This issue brief, the first in a series prepared by Breakaway Policy Strategies for FasterCures, discusses what is known—and not known—about coverage decisions of private commercial health plans and government programs. It provides information on the general coverage policy process used by private and government payers, and provides more detailed information about pharmacy coverage decisions and provider network design. It also discusses the strategies plans use to help control overall costs even when a health care item or service is covered.

Introduction

Health plans decide whether and how to provide coverage for specific health care items and services based on whether the item or service is “medically necessary.” Medical necessity is the basis for most coverage policy in the United States but there is no single, consensus-based, definition of medical necessity. Whether a treatment is “medically necessary” is often at the heart of coverage disputes between patients and insurers. Patients can appeal coverage denials using different processes in different states.

Coverage decisions are made by medical professionals who are employed by individual health plans, typically Medical Directors or Chief Medical Officers who use different coverage decision processes depending on the type of health care item or service being considered. For instance, the limited literature available often describes a fairly uniform approach on how plans decide which drugs to cover within their pharmacy benefit and then, for those that are covered, exactly what the terms of coverage will be. However, a new genetic diagnostic test (or particular medical device) will likely go through a completely different process.

An important consideration is that it can be difficult for a commercial health plan or government program to outright decline to cover a service, even if it views the evidence as indicating only a modest clinical/health benefit.

While binary “yes” or “no” decisions are sometimes made, it is more common for health plans to come to a “yes, and” or “yes, but…” decision. In this scenario, an item or service meets the threshold for being covered, but the terms of coverage may limit the circumstances under which it is covered or provide a disincentive to using it. Thus, the initial coverage decision may not be predicated on costs, but rather clinical evidence, patient/consumer benefit and risks, and provider practice among other considerations. However, the terms of coverage can and do consider costs. After an affirmative coverage decision, there can be a separate, hybrid, medical/business policy process to decide if there is a need for coverage parameters that limit access, limit utilization, or drive down price in some way. Those parameters typically involve utilization management, benefit design, or provider networks. Health plans view these parameters as medically appropriate, while clinicians, patients or others sometimes disagree about the appropriateness.

Transparency of Coverage Decisions

There is little public information available about how health plans and government programs develop coverage policies. One reason that the information may not be transparent is that it may be competitively important (business confidential). In other instances, the process itself is quite variable and not easily described in ways to cover all situations.

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* In the case of drugs, it is not uncommon for a plan to wholly exclude a drug from coverage.
The lack of complete transparency also extends to government programs. For example, Medicare coverage policy is relatively transparent at the national level, which only applies to a very small portion of all covered services. Within broad categories of services, such as in-patient hospital services, Medicare coverage is decided at a regional level by individual contractor medical directors acting on behalf of the program. Each Medicaid program has its own process that can be variable, depending on the issue to be decided.

**Coverage Policy Processes**

*General Considerations and Influences*

Most recent research into the question of how insurers make coverage decisions is very targeted and specific—defibrillators, gene assays for specific diseases, vaccines, or diabetes education, for example. One study took an interesting approach of interviewing health plan policymakers about the key considerations and influences that affected the plan’s coverage decision. The work showed that health plans are quite variable in the level of evidence required for coverage (in this case a gene expression assay). While all plans preferred evidence of clinical effect on the patient disease state, most reported using various other evidence inputs— independent validation studies, Medicare coverage decisions, and specialty society recommendations. In the absence of important evidence, health plans also consider the level of provider and patient acceptance and/or regulatory review among other influences and sources of evidence. In this study, no health plan cited financial/cost data as part of the coverage process and this seems consistent in the available literature—cost is not part of the consideration at the level of yes/no coverage. But, once a health plan has an affirmative decision, then constraints may be applied that seek to address the cost issues (if any). As noted, this can sometimes become the source of debate, with health plans viewing the constraint as clinically appropriate and consistent with clinical evidence, while some clinicians and patients may view them as barriers to medically necessary care.

**Pharmacy Coverage Decisions**

The exception to all this generality lies in pharmacy coverage policy, where most private health plans and government programs have Pharmacy and Therapeutics (P&T) Committees. While specific practice varies, these committees are populated by medical professionals from outside the organization who are contracted to serve on the committee, medical professionals from inside the organization and often, patient representatives as well.

