Plan Design Review Guide

Express Scripts
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Introduction to Express Scripts’ Plan Design Review Guide

The role of the pharmacy benefit manager
Pharmacy benefit managers (PBMs) are organizations that provide administrative services for processing and analyzing prescription claims for pharmacy benefit and coverage programs. PBM services can include

- contracting with a network of pharmacies
- establishing payment levels for provider pharmacies
- negotiating rebate arrangements
- developing and managing formularies, preferred drug lists, and prior authorization programs
- maintaining patient compliance programs
- performing drug utilization review
- operating disease management programs

Many PBMs also operate mail-order pharmacies or have arrangements to include prescription availability through mail-order pharmacies.

How can I benefit from reading this guide?
This reference guide describes some of the essential elements of a pharmacy benefit design (sometimes referred to as plan design). It also describes the strategies and tools—such as drug coverage, generic medications, member cost share, formulary management, therapeutic interchanges for both retail and mail-order pharmacies, drug utilization review, and utilization management programs—that Express Scripts customers can employ to help better manage their pharmacy benefits. Express Scripts developed this guide to give plan administrators more insight into concepts, practices and strategies used to manage a pharmacy benefit.

Some of the programs described in this guide may be included in the base services provided by Express Scripts and others may be available for additional fees. If you have questions, please contact an Express Scripts representative.
Chapter 1: Drug coverage and coverage strategies

The pharmacy benefit encompasses a plan’s drug coverage. Drug coverage decisions impact the cost of the benefit to plan sponsors. Many plan sponsors (organizations that provide a prescription drug benefit) make decisions to exclude or limit coverage for specific drugs or drug categories that may be considered elective or cosmetic, and for those drug products that could create duplication or inconsistency with their medical health-care coverage. Common drug categories that are excluded or limited in the drug benefit include experimental drugs, over-the-counter drugs (OTCs), hair-growth stimulants, smoking-cessation aids, fertility drugs, injectable drugs, and cosmetic drugs.

The Patient Protection and Affordable Care Act (PPACA) under Healthcare Reform (HCR) provides additional guidance for non-grandfathered plans that implicates their coverage of specific preventive services that could require coverage of certain medications for non-grandfathered plans with plan benefit years on or after September 23, 2010. Plans will need to evaluate any changes with their legal counsel.

Drug coverage options available to plans include:
1. Cover a drug, subject to the applicable cost-share
2. Cover a drug conditionally, subject to rules and algorithms that ensure evidence-based clinical use
3. Exclude a drug from coverage

Drug inclusions
Prescription drug programs generally define the drugs covered by the plan. Most plans define a prescription drug as any drug or biological agent (such as certain specialty medications) that requires a written prescription to be dispensed. These drugs must bear the federal “legend” which states “Caution: Federal law prohibits dispensing without a prescription.” Commonly covered non-legend (OTC) products include insulin, insulin syringes, and diabetic testing supplies.

Covered benefits generally include benefits that the Internal Revenue Service (IRS) has recognized as deductible or tax-exempt medical expenses. Prescription drugs and insulin are generally considered deductible medical expenses under IRS rules. Other medications that may be purchased “over the counter” are generally not considered tax exempt medical expenses, at least if not accompanied by a prescription. New guidance under PPACA extends coverage to additional preventive OTC drugs including iron, aspirin, folic acid, fluoride, smoking cessation products, and contraceptives within specific age and gender requirements when prescribed by a physician.

With the exceptions noted above, most pharmacy benefit plan designs exclude OTC products. Managed Medicaid plans may cover select OTC drugs when prescribed by a physician. These OTC products may include vitamins, cough and cold medications, analgesics, antacids, and laxatives. After PPACA, however, a plan may want to consider potential tax implications of covering any OTC product without a prescription. Medicaid benefits are not employment-related and therefore not subject to IRS tax code considerations.

Drug exclusions
Prescription drug programs generally list the drugs and/or drug categories excluded from the pharmacy benefit coverage. The list of excluded drugs and/or devices will vary from plan to plan, and the variability is usually related to a plan’s benefit philosophy, the line of business, or the competitiveness of the plan’s marketplace. In addition, product exclusions may be based on the drug’s legal status, source or distribution channel, or the dosage form.
Because OTC products can be purchased without a prescription they are typically excluded from the prescription drug benefit. Many OTC products on the market today were originally available as prescription drugs and have been reassigned to nonprescription drug status. This process, known as Rx-to-OTC switch, occurs only after the Food and Drug Administration (FDA) reviews the drug and approves its labeling as safe and effective for self-medication without physician supervision.

Prescription products with the same drug and same dosage strength as in the OTC versions typically are excluded from the prescription benefit. An example is the prescription product Lotrimin® 1% and the OTC product Lotrimin® AF. However, plans that are considered non-grandfathered under PPACA that cover certain preventive services may be required to cover certain drugs (that also may be available OTC) as part of their preventive services. Non-grandfathered plans and plans should carefully evaluate the PPACA requirements in this regard.

**Standard exclusions**

Generally plans exclude the following drugs and/or drug categories:

- Investigational or non-FDA-approved drugs.
- Drugs used for cosmetic purposes or aesthetic enhancement (cosmetic drugs).
- OTC drugs other than insulin.
- Drugs available in the same strength as an OTC version.

Plan sponsors can also manage costs by excluding additional drugs or drug categories from coverage, depending on the plan’s overall pharmacy and health benefit philosophy. These categories may include weight-loss drugs, fertility drugs, oral contraceptives*, drugs for erectile dysfunction, smoking cessation products*, vitamins, or compounded drug products (a prescription requiring a pharmacist to mix two or more drugs).

* Non-Grandfathered plans should carefully evaluate PPACA requirements

**Plan considerations**

- Excluding coverage for certain types of medications can result in savings to plans. However, plan sponsors need to weigh many factors when determining coverage exclusions—including the organization’s benefit philosophy, regulatory issues, financial resources, and member demographics. One consideration is whether the plan will focus primarily on treating illnesses, or whether (and to what degree) it will also provide coverage for drugs that enhance health, function, and appearance.
- Some categories of drugs may address lifestyle and behavioral risks that can have a significant and direct impact on healthcare costs and medical outcomes. For example, weight-loss and smoking cessation drugs, when successfully used, can provide a major benefit.
- Plan sponsors should also consider inclusion or exclusion questions in the context of the organization’s medical plan (such as coverage for infertility) to ensure alignment of the coverage offered through the medical and pharmacy benefits.
- Plans offering preventive services should also consider the PPACA rules and any applicable coverage requirements.
- Some plans allow members to purchase excluded drugs at the plan’s discounted rate. This offers members the added security of having all their medications, including those that are not covered by the plan, reviewed through the plan’s health and safety checks.
• Prior authorization rules can be established to allow coverage under defined conditions for a drug that is normally excluded. Plans can also offer clinical review and appeals procedures for certain categories of excluded drugs.
• When deciding to include or exclude coverage of various drug categories, plans often find it helpful to know average utilization and drug spend for each category.

Drug coverage limits
Plans can choose to cover a drug, subject to all the customary cost-share features such as co-payments and deductibles, or exclude a drug from coverage, making the member responsible for 100 percent of the cost. Another option is to apply predefined drug coverage limits.

Drug coverage limits are claim adjudication edits (rules that a pharmacy plan’s systems will follow when processing a prescription) applied to drugs that are covered. Coverage limits help reduce drug benefit costs. For example, a pharmacy benefit that includes insulin may limit the coverage to two vials per claim or co-payment rather than a “days-supply” allowance (the maximum amount of medication a patient is allowed to purchase at one time as defined by the plan). This amount can vary based on whether the patient is purchasing their medication in a retail setting (typically 30 days of therapy) or through a mail pharmacy (usually 90 days of therapy).

Drug coverage limits are primarily financially focused and fundamentally different than clinical management rules. Unlike drug coverage limits, clinical programs such as Prior Authorization or Dispensing Quantity require clinical review and evaluation. Drug coverage limits are categorical drug coverage limits and are usually not subject to review and override.

Drug coverage limit options
Drug coverage limit options include:
• Dispensing Limits*
• Drug-Specific Quantity Limits*
• Refill Limits*
• Lifetime Caps (Limits)*
• Gender Edits
• Age Edits
• Drug-Specific Caps (Limits)*
• Benefit-Period Caps (Limits)*
• Tablet Splitting

Each of these options is described in detail below.

PPACA changes also prohibit any plan (whether or not grandfathered) from imposing lifetime caps on “essential health benefits,” and limits a plan’s ability to impose annual limits on essential health benefits (there is a dollar phase-in, where plans are permitted to implement certain annual dollar limits until 2014, after which time most plans can no longer impose annual limits on

* PPACA rules may prevent non-grandfathered plans that provide certain preventive care services from imposing co-payments on preventive medications. Plans should carefully evaluate these changes with their counsel. In addition, grandfathered plans not currently imposing limits or currently imposing a limit that is more generous to members then a new limit they are considering implementing should carefully evaluate with their counsel whether any such changes might impact grandfathered status under HCR requirements (for example, a change that might be viewed as increasing the percent of a member’s cost-sharing by more than a permitted amount).
essential health benefits). Individual insurance contracts that are grandfathered can continue to impose annual limits on all benefits including essential health benefits. Many government agencies have not yet provided definitive guidance on what constitutes an “essential health benefit” under PPACA. Plans seeking to impose limits should carefully evaluate their decisions with their legal counsel prior to implementing these types of limitations.

