



Common Practices in Formulary Management Systems:

A Report Prepared by the
Academy of Managed Care Pharmacy

About AMCP

The Academy of Managed Care Pharmacy (AMCP) is a professional association of pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy by the application of managed care principles. The mission of AMCP is to serve as an organization through which the membership pursues its common goals; to provide leadership and support for its members; to represent its members before private and public agencies and health care professional organizations; and to advance pharmacy practice in managed health care systems.

The Academy's national membership provides comprehensive coverage and services to over 170 million Americans served by managed care.

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Introduction

In January 2000, the Academy of Managed Care Pharmacy (AMCP) canvassed eight organizations to document common practices used in private sector managed care pharmacy benefit administration. Six PBMs and two health plans — administering pharmacy benefits for approximately 176,000,000 individuals — responded to a questionnaire which covered the following major areas:

- ▶ Pharmacy and Therapeutic Committee Composition
- ▶ Type of Formulary Structure Used
- ▶ Cost Containment Measures Employed
- ▶ Categories and Classes of Drugs Excluded from Coverage
- ▶ Appeals Processes In Place

Respondent Demographics

- ▶ Six pharmacy benefit management companies
 - ▶ 4 PBMs with greater than 10 million managed lives
 - ▶ 2 PBMs with less than 10 million managed lives
- ▶ Two health maintenance organizations with less than 10 million covered lives

Limitations of the Collected Data

- ▶ The questionnaire was not a validated instrument.
- ▶ The PBMs and HMOs were not randomly chosen.
- ▶ The sample size was small.
- ▶ Information was reported only in aggregate form.
- ▶ The data were averaged across all 8 organizations, irrespective of size.
- ▶ The 176,400,000 reported population includes double counting of lives due to the incidence of dual coverage of individuals from two wage-earner households; the extent of double counting is not known

Due to clear differences in the organizations that responded to this questionnaire, extreme caution must be exercised in drawing any inferences regarding the formulary management practices of other managed health care systems or the health care industry as a whole.

The Institute of Medicine (IOM) subsequently used this aggregated, blinded data for its report — *Description and Analysis of the VA National Formulary*. As reported in the June issue of *AMCP News*, the IOM report analyzes the restrictiveness of the VA National Formulary, its impact on the costs and quality of care in the Veterans Health Administration, and ways it compares to formularies and drug management practices in the private sector. The IOM released its report to the public on June 7, 2000.

Question 1: What is the composition of the Pharmacy & Therapeutics (P&T) Committee?

Aggregate Response: P&T committees reflected a membership that was comprised primarily of physicians and a small number of pharmacists. The P&T committee composition is shown in Figure 1.

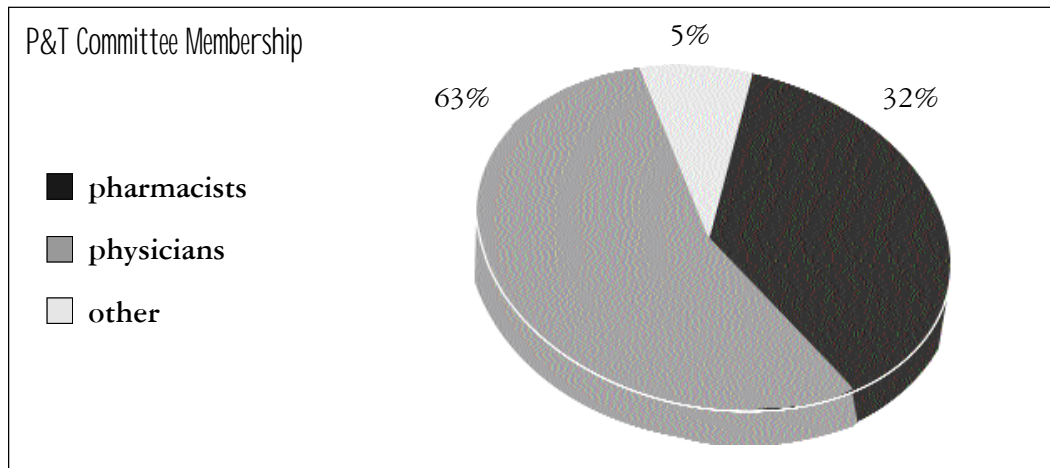


Figure 1.

Question 2: Regardless of the existence of a formulary or prior authorization process, how many covered lives are in health plans that exclude the following: DESI, experimental, OTC, cosmetic, or life-style drugs or off-label use prescribing?

