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In or Out: An Examination of Medicaid's Coverage Determination Policies

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Manatt Health Solutions is the interdisciplinary policy and business advisory division of Manatt, Phelps & Phillips. Manatt Health Solutions provides expertise in health care coverage and access, health information technology, health care financing and reimbursement, and health care restructuring. For more information, visit www.manatt.com.

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About the Foundation

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Introduction

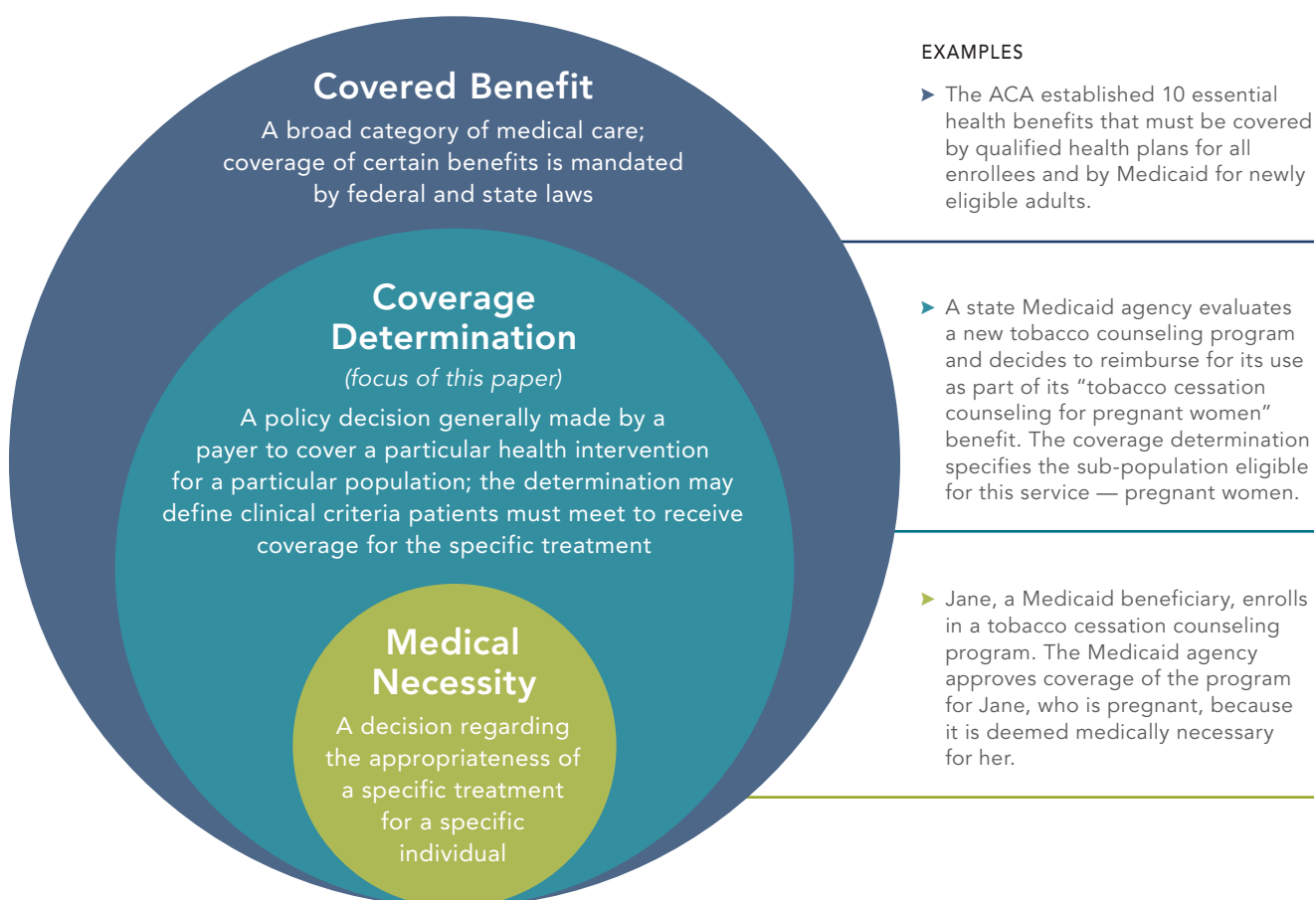
Medicaid, the joint federal and state program that provides health insurance for low-income individuals, is rapidly becoming the largest purchaser of health care services in the United States. Providing coverage for an estimated 70 million people (as of February 2015), at an annual cost exceeding \$460 billion, Medicaid now serves as the foundation of the new coverage continuum established by the Affordable Care Act (ACA).¹

Given Medicaid's size and scope, and the central role it plays in the health insurance market, information on how it determines which health care services and interventions to cover has significant implications, not only

for Medicaid enrollees but also for the entire health care system.

This report reviews how other large public health insurance programs in the US and abroad make coverage determinations with respect to specific interventions (e.g., procedures, therapies, technologies, and devices) within a covered benefit category (Figure 1). It highlights themes from research on and interviews with select state Medicaid agencies regarding their coverage determination processes and standards, including approaches to covering behavior change interventions. Finally, it discusses policies and procedures for achieving greater rigor and transparency in these important public health

Figure 1. The Layers of Health Coverage Decisions



Source: Data adapted from Alan M. Garber, Institute of Medicine, *Medical Necessity, Coverage Policy, and Evidence-Based Medicine: Determination of Essential Health Benefits*, 2011, www.iom.edu.

decisions. (State policies and procedures with respect to drug coverage are governed by specific provisions of federal law and were not reviewed for this report.)²

Background

Given Medicaid's expanded role in the health insurance market, the time is ripe for state Medicaid agencies to revisit, or to consider for the first time, the policies and procedures they use to decide whether and under what circumstances to cover new interventions.