**Dispensing limits**
Dispensing limits define the amount of medication allowed for a single drug claim. A dispensing limit may be a maximum quantity allowed, a maximum days supply allowed, or a combination of the two. Express Scripts recommends a 30-day supply at retail and a 90-day supply at mail.

Dispensing limits directly influence cost share. They determine how much drug a member may receive for a single co-payment. Fixed-dollar co-payment plan designs experience erosion. By limiting prescriptions to a 30-day supply in retail and a 90-day supply at mail, member cost share is consistent across retail claims, while maintenance prescriptions can be filled at mail service, which is typically the less expensive channel.

Dispensing limits are important for fixed-dollar co-payment plans, since cost share is the same regardless of the quantity of drug dispensed.

Dispensing limits become less important for maintaining cost share when plans utilize coinsurance. As prescription quantity and cost increases, so does the member’s cost share. At first glance, it may seem acceptable to allow a 90-day supply at retail as long as the cost share is a percentage of the price. However, it is still important to manage the amount of drug dispensed, particularly at retail. A liberal dispensing limit at retail creates less incentive to use the plan’s mail-order pharmacy which offers convenience and typically a lower cost to the plan sponsor.

**Drug-specific quantity limits**
Drug-specific quantity limits, which include prepackage limits, identify the number of units or prepackaged products that will be covered with one co-payment. These limits are applied at the drug-specific level to support appropriate drug use and to reduce plan costs by increasing the member cost share. Plans often apply unit-of-use limits to inhalers, injectables, patches, and other prepackaged units. For example, a plan sponsor may limit Estraderm® Patches, a twice-weekly estrogen patch system, to one package of eight units per retail co-payment.

Plan sponsors must have appropriate benefit language to support the implementation of unit-of-use quantity limits. For example:

- Benefits for injectable insulin shall be limited to up to two 10-cc vials per co-payment or up to six 10-cc vials through the plan’s mail-order pharmacy when the insulin is dispensed.

Use of these limits should be based on sound and appropriate guidelines.

**Refill limits**
Refill limits establish a maximum number of refills for long-term drugs in the retail channel to direct these prescriptions to the plan’s mail-order pharmacy. (Long-term drugs are those used to treat chronic conditions, such as high blood pressure or high cholesterol.) Plans can apply refill limits at the general plan or drug-specific level. Members can continue to use the retail pharmacy, but will pay a higher co-payment.
**Lifetime caps**
Lifetime caps limit drug coverage to a specific dollar amount for the member’s lifetime in the plan. Lifetime caps are also a part of benefit maximum caps. As a result of HCR, plans can only apply this cap to "non-essential health benefits*. Once the cap amount is reached the plan has a variety of choices on how the claim will adjudicate.

The most common choices are to reject the claim or pass a 100 percent co-payment to the member.

Examples of lifetime caps per individual include:
- Plan-level: $10,000 for all non-essential prescriptions.
- Drug class specific: $5,000 for fertility drugs.

Lifetime caps shift insurance risk from the plans to individuals, exposing them to potentially catastrophic costs. Plan sponsors must ensure that such caps do not discriminate against individuals in violation of state or federal regulations.

**Gender edits**
Gender edits are used to exclude specific drugs based on gender. Plan sponsors use gender edits to ensure appropriate use. An example of a gender edit is allowing coverage of erectile dysfunction drugs for males only.

**Age edits**
Age edits are used to limit drug coverage based on patient age. This capability includes both a minimum age and a maximum age limit: The minimum age where coverage can start, and maximum age where coverage should be denied. Like gender edits, plans apply age edits to ensure appropriate drug use. For example, the coverage of Relenza® (zanamivir) for adults and children no younger than seven years of age and Retin-A® (tretinoin) for patients no older than 35.

**Drug-specific caps**
Drug-specific caps are also part of benefit maximum caps and are the most common cap utilized by plans. Drug-specific caps limit plan coverage to a cumulative amount of a specific drug or class of drugs. This cap limits a drug or class of drugs by dollar amount, number of claims, or days supply for a defined time period (e.g., monthly, annually, or lifetime).

A typical example of a drug-specific cap is limiting coverage to one glucose monitor per year.

Plan sponsors must ensure that such caps do not discriminate against individuals in violation of state or federal regulations.

**Benefit-period caps**
Benefit-period caps limit the cumulative total dollar amount of pharmacy benefits for an individual or family. The benefit-period cap is applied at the plan level and can accumulate for a specific number of months.

*Note that PPACA regulations prohibit plans from implementing lifetime caps on essential health benefits for plan years starting on or after September 23, 2010. Until further guidance is issued plans and issuers are required to use a good faith interpretation of what benefits are considered “essential health benefits.” Under HCR, lifetime limits can continue to be imposed on non-essential health benefits.*
PPACA regulations limit group health plans and insurance issuers with respect to group health insurance policies from imposing annual caps on essential health benefits for plan years starting on or after September 23, 2010. Generally, beginning in the plan’s first benefit year after September 22, 2010, annual maximums on all essential health benefits under the plan can be no less than $750,000 per individual, per year. This limit is a combined healthcare benefit limit (e.g., including medical, prescription, dental, etc.). The second year, this limit increases to $1.2 million per individual and the third year the limit increases to $2 million per individual. Beginning with the fourth year (plan or contract years beginning on or after January 1, 2014), the annual cap must be removed on essential health benefits. Grandfathered individual insurance policies may continue to impose different annual limits on essential health benefits (as can certain plans who have received a waiver from the minimum limits through 2014). PPACA does not prohibit annual limits on non-essential health benefits.

Examples of drug coverage limit options
The following programs utilize drug coverage limits:
- Retail Refill Allowance (RRA) Program.
- Retail Maintenance Program.
- First Fill Limits.

Retail refill allowance (RRA) program
The RRA program provides incentives for members to move their long-term drugs from retail to the plan’s mail-order pharmacy. This program alters the member’s cost-share for refill prescriptions at retail, and is called a co-payment incentive program.

Co-payment incentive program
The co-payment incentive program employs a tiered retail co-payment that increases incrementally with subsequent refills of the same medication. For example, a plan may require a $20 retail co-payment for the first two fills and then increase member cost share for the third and subsequent retail refills to $40 or up to 100 percent coinsurance. The member can still use the retail pharmacy, but will have a higher cost share.

Retail maintenance program
Retail maintenance programs provide members a three-month supply of maintenance drugs at retail network pharmacies. Plans can apply the retail maintenance program at the general plan level by allowing up to a 90-day supply for all medications at retail. This provides the member with the same drug coverage benefit for both retail and mail service while maintaining appropriate cost share. The design may be most appropriate for insured plans who must comply with “any willing provider” legislation, requiring the member’s pharmacy benefit to be the same whether provided through a mail service or retail pharmacy.

The recommended approach is to create tiers based on the days supply dispensed (that is, apply an incremental co-payment as the days supply dispensed increases up to the maximum allowed). For example:
- Tier 1 $20 All drugs up to a 30-day supply.
- Tier 2 $30 Long-term drugs 30- to 60-day supply.
- Tier 3 $40 Long-term drugs 60- to 90-day supply.
Since a mail-order pharmacy option exists, most plans benefit from designing their retail prescription benefit with a maximum 30-day supply and integrate a mail service benefit that permits up to a 90-day supply. Express Scripts can provide more aggressive mail service ingredient discounts to a plan, and if co-payments are aligned appropriately, the plan will achieve overall plan cost savings through the mail-order pharmacy.

**First fill limit**

A small percentage of long-term medications are wasted due to ineffectiveness, patient non-compliance, or side effects from the medication itself. Express Scripts has the capability to limit the first fill of select medications to reduce the possibility of wastage. This benefit design limits the first fill of prescriptions at mail service and retail to a 30-day supply.

To implement this plan design element, a PBM’s system should review 365 days of claim history at both retail and mail service to determine if the prescribed drug is a first fill of a specified Generic Code Number (GCN). Categories of medications (e.g. antibiotics or pain medications) or a select group of GCNs can be excluded from the first fill limit.

In evaluating this option, consideration should be given to the possibility that some patients may appear in the claim record to be requesting a first fill, but may have actually been obtaining the drug from other sources (e.g., drug samples, cash discount programs).
Chapter 2: Retail and mail distribution channels
A pharmacy network is a group of pharmacies from which plan members may obtain prescriptions at a pre-established cost to both themselves and their plan sponsors. Within the network, there are three main channels to manage: retail, mail, and specialty/biologic.

Retail pharmacy networks
Retail pharmacy networks are contracted to dispense prescriptions at a negotiated discounted rate or under a fee schedule. This is similar to other provider networks used by healthcare organizations, often called “preferred provider organizations” (PPO) or “exclusive provider organizations” (EPO). The discounted retail claim price is the participating pharmacy’s total allowed charge for a prescription, which includes the drug ingredient cost, the dispensing fee, and where applicable, the sales tax.