Aggregate Response: Ninety percent (90%) of covered lives are in plans that exclude the following drug categories: experimental, OTC, and life-style drugs. Off-label prescribing was excluded in approximately thirty percent (30%) of all plans. Some plans also reported that prenatal vitamins, fertility agents, drugs for sexual dysfunction, and oral contraceptives were excluded.

The total percentage of covered lives that are *not* eligible for coverage of drugs in the categories of DESI drugs, experimental drugs, off-label prescribing, over the counter (OTC) drugs, and life-style drugs are shown in Figure 2.

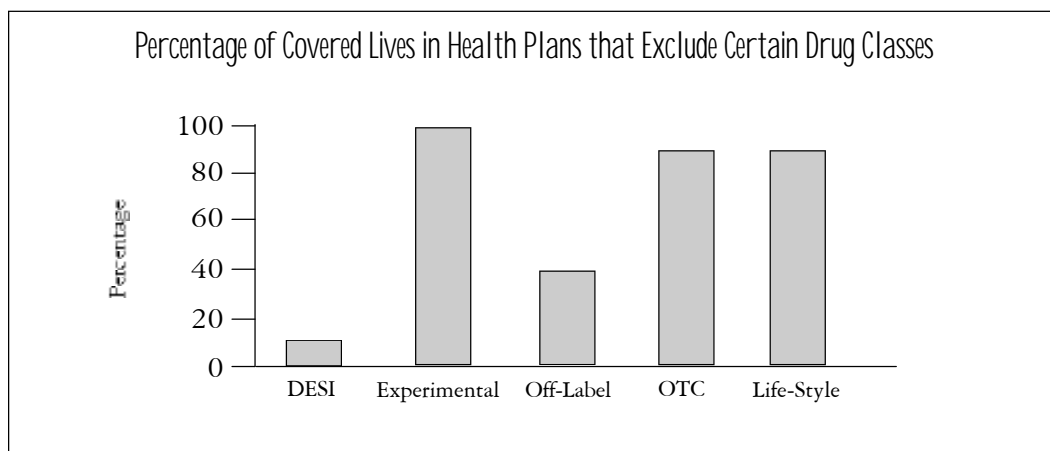


Figure 2.

Question 2a: How many therapeutic drug classes are excluded?

Aggregate Response:

Commonly excluded classes included prenatal vitamins, fertility agents, sexual dysfunction agents, and oral contraceptives. Larger health plans were more likely to exclude 1–2 therapeutic classes of drugs, while smaller plans were more likely to exclude more than 5 therapeutic classes.

The percentage of covered lives that are in health plans that exclude 1–2, 3–5, or greater than 5 therapeutic drug classes are shown in Figure 3.

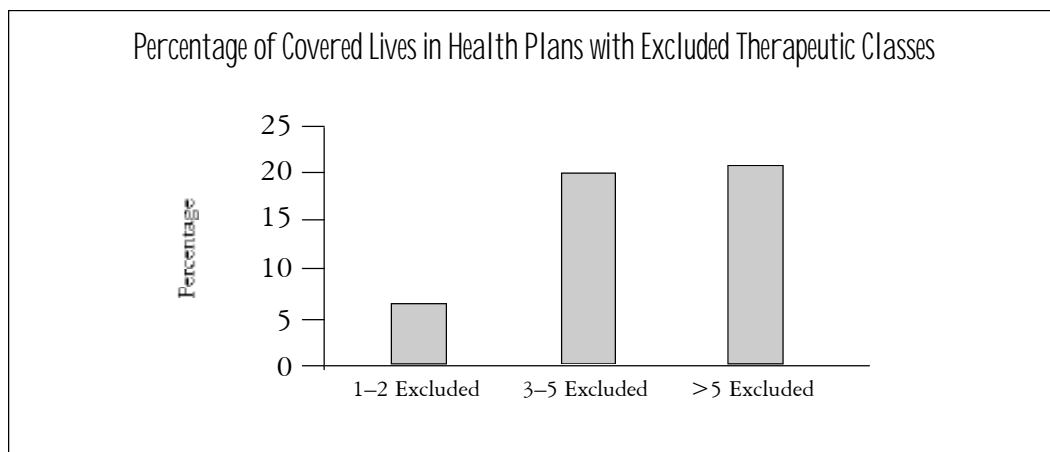


Figure 3.

Question 3: What is the distribution of covered lives under various formularies?

For purposes of this questionnaire, types of formulary structures were defined as follows:

Closed/ partial closed is a formulary structure that limits and requires justification for use of drugs not listed on the formulary independent of those drugs excluded through benefit design.