Medicaid has been slow to adopt the kind of transparent and rigorous coverage review procedures that Medicare has long relied upon. When it was first enacted 50 years ago, Medicaid was an adjunct to the state welfare programs. It was not until 1996, under federal welfare reform, that Medicaid was delinked from welfare; in 2010 with the enactment of the ACA, Medicaid became the foundation of the new health insurance continuum.

Today, Medicaid is the first or second largest item in every state budget and the first or second largest insurer in state markets. Five years ago, Medicare dominated health care policy discussions of new payment and delivery models and value-based purchasing reforms. At that time, Medicaid was barely at the table, as it continued to rely on antiquated fee-for-service payment methodologies and limited managed care programs. In the old world of Medicaid, cost containment meant imposing arbitrary across-the-board rate cuts or cutting eligibility standards and benefits.³ Today, there is hardly a state that has not embraced new integrated delivery models and developed value-based purchasing strategies, ranging from shared savings to bundled payments, with the goal of purchasing cost-effective, quality care for Medicaid beneficiaries and driving multi-payer reforms.⁴

Smart coverage policies, ones that use defined processes and procedures to appropriately balance benefits and costs of new interventions, can and should be expected to follow Medicaid's transformation. Coverage determination policies go hand in hand with value-based purchasing in assuring that payers, such as Medicaid, purchase quality, cost-effective care. Here, too, Medicaid has lagged behind Medicare, but that is starting to change as Medicaid begins to exploit its potential and assume its responsibilities as a key player in the health insurance market.

"Coverage policy, in its broadest sense, is intended to promote value in medical care by using reimbursement to favor the use of effective care and avoid payment for ineffective care."

— Alan M. Garber
"Evidence-Based Coverage Policy"
Health Affairs (September 2001).

What Can We Learn from Other Major Payers?

State Medicaid agencies are not the only health care payers confronting the challenge of making coverage determinations. This challenge must also be addressed by Medicare, the federal health insurance program for people 65 years of age and older and for individuals with disabilities; the US Department of Veterans Affairs; commercial insurance carriers; and national health insurance programs in other countries.

Some programs create broad standards and allow local actors to make coverage determinations, such as Canada's Medicare program, while others, such as the US Medicare program and the UK's National Institute for Health and Care Excellence (NICE), have very specific processes and protocols in place to evaluate whether a treatment or service warrants coverage. These programs are summarized in Appendix A and their processes and standards are described in detail in Appendix B.

Commercial Insurance Carriers

Federal and state laws and regulations require that US health insurance carriers cover broad categories of benefits, such as preventive care or emergency services, but commercial carriers retain a high degree of discretion over specific coverage determinations. Commercial carriers generally provide only high level information on their coverage determination processes.

- ▶ Aetna creates medical clinical policy bulletins (CPBs), which detail the services and procedures it considers medically necessary, cosmetic, or experimental and unproven. These classifications are based on peer-reviewed medical journals, analyses of studies on a

topic, evidence-based consensus statements, expert opinions, and guidelines from nationally recognized health care organizations such as Milliman Care Guidelines.⁸

- UnitedHealthcare’s website notes that, “Medical Policies, Drug Policies and Coverage Determination Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making.”⁹

Public Programs

Some public programs, such as the US Medicare program, have detailed standards and processes for making coverage determinations. Codified in federal statutes and regulations, these policies are clearly defined and create opportunities for formal and informal public input for individual coverage determinations.

In contrast, similar to the discretion granted to Canadian provinces by the Canadian Medicare program, federal Medicaid law grants a significant amount of discretion to states, mandating only the categories of care a state must cover and permitting states to determine the specific interventions within those categories to cover.

Medicaid Covered Benefits: The Basics

Title XIX of the Social Security Act authorizes the federal government to provide matching funds to states to administer Medicaid programs and stipulates that, “Within broad federal rules, each state may decide eligible groups, types and range of services, payment levels for services, and administrative and operating procedures.”¹⁰

Federal rules require that states cover a broad range of benefits, but what qualifies as a covered service in each of these categories is left up to the states. Under these Medicaid coverage rules, mental health and substance use treatment services are optional benefits, and, with limited exceptions, the mental health parity law does not apply.

Medicaid Mandatory Benefits:

- Inpatient hospital services
- Outpatient hospital services
- Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services
- Nursing facility services
- Home health services
- Physician services
- Rural health clinic services
- Federally qualified health center services
- Laboratory and x-ray services
- Family planning services
- Nurse midwife services
- Certified pediatric and family nurse practitioner services
- Freestanding birth center services (when licensed or otherwise recognized by the state)
- Transportation to medical care
- Tobacco cessation counseling for pregnant women

Source: “Benefits,” Medicaid, www.medicaid.gov.