The key features of retail networks are: access, density, and price. Access and density are measures of convenience for members. Access refers to the distance between a member’s home and the nearest participating retail pharmacy and density refers to the number of participating pharmacies in a given geographic area. Price includes maximum allowable cost (MAC), average wholesale price (AWP) discounts, and dispensing fees.

Access is one measure for the ease with which members can obtain their retail network benefit. It is important to remember that many people find it convenient to use more than one retail pharmacy, including locations close to their home, workplace, or the doctor’s office. PBMs and other managers of provider networks use the member’s home ZIP code to measure access. Convenient access to retail network pharmacies is not always determined by proximity to a member’s home.

Density (also known as choice) is the number of participating retail pharmacies in a given geographic area expressed as a percentage of all existing retail pharmacies in the same geographic area. As networks become more restrictive, density is lower resulting in less choice (but not necessarily greater travel times) for the member, but typically greater discounts for the plan.

Density is the primary driver of discounts because most retail pharmacies are willing to accept slight reductions in gross margin on prescriptions in exchange for an anticipated increase in customer traffic. Price discounts increase as retail network size is reduced. For example, a typical broad network includes about 95 percent of pharmacies. A typical select network generally includes about 73 percent of available pharmacies and may provide an additional discount of one to two AWP percentage points to the discount for many plans.

Important terms to know
Network pricing: network pricing relates to the gross price a plan pays for a prescription. This pricing calculation includes the lesser of
- [usual and customary price, AWP discount, or MAC price] plus the dispensing fee, and tax as required.

Pharmacy reimbursement schedules are a major factor in determining a plan’s retail pricing offer. The net price a plan is charged for a prescription starts with the gross price and is adjusted for member cost-share factors such as the member’s co-payment and deductible.

Following are common pricing definitions for pharmacy networks:
Usual and customary (U&C) price: the lowest net cash price a retail pharmacy would charge a cash-paying customer. This definition covers senior citizen discounts, frequent shopper discounts, and any other discounts passed to the patient at the time of dispensing had the member been a cash-paying customer.

Average wholesale price (AWP) discount: limits the ingredient cost of a drug to a percentage of the Average Wholesale Price as published by a national pricing source. AWP is determined from information supplied by drug manufacturers and labelers. AWP is somewhat of a misnomer, as it does not represent an “average” of prices. The AWP for most brand-name drugs is 20 percent above the wholesale acquisition cost (WAC) of the drug. Wholesalers are able to sell drug products to retailers at a discount from AWP, or a markup from WAC. AWP is standard industry benchmark for pricing brand-name drug claims because it is nationally published, updated regularly, and bears a relationship to the actual cost to pharmacies.

Maximum allowable cost (MAC): MAC is the upper limit paid by a plan sponsor for most generic drugs. Several pharmaceutical companies may manufacture or market a generic medication. This competition produces widely varying AWP prices for the same drug. MAC pricing minimizes price variability for a single medication by establishing a maximum price for all sources of the drug. All retail pharmacy networks managed by ExpressScripts accept MAC pricing.

Retail network options
A plan can choose a custom retail network that usually stems from a broad, select, regional or Medicare network described below. Plan-specific requirements are then layered onto the base network creating a custom network.

Broad networks
A typical broad network includes more than 55,000 pharmacies. All major national chain pharmacies and the majority of independent pharmacies participate in this type of network. A broad network generally provides 99 percent of plan members with access to a network pharmacy within three miles of their home ZIP code. A broad network is best suited for plans that require broad national access to pharmacies, such as a large employer with multiple sites throughout the country.

Select networks
A typical select network features a deeper discount in exchange for reduced pharmacy density. A select network is contracted to allow for participation levels between 32,000 and 50,000 retail pharmacies and generally provides over 98 percent of plan members with access to a network pharmacy within three miles of their home ZIP code. This type of network may exclude some major chains. It is important to note that chain exclusions are finalized based upon pre-implementation market conditions.

Mail Pharmacy
The mail pharmacy provides members with a convenient, cost-effective, and accurate method for obtaining prescriptions. The mail pharmacy is a more cost-effective channel than retail for long-term drugs, delivering higher and faster generic substitution and formulary compliance rates than retail pharmacies.

The mail pharmacy provides health plan members a convenient and economical source for covered drugs. Member prescriptions are received through the mail, through the Internet, by fax, or by phone/interactive voice response from customer service and physician point of care (POC).
systems. Once prescriptions have been received, the prescription data is entered, reviewed for missing or inaccurate information and clinical appropriateness (including generic substitution, if appropriate), filled, checked for accuracy, packaged, and then shipped to the member.

The mail pharmacy offers plans:
- Exceptional dispensing accuracy
- Greater compliance with utilization and safety rules
- Specialized pharmacy care for chronic conditions from our Therapeutic Resource Centers
- 24-hour toll-free access to member services or a pharmacist
- Automatic generic substitution where allowed by law, which usually results in additional cost share savings
- Sophisticated drug utilization review that alerts the pharmacist to the member’s total medication profile
- Tamper-evident packaging

Mail-order pharmacies enable its pharmacists to best meet a plan’s expectations. We operate nine Therapeutic Resource Center pharmacies and five call center pharmacies.

More details on the benefits of the mail pharmacy
The cost and quality advantages of mail-order pharmacy are well-known. Numerous government and independent studies have examined the increased savings provided by mail-service pharmacies.

The mail pharmacy is less expensive than retail due to our buying power, and the efficiency of centralized dispensing technology. Our dedicated physician call staff is especially effective at maximizing generic and formulary compliance. The Express Scripts member website also makes mail-order pharmacy more convenient for members.

Plans also benefit from faster and higher generic substitution rates, and they pay fewer dispensing fees (the 90-day supply at mail means fewer refills, on average, than at retail). Automated mail-order pharmacies have also been shown to have an advantage over retail pharmacies in terms of reduced dispensing errors.

Plans with heavy mail-order pharmacy usage typically see improved compliance with formularies and with utilization and safety rules. Many plan members have an incentive to purchase their prescriptions through mail-order pharmacy when co-payment/coinsurance levels are lower for mail-order prescriptions on a days supply basis.

To encourage members to use the mail pharmacy, plans can communicate broadly with members or target communications only to those members obtaining maintenance drugs from retail pharmacies. In addition, plans can offer the following incentives:
- Lower co-payments for mail than retail
- Refill limits for maintenance drugs at retail

Specialty/biologics pharmacy
Specialty pharmaceuticals (medications generally administered by injection or intravenously) have become the fastest rising cost component in pharmacy benefits. Plans have become more focused in recent years on managing these types of medications and have turned to specialty pharmacy managers for help.
Specialty pharmacy managers such as Express Scripts’ Accredo Health subsidiary combine the strengths of Express Scripts and Accredo to offer plans a customized and comprehensive solution for specialty pharmacy care. Specialty pharmacy care is for patients with chronic or complex conditions who receive high technology or specialty drugs at home or in their doctor’s office. These conditions include cancer, growth hormone disorder, hemophilia, rheumatoid arthritis, Gaucher’s Disease, cystic fibrosis, hepatitis C, and multiple sclerosis. Specialty drugs are high cost and generally biotechnological in nature. The medications used to treat them often require special handling.

Accredo ensures that patients properly administer the right medication in the correct dose for the appropriate duration. Also, the medication is delivered through cost-effective channels with clinical support. Given the considerable expense of specialty medications, plans tend to focus primarily on lowering unit cost. However, because of the complexities of specialty drugs, focusing on unit price alone is unlikely to yield the most cost-effective solution. Accredo provides a comprehensive specialty management program to maximize the efficiency and effectiveness of the plan’s specialty drug spend.
Chapter 3: Generics

Drugs are classified as “brand” and “generic” because of the nature of drug discovery and development, and the role of patent protection for intellectual property. New drugs, like other new products, are developed under patent protection. The patent protects the investment in the drug’s development by giving a company the sole right to sell the drug while the patent is in effect. Drugs in this category are called “single-source.”

When patents or other periods of exclusivity expire, manufacturers can apply to the FDA to sell generic versions. Because significant research and development (R&D) resources are not required for generic drug manufacturing, the cost of a generic drug is typically 30 percent to 80 percent below that of the innovator brand. When a brand-name drug first loses its patent, a single generic manufacturer typically obtains exclusive rights to sell the equivalent medicine, usually for 180 days, and the price of both drugs often stays relatively high during this period.

Programs that promote generic drug use are based on the following concepts and terminology.

Important terms to know

**Single-source brands:** single-source brand drugs are branded products that have patent protection. As a result, no other drug company is permitted to manufacture a generic equivalent. The product is typically available from only one manufacturer or source, generally the innovator.

**Multisource drugs:** multisource drugs are branded products for which the patent protection has expired. As a result, generic equivalent drugs are available in the marketplace, and the drug product is available from multiple sources.