Open-preferred is a formulary structure that encourages the use of certain drugs through the use of incentives (lower co-pay, academic detailing, DUR, soft edits), usage criteria, etc.

Open-passive is an open formulary structure that includes drugs that are only passively promoted through the use of educational materials, few soft edits.

No formulary, PA – means that selected drugs are labeled as “requires prior authorization.”

No formulary, DUR – means that the health plan does not use a formulary or prior authorization process. Pharmacists perform DUR and notify physicians when inappropriate use is identified.

No formulary, open access – means there are no checks on the physicians’ practice patterns. All drugs are covered.

The percentage distribution of covered lives in health plans with various formulary structures is shown in Figure 4. *(Results total greater than 100% due to rounding on the part of respondents.)*

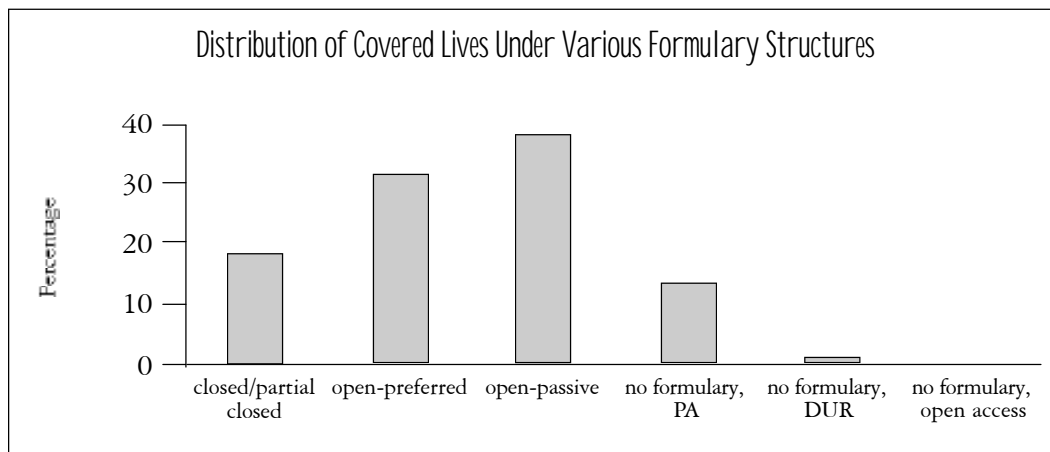


Figure 4.

Distribution of Covered Lives in Health Plans with Various Formulary Structures
(Results total greater than 100% due to rounding on the part of respondents)

- ▶ Closed/partial closed 18%
- ▶ Open-preferred 33%
- ▶ Open-passive 38%
- ▶ No formulary or prior authorization used 13%
- ▶ No formulary or drug utilization review used 1%
- ▶ No formulary, open access 0%

Question 3a: Of those health plans with closed therapeutic classes, how many classes are closed?

Aggregate Response:

Respondents' answers to this question were charted as the percentage of the covered lives that are in health plans using closed formularies that exclude coverage in certain classes as shown in Figure 5. The results were as follows:

- ▶ 1 to 2 classes closed 38%
- ▶ 3 to 5 classes closed 2%
- ▶ More than 5 classes closed 58%
- ▶ Larger health plans reportedly close more classes than smaller organizations. Approximately 6 million lives are covered under plans that have at least one closed-class containing only 1 drug.
- ▶ The majority of lives (97%) are covered by health plans that have more than one drug choice per class.

The bimodal results to this question (1–2 classes closed and more than 5 classes closed) prompted additional questions regarding the distribution of covered lives in plans with closed therapeutic classes. One large PBM respondent explained that over the past two to three years the number of closed classes has been reduced as a counterpoint to the “managed care backlash” their health plan clients are experiencing. This respondent also explained that PBMs have moved former closed formulary clients to tiered co-payment benefit structures.