Newly Eligible Adults and the Alternative Benefit Plan

The ACA established different coverage rules for the Medicaid expansion adult group, which includes childless adults and parents above a state’s pre-2010 eligibility levels. These newly eligible adults must receive an Alternative Benefit Plan (ABP) which includes:

- All 10 essential health benefits (including mental health and substance use treatment services)
- Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services for those under 21 years of age
- Care provided by federally qualified health centers (FQHCs) and rural health centers (RHCs)
- Family planning services and supplies¹¹

In addition, ABPs must satisfy the Mental Health Parity and Addiction Equity Act (MHPAEA), which requires ABPs to cover mental health and substance use disorders at a level equal to that of medical and surgical benefits.¹²

Collectively, these are the minimum benefits that states must provide to the newly eligible adults through the ABP. Some states (e.g., New York and California) have chosen to provide the same benefits to the newly eligible adults that they provide to previously eligible populations, and accordingly have expanded their ABP to include benefits such as personal care.^{13,14}

Federal Medicaid law also dictates that services must be covered in sufficient amount, duration, and scope to reasonably achieve the purpose of that service, and allows states to place appropriate limits on a service based on criteria such as medical necessity.^{15,16}

While federal Medicaid law sets out coverage parameters for Medicaid enrollees, states have discretion to decide on the specific services to cover within a benefit category for both standard Medicaid and the ABP offered to newly eligible adults. In addition, Medicaid managed care plans can choose to cover interventions not covered by the state Medicaid program.¹⁷

Examples of health interventions that state Medicaid agencies are currently grappling with for coverage determination include genetic testing, sexual reassignment surgery for transgender individuals, and weight management programs for children. With technological advances, an increasing number of diagnostics and therapies are coming to market, putting pressure on states to establish transparent coverage determination processes and standards.

Medicaid Coverage Determination Standards and Processes

States have broad discretion to decide which particular health interventions to cover within each covered benefit category. There is no federal guidance as to the standards states should apply, the evidence they should consider, or the process they should follow in making these coverage determinations. Furthermore, there is no central repository of state coverage policies, nor were this report's authors able to locate any research collecting those policies. Thus, the authors began work on this paper by researching state-specific Medicaid coverage determination policies and procedures through interviews and online searches.

This review focuses on how states decide whether to cover a particular intervention and the standards and decisionmaking criteria used in making that determination. The paper does not consider how states determine whether a covered intervention is considered "medically necessary" for a specific individual. The authors found that many state Medicaid programs had published definitions of medical necessity, but only a handful of states posted coverage determination standards, policies, and procedures setting out the process to initiate a Medicaid coverage review, the evidence that would be evaluated, and/or the standard that would be applied in determining whether to cover an intervention.^{18,19}

The Standard for Decisionmaking

Federal statute requires that the US Medicare program cover items or services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."²⁰ And though the terms "reasonable" and "necessary" leave room for interpretation, Medicare has articulated this standard to guide its decisions on whether to cover health interventions. If policymakers decide that the items or services meet that standard, the program is expected to cover them.

With respect to Medicaid programs, Oregon was the only state found that has a clearly defined standard guiding its coverage determinations. If the service or line item is ranked above the legislature-approved funding line on the Prioritized List of Health Services, Oregon Medicaid will cover the service. (See sidebar at the top of page 7.) The state's Health Evidence Review Commission (HERC) applies a highly analytical methodology for developing the prioritized list, with explicit consideration of a service's magnitude of benefit to a patient, impact on pain and suffering, population effects, impact on vulnerable populations, ability to prevent complications, effectiveness, and cost.

When the New York Department of Health (DOH) redesigned its Medicaid program in 2011, it explicitly referenced cost and cost control as appropriate criteria for coverage determinations so that the state could "make the most efficient use possible of available resources and maximize the public good."²² DOH has articulated various biostatistical methodologies for assessing the impact of health services (e.g., calculation of odds ratio and number needed to treat, sensitivity and specificity for

Prioritizing Services Based on Population Health Impact in Oregon

Oregon's process for determining what services to cover under Medicaid is well documented and publicly accessible, includes opportunities for public input, and is driven by data on the clinical, cost, and comparative effectiveness of treatments. Oregon's Section 1115 waiver authorizes the state to limit covered services to those included on a prioritized list of "treatment and condition pairs." The Oregon Health Evidence Review Commission (HERC) issues this prioritized list, ranking treatment-condition pairs and establishing a funding line, below which it will not reimburse for services. The waiver specifically provides that HERC will rank the list according to "the comparative benefits of each service to the population to be served...[using] clinical effectiveness, cost of treatment and public values obtained through community meetings in ordering the list." The state uses an explicit scoring methodology, placing a higher emphasis on preventive services and chronic disease management than on curative services.²¹

diagnostic tests, hazard ratio to assess harm) and states that its coverage determinations are driven by a combination of the strength of the evidence and the size of the net impact on the population. (See sidebar below.)

While not a standard per se, New York's guiding principles help policymakers frame their decisions based on whether an intervention is well-substantiated and

New York State's Process for Determining Coverage²³

According to information published by the New York DOH, it will generally decline to cover interventions with any of the following criteria:

- ▶ Zero or negative net impact
- ▶ Very low "strength of the body of evidence"
- ▶ No evidence

An intervention will generally be covered when both of the following criteria are met:

- ▶ High "strength of the body of evidence"
- ▶ Substantial or moderate positive net impact

maximizes health outcomes for the Medicaid population, and they provide stakeholders and the public with an understanding of the criteria which will influence a coverage determination.

States reported that if a new service had the potential to be a budget buster, ranging in cost from \$500,000 to \$1 million or more, the decision to cover it would be determined by the health commissioner, the legislature, or the governor. For instance, California Medicaid officials noted that because its Medicaid population is so large, making a coverage determination could have a significant impact on the state's budget and therefore large-ticket items would need to be taken to the legislature for review.

Implicit in all of these examples is the standard of cost-effectiveness: Is the intervention under consideration effective for the Medicaid population and does the benefit to the population warrant the expense? Other than Oregon, the authors found that no states articulated an explicit threshold above which items would be covered. Notably, in Oregon, the threshold is driven by budget, not by a traditional cost-effectiveness measure (e.g., the Quality-Adjusted Life Years [QALY] threshold used by NICE in the UK).