**Generic drugs:** generic drugs are produced by other manufacturers or labelers once the innovator company’s patent has expired. According to the FDA, generic drugs are identical or bioequivalent to brand drugs in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Health professionals and consumers can be assured that FDA-approved generic drugs have met the same rigid standards as the innovator drug. To gain FDA approval, a generic drug must:
- Contain the same active ingredients as the innovator drug (inactive ingredients may vary).
- Be identical in strength, dosage form, and route of administration.
- Have the same use indications.
- Be bioequivalent (they have the same effect on the body as brand-name medications).
- Meet the same batch requirements for identity, strength, purity, and quality.
- Be manufactured under the same strict standards of the FDA’s manufacturing practice regulations required for innovator products, called Current Good Manufacturing Practices.

**Equivalence:** Multisource generic drugs are intended to be equivalent to the brand-name versions, but there are different types of equivalence: pharmaceutical equivalence and bioequivalence.

- **Pharmaceutical equivalence:** Pharmaceutical equivalence is also known as chemical equivalence. The same identity and amount of chemical are present in pharmaceutically equivalent drug products.

- **Therapeutic equivalence:** Drugs are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile.
Bioequivalent drugs: A bioequivalent drug is pharmaceutically equivalent to the “reference drug,” usually the brand-name drug, and has been proven equivalent in terms of the rate and extent of absorption into the bloodstream. The term commonly refers to tablets and capsules that must be taken by mouth, dissolved in the gut, and absorbed into the bloodstream. Bioequivalence demonstrates that two drug products with the same amount of the same drug will also act the same in the body.

Generic substitution: generic substitution is the process of substituting the lower cost generic drug in place of the more expensive multisource brand drug. Generic substitution is encouraged by pharmacists, plan sponsors, pharmacy benefit managers (PBMs), and in some cases, required by state law to lower prescription drug costs.

Therapeutic equivalency rating: The FDA assigns therapeutic equivalency ratings to generic products to indicate whether each manufacturer’s generic drug is therapeutically equivalent to the reference product, generally the innovator drug. The FDA’s Center for Drug Evaluation and Research (CDER) publishes these ratings in Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. The Orange Book is available as a PDF file at the following URL:

Ratings include:
- “A” rating: signifies the product is deemed therapeutically equivalent to the reference product.
- “B” rating: indicates the product is not considered equivalent to the reference product.
- “Non-rated product”: indicates the company has not filed for FDA review of therapeutic equivalence or the drug was marketed prior to the requirement for therapeutic equivalency studies.

Pharmacies usually dispense A-rated generics. However, there are drugs that do not have an A-rated generic available. In fact, some states with mandatory substitution laws require that B-rated or non-rated generics be dispensed if an A-rated generic is not available. Dispensing of generic products depends on the following:
- FDA Orange Book rating and whether a rating is available.
- How the prescription was written by the physician.
- State regulations.

Generic substitution regulations
All 50 states in the United States have passed generic substitution regulations that define the physician’s, pharmacist’s, and member’s role in generic drug product selection. These pharmacy practice regulations were designed to increase the public’s access to less expensive generic drugs.

According to the National Association of Boards of Pharmacy (NABP), most states have permissive substitution laws, which allow a pharmacist to substitute a generic when one is available.

Some states have mandatory substitution laws that require pharmacists to substitute a generic when one is available. In these states, the ability of benefit design or other benefit incentives to add incremental value is limited.
Generic financial incentives
Generic financial incentive programs improve generic utilization by rewarding members using less costly generics. This ultimately leads to lower drug costs. Examples include:
- Incentive co-payments
- Pharmacy/Retail Refill Allowance Programs
- Member pays the difference
- Co-pay waiver

Incentive co-payments
Incentive co-payments are a commonly used tool for encouraging members to use generic drugs. This is achieved by setting lower co-payment or coinsurance levels for generic drugs. Many plans use incentive co-payments. The following are three common incentive co-payment structures (that is, two-tiered and other multi-tier co-payments) that encourage generic and formulary drug use:
- Tier 1 $10 generics
- Tier 2 $30 brands
- Tier 1 $10 generics
- Tier 2 $25 formulary brand drugs
- Tier 3 $40 non-formulary brand drugs
- Tier 1 $10 generics
- Tier 2 $25 up-tiered generics
- Tier 3 $45 formulary brand drugs
- Tier 4 $60 non-formulary brand drugs

Retail refill allowance
The Retail Refill Allowance (RRA) program increases mail-order use and is sometimes referred to as a “mandatory mail program.” The program uses member incentives, such as lower co-payments and/or continued plan coverage of long-term medications, by using the mail pharmacy for long-term medication. RRA includes non-specialty and specialty medications. Plans may also choose RRA only for specialty medications.

Member-pays-the-difference (MPD) programs
MPD programs use cost-share differentials to drive generic usage and are sometimes referred to as “mandatory generic programs.” Instead, members must pay the co-payment plus the difference in cost between the multisource brand and generic MAC price when a multisource brand drug is dispensed. In most situations, the differential is added to the generic co-payment or coinsurance. The plan’s generic objectives are met by paying no more than the cost of a generic claim, while the member is allowed to “buy up” to the brand name version of the same identical drug.
Chapter 4: Cost share
Cost share represents the proportion of the total claim price paid by members. Member cost share is the most important element of benefit design. Cost share determines member expense and the plan’s cost for prescription benefits. Ultimately, integrating several cost-share features may be necessary to achieve both the desired level of cost share and an acceptable, easy-to-understand drug benefit for members. Cost-share options include:

- Co-payments and coinsurance
- Deductibles
- Out-of-pocket maximum (stoploss)
- Benefit maximum caps

Co-payments and coinsurance
Co-payments (fixed-dollar amounts) and coinsurance (percentage co-payment) represent the portion of the prescription claim price paid by the plan member. Cost-share structure influences member behavior while indirectly influencing physician behavior. For example, the member who has a choice between a brand-name drug with a higher co-payment and a therapeutically equivalent generic drug with a lower co-payment may be motivated to consider the generic alternative.

Co-payment options
Plans can choose from a variety of co-payment structures, including flat, multi-tiered, or value-based, with or without member-pays-the-difference (MPD).

Flat co-payments: flat (non-tiered) co-payments do not vary based on the type of drug being dispensed. For example, in a flat co-payment structure the co-payment is the same for both generic and brand drugs. Due to the inability of flat co-payments to influence generic utilization, formulary compliance, or other desired cost-effective behavior, they are uncommon and not recommended. Flat co-payments fell out of favor in the late 1980s.

Multi-tiered co-payments: multi-tiered co-payments—the most common co-payment structure—vary depending on the type of drug (that is, the drug source or formulary status). These co-payments may have two, three, four or more tiers. The most common is the three-tier structure, but many variations exist.

Two-tiered co-payments: two-tiered co-payments are applied to generic versus brand name drugs. For example, a two-tiered co-payment structure may be:
Tier 1 $10 generics
Tier 2 $20 brands

For a typical active employee population this would achieve a cost-share of 20-25 percent. Two-tiered strategies are less common and generally not recommended.

Three-tiered co-payments: three-tiered co-payments are applied to generic, formulary brand, and non-formulary brand drugs. An example of a three-tiered, fixed-dollar co-payment structure is shown below:
Tier 1 $10 generics
Tier 2 $30 formulary brand drugs
Tier 3 $45 non-formulary brand drugs
For a typical active employee population, this would achieve a cost share of 25-30 percent. Three-tiered cost-share structures have become the norm in pharmacy benefits.

**Four-tiered co-payments**: these structures may feature a split within the preferred drug category, thus elevating co-payments for those preferred drugs that are higher priced. Other options exist as well, and some of these are depicted in the chart below. An example of a four-tiered, fixed-dollar co-payment structure is shown below:

Tier 1 $10 generics
Tier 2 $30 preferred formulary brand drugs (lower cost category)
Tier 3 $45 preferred formulary brand drugs (higher cost category)
Tier 4 $60 non-formulary, non-preferred brand drugs

<table>
<thead>
<tr>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>All generics (formulary and non-formulary)</td>
<td>Less expensive generics, preferred brands (generally less than $20), with a high potential to prevent other health care costs. Co-payment = $10</td>
<td>Low cost generics (less than $15) Co-payment = $3</td>
</tr>
<tr>
<td>Tier 2</td>
<td>Tier 3</td>
<td>Tier 4</td>
</tr>
<tr>
<td>Single-source drugs, lower cost drug categories, e.g. Beta Blockers, ACE Inhibitors, etc.</td>
<td>All other generics and preferred brands Co-payment = $20-$25 *</td>
<td>More costly generics (more than $15) Co-payment = $15</td>
</tr>
<tr>
<td>Tier 4</td>
<td>Tier 5</td>
<td>Example 3</td>
</tr>
<tr>
<td>Non-formulary single-source drugs Non-formulary multisource drugs</td>
<td>Specialty pharmacy drugs (biotech manufacturers and gene therapies), most self-injectable drugs. Prior authorization may apply. Co-payment = 25% of cost</td>
<td>Preferred brands Co-payment = $20</td>
</tr>
<tr>
<td>Tier 5</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>Co-payment = $15 between tier 1 and tier 2</td>
</tr>
</tbody>
</table>

Other cost-share strategies include:

**Value-based benefits**: apply lower (and sometimes $0) co-payments for critical, high value medications or treatments. Examples of these drug classes are diabetes, cardiac, and asthma medications. This strategy encourages adherence to medication therapy by removing the patient’s cost barrier, which may contribute to lower overall costs by avoiding complications due to non-compliance (e.g., stroke, heart-attack, emergency room visits, etc.).

