



Workers' Compensation Formulary Development

Express Scripts provides services to health benefit plan sponsors and individual patients of health plans to provide affordable access to clinically-sound, high quality pharmaceutical products. Formularies are one method of achieving this result.

From time to time, Express Scripts receives questions about how it develops the clinically-sound formularies it recommends to workers' compensation clients. This white paper is designed to answer this question.

Express Scripts has many years of formulary development expertise and an extensive clinical pharmacy department; development of Express Scripts' standard Workers' Compensation Formularies benefits from that rich heritage. Most important are the principles that guide our actions in this area:

1. *Clinical appropriateness and association with workplace injury*, not drug cost, are Express Scripts' foremost considerations.
2. The prescribing *physician always makes the final decision* regarding an individual patient's drug therapy.
3. Express Scripts develops clinical parameters *based on evaluations of independent physicians* and assesses those parameters for application to workers' compensation

Consistent with these principles, Express Scripts recommends Workers' Compensation Formularies tailored to meet the needs of its many plan sponsors.

How Express Scripts Develops Workers' Compensation Formularies

Express Scripts' standard drug lists include a general Workers' Compensation Formulary as well as eight Injury-Specific Formularies. Development of standard formularies takes place through a process involving the work of the following committees:

1. Therapeutic Assessment Committee (TAC),
2. National Pharmacy & Therapeutics (P&T) Committee
3. Workers' Compensation Clinical Advisory Committee (WC-CAC).

Therapeutic Assessment Committee – The Therapeutic Assessment Committee (TAC) is an internal clinical review body, consisting of clinical pharmacists and physicians 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, FDA-approved package inserts, and input from actively practicing physicians and other health care practitioners. The drug evaluation documents include, at a minimum, a summary of the drug's pharmacology, safety, efficacy, dosage, mode of administration, and the relative place in therapy of the medication under review compared to other pharmacologic and non-pharmacologic alternatives.

National Pharmacy & Therapeutics (P&T) 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' net cost of the drug after application of 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 group health 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 three formulary placement designations (referred to as clinical parameters): include, exclude, or optional from a formulary. Drugs with a designation of include are recommended for placement on all group health 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 group health 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 may also be designated as optional on a group health formulary. Drugs are given an optional designation based on the conclusion that they are clinically similar to other currently available drug alternatives. Medications recalled from the market take an automatic exclude status, and are formally reviewed at the next P&T Committee meeting.

Workers' Compensation Clinical Advisory Committee (WC-CAC) – Composed of Express Scripts' clinical pharmacists and medical director, WC-CAC leverages the clinical expertise provided by both TAC and P&T to develop standard Workers' Compensation Formularies appropriate for workers' compensation clients. WC-CAC evaluates drugs that have been given a clinical parameter of either include or optional for applicability to cases of workplace injury. WC-CAC reviews prevalence of various types of workplace injuries and utilization of drug therapies associated with those injuries; drugs that are not generally associated with cases of workplace injury are given a designation of Prior Authorization Required and require the review and approval of the client for coverage; Express Scripts does not administer clinically-based prior authorization criteria on behalf of clients. Generally, WC-CAC focuses on the short-term



management of acute complaints and the prevention of complications, such as infections as well as ongoing pain management and long-term complications of permanent disability cases. WC-CAC then evaluates formulary drugs for application of plan limitations; based on utilization patterns and Express Scripts' expertise with workers' compensation cases, timeframe (based on date of injury or claim) or number of refill limitations may be applied to certain drug therapies.

The process for drug list development for Injury-Specific Formularies is in alignment with that of the general Worker's Compensation Formulary. Injury-Specific Formulary development, however, focuses on a specific injury type and requires Prior Authorization for drug therapies not typically associated with the specific injury.

This process assures clinically sound drug list(s) while providing cost effective pharmaceutical care to plan sponsors and their patients.

How Express Scripts' Plan Sponsors Manage Their Workers' Compensation Pharmacy Trend

Express Scripts works with its plan sponsors in a consultative capacity to design a workers' compensation pharmacy 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 plan limitations, refill limits, etc.
- Utilization management offerings, such as step therapy and quantity level limits

Express Scripts will recommend one or more of its Workers' Compensation Formularies to a plan sponsor or the plan sponsor may use them as the foundation for their own custom formulary(ies). In every case, the plan sponsor actually selects the formulary. Similarly, Express Scripts recommends plan designs to assist clients in achieving their objectives goals, but in every case, the plan sponsor makes the decision on what it will offer.

Arriving at a plan design is a complex process. Express Scripts has an account setup form that the plan sponsor, working with the Express Scripts account team, completes to select plan features. Throughout the process, Express Scripts provides consultative services 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 plan sponsor.

Conclusion

Workers' compensation is full of unique challenges for payers and injured workers. Our proven solutions are hard evidence that we have been successful in helping clients navigate, dissect and master their workers' compensation pharmacy program. Our process for developing clinically-sound Workers' Compensation Formulary options that leverage our robust heritage of clinical integrity is a prime example of how Express Scripts remains committed to making the use of prescription drugs safer and more affordable.