Minnesota's Health Services Advisory Council

In Minnesota, the Health Services Advisory Council, a 13-member panel made up of physicians, other health care providers, and a consumer representative, provides leadership in designing health care benefit and coverage policies for Minnesota's public health care programs. Its charter explicitly discusses the use of cost-effectiveness to "guide decisionmaking" and outlines clear cost-effective standards, including covering interventions that are²⁴:

- ▶ At least as effective and less costly than alternatives
- ▶ More effective and more costly than alternatives, but resultant patient outcomes justify additional expenditure
- ▶ Less effective and less costly than alternatives, but resultant patient outcomes from the use of more expensive alternatives do not justify additional expenditures

Evidence of Effectiveness

States run a risk of wasteful spending if they do not adopt evidence-based coverage policies. Dr. Alan Garber, provost of Harvard University and professor of health care policy, explains: “Comprehensive assessment of evidence of effectiveness is the central activity of evidence based coverage policy. It draws upon formal methods for summarizing and integrating information, such as meta-analysis and decision analysis. It compiles and analyzes the evidence to determine whether an intervention improves outcomes.”²⁵

Similarly, in his discussion paper, “Evidence-Based Coverage,” Michael Bailit, president and founder of the consulting firm Bailit Health, posits that “somewhere between 25% and 50% of all US health care spending produces no benefit to the patient — and some of it produces clear harm....Payers should minimize, to the degree practical, the coverage of services without...evidence, or with evidence of effectiveness and benefit that is inferior to that of other treatment options.”²⁶

Many state representatives whom the authors interviewed referenced evidence of an intervention’s effectiveness as a key decisionmaking criterion and noted that they strive for the development of evidence-based coverage policies.²⁷ Few states, however, have systematic processes for accessing the data that quantifies effectiveness, or the resources or expertise to evaluate it. Medicaid officials cited small review teams and limited clinical expertise, particularly in the area of behavioral health, as constraints to conducting comprehensive evidence review.

Medicaid Evidence-Based Decisions Project

To address this challenge, 17 states are participating in the Medicaid Evidence-Based Decisions (MED) Project, a collaborative run by Oregon Health & Science University. MED provides analyses on the evidence for some health interventions pertinent to the Medicaid programs of participating states.

Member states may nominate topics for review, after which MED compiles and assesses the studies that analyze the intervention’s effectiveness, including systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines. MED uses the PICO framework for literature review, which identifies the following:

- ▶ Population of interest

The Medicaid Evidence-Based Decisions Project

Founded in 2006, the Medicaid Evidence-Based Decisions (MED) Project is a collaboration of 17 state agencies, housed at the Center for Evidence-based Policy at Oregon Health & Science University, which produces tools “to help state policymakers make the best, evidence-based decisions for improving health outcomes.”²⁸

MED currently includes Alabama, Alaska, Arkansas, Colorado, Louisiana, Michigan, Minnesota, Missouri, New York, North Carolina, Oklahoma, Oregon, Rhode Island, Tennessee, Texas, Washington, and West Virginia. The multi-state collaborative defines the project’s agenda by nominating and deciding on the topics MED should research. Topics reviewed recently include:

- ▶ Coronary computed tomographic angiography
- ▶ Elective induction of labor
- ▶ Treatment of obesity and overweight in adults, adolescents, and children
- ▶ Social support and community health interventions to prevent adverse birth outcomes
- ▶ Comparative effectiveness of treatments for macular degeneration

Reviews can take anywhere from two to eight months depending on the level of evidence required by the state and the availability of information.

- ▶ Intervention under consideration (e.g., dose, frequency, method of administration)
- ▶ Comparator(s), or alternatives against which the intervention is compared
- ▶ Outcome, or specific short- and long-term results of interest (e.g., morbidity, mortality, quality of life, complications, outcomes specific to the condition)

“MED is one of the most valuable investments we’ve made. . . it has probably saved the state millions.”

— state Medicaid official

MED synthesizes its evidence review findings in reports, highlighting the documented benefits and risks of the intervention, the sub-populations for whom the intervention is effective, and other relevant information about the intervention's impact and safety. MED also assigns a score of poor, moderate, or good to the quality of the available evidence.

After MED distributes its reports and analyses, it is up to each state to decide if and how it will use the information to make coverage determinations.

"States are sophisticated consumers of research. They understand that research evidence informs but doesn't dictate policy."

— Mark Gibson, director
Center for Evidence-Based Policy, OHSU

States and Implementation of Evidence-Based Coverage

New York established a process for evidence compilation and evaluation. The state also uses the PICO framework to guide the search for evidence regarding services under consideration for coverage. It has established a hierarchy of evidence based on the susceptibility of a type of evidence to bias. Systematic review of randomized controlled trials with or without meta-analysis are at the top of the hierarchy, single expert and case reports are at the bottom, with observational studies in the middle. After gathering evidence, the state engages in an appraisal process to assess the "methodological quality, risk of bias and applicability to the PICO and research questions."²⁹ Finally, the state grades the quality of the evidence, indicating the degree to which future research likely will or will not alter the estimate of effect. As a member of MED, New York leverages available MED reports in its review process.

In Oregon, HERC relies heavily on "high quality" evidence to help make decisions, relying on "medium or lower quality" evidence only when necessary.³⁰ HERC does not specifically define what "high quality" or "medium quality" means, but rather provides examples under each category. HERC's high-quality sources include MED, the Agency for Healthcare Research and Quality, the UK's NICE, and the Cochrane Database of Systematic Reviews. "Medium and lower quality sources" include

industry guidelines, commercial policies, and reports that are unpublished or not peer-reviewed.