**Member-pays-the-difference (MPD)**: is a generic incentive program that can be added to almost any cost-share structure. MPD adds financial incentives for members to choose a generic drug...
rather than the multisource brand counterpart. Members who choose the brand-name product will pay the generic co-payment plus the difference in cost between the maximum allowable cost (MAC) generic price and the multisource brand drug ingredient cost. This difference is sometimes called a brand/generic differential or MAC differential. Managed MPD is the most effective generic incentive for a pharmacy benefit design, and when combined with incentives to utilize mail service produces the best generic performance.

**Coinsurance options:** also referred to as percentage co-payment, coinsurance is a percentage of the total cost of a prescription that the member pays. For example, if the cost of the prescription is $80, the member’s coinsurance may be 20 percent or $16. Coinsurance can also be flat or tiered and may be combined with MPD where the member pays a brand/generic differential. For example, a two-tiered coinsurance might be 10 percent for generics and 30 percent for brand drugs, with or without MPD for multisource brand drugs. Coinsurance is frequently combined with a fixed-dollar minimum or maximum. For example, a member may have 20 percent coinsurance with $10 minimum co-payment.

**Co-payment and coinsurance combinations:** co-payments and coinsurance may coexist in a benefit design to increase mail utilization and to protect against co-payment erosion in retail. For example, a member may pay a co-payment for mail and coinsurance for retail. Different co-payment and coinsurance levels can be applied to specific drugs or groups of drugs. This approach is used when plans want members to pay more for selected medications such as fertility or lifestyle drugs.

Although co-payments and coinsurance are the primary determinants of cost-share, benefit limits also affect member cost share. For example, limits on days supply or number of retail refills will impact cost share. Drug-specific exceptions may involve variable co-payments or coinsurance, and this also impacts overall cost share.

**Accumulators in benefit design**
Since the inception of indemnity health insurance, benefit administrators have used accumulators to design healthcare benefits. Plans accumulate claim dollars for individuals or families, and use dollar thresholds to define benefit stages. The most recognized accumulators are the deductible, the stoploss, and the benefit maximum.

**Deductible**
A deductible is the amount members pay before healthcare benefits begin. It is defined by a specific coverage period (for example, annually). During the deductible phase the member pays the total negotiated claim price. After the deductible is met and the co-payment or plan coinsurance is applied, the plan pays the claim up to any benefit maximum or stoploss if applicable.

**Deductible configurations**
Plans must determine which claims and drugs will apply to the deductible, the specific time period for deductibles to accumulate, and how to apply the deductible to members and their families.

**Claim types**
Plans may establish deductibles for retail, mail, or direct claims either separately or in any combination. For example, deductibles can be applied to both retail and mail claims or either retail or mail claims only. Plans can apply different deductibles to mail, retail, and direct claims,
or the same deductible to mail and retail. In the latter example, the plan can require the member to meet both deductibles separately.

A plan may elect to count toward the deductible:
- In-network retail claims only.
- In-network retail with mail claims only.
- Both in-network and out-of-network retail claims while disallowing the out-of-network member penalty from counting towards the deductible.
- Combined pharmacy and medical claims. In this situation, the plan accumulates pharmacy and medical expenditures towards an integrated deductible.

**Specific drug-source types**
Deductibles can also be applied to a specific drug-source type. For example, a plan may apply a deductible to brand drugs while having generics bypass the deductible and immediately enter the benefit stage. This is a form of generic incentive.

**Multi-level deductibles**
Occasionally a plan may ask their PBM to provide two or more different deductible levels at mail and retail, for brand drugs and generics and, for in and out of network. For example, a plan may want to charge a $50 deductible for generics and a $100 deductible for brand drugs to incent generic drug use.

**Benefit accumulation period**
The benefit accumulation period is the period of time over which the deductible is accumulated. Although the benefit accumulation period is typically 12 months, almost any desired range defined in months can be accommodated. Automatic renewal of the deductible is based on the effective date and the benefit accumulation period unless the plan specifies otherwise.

Maximum allowable benefits and out-of-pocket maximums also use the benefit accumulation period. When plans use any of these features, they must have the same effective date and benefit period.

**Carryovers and transfers**
Deductible accumulation for one to nine months can be carried over to the next benefit period. Members can also transfer their accumulated deductible amounts from one benefit entity with plan to another dependent on configuration.

This feature is critical to large plans with members moving between groups.

**Individual and family options**
Deductibles may apply to individual family members, all family members, or in combination.

**Individual with family aggregate**
Member deductibles can be applied to each family member with an aggregate family deductible, such as a $50 deductible per member with a $100 aggregate per family. In this example, the member deductible of $50 for each family member or a maximum of $100 aggregate for the entire family, whichever occurs first, must be met before satisfying the deductible.
Individual without aggregate
Member deductibles can also be applied to each member in a family without an aggregate. Using the previous example for a family of six, each of the six would each have to meet his or her $50 deductible.

Family aggregate
A family aggregate deductible, such as $100 per family, can also be applied. The deductible is met when any or all family members reach this amount.

Multi-individual
A deductible can be applied to a specified number of individuals before claims are paid for all family members. For example, suppose a $50 deductible is applied to two individuals, a member and spouse. When the individual $50 deductible is met, or the husband and wife meet the aggregate amount ($100 = $50 x 2 people), each individual in the family will have their claims paid.

Consumer driven health plan deductibles
The benefit design for Consumer Directed Health Plans (CDHP), employs high deductibles which often integrate medical and pharmacy claims, and have a consumer healthcare account attached, such as a health savings account (HSA) or healthcare reimbursement account (HRA). Deductibles for CDH plans are often over $1,000 per member for combined pharmacy and medical expenses.

IRS rules for qualifying high deductible health plans, often referred to as CDH/HSA plans, allow sponsors to provide first dollar coverage for preventive medical services and medications.

Out-of-pocket maximum
Out-of-pocket (OOP) maximum, commonly known as “stoploss,” is the maximum dollar amount that a member or family has to pay during a defined benefit period. When the total deductible and co-payment amounts reach the OOP limit, any subsequent claims will not require co-payment. The OOP limit protects members with the greatest healthcare needs, and is sometimes called “catastrophic” coverage.

Out-of-pocket maximums are becoming more common as benefit designs continue to shift to coinsurance or high fixed-dollar co-pays that can expose individuals and families to burdensome costs.

Options for applying OOP maximum
Plans must decide how the OOP maximum accumulates, which claims apply to the OOP, the benefit accumulation period, and to whom the OOP applies.

OOP dollar accumulation
The most common OOP dollar accumulation allows both the co-payment and the deductible amounts to contribute toward the OOP limit; however other configurations are supported.

Once the limit is met, no further co-payments are required.

Post OOP cost share options
This setup option allows the plan to administer one cost share amount during the benefit phase, and another amount after the OOP limit is met. For example, the member cost share may be reduced to a nominal 5 percent coinsurance, rather than 0 percent, once the stoploss is reached.
Claim type
Stoploss is intended to protect members from excessive out-of-pocket costs. Accordingly, most insurers allow deductible and allowed claim costs to accumulate toward the OOP level. Out-of-network and member pay-the-difference claims may or may not count towards the stoploss depending on configuration. OOP limits can be established for retail, mail order, or direct claims either separately or in any combination, similar to rules governing deductible accumulation (such as in and out of network). Plans can apply different OOP limits to mail service, retail, and direct claims or the same OOP limit to mail service and retail.

The following are some OOP accumulation options: A plan may elect to count toward the deductible:
- In network retail claims only
- In network retail with mail order claims
- Both in network and out-of-network retail claims while excluding the out-of-network member penalty from counting toward the OOP limit. This is not a common configuration
- Combined pharmacy and medical claims. In this situation, the plan accumulates the pharmacy co-payment and deductible amounts and medical expenditures

These expenditures accrue toward an integrated medical/pharmacy OOP limit.

Below are some exceptions that can be supported:
- Excluding out-of-network retail and mail service
- Excluding out-of-network retail
- Excluding out-of-network mail service
- Excluding out-of-network penalty amounts

Specific drug-source types
Plans can also include or exclude MPD co-pay differentials as well as elected penalties that may apply for OOP accumulation. After the OOP limit is met, the plan must determine whether the member will remain responsible for the generic/brand differential or other elected penalties.
Chapter 5: Formulary management

The formulary is a list of drugs reviewed and approved by a Pharmacy & Therapeutics (P&T) Committee based on clinical merits. The P&T Committee reviews drugs and makes recommendations regarding formulary status. The goal is to create and utilize a list of formulary drugs that will help provide overall quality of care provided to the members while helping to reduce the plan’s drug spend (the amount of money a plan spends on its pharmacy benefit). Formulary content works in conjunction with benefit design. Combined with various benefit design components, the formulary content plays a significant role in driving member cost share through formulary status, limits, and exclusions.

