee's feedback, which reflected the members' clinical assessment, Express Scripts does not seek to secure substitutions involving anti-depressant drugs. On the other hand, many branded medications in various therapeutic categories, such as those used for gastroesophageal reflux disease, are found to be clinically appropriate for substitution, and Express Scripts may implement formulary compliance programs in those categories. Such programs are implemented only with the plan sponsor's approval, and substitution occurs only with the prescribing physician's approval. The P&T Committee considers substitution programs appropriate only for drugs that have a high level of clinical substitutability and votes to disallow such programs for all drugs that do not meet this criterion.

This process assures a clinically sound formulary while providing cost-effective pharmaceutical care to plan sponsors and their members.

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 exclusion override 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, non-formulary products could be placed on the third tier — available, but at a higher copay. In a different therapeutic category, however, the plan sponsor may want to include many products on its formulary as preferred, second-tier products and designate few agents as non-preferred, third-tier products.

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. All formularies offer generics at the lowest cost and typically include all available generic products.

In part, Express Scripts delivers lower-cost prescription drugs to its plan sponsors through discounts (rebates) from manufacturers. A rebate is simply a discount paid after the fact — a refund of a portion of the undiscounted original purchase price of the drug. Many factors can affect the amount of the discount, but in general, higher discounts are achieved when a plan sponsor adopts a formulary and plan design that provide greater incentives to its participants to use a formulary (preferred) drug.

Express Scripts Formulary Compliance Programs

Express Scripts never recommends switching from a lower-priced drug to a higher-priced drug.

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 through intervention strategies.

Express Scripts never recommends changing to a higher-cost drug, but it may be able to suggest an equally-effective formulary drug instead of a non-formulary choice. 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 the drug choice management (DCM) program. Clients that enroll their members in DCM share our confidence in choices made by informed members. In DCM, letters are sent to inform mail-service pharmacy members about savings opportunities that may result from making a prescription change. The informed member may then discuss options with the prescriber, before they make the final decision whether or not to change.

Express Scripts provides formulary support programs for our clients without accepting any manufacturer funding for such programs.

Formulary Notification programs involve targeted letters to members who take a maintenance formulary drug that will become non-formulary. These targeted benefit communications are intended to improve member understanding of their drug benefit.

Web-based tools provide Express Scripts members with copies of their formulary, relative price comparisons of therapeutic alternatives, and information about what drugs have generic equivalents.

How Express Scripts' Plan Sponsors Manage Their Pharmacy Benefit

Express Scripts works with its plan sponsors in a consultative capacity to design a prescription-drug benefit program that meets the plan sponsor's needs. The Express Scripts plan sponsor makes all decisions relating to:

- The coverage of the drug plan
- The formulary
- Plan-design features, such as copay structures, stop-loss amounts, benefit caps, zero dollar copays for generics, High Performance Formulary, Closed formulary benefits etc.
- Utilization management offerings, such as step therapy, prior authorization, quantity level limits and physician consultation

Express Scripts will recommend one of its formularies to a plan sponsor; however, the plan sponsor may require that the formulary be changed in certain respects. Express Scripts' managed-care plan sponsors, in particular, often require custom formulary-management options. In every case, however, the plan sponsor actually selects the formulary. Similarly, Express Scripts recommends plan designs to assist clients in achieving their pharmacy benefit objectives (e.g., cost management, generous benefit) goals, but in every case, the plan sponsor makes the decision on what plan it will offer.

Arriving at a plan design is a complex process. Express Scripts has a 40-page account-setup form that the plan sponsor, assisted by the Express Scripts account manager, completes to select plan features. Throughout the process, Express Scripts provides consultative services, including financial modeling, to the plan sponsor, but the plan sponsor ultimately decides what plan to offer. Once the plan is implemented, Express Scripts administers the plan according to the guidelines selected by the guidelines determined by the plan sponsor.

Conclusion

Prescription drug costs, which represent more than 10 percent of the overall healthcare dollar, have been increasing at double-digit rates due to new-drug introductions, more-sophisticated drug therapies, and patients' increasing desire to take more control of the healthcare decision-making process. 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.

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