The information considered by a P&T committee varies based on what information is available for consideration: information from the drug manufacturer, information from studies conducted by other parties, information about the disease-state burden of illness, and existing treatment options, for example. P&T Committees can recommend that a product must be covered, may be covered, or should not be covered.

When a positive coverage decision is made, then there is a decision as to whether there is a need for utilization controls for medically specific reasons related to patient risks. In other cases, if a product has many therapeutically similar competitors, coverage may depend on whether the health plan can negotiate satisfactory prices with pharmacies, and/or satisfactory rebates from the manufacturer. As with many matters surrounding coverage decisions, there can be differences of opinion about what should be considered therapeutically similar and if any clinically important differences have been fully taken into account.

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**Box 1: Pharmacy Benefit Managers**

Pharmacy Benefit Managers (PBMs), which contract with payers (health plans or self-funded employer plans) have their own coverage processes and can develop a formulary they recommend for any payer with which it contracts. However, payers often develop their own formularies and contract with a PBM to execute on their desired formulary. The PBM contracts with retail pharmacies to establish drug reimbursement and professional fee levels regardless of which formulary is used. The PBM often runs a mail-order business (or contracts for that), and negotiates with manufacturers for rebates on top of discounts it might extract from pharmacies and payments from the insurer. Express Scripts, a national PBM, made news in 2013 by announcing that there were 48 drugs that would not be covered under its recommended formulary beginning on January 1, 2014. From Express Scripts’ perspective, the drugs were generally among groups of therapeutically similar drugs so that consumer choice remains. Notably, Express Scripts’ decision also included medicines in what it described as “five specialty classes.” However, a more typical approach rather than exclusion is for the formulary to be designed to levy much higher consumer copays on some drugs in therapeutic groups in order to drive utilization to drugs in the group with a more favorable cost profile for the PBM (or other payer).

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In this case, the specialty society recommendations were among the last influencers and most of the plans in the study had made coverage decisions well before those recommendations were published.

Not all medical interventions undergo review and approval by the FDA. Pharmaceuticals and devices undergo the process but lab tests and surgical procedures generally do not undergo FDA review.
External Expertise

Other paths to coverage for a new health care item or service include outside external expertise. For example, over 98 percent of health plans in a 2008 survey indicated that they covered vaccines once the Advisory Committee on Immunization Practices (ACIP) made a recommendation for routine use of a vaccine. The vast majority of plans in the survey provided first dollar coverage of vaccines once they made the coverage decision (no deductible or other out-of-pocket costs). 2

This study shows that plans used ACIP as the basis of vaccine coverage policy and provided first dollar coverage two years before federal law required first dollar coverage of all ACIP routine-use recommendations.

Another example of external expert guidance is the U.S. Preventive Services Task Force (USPSTF), which reviews and rates the effectiveness of various clinical preventive services. In the past, health plans could use USPSTF recommendations as the basis for their coverage policies and doubtless many did so. Since the fall of 2010, health plans (and Medicare) have been required to cover, at first dollar, all clinical preventive services highly rated by the Task Force.

Another source of external guidance for health plan coverage decisions is specialty medical societies. Societies of medical specialists, such as cardiologists, endocrinologists, and radiologists, have processes in place to develop clinical treatment guidelines in their specific disease areas. Plans will often adopt those guidelines as their coverage policies or use guidelines as a basis for their own coverage even if slightly different. It is unclear how health plans keep up with evolving specialty society guidance about specific treatments. Some research indicates that health plans do not always keep pace so that coverage policy lags behind the science, creating difficulties and/or conflicts for treating physicians.

Similarly, health plans often follow Medicare coverage decisions. Typically the first level of Medicare coverage policy is the regional level, which can influence the decisions of commercial health plans in the region. It is only after a new intervention has been in use for some time, and where regional Medicare coverage decisions are not uniform, that Medicare coverage policy would be debated and then applied nationally. 3

Automatic Coverage

Some coverage policy occurs in an almost automatic manner. A new item or service receives a billing code and payments are made. Or the item or service becomes part of a bundle of services billed as a group and is covered in that manner. It is not clear how many new medical interventions are actually linked to coverage in this essentially laissez faire manner. While there is no ready research on this topic, it would appear that new interventions that achieve relatively automatic coverage have one or more important characteristics: low risk to the patient, infrequently occurring, or low cost on a per unit basis.