Formulary administration type determines how a drug’s formulary status impacts the pharmacy benefit. Formulary administration type options are interdependent with a number of benefit design and clinical management components. For example, cost share and generic utilization are significantly affected by tiered administration. The financial impact of formulary administration options is also dependent on the breadth of the underlying formulary content, as in the case of incentive formulary co-pays where narrow formulary content will drive higher member cost-share and lower plan costs compared to a broad formulary. Various management features are offered to help plans maximize acceptance and minimize negative reaction to the more restrictive formulary administration options.

A plan may choose a number of ways to administer its formulary.

Open administration

Open administration is the least restrictive approach. All brand drugs are covered without a financial cost-share incentive to promote formulary compliance. Members can receive any brand drug covered under the plan, at the same copay regardless of its drug source or formulary status with no financial incentive or penalty. However, a Point of Service (POS) message may inform the pharmacy technician or dispensing pharmacist of the formulary status of the drug and identify the preferred formulary alternatives when a non-formulary drug has been prescribed.

Incentive administration

Incentive administration features financial incentives for members to use formulary drugs through lower co-payments. Members can receive any brand drug covered under the plan, regardless of formulary status, but they pay a lower co-payment for brand formulary drugs.

Incentive administration uses multi-tiered co-payments. For example, in a three-tiered structure, the plan may apply the lowest tier to generics, the middle tier to formulary brand drugs, and the highest tier to non-formulary drugs.
As with the open administration, the point of service (POS) message the PBM sends to the pharmacy informs the pharmacist of the preferred formulary alternatives when the physician prescribes a non-formulary drug. The pharmacist may contact the prescribing physician and ask him/her to consider the preferred formulary drug when clinically appropriate. The cost-share differential is an incentive for members to ask the pharmacist to speak with their doctor regarding a change to a preferred alternative. The financial incentive typically promotes better formulary compliance.

**Closed administration**

Closed administration is a tightly managed formulary program. It is uncommon to find closed formularies used in employee benefit plans. A closed formulary provides coverage for only formulary brand drugs. Non-formulary generics may or may not be covered under a closed administration type. Coverage of a non-formulary drug is often possible if there is no viable formulary alternative. The member may use any non-formulary drug but the entire cost of the prescription is the member’s responsibility. Formulary compliance is nearly 100 percent since non-formulary claims are denied at the POS and members are responsible for 100 percent of the cost. A closed administration creates the greatest amount of patient and physician impact due to denials of coverage. With the exception of the most aggressive plans, most employee benefit plans are unwilling to accept the level of dissatisfaction usually associated with closed formularies.

An appeals process for members must be available for medications in the closed categories.

**Hybrid administration**

Hybrid administration blends the features of open and closed administration. Select drugs are not covered based on formulary status. For example, a member would be responsible for the entire cost of select non-formulary drugs. Hybrid administration is a simpler alternative to creating and maintaining a completely closed formulary.

The two types of hybrid administration are open and closed.

- **Hybrid-open administration:** a hybrid-open formulary is primarily open with a limited number of closed drug categories. It is sometimes called a negative formulary, meaning it is an open formulary, except for a short list of excluded nonformulary drugs. For example, a plan with a hybrid-open administration could elect to close only the ACE Inhibitor category of drugs. The formulary drugs in this category would be covered, and the non-formulary drugs in this category would be excluded from coverage. The majority of the formulary remains open. This approach allows selective therapeutic category targeting for formulary closure.

As with fully closed formularies, an appeals process for members should be available for medications in the closed categories.

- **Hybrid-closed administration:** the hybrid-closed administration excludes the majority of non-formulary drugs from coverage, while allowing fewer, select nonformulary drugs to adjudicate as a covered benefit. These covered non-formulary drugs are generally low-cost, low-volume drugs that may not have suitable preferred formulary alternatives. It may be less costly to allow coverage for these drugs than to incur the member dissatisfaction and the administrative costs for targeted communications and coverage review that would be needed to support these drugs.

An appeals process for members must be available for drugs that are in the closed categories.
Formulary interchange programs

Therapeutic interchange is the process of obtaining prescriber authorization to dispense a therapeutic alternative in place of the prescribed drug. The alternative product is often in the same therapeutic category as the prescribed drug, but is a different chemical entity. The interchange can result in dispensing either a brand or a generic as the preferred alternative. For example, a physician may initially prescribe one brand-name inhaler (e.g. *Aerobid®*) but upon request authorize the dispensing of a different preferred brand-name inhaler (e.g. *Flovent HFA®*). Or, a physician may prescribe a brand-name ACE inhibitor (e.g *Monopril®*), but upon request authorize a generic ACE inhibitor such as enalapril to be dispensed.

The prescribing physician is required to authorize all therapeutic interchanges. The authorization may be communicated by the physician’s office staff.

Therapeutic interchange is not a direct benefit design component— rather a process initiated by an Express Scripts Pharmacy pharmacist. Ninety percent of plans using a standard formulary participate in the Therapeutic Interchange process because of the consistent savings that are delivered. Our program is designed to achieve plan savings, through the interchange of non-preferred brand products for less expensive brand or generic products. For example, a plan may achieve ingredient cost savings (for example, through a lower AWP) on preferred products, rebates on preferred products under our agreements with manufacturers (as opposed to non-preferred products for which a rebate is not available), or both. Therapeutic interchange is an effective means of achieving formulary compliance. If the plan has a custom formulary, a custom drug pair list may be developed to support the Therapeutic Interchange process.

A timely and complete member communication process is initiated when the physician authorizes the Express Scripts Pharmacy pharmacist to dispense the new interchange alternative. The member receives:

- An immediate outbound telephone call explaining the interchange.
- A letter mailed within 24 hours of the new prescription being authorized by the prescriber. The letter includes details of the interchange and a summary of member and plan savings. There is also information about the reimbursement policy for healthcare related co-payment costs associated with mid-stream interchanges.
- An additional literature packet confirming the interchange when the prescription is dispensed and mailed.

Interchanges at the mail pharmacy and interchanges at retail pharmacies

The major difference in the interchange process for the mail pharmacy (mail-order) and a retail pharmacy is in the timing of the interventions. At the mail pharmacy, interventions are concurrent, meaning the pharmacist obtains physician authorization to interchange a prescription before it is dispensed. For those members who fill their prescriptions at a retail pharmacy, we identify prescriptions eligible for intervention via a weekly claims analysis, and then communicate the opportunity to the physician. If the physician agrees to the therapy change, the member receives a letter describing the physician’s decision and instructions for the next retail fill.

Express Scripts pharmacists will contact the patient if they are unable to reach the member’s physician. The Express Scripts prescription benefit specialist may contact members by telephone to describe specific savings opportunities. This type of member engagement optimizes the program by involving members upfront in the decision making process, and also provides them with direct access to an Express Scripts pharmacist who can answer any questions and address any concerns regarding their brand and generic options. If the patient agrees to the change,
Express Scripts then contacts the physician to obtain authorization for the interchange. If the member declines the offer, that opportunity is excluded from the calling process for future refills.

Express Scripts can also send personalized letters to members who are currently using a targeted multi-source brand by their own request or their physician’s request. The letter is designed to address the concerns a member may have with using a generic versus a brand name drug. Each letter includes member-specific brand to generic opportunities. Members are encouraged to discuss the appropriateness of the generic medication with their physicians and/or local pharmacists.

The methodology employed by Express Scripts pharmacists during interchange calls to physicians is generally as follows. After having reviewed appropriate clinical rules and/or other product specific issues, patient and plan cost information; Express Scripts pharmacists contact prescribers using approved interchange program materials. Interchange opportunities are typically presented by telephone, but communications between pharmacist and physician may be by other means of communication, such as facsimile, when appropriate. (Fax communications follow the same rules and qualifications as do oral telephone communications.).

Express Scripts pharmacists are required to introduce themselves, identify that they are calling from Express Scripts, indicate that the call may be monitored, identify the patient who is the subject of the call, and the reason for the call, that is, that as a service to the patient’s benefit plan, the pharmacist is calling about a potential cost savings opportunity to the patient and/or plan. The pharmacist will provide to the prescriber relevant cost information for the plan and patient, including any patient or plan cost savings, no savings, or increased costs that may result upon an interchange to the preferred medication. The pharmacist will also discuss any coverage conditions of the currently prescribed medication and any therapeutic issues relevant to the specific interchange proposal.

The pharmacist will ask that the prescriber consider whether the plan’s preferred drug would be appropriate for the patient considering either the plan’s preference and/or potential savings. For certain interchanges, the Express Scripts pharmacist will also convey that Express Scripts will reimburse the patient for his or her portion of the cost that may result from appointments, tests, or other healthcare services the prescriber deems necessary to assess the effect of the change, and that Express Scripts may receive manufacturer rebates based on the use of plan-preferred drugs and such rebates may be shared in some manner with the plan to help manage healthcare costs.

Whether the communication is conducted via a verbal telephone conversation or a fax, pharmacists record in the Express Scripts Therapy Management Workstation system, the name and title of the contact person (whether the prescriber or the prescriber’s designated agent). If the disposition of the communication is authorization of an interchange, the pharmacist enters that disposition along with all pertinent prescription component information necessary to communicate the change to the patient and to dispense the prescription. If the disposition of the communication is not an authorization to change, the pharmacist then enters the contact information and a system code representing a resolution based upon the prescriber's rationale for declining the change.