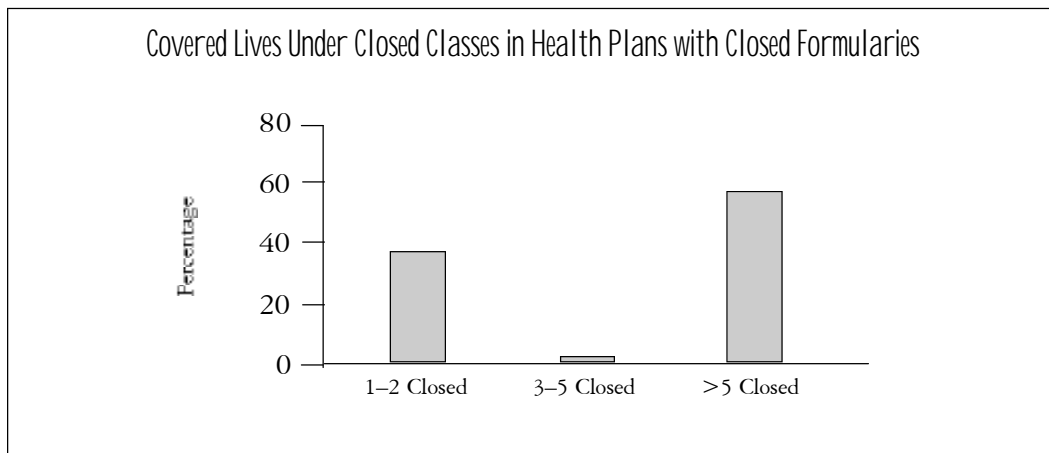


Figure 5.

Question 3b: **What therapeutic classes are closed?**

Aggregate Response:

Some of the typical closed classes reported by the eight respondents are shown in Figure 6.

- ▶ Leukotriene Modifiers
- ▶ Urinary Incontinence
- ▶ Oral Contraceptives
- ▶ Antifungals
- ▶ Angiotensinogen Receptor Blockers
- ▶ Calcium Channel Blockers
- ▶ HMG CoA Reductase Inhibitors
- ▶ Sulfonylureas
- ▶ Thiazolidinediones
- ▶ Glucose Blood Strips
- ▶ Migraine-Serotonin 5-HT₁ Receptor Agonists
- ▶ Beta Agonist Inhalers
- ▶ Corticosteroid Inhalers
- ▶ Interferons for Multiple Sclerosis
- ▶ Proton Pump Inhibitors
- ▶ ACE Inhibitors
- ▶ Antihistamines
- ▶ Non Steroidal Anti-Inflammatory Drugs
- ▶ Histamine-2 Blockers

Figure 6.

Question 3c: Of those plans reporting preferred agents, how many classes were preferred?

Aggregate Response:

Respondents' answers to this question were charted as the percentage of covered lives that are in health plans using open formularies that have preferred therapeutic classes, as shown in Figure 7. The results were as follows:

- ▶ 1 to 2 preferred classes 2%
- ▶ 3 to 5 preferred classes 7%
- ▶ More than 5 preferred classes 95%

Examples of some of the preferred classes are oral contraceptives, proton pump inhibitors (PPI), angiotensin-converting enzyme inhibitors (ACEIs), angiotensinogen receptor blockers (ARBs), calcium channel blockers (CCBs), and HMG CoA reductase inhibitors. Of the health plans that use preferred classes in their formularies, respondents noted that the highest percentage of covered lives are in health plans that have formularies with more than 5 preferred classes.

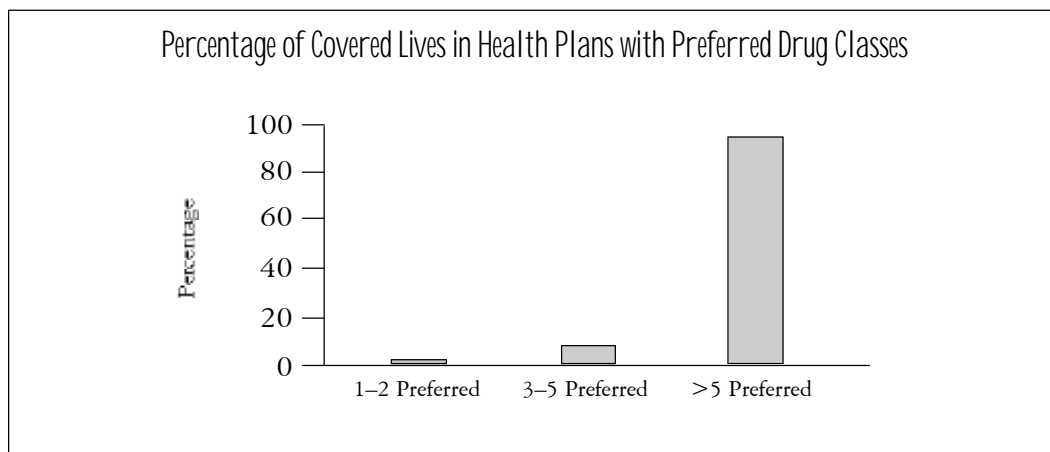


Figure 7.