Cost Constraints

Despite overall agreement on the need to contain cost, patients, providers and the public do not want to see claims turned down. A recent study of consumer sentiment highlighted how consumers do not like to think about cost of care relative to their own medical needs and that they do not like it when doctors and health plans think about costs. 4 As a result, health plans have a difficult path to chart because they must simultaneously accomplish two seemingly incompatible goals—constrain costs to hold down premiums and satisfy customers by meeting their need for medically necessary care.

Some of the cost containment tools available to private sector health plans have become more limited as a result of the ACA. What was rational market behavior in the past is now not permitted.

The theory underpinning the ACA is that once everyone is required to have insurance and mechanisms exist to hold health plans financially harmless for enrolling high risk and sick individuals, then old business models can be banned.

The old business model sought to:

- Limit financial exposure by underwriting individuals based on their health status (charging premiums related to one’s health), and/or
- Avoid unhealthy people altogether, and/or
- Limit services covered to discourage enrollment of individuals who might need those services.

Instead, the ACA reorganized marketplace rules to move competition to a new place. The law:

- Instituted modified community rating across large geographies, limiting premium rates that insurance carriers may charge for older individuals,
- Required all people to obtain insurance,
- Prohibited insurers from turning people away,
- Stipulated the broad outline of the different services to be covered by each and every health plan—including
The new limitations on health plan practices have benefits for many consumers in the marketplace. At the same time, they prohibit practices that health insurance plans had employed to help control costs. As a result, there is a greater emphasis placed on strategies that are not constrained by the ACA, including nuanced coverage policy, provider network development, applying cost sharing within the broad parameters established by the act, and innovative benefit design. Each of these is discussed in more detail below.

**Nuanced Coverage Policy**

Nuanced coverage policy is when a health plan has the option to institute medically appropriate utilization management (UM) as a business consideration rather than simply as a medical imperative. Utilization management typically is prior authorization, step therapy, or linked services.

**Prior Authorization**

Prior authorization is a system of health plan pre-approval of a health care item or service. Hospitalization or surgeries might require pre-approval where the health plan might review the necessity of the hospitalization relative to other less costly alternatives or to review the treatment history and diagnosis. Health plans view prior authorization within the context of medically appropriate business decisions as seeking to ensure that lesser cost, lesser risk interventions have been tried and to ensure that the surgical intervention is the most appropriate option at a point in time. For example, if there is an expensive therapy for one condition that is also effective for a second condition for which there are many other treatments, the therapy may be prior authorized to ensure that it is only dispensed for the first diagnosis. There may be disagreements about what is medically appropriate for an individual patient in this situation.

**Step Therapy**

Step therapy may be a result of prior authorization. A health plan may require that a patient exhaust what it has determined to be less costly, less invasive, less risky treatment alternatives prior to receiving whatever therapy the health plan has put at the top of the staircase. Clinicians and patients may view step therapy as a barrier to clearly indicated care. One issue with step therapy arises when a patient has changed health plans and might have to undergo the treatment steps again as a result of the switch if the patient does not request an exception or is not successful in gaining an exception from the step therapy. In this case, new health plan is spending more than it should on already-tested alternatives.

**Linked Services**

Health plans may make coverage of one service contingent on utilization of another service such as case management, disease management, health education, or development of a comprehensive care plan that captures the full scope of care. The linked service is designed to improve the effectiveness of the underlying service so the two services are only covered in tandem.

**Box 2: How Grievance and Appeals Affect Coverage**

The ACA requires that states contract with Independent Review Organizations (IROs) to resolve consumer complaints that a health plan inappropriately denied coverage that was medically necessary. These organizations resolve individual complaints; their decisions do not affect overall coverage policy of the health plan regarding the service that was in dispute. The process by which an independent reviewer came to his or her conclusion is not public. Like health plans, these independent reviewers come to different conclusions about what services should be covered and how they should be covered. Although states have laws that require different levels of public reporting on grievances, the majority of states only report information such as counts of grievances and number resolved. With the exception of a few states, there is no systematic review of grievances brought to IROs that might reveal patterns of coverage policies that are problematic for patients.