Therapeutic interchange program development
For inclusion in the Therapeutic Interchange Program, a drug must pass both a clinical and financial evaluation. Express Scripts reviews pertinent medical literature, medical compendia, and product labeling, and may consult with individual advisors or groups of independent clinical experts to review the clinical implications of a proposed intervention. If it is determined that the
proposed intervention is consistent with general interchangeability (that is, the drugs involved produce the same effects most of the time for most people), an Intervention Proposal is developed.

The Intervention Proposal consists of the intervention plan/procedures, therapeutic management issues and proposed resolutions to such issues, and methods of communication to the member/physician. The Intervention Proposal is then reviewed, and must be approved by, the independent P&T Committee based upon their thorough clinical evaluation.

Express Scripts **interchange returns policy**
When the mail pharmacy has already dispensed a preferred (formulary) drug, as authorized by the prescriber, and the patient requests reversal of the interchange to the originally prescribed (non-formulary) drug, Express Scripts responds by:

- Educating the patient on the rationale for conducting formulary management interventions on behalf of their plan, and discussing the general interchangeability of the drugs in question, as well as confirming the prescriber’s authorization to dispense the drug they received.

If the patient still requests reversal of the interchange:
- Express Scripts will cancel the preferred prescription and credit the patient for the copay of the preferred (formulary) drug

Express Scripts will contact the prescriber to:
- Notify him/her that the patient will not be taking the preferred drug that he/she authorized, but rather wants to stay on the original, non-preferred drug.
- Obtain a new prescription for the non-preferred drug
- Express Scripts will dispense the originally prescribed (non-formulary) drug. The patient will be charged only the co-payment for the originally prescribed drug (non-formulary) drug.
- The plan sponsor will be charged for both dispensed drugs. By law, returned drugs cannot be restocked to inventory. All returned drug product is sent to a central Express Scripts facility and destroyed. In the event Express Scripts obtains a credit from the manufacturer for returned product, Express Scripts will provide an appropriate credit to the plan. Note that manufacturers typically do not provide credits for returned products.
- Plans using Express Scripts may request information regarding the cost to them resulting from members’ rejection of preferred drugs.

Express Scripts will provide the patient with a pre-paid return shipping envelope to return the unused interchanged prescription.
Chapter 6: Drug utilization review programs

Drug utilization review (DUR) is a system used by pharmacists and pharmacies to check or monitor the frequency, type, appropriateness and use of prescription medications. All prescriptions undergo a full Drug Utilization Review. Those items where a potential issue may exist are routed to a pharmacist for review and/or patient/prescriber intervention. DUR is based on a specific set of clinical criteria and professional judgment. DUR may be concurrent (performed before dispensing as a series of checks against a patient’s medical history and plan guidelines), retrospective (analysis of a plan’s prescribing trends over time) or prospective (programs directed to heavy prescribers of specific drugs).

Concurrent drug utilization review

Concurrent Drug Utilization Review (CDUR) is a systems-based, rule-driven process that occurs at the point of sale and screens all incoming prescriptions for a broad range of safety considerations prior to dispensing. The goal of the program is to ensure the health and safety of members.

CDUR enhances member safety while avoiding unnecessary costs at the point of service, before the prescription is even filled. When a prescription violates one or more of the program’s rules, pharmacists receive an alert to a potential issue and claim adjudication may be prevented until appropriate action is taken. The program integrates prescription and diagnosis information, when available, for a more complete member profile, increasing member safety and plan savings.

Each prescription being filled is screened for a broad range of safety considerations prior to dispensing by evaluating the member’s prescription and medical profile. The pharmacist is notified of any health and safety issues at the point of service. Plans have the option to include additional enhanced alerts at retail for severe drug interactions, excessive dosing, and refill-too-soon that require overrides prior to dispensing.

At retail pharmacies, our Concurrent DUR allows plans the option of sending a warning (“soft” alert) or reject message (“hard” alert) for select alerts (refill-too-soon, excessive dosing, and severe drug interactions). Hard alerts are clinical warning messages sent to the dispensing pharmacist to alert them to a potential issue and to prevent claim adjudication until appropriate action is taken by the pharmacist. Hard alerts are built with an override capability that allows the pharmacist to adjudicate the claim if the medication is appropriate for the patient.

At the mail pharmacy, the concurrent DUR system requires each DUR warning to be addressed before the prescription can be dispensed. (All alerts at the mail pharmacy are “hard” edits.)

Clinical edits at the point of sale

The tables on the following pages explain each clinical edit and how we identify each potential clinical conflict.

<p>| Integrated Retail and Mail-Order Concurrent DUR |</p>
<table>
<thead>
<tr>
<th>Rules</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Drug Interactions*</td>
<td>Identifies a claim where the incoming medication may result in unsafe or potentially fatal therapy when used in combination with another drug on the</td>
<td>When taken together, Amitriptyline and Parnate may cause serious side effects that can potentially increase morbidity and mortality.</td>
</tr>
<tr>
<td>Rules</td>
<td>Description</td>
<td>Example</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Drug Interactions</td>
<td>Identifies a claim where the incoming medication may potentially result in increased side effects of the incoming drug or another drug the patient is taking</td>
<td>Quinidine and Digoxin may cause side effects such as visual disturbances and hyperkalemia when taken concomitantly</td>
</tr>
<tr>
<td>Drug-Allergy</td>
<td>Identifies a claim where the incoming drug may potentially cause the patient to have an allergic reaction to the prescribed medication based on patient reported allergies</td>
<td>Amoxicillin will cause an allergic reaction in patients allergic to penicillin</td>
</tr>
<tr>
<td>Drug-Disease</td>
<td>Identifies potential contraindications (i.e., may worsen patient condition) with an existing patient reported or inferred disease</td>
<td>Beta blocker in patients being treated for asthma</td>
</tr>
<tr>
<td>Refill Too Soon (with or without Stockpiling Prevention)*</td>
<td>Identifies a patient who has more than an adequate supply of medication remaining. Stockpiling Prevention, an option to the Refill Too Soon alert, identifies a patient who has more than an adequate supply of medication and based on all prior prescriptions filled, not just the last prescription received (enhanced Refill Too Soon logic)</td>
<td>Patient regularly obtains refills when 50 percent of current supply is consumed - by second refill, patient has accumulated an extra prescription</td>
</tr>
<tr>
<td>Duplicate Therapy</td>
<td>Identifies the dispensing of two or more drugs within the same therapeutic category for the same patient</td>
<td>Naprosyn and Relafen, when taken together, may cause increased risk of side effects associated with NSAIDs and results in no therapeutic advantage to the patient</td>
</tr>
<tr>
<td>Maximum Daily Dose/Excessive Daily Dosing*</td>
<td>Identifies prescription being filled for more than the manufacturer’s maximum recommended daily dose. Maximum daily dose rule is based on clinically recommended dosing guidelines</td>
<td>Vicoden at doses greater than the manufacturer’s recommended maximum dosage can potentially cause hepatic toxicity and respiratory depression</td>
</tr>
<tr>
<td>Cyclic Maximum Dosing</td>
<td>Identifies prescription excessive dosing for greater</td>
<td>Chemotherapy medications can accumulate in the body and taking doses</td>
</tr>
<tr>
<td>Rules</td>
<td>Description</td>
<td>Example</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Integrated Retail and Mail-Order Concurrent DUR</td>
<td>than the recommended maximum dose per cycle</td>
<td>incorrectly can result in lethal drug blood levels. Rules look at for example: single oral dose medications that are administered once every six weeks. The alert is sent to stop a repeat dose sooner than six weeks</td>
</tr>
<tr>
<td>Ineffective Daily Dose</td>
<td>Identifies prescriptions being filled for less than the recommended minimum daily dose</td>
<td>Oxacillin at doses less than 500 mg/day for the treatment of cellulitis will not effectively cure the patient’s condition</td>
</tr>
<tr>
<td>Under-Utilization</td>
<td>Identifies patients who are non-compliant with their drug therapies</td>
<td>Cardiac medication refilled after supply is exhausted may cause increased risk of adverse events because maintenance medication requires continuous therapy</td>
</tr>
<tr>
<td>Adult Daily Dose Quantity Greater Than Maximum</td>
<td>Identifies prescriptions for which the daily dose in dispensing units (for example, tablets, capsules) exceeds the quantity recommended for most users in the same age band</td>
<td>Hyperlipidemics prescribed at more than the usual daily dose interval (for example, Lipitor prescribed for more than once a day dosing)</td>
</tr>
<tr>
<td>Adult Daily Dose Quantity Less than Minimum</td>
<td>Identifies prescriptions for which the daily dose in dispensing units (for example, tablets, capsules) is less than the quantity recommended as effective for most users in the same age band</td>
<td>A prescription for Precose (acarbose) would present a minimum quantity per day alert, since Precose is typically administered with meals</td>
</tr>
<tr>
<td>Potential Drug Name Confusion</td>
<td>Identifies drugs in the member’s history that sound-alike or when written, look-alike</td>
<td>A medication error due to confusion between products such as the antifungal medication Lamisil which sounds and looks similar to the anticonvulsant medication Lamictal can potentially cause confusion and even seizures</td>
</tr>
<tr>
<td>Drug-Gender</td>
<td>Identifies drugs that may have been inappropriately prescribed to a patient based on their gender</td>
<td>Proscar provides no therapeutic benefit for females and is used exclusively in males</td>
</tr>
<tr>
<td>Drug-Pregnancy Contraindication</td>
<td>Identifies drugs contraindicated for use by pregnant women</td>
<td>Isotretinoin (acne medication) taken during pregnancy has been shown to put the fetus at increased risk</td>
</tr>
</tbody>
</table>

* These edits are part of our Enhanced Concurrent DUR offering when set as a hard alert at retail.