Texas is currently developing its evidence-based coverage policy process and, as such, is compiling a list of core evidence sources, including the US Preventive Services Task Force (USPSTF), the Centers for Disease Control and Prevention, and MED, among others. These core sources are meant to ensure that internal reviewers reference reputable, high-quality sources of information when evaluating a new treatment or service for coverage.³¹

Few states have systemic processes by which they review the evidence base for new interventions. Likewise, it appears that states generally do not systematically review past coverage determinations or revise determinations for outdated, less effective services.

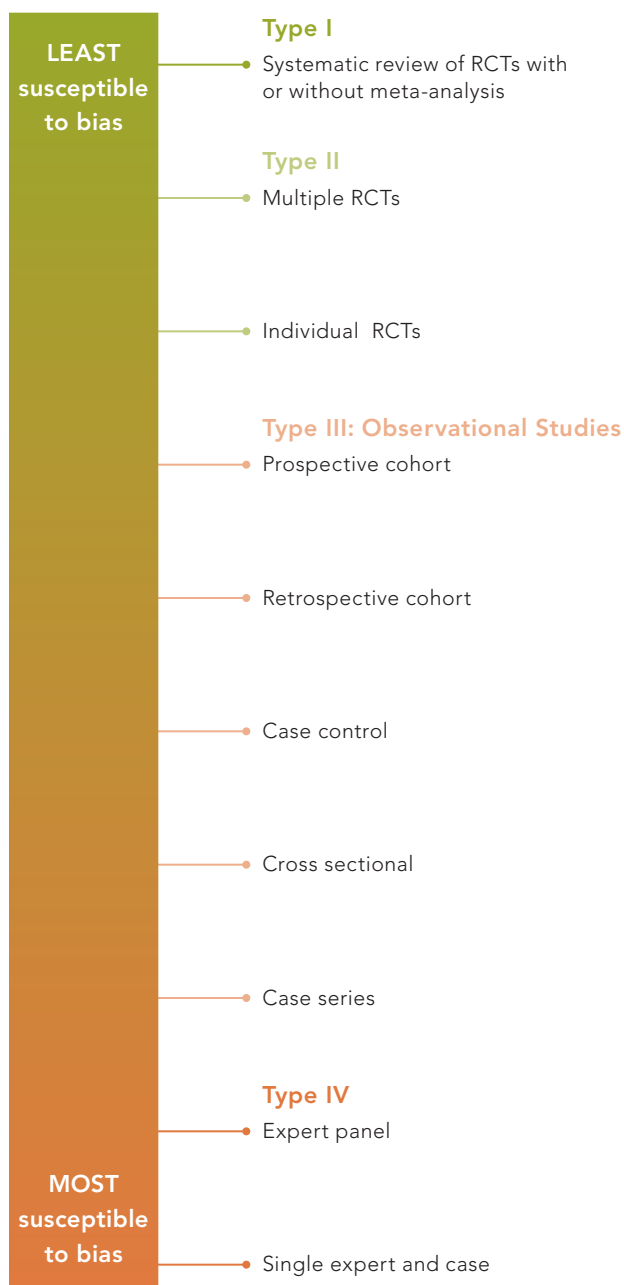
As part of its new benefit review process, New York has committed to reviewing "those services with high programmatic costs, high utilization, or new or emerging evidence" on a "regular and recurrent basis" as part of its redesigned benefits coverage determination process.³² Idaho cited an example in which their utilization management contractor identified an increased use of spinal surgeries. Idaho then reviewed the evidence and ultimately altered its coverage policies by using narrower clinical criteria to specify the eligible population, supported by evidence of effectiveness for that sub-population.³³ MED research may also help states identify covered treatments for which there is little evidence of effectiveness, as may organizations that undertake comparative effectiveness reviews like the Patient Center Outcomes Research Institute (PCORI), created by the ACA in 2010, and the New England Comparative Effectiveness Public Advisory Council (CEPAC).³⁴

The Process: Reviewing New Interventions

Historically, as New York noted in adopting its Evidence-Based Review Process for Coverage Determinations, few states have established processes for reviewing new interventions. However, this is beginning to change.

In 2013, New York adopted a dossier requirement — a systematic intake process enabling stakeholders to submit requests for a coverage determination. The dossier process requires the submission of information on clinical evidence, outcomes, impacts of the service on the

Figure 2. The New York DOH Evidence-based Review Process's Hierarchy of Evidence



Note: RCTs are randomized controlled trials.

Source: Data from "Evidence-based Review Process for Coverage Determinations: Dossier Methods Guidance," New York Department of Health, last modified November 2013, www.health.ny.gov.

target population, costs, and any coverage of the service by other payers. Alabama has implemented a similar process.³⁵ After years of being inundated with requests from vendors and manufacturers, Texas is developing a topic referral form to gather information about clinical evidence, outcomes, population impact, costs, other payers who cover the service, and supporting publications that demonstrate evidence of effectiveness.³⁶

These intake processes help the Medicaid agency gather available evidence, assess the intervention's potential benefit to the Medicaid population, and understand its cost. One state reported that, after instituting the dossier process, it saw a noticeable drop in the number of review requests that were not well supported.