The respondents were also queried about the use of other formulary management tools:

- ▶ 71% of the 176,400,000 covered lives are in health plans that restrict coverage or reimbursement of specific drugs or classes of drugs to specific prescribers, settings, or disease conditions.
- ▶ 38% of the covered lives are in health plans that require mandatory generic substitution. Most of the smaller health plans employed mandatory generic substitution. *Respondents explained that the seemingly low figure was probably due to the inclusion of the “requirement” feature in the question. Respondents also explained that if the question had merely asked whether generics were preferred, the figure would have been closer to 100%.*
- ▶ In terms of the accessibility to non-formulary drugs, respondents reported that 100% of the health plans have a non-formulary exceptions process and 100% of the health plans use co-pay design controls to influence the use of non-formulary drugs.

Some of the quality and cost-containment measures employed by the responding HMOs and PBMs are shown in Figure 8.

Distribution of Covered Lives in Health Plans that Employ the Following Cost Containment Measures

- ▶ Limit number of prescriptions 23%
- ▶ Limit number of refills 46%
- ▶ Limit duration of use 21%
- ▶ Limit supply of drug 71%
- ▶ Use of prior authorization 53%

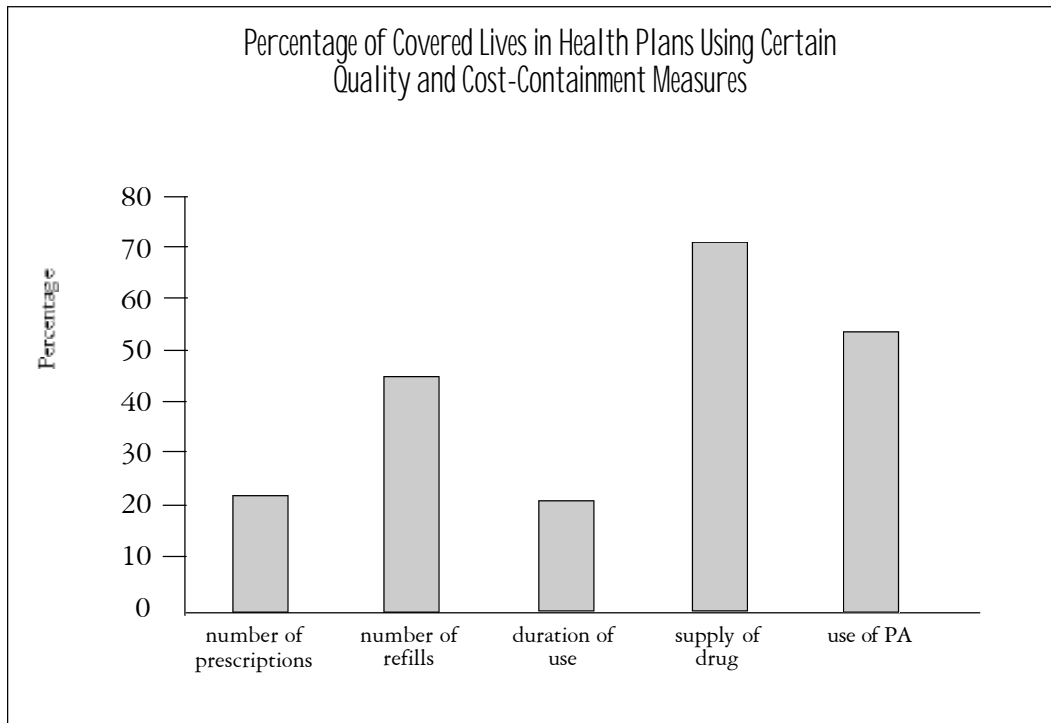


Figure 8.

Many managed health care systems have been criticized for imposing a waiting period before some newly approved drugs are reviewed by their P&T committees. Therefore, respondents were asked how many of their covered lives were in health plans that have a waiting period requirement. They replied that only 1% of covered lives is in health plans that have a waiting period requirement greater than 6 months for newly approved drugs. The percentage of covered lives that are in health plans that have a waiting period requirement of less than 6 months for newly approved FDA drugs is approximately 6%. See Figure 9.