Concurrent DUR rules are also designed to address the special needs of seniors (drug-drug interactions, drug-disease contraindications, drug-age precautions, minimum and maximum daily
dose limitations), children (e.g., drug-age contraindications and age-dosing issues), and women (e.g., drug-pregnancy contraindications).

Additionally, our DUR system incorporates special protocols in our mail-order pharmacies that will monitor Schedule II Narcotics.

<table>
<thead>
<tr>
<th>Rules</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled Substance Verification</td>
<td>Express Scripts may consult with physicians before filling new orders for a Schedule II controlled substance</td>
<td>Oxycontin prescription is received by the mail pharmacy. Doctor’s DEA number and verification that the physician appropriately prescribed this medication for the written patient is obtained prior to any medication being dispensed to the patient that submitted the prescription.</td>
</tr>
</tbody>
</table>

**Retrospective DUR**

After a prescription has been dispensed, the Retrospective DUR evaluates the prescription against the patient’s profile and evidence-based guidelines to alert the prescribing physician by mail to important, drug-specific, patient-specific health, safety and utilization issues. To facilitate changes in therapy, the physician is provided with a written and literature-referenced description of the drug-specific, patient-specific issue identified, and a patient profile including key demographic information, the patient’s medication history, and for each medication, the dates of service, days supply and prescribing physician. Plans can enroll into this program for an additional fee.

**Clinical rules**

The Retrospective DUR health and safety (clinical) alerts are comprised of three rule categories.

<table>
<thead>
<tr>
<th>Integrated Retail and Mail-Order Retrospective DUR: Rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential Drug-Drug Interaction</td>
</tr>
<tr>
<td>Drug Age Consideration</td>
</tr>
<tr>
<td>Therapy Duplication</td>
</tr>
</tbody>
</table>

**Retrospective DUR intervention process**

DUR interventions are conducted continuously, by reviewing a full year of historical paid claims data to detect meaningful patterns of therapy. The clinical database identifies therapeutic concern and generates clinical alerts. We then aggregate the clinical alerts and their associated patient
profiles by physician, and send a written intervention communication, specifically designed to improve therapeutic outcomes and the quality of patient care. These interventions are sent quarterly. The physicians receive:

- A cover letter outlining the goals of the program and a list of all the patients involved.
- A patient-specific communication outlining the clinical issues involved and recommended courses of action for each patient, with supporting clinical references and citations.
- A fully integrated patient drug history profile for all alert drugs and other medications.

Physicians are provided with an in-bound, toll-free telephone number to communicate directly with our physician service center for prompt resolution of any of the clinical utilization issues outlined in the intervention communication. We document, analyze, and report all interventions and their outcome to the plan quarterly through our prescription drug plan report package.

We intervene to improve the patient’s overall outcome, not just the choice of drug. Our communications to physicians include medical literature reference citations along with specific recommendations for changes in therapy, an element that other programs often do not offer.
Chapter 7: Utilization management programs

Utilization management is the process of evaluating the necessity, appropriateness and efficiency of healthcare services against established guidelines and criteria. Plans can enroll into each program for an additional fee. Utilization Management programs include:

Coverage management

Coverage Management is a set of options that ensure the clinical appropriateness of coverage defined by the plan for specific drugs or specific amounts of drugs, thereby helping to manage drug spend. The programs fall into two main categories: drug selection and quantity management.

Drug selection includes prior authorization and step therapy (a plan rule that requires a member to first try one or more specified drugs to treat a particular medical condition before the plan will cover another (usually more expensive) drug that the member’s doctor may have prescribed). Covered drugs that require step therapy are indicated in the formulary rules. Quantity management includes options that address issues related to overuse and waste.

These programs lower drug spend without compromising the quality of care, and allow drug-level coverage consistent with a plans’ benefit. Targeted communications support the plan’s coverage authorization objectives by educating members on aspects of the coverage authorization capabilities, in turn reducing member impact. Throughout the benefit year, members can be sent customized communications that include patient pre-notification letters, patient coverage authorization trigger letters, coverage authorization confirmation letters, and authorization renewal reminder letters.

High utilization

The high utilization program alerts physicians about the potential misuse or abuse of drugs prescribed by multiple physicians and filled at multiple pharmacies. This program has two levels of intervention. Level 1 consists of a series of queries and reports available to all plans via the client website. Level 2 alerts all prescribers to utilization concerns for individual members and makes recommendations for corrective action to limit ongoing misuse of drugs.

The high utilization program promotes the coordination of care among physicians, which enhances member safety. Improved utilization habits include decreasing claims within the targeted high utilization categories, decreasing the number of prescribing physicians, and decreasing the number of pharmacies used.

The patient’s prescription history is analyzed and the prescribing physicians are contacted to determine whether overuse or abuse exists. With a plan’s authorization and that of the physicians, the patient can be contacted to restrict his or her coverage to one retail pharmacy.

Polypharmacy

The Polypharmacy program—targeted at seniors age 65 and older—alerts prescribing physicians about their senior patients who have prescription claims from multiple physicians, filled at multiple pharmacies, placing them at a higher risk for adverse drug events. The Polypharmacy program:

- reduces risk and medication costs by discontinuing unnecessary medications
- improves members’ safety while reducing waste and plan costs
- includes physician review of the identified patient drug profiles
- identifies all prescribers
- makes recommendations for corrective action to better coordinate care
Physician practice summaries
The Physician Practice Summaries are quarterly communications sent to targeted physicians with useful comparative information about their prescribing behaviors. The goal of these communications is to encourage physicians to adhere to the best prescribing practices, increase generic prescribing, and increase formulary compliance rates. These summaries provide physicians with member-specific, actionable information to change prescribing patterns and improve a plan’s performance. It also increases the prescribing rate of generic and plan-preferred brands, thereby helping to manage a plan’s drug spend.

These summaries are a snapshot of a physician’s specific prescribing patterns and explain how he or she could change their behaviors to better support the plan’s objectives. For an additional fee, plans can customize the guidelines of the program and determine the frequency of these mailings throughout the year.

RationalMed
The RationalMed® safety program has been in place for more than a decade, and has a proven track record of achieving clinical and financial outcomes complementary to traditional PBM, health plan and disease management programs. With more than 200 plans representing more than 13 million covered lives, RationalMed effects thousands of changes in care each week—changes that correct important errors in care and improve patient safety to lower both medical and prescription drug costs. RationalMed is designed to deliver:

- Safer use of medications and evidence-based prescribing
- More appropriate, evidence-based patient care
- Fewer avoidable hospitalizations
- Prescription drug savings
- Medical savings
- Insights into the health of a plans population
- Enhanced member care coordination and advocacy

While traditional clinical programs such as DUR, disease management and case/care management address some issues related to prescription drug therapy, the RationalMed program employs added health and safety protection across a plan’s total population, not just for those with chronic conditions. RationalMed alerts physicians, pharmacists, and patients (when applicable) to the increased health and safety risk, and then tracks and reports on the outcomes.

RationalMed uses thousands of evidence-based clinical rules and a proprietary predictive modeling capability, and identifies patients across a plan’s population who may be at risk for near-term hospitalizations, adverse events and longer-term health complications by evaluating integrated health information (medical, pharmacy, lab and patient self-reported data). Potential safety issues are sent to the prescribing physician in the form of a RationalMed alert. Alerts are also sent to pharmacists, patients, and case/care managers as determined by the plan’s preference. As a result, the plan realizes greater program savings from reduced hospitalization costs and appropriate use of prescription drugs. RationalMed offers:

- Extra safety across a plan’s total population
- Program reporting
- Optional third party real-time web access
Originally received in 2005, RationalMed maintains a Disease Management Systems Certification from the National Committee for Quality Assurance (NCQA) for its Patient Safety Solutions system. NCQA Certification is a designation that indicates a program has passed a rigorous review across multiple standards of quality. RationalMed underwent this voluntary review process and met NCQA’s certification requirements in the following areas:

- Patient Identification
- Stratification and Assessment
- Coordination of Information
- Patient Safety
- Quality Improvement
**Conclusion**
Express Scripts hopes this guide has given you insights into managing your pharmacy benefit and sparks productive discussions with your current PBM. We believe effective plan-PBM relationships are built on aligned interests, rigorous analysis, a commitment to clinical excellence and ongoing communication.

(11/29/2010)