States that have a review process require its use by an individual or entity requesting coverage for a new service including manufacturers, providers, patients, and advocacy groups. For states without this process, stakeholders can directly contact Medicaid agency officials. California officials reported a willingness to speak to anyone interested in raising a health intervention for coverage consideration.³⁷

Medicaid agencies themselves may also initiate coverage reviews. Oregon's HERC reviews the new Current Procedural Terminology (CPT) codes released annually to determine whether they should be covered.³⁸ In addition, Texas is developing an analytics system to rapidly identify services for coverage determinations. The system will, among other things, look for major swings in use, such as a spike in the use of "miscellaneous" billing

"The topic referral form is just one way in the door, a vendor could always go directly to the Legislature."

— Texas Medicaid official

codes, the decrease in use of old billing codes, or both. These analyses may trigger an initial review or a review of a past coverage determination, respectively.

Though vendors and providers were cited as the most common external sources for coverage requests, governors and state legislators also initiate coverage determination reviews, albeit to a much lesser degree.

A Unique Model: A Review Process Driven by the California Legislature

In 2002, legislation authorized the creation of The California Health Benefits Review Program (CHBRP) within the University of California's Office of the President.³⁹ CHBRP responds to requests from the state legislature to provide independent analyses of the medical, financial, and public health impacts of proposed legislation regarding health insurance benefit mandates and repeals, specifically legislation that requires (or repeals the requirement) that a health insurer and/or health care service plan do one of the following:

- ▶ Permit an enrollee to obtain health care treatment or services from a particular type of health care provider
- ▶ Offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition
- ▶ Offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service

At the conclusion of its review, CHBRP prepares a written report reviewing relevant data on the legislation's public health, medical, and financial impacts, as defined in CHBRP's authorizing statute. The program is funded through a small annual assessment of health plans and insurers in California. It was set to sunset on December 31, 2015, but was recently reauthorized to continue operating through June 2017.⁴⁰

As a result of this broad mandate, CHBRP's analyses span both legislation regarding covered benefits (broad categories of health benefits) and coverage determinations (specific services within a covered benefit category). A review of 2014 and 2015 analyses, however, found that, in practice, CHBRP's reports tend to focus more on the latter, likely because proposed legislation focuses more closely on coverage determinations than on covered benefits.⁴¹

Opportunity for Public Comment

Once a review has been initiated, the opportunity for public input and participation in the coverage determination process varies greatly by state. In Oregon, HERC holds public meetings at least once a month, frequently incorporates time for public comment into these meetings, and accepts written and oral testimony from the public during the public comment period.⁴² In New York, after the Department of Health reviews a dossier submission, it offers a 30-day period to the general public during which additional sources of evidence may be submitted.⁴³ Idaho indicated that public input is not formally collected on most coverage determinations unless the decision requires administrative rule changes or submission of an amendment to the state's Medicaid State Plan.⁴⁴

Behavior Change Interventions

At the outset of this research, the authors sought to focus on the policies and procedures states used in deciding whether to cover interventions intended to advance healthy behaviors. However, as described below, while such interventions present different challenges, states do not evaluate behavior change interventions differently from medical interventions.

Behavior change intervention. An intervention aimed at changing an individual's behavior to prevent that person from acquiring a chronic condition or continuing a harmful behavior, or to mitigate the effects of harmful behaviors or medical conditions.

Whereas, in the past, medical innovation was driven largely by new surgical procedures and new medications, today, behavior change interventions are on the rise. These interventions take many forms and may include: rapid interventions or screenings to assess substance use disorder risk and connect at-risk people with resources, such as the Screening, Brief Intervention, and Referral to Treatment (SBIRT) program; high-touch care models, such as repeated interactions with a nurse through the Nurse-Family Partnership (NFP) program; or virtual interventions, such as a technology application aimed at helping people to quit smoking.

The emergence of these behavior change models of care are being driven by a variety of factors, including:

- ▶ **The increase of incentives to focus on prevention instead of treatment**, resulting from the shift from fee-for-service reimbursement to a value-based system, promoted by the ACA and commercial insurers alike
- ▶ **The growing burden of chronic conditions**, such as diabetes, for which there is no cure, and for which behavioral modifications can greatly reduce the risk of complications or the onset of the disease
- ▶ **The recognition of the role of social determinants of health**, leading to an increasing acknowledgment that health interventions must address a patient's socio-economic environment to be effective and have a sustained impact
- ▶ **The increasing coverage of behavioral health services**, including the mental health parity requirement, for Medicaid's newly eligible populations and Qualified Health Plan enrollees
- ▶ **Advances in technology** that have made it easier to expand the reach of health care from the doctor's office to the patients' homes, phones, and computers

Evaluating whether to cover a behavior change intervention presents certain challenges, including:

- ▶ **Effectiveness is hard to ascertain.** Programs that are behavioral in nature are often community-based, which makes it difficult to control confounding factors that, in randomized controlled trials, can be isolated and managed.
- ▶ **Adherence to protocol is difficult to ensure.** Even if an intervention proves effective in a study setting, effectively deploying it to a population of patients presents its own set of challenges. By their very nature, the success of behavior change programs are dependent upon human interactions and repeated behaviors as opposed to biological or chemical processes (e.g., medications) or one-time interventions (e.g., surgery). As a result of their interpersonal and longitudinal nature, it is difficult to ensure that behavioral change interventions are implemented according to protocol.
- ▶ **Provider reimbursement and oversight is challenging.** Behavior change interventions may be provided by unlicensed providers, such as peer support

specialists (for instance, individuals who have recovered from substance use disorders or other mental or behavioral health issues) rather than traditional licensed providers. For these programs, Medicaid agencies must grapple with ensuring appropriate regulation of providers and establishing reimbursement mechanisms for them.