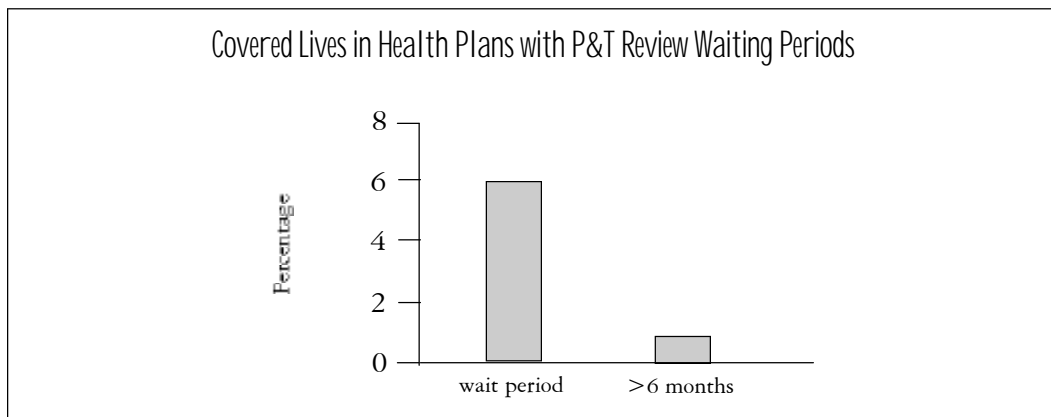


Figure 9.

The respondents were also asked whether they actively monitored FDA activities in order to proactively review newly approved drugs for HIV/AIDS, cancer, and FDA “1P” (priority) drugs. They responded that 71% of covered lives are in health plans that monitor FDA approvals for AIDS/Cancer, and 34% are in health plans that monitor FDA “1P” drugs. See Figure 10.

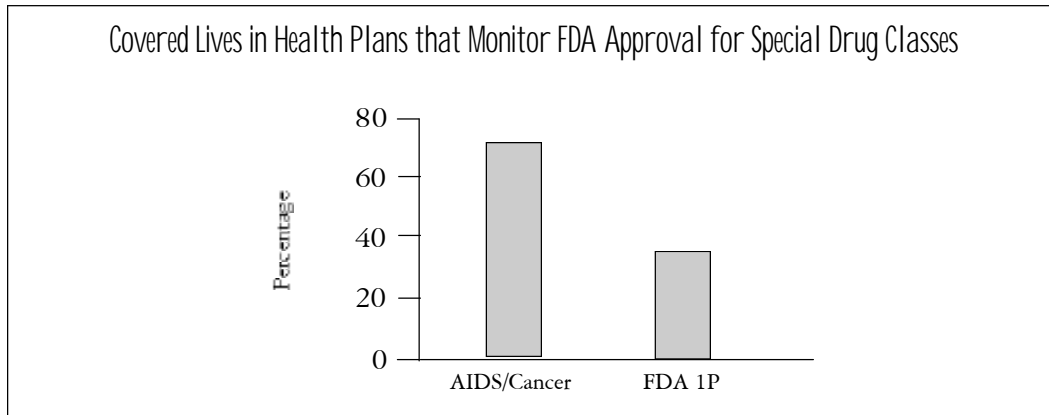


Figure 10.

Lastly, respondents were asked how many covered lives are in health plans that have an internal process whereby members may appeal denials of drug coverage or non-formulary drug requests or request reimbursement for excluded drugs. Since most states mandate that health plan members have access to an appeals process, respondents were asked to verify the seemingly low number of covered lives reportedly having access to appeals processes. Three of the 4 large PBMs reported that they lacked specific information to report on the various appeals processes in place in their client health plans. (Therefore, Figure 11 reflects this lack of individual health plan data.) Those respondents that had information on the existence of appeals processes reported 73% of the health plans had drug specific appeals processes. The appeals processes available and the percentage of covered lives that have access to various appeals processes according to information available to PBMs and HMOs is listed in Figure 11.

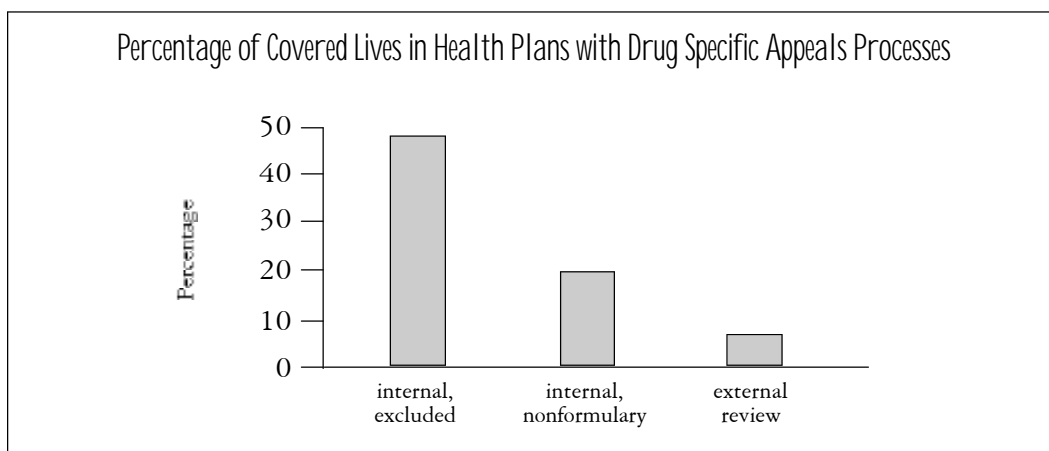


Figure 11.