**Provider Networks**

As of early 2014, it appears that health plans in some regions of the country are beginning to become more aggressive in their development of exclusive provider networks. In this process, health plans choose to contract with a limited number of providers in a geography and any providers without contracts are “out-of-network.” In the past, using an out-of-network provider meant that the patient had higher copays. Today, it can mean that the service is simply not covered—100 percent copay that does not count toward a deductible or out-of-pocket protective maximum. This non-covered status is appearing among plans in the newly reformed individual and small group market; federal regulations that guide those markets specifically permit 100 percent out-of-pocket costs for use of out-of-network services.
Health plans have their own metrics by which to select providers for their network. However, one metric is likely cost. Contracting providers may reduce their fees considerably in exchange for more patient volume which results from a smaller patient choice of network providers. Strict provider network rules are new to consumers. It may come as a surprise that otherwise well-known and well-regarded facilities are not included in the networks of major insurers.

It is not clear how the new emphasis on provider networks will play out in terms of public opinion, political opinion, and market performance. Already, the federal agency with oversight of Medicare and the reformed individual and small group insurance market has indicated that it will be closely monitoring “network adequacy” in the commercial and Medicare Advantage markets, as well as in the Medicare prescription drug program where provider network exclusivity has become an issue among pharmacies.

**Benefit Design**

**Increasingly, health plans are shifting costs to patients in the form of point of service copays or coinsurance (out of pocket costs) rather than have cost increases reflected directly in the premiums. This trend was well underway prior to implementation of the ACA, but has accelerated in recent years.**

Premiums are essentially shared costs between consumers and employers, or consumers and the government. When costs move to point of service, they are not shared with the employer/sponsor of the health plan, nor are they shared with government in Medicare or Medicaid or other government insurance/coverage programs. So payers save money when health care costs move to consumer out-of-pocket at the point of service, where the burden is heaviest on consumers who use more health services.

Tiering in the drug benefit, where the patient pays out-of-pocket costs in relation to the “tier” on which the drug is placed, is a common benefit design. Tiering moves cost to consumers and may steer them toward one treatment and away from another. Higher level tiers equal higher patient costs. Some tiers can result in coinsurance of up to 30 percent of the cost of the drug if the drug costs more than $600/month in the Medicare Part D prescription drug program. In many plans participating in Exchanges created by the ACA, specialty tier coinsurance is well above 30 percent. Tiering became common in the commercial market after it was used successfully in Medicare Part D. In addition to moving costs between plans and consumers and steering treatment choices, copay amounts may also affect the likelihood of initiating and remaining in treatment.

Tiering is now beginning to extend beyond the pharmacy benefit, to the medical benefit in commercial health coverage. Preferred providers cost patients less out of pocket while non-preferred providers (on a higher tier) cost patients more out of pocket. Some plans have multiple levels of provider tiers, in contrast to just “in-network” and “out of network.”

**Conclusion**

Health plan coverage decisions and processes are extremely complex. There are many factors that impact coverage decisions, including the type of health care item or service and the type of payer making the decision.

Not only is the topic complex, but coverage policy and processes are changing rapidly against a backdrop of rising health costs and additional market rules put in place by the ACA. The tension between cost containment, consumer satisfaction, and provider satisfaction will continue and grow. Provider networks and tiering could create issues relative to coverage and access to care if health plans are not alert. We are likely to continue to see “yes but” coverage with increasingly complex coverage rules that combine benefit design features, provider network rules, and linked services in new and innovative ways that will have implications for individual consumers or groups of consumers.

**By design, health plans have been put on the front line of cost containment in the U.S. By design, cost containment will become an unavoidable issue and coverage policy will be at the heart of the discussion about the issue.**

**Thus, patient advocates and consumers need to be aware of how coverage decisions are made and how coverage policy (tiering, copayments, etc.) affects access to clinical care. As new treatments are developed, advocates will need to understand the processes and environment in order to influence the**
outcomes and advocate for the most appropriate access to advances in medical care and treatments.

References:


Centers for Medicare and Medicaid Services, CCIIO. “Draft 2015 Letter to Issuers in the Federally-Facilitated Marketplaces.”


2 Hunsaker, J. et al.
4 Sommers, R. et al. “Focus Groups Highlight That Many Patients Object To Clinicians’ Focusing On Costs.”

Box 1:

“Formulary” is the term to describe the sum total of any particular pharmacy benefit within a health plan or a stand-alone PBM offering—all the drugs covered and how they are covered (e.g., patient costs, utilization controls).