"The process for considering a behavioral health intervention for coverage is the same as for other services, but behavioral health and preventive care services always seem to have many more layers to consider."

— Texas Medicaid official

In discussions with officials about how and why their state decided to cover SBIRT and NFP, it became clear that emerging behavior change interventions must have both a strong evidence base and a strong advocacy community to secure coverage.

When asked whether they would consider coverage for virtual coaching programs focused on weight management and diabetes prevention (e.g., Omada Health's Prevent Program), most state officials responded that if there was strong evidence of the program's success, they would consider covering the service.⁴⁹ Certainly the path to coverage of interventions like SBIRT and NFP suggests that Medicaid programs are receptive; compelling evidence and focused advocacy are key. It is also likely that as some states decide to cover these benefits and demonstrate positive impact for their population, other states will follow suit.

As opposed to surgical interventions and drugs, for which there are manufacturers who stand to benefit financially, behavior change programs are more reliant upon governmental agencies, nonprofits, and providers — all of whom likely have fewer resources than industry to invest in conducting effectiveness studies — to demonstrate effectiveness and advocate for coverage.

By offering incentives to cover certain services, the federal government serves as an effective advocate for new programs that promote behavior change and preventive health care. For example, the ACA established that any

Case Studies:

SBIRT and NFP Behavior Change Programs

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is an evidence-based practice used to identify, reduce, and prevent problematic use, abuse, and dependence on alcohol and illicit drugs. When asked why they decided to cover SBIRT, states mentioned that the program is backed by strong evidence of its effectiveness — SBIRT can result in health care cost savings that range from \$3.81 to \$5.60 for each \$1.00 spent — and a strong advocacy campaign, supported by the federal government's Substance Abuse and Mental Health Services Administration.⁴⁵ Currently, SBIRT is covered by Medicaid in 16 states.⁴⁶ Some states, such as Texas, only cover SBIRT for specific subpopulations, such as people under 18, and are debating whether to expand the program. Oregon covers SBIRT for all Medicaid beneficiaries and selected it as an explicit quality measure for its Coordinated Care Organizations (the state's Medicaid Managed Care program).

The Nurse-Family Partnership (NFP) is a community-based intervention of ongoing home visits from registered nurses to low-income, first-time mothers to provide the care and support they need to have a healthy pregnancy, provide responsible and competent care for their children, and become more economically self-sufficient. NFP implementing agencies exist in 43 states, the US Virgin Islands, and six Tribal communities. Although there is no comprehensive coverage category for preventive nursing home visits in Medicaid, NFP agencies are able to access some form of Medicaid reimbursement in 21 of the 43 states.⁴⁷ NFP produced a number of controlled trials and published results detailing the impact of its program, including improved prenatal health, fewer childhood injuries, fewer subsequent pregnancies, increased intervals between births, increased maternal employment, and improved school readiness.⁴⁸

state could receive a one point increase in their Federal Medical Assistance Percentage (FMAP) for all expenditures related to clinical preventive services and adult vaccines provided they covered all preventive services receiving a grade of A or B from the USPSTF and all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).⁵⁰ State Medicaid officials

from Colorado noted that the 1% FMAP increase influenced their decision to cover all grade A and B USPSTF services.⁵¹

Going Forward

Historically, state decisions to cover new interventions were made informally, often triggered by a vendor, consumer, or provider, at times with the backing of one or more elected officials. The review process was likewise informal, with no written procedures or review standards. This is all changing with the growing role of Medicaid in the health insurance market and states' value-based purchasing goals. In addition, smart coverage determinations, ones that have defined processes and procedures that balance benefits and costs of new interventions, are central to Medicaid effectively managing its resources.

There are several core features that states may want to consider incorporating into their coverage determination policies:

- ▶ **A defined process by which third parties may initiate a coverage review.** Alabama and New York have recently implemented a dossier process, and Texas is planning on implementing a similar process, which includes, among other elements, a requirement that the third party provide evidence of the effectiveness of the new intervention. This intake process helps the Medicaid agency gather available evidence, assess the intervention's potential benefit to the Medicaid population, and understand its cost. A formal process for public input into the coverage review is an additional mechanism to ensure that the state has access to complete information before making a coverage determination.
- ▶ **A systematic approach to securing and evaluating evidence of the effectiveness and value of the new intervention.** A handful of states are strengthening their use and scrutiny of clinical evidence regarding the effectiveness of new interventions for the Medicaid population. Those states are explicitly defining the sources and standards of evidence that must be incorporated in their review processes.
- ▶ **A systematic evaluation of high-cost, high-utilization services.** Not surprisingly, most states focus their coverage determination resources on new interventions. However, conducting systematic

reviews of highly used, high-cost services and refining the indications for their use based on evidence of effectiveness can help states curb wasteful spending. Reviewing comparative effectiveness studies can also help align coverage policies with promoting the most efficacious interventions. Organizations like PCORI, CEPAC, and MED can make this task easier for states.

- **A defined standard by which the state will evaluate whether to cover the intervention.** Many states have an implicit cost-effectiveness standard, weighing the benefits of the intervention against its costs. States will be well served by developing, refining, and systematizing their approaches to cost-benefit analysis and developing more explicit standards by which to make decisions.

Finally, while behavior change interventions may not be backed by the same quality of evidence as new drugs or surgeries (for which it is easier to conduct randomized controlled trials, and for which there is typically a vendor who stands to gain financially by demonstrating effectiveness), they represent important opportunities to drive intervention upstream and prevent costly downstream health care interventions, such as diabetes treatment for people with obesity or emergency room visits for people with substance use issues. Review of such interventions will require additional attention and clinical expertise from states.