Internal, excluded = internal appeal of excluded drugs

Internal, nonformulary = internal appeal of nonformulary requests

External review = external review of the appeals process

Strengths

This questionnaire notes differences in the formulary and pharmacy benefit designs between large (over 10,000,000 lives) and small (less than 10,000,000 lives) respondents. Practices did not differ significantly between respondents by the size of the population covered. The questionnaire did note that larger respondents were more likely to report 1–2 excluded classes, while smaller respondents were more likely to report greater than 5 excluded classes.

Weaknesses

The questionnaire was not validated prior to its use. There may have been lack of clarity on the part of respondents with respect to some of the questions included in the survey.

Glossary

Appeal – A formal request by a covered person or provider for reconsideration of a decision, such as a utilization review recommendation, a benefit payment or administrative action.

Brand Name – The trademark drug name given by the manufacturer.

Copayment – A cost-sharing arrangement in which a covered person pays a specified charge for a specific service, such as a fixed dollar amount for each prescription received; (e.g., \$5.00 per generic prescription, \$10.00 per preferred brand name prescription, and a higher charge such as \$25.00 for a non-formulary product).

Covered Lives – Refers to the number of persons who are enrolled within a particular health plan, or for coverage by a provider network; includes enrollees and their covered dependents.

Drug Types –

Cosmetic – A drug used to improve complexion, or to enhance beauty.

DESI (Drug Efficacy Study Implementation) – To comply in part with the 1962 amendments to the Food, Drug and Cosmetic Act, the FDA contracted in 1966 with the National Academy of Sciences/National Research Council to study drugs approved between 1938 and 1962 from the standpoint of efficacy. The DESI program evaluated over 3000 separate products and over 16,000 therapeutic claims. By 1984, FDA had completed final regulatory action on 3,443 products; of these, 2,225 were found to be effective, 1,051 were found not effective, and 167 were pending. The ineffective drugs were designated as DESI drugs and the Omnibus Budget Reconciliation Act of 1981 prohibited payment for these drugs by Medicaid programs and under Medicare Part B.

Experimental – Experimental drugs are those currently under investigation and not yet approved for use by the FDA for any indication. There is not enough accumulated scientific data to establish medically appropriate use of the drug for treatment of a disease. However, FDA has established programs to allow patients with an immediately life-threatening disease “early access” to new treatments. Since patients who have exhausted standard therapeutic options may be willing to accept additional risks and potentially dangerous side effects from drug products still under study, these programs allow patients access to investigational drugs.

Life Style – Drugs designed to improve the quality of life or extend the normal life span. These may include drugs that would successfully restore or improve sexual potency, restore hair growth, allow acute treatment to prevent conception (so-called morning-after pill), or reverse the effects of aging.

OTC (Over-the-counter drug) – A pharmaceutical that may be sold without federal or state prescription requirements, and may be purchased without a doctor’s order; a benefit option in some plans.

Effectiveness – The actual effects of treatment by the drug under “real life” conditions [e.g., patients not always remembering to take their doses, physicians often not prescribing the lowest FDA recommended doses, side effects not all controlled, etc]. ‘Head to head’ effectiveness studies with similar medications are preferable.

Efficacy – The potential effects of treatment by the drug under optimal circumstances [e.g., patients all taking their doses at the right times, physicians prescribing correct doses, side effects appropriately monitored, etc]. Efficacy studies are typically the foundation of new drug submissions to the FDA. Studies that compare the efficacy of similar drugs, rather than just efficacy compared to placebo are preferable.

Exclusions – Drugs not covered under the pharmacy benefit of the health plan. Examples of drug exclusions may include cosmetic and fertility drugs, investigational drugs, and over-the counter (OTC) products. Specific examples include amphetamine and non-amphetamine appetite suppressant drugs.

FDA 1P Drugs – FDA classifies investigational new drug applications (INDs) and new drug applications (NDAs) to assign review priority on the basis of the drug’s chemical type and potential benefit. Drugs assigned a “1P” classification contain an active ingredient that has never been marketed in the United States and appears to represent an advance over available therapy. The FDA gives these drugs an expedited review and a more rapid decision is made regarding approval for the indication of use as suggested by the manufacturer.

Formulary – A continually updated list of medications, related products and information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health.

Formulary system – An ongoing process whereby a health care organization, through its physicians, pharmacists and other health care professionals, establishes policies on the use of drugs, related products and therapies, and identifies drugs, related products and therapies that are the most medically appropriate and cost effective to best serve the health interests of a given patient population.

Formulary Management – An integrated patient care process that enables physicians, pharmacists, and other health care professionals to work together to promote clinically sound, cost effective pharmaceutical care. The formulary management process provides the managed health care system with the ability to objectively discriminate between superior and marginally effective drug products.

Generic Substitution – Involves dispensing a drug product that is chemically and physically identical to an original “brand name” product. Manufacturers may produce and market a generic equivalent to the public only after the patent(s) or other intellectual property protections of the original brand name product expire.

Institute of Medicine (IOM) – The mission of the Institute of Medicine is to advance and disseminate scientific knowledge to improve human health. Established in 1970 by the National Academy of Sciences, the Institute, upon its own initiative, identifies issues of medical care, research, and education. It provides objective, timely, authoritative information and advice concerning health and science policy to government, the corporate sector, the professions and the public.

Mandatory Generic Substitution – A pharmacy benefit management tool that mandates the use of a generic equivalent drug product whenever one is available. Prescribers must justify the use of a brand-name product over the use of its generic equivalent.

Non-Formulary Drugs – Drugs not included in the formulary. Health plans that use formularies have policies in place to give physicians and patients access to non-formulary drugs where medically appropriate.

Off Label Use – The use of a drug for clinical indications other than those stated in the product labeling approved by the Food and Drug Administration. An example would be using a drug to treat one form of cancer (e.g., pancreatic) that had received FDA approval for the treatment of other types of cancer (ovarian, bladder, breast).

PBM (Pharmacy benefit management company) – A relatively young industry that specializes in reducing the amount of cost for pharmaceuticals, either in support of a health maintenance organization (HMO) or a hospital-based system. PBMs now connect most of the U.S. pharmacies via computer network with programs to provide data reporting, educational information directed toward least-cost prescribing alternatives, software to support drug-to-drug interactions with an entire community and to keep patients from receiving redundant and costly services. Some PBMs are independent organizations, while others are subsidiaries of drug companies or insurance companies.

P&T Committee (Pharmacy and Therapeutics Committee) – An advisory committee that is responsible for developing, managing, updating, and administering the drug formulary system. P&T Committees are comprised of primary care and specialty physicians, pharmacists, and other health care professionals. Often, P&T Committees include nurses, legal experts, and administrators.

Pharmacy Benefit Design – Contractually specifies the level of coverage and types of pharmaceutical services available to health plan members. A sound pharmacy benefit design strikes a balance between patient care outcomes, costs, quality, risk management, and provision of the services that beneficiaries expect. The pharmacy benefit design establishes coverage parameters and sets liability limits.

Preferred Therapeutic Class – A specific drug class or classes selected as the most appropriate for treatment of a particular disease or condition as determined by a P&T Committee or similar entity using the best available scientific evidence. There is usually a reduced copayment if the patient uses a specific drug from such a class of drugs. For example, the P&T Committee may determine that H2-blocking agents rather than Proton Pump Inhibitors are the most appropriate first-line therapy for Gastro-Esophageal Reflux Disease (GERD).

Prior Authorization – Prior authorization programs establish specific pre-defined conditions that must be satisfied before a prescription can be dispensed. This mechanism allows for control over medications that are often misprescribed and helps to ensure appropriate use without denying access to those patients who would benefit from the therapy. In addition, prior authorization is often required for medications that have defined clinical advantages, but are commonly prescribed for cosmetic purposes.

Tiered Copayment Benefits – A pharmacy benefit design that financially rewards patients for using generic and formulary drugs by requiring the patient to pay progressively higher copayments for brand-name and non-formulary drugs. For example, in a three-tiered benefit structure, copayments may be \$5.00 for a generic, \$10.00 for a formulary brand product, and \$25.00 for a nonformulary brand product.

VA National Formulary – A drug formulary implemented in 1997 by the Veterans Health Administration (VHA) intended to help control costs and improve quality of prescribing in the VHA's 172 hospitals, more than 600 ambulatory facilities, 132 nursing homes, and other health care facilities.

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