As part of their delivery system reform efforts, states should consider piloting promising behavior-change interventions, possibly in partnership with Medicaid Managed Care plans, as a way to build up the evidence base for those interventions. While there may not be a vendor or provider with a large financial interest in demonstrating the effectiveness of these interventions, state Medicaid agencies, as major payers of costly health care services, do have an interest.⁵²

Managed care plans have the flexibility to test new and innovative interventions. To encourage plans to do so, state officials noted the importance of ensuring that the plans, as well as the Medicaid program, share in any savings that accrue from these innovations.

By refining their coverage determination standards and processes, state Medicaid agencies are in a position to promote the adoption of effective new health interventions and prevent wasteful spending on ineffective interventions. Many states are embracing this responsibility by enhancing the analytic rigor and transparency with which they make coverage determinations, thus providing strong examples from which others can learn.

Appendix A. Public Payer Coverage: Decision Standards and Processes

PUBLIC PROGRAM	COVERED POPULATION	STANDARD OR GUIDANCE FOR COVERED SERVICES	COVERAGE DETERMINATION PROCESS FOR SPECIFIC SERVICES AND TREATMENTS	HIGHLIGHTS
US Medicare	Individuals 65+ and those with certain disabilities	Covers items or services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,” within the categories of covered benefits: ⁵ <ul style="list-style-type: none"> ▶ Hospital services ▶ Ambulatory services ▶ Prescription drugs 	Uses National Coverage Determination (NCD) and Local Coverage Determination (LCD) Processes to allow program officials to: <ul style="list-style-type: none"> ▶ Review existing evidence of an intervention’s impact ▶ Assess whether the intervention meets the “reasonable and necessary” standard ▶ Determine whether it meets that standard for the entire Medicare population or for a sub-population that meets certain clinical requirements 	<ul style="list-style-type: none"> ▶ Defined formal submission and review process ▶ Rigorous review of clinical evidence and consultation with subject matter experts as needed ▶ Public comment period, enabling a degree of transparency and public input into the decision-making process ▶ Defined timeline for reaching a decision
US Department of Veterans Affairs (VA)	Veterans	Provides basic and preventive care to individuals “only if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice.” ⁶	Relies on the judgment of the treating health care professional(s) regarding the standard of care and potential impact for the given patient.	<ul style="list-style-type: none"> ▶ Definition of the criteria “to promote, preserve, and restore” health ▶ Reliance on judgment of the treating health care professional(s)
The United Kingdom’s National Health Service (NHS)	All United Kingdom residents	Requires that the Secretary of State provide, “to such extent as he considers necessary”: ⁷ <ul style="list-style-type: none"> ▶ Hospital accommodation ▶ Medical, dental, ophthalmic, nursing, and ambulance services ▶ Care for pregnant women, women who are breastfeeding, and young children ▶ “Such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service” ▶ Any other service required for the “diagnosis and treatment of illness” 	The UK’s National Institute for Health and Care Excellence (NICE) makes recommendations to the NHS regarding medicines, medical devices, diagnostic techniques, surgical procedures, and health promotion activities, using both clinical evidence review and cost-effectiveness analysis.	<ul style="list-style-type: none"> ▶ Defined review process incorporates both clinical evidence and cost effectiveness ▶ Incremental Cost-Effectiveness Ratio, which looks at the cost per Quality-Adjusted Life Year gained, is used to help guide coverage recommendations
Canada’s Medicare	All legal residents of Canada	Provides block grants to provinces, allowing them to make coverage determinations within general guidelines and requirements.	Delegated to the provinces	<ul style="list-style-type: none"> ▶ Coverage determination processes vary by province

Source: Compiled by Manatt Health.

Appendix B. Public Payer Coverage Standards and Determination Processes

US Medicare: “Reasonable and Necessary”

Medicare is the largest single purchaser of health care in the US, spending \$58 billion on direct patient care in 2012.⁵³ It provides health benefits for people ages 65 and over and people with disabilities. Federal statute requires that Medicare cover items or services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”⁵⁴ There has never been a regulation clarifying the definition of “reasonable and necessary.” Medicare covers the following broad categories of services:

- ▶ Part A: Hospital Services
- ▶ Part B: Outpatient Services
- ▶ Part C (“Medicare Advantage”): Includes at a minimum all the items and services available under Part A and Part B to individuals enrolled in a Medicare Advantage plan
- ▶ Part D: Prescription drugs

Medicare has a National Coverage Determination (NCD) process that applies to services for the entire Medicare population regardless of geography. It also has a Local Coverage Determination (LCD) process, which applies to Medicare populations within a sub-region of the country. As of August 2013, about 15% of active Medicare coverage determinations were made at the national level through the NCD process, while 85% were made at the local level.⁵⁵

The NCD process begins with a formal request, which comes either internally from the Centers for Medicare & Medicaid Services (CMS) or externally from the public. Medicare may initiate the NCD internally, under a number of circumstances, including:

- ▶ When members of the public have raised “significant questions about the health outcomes attributable to the use of the items or services for the Medicare beneficiary population,” prompting Medicare to evaluate the service,
- ▶ New evidence arises,
- ▶ Local coverage policies on a particular item or service vary in language or implementation, or

- ▶ If the new item or service is a substantial clinical advance and likely to result in significantly improved health outcomes.

A formal NCD request must, amongst other things, “clearly identify the statutorily-defined benefit category the requestor believes the benefit belongs in, be accompanied by sufficient, supporting evidence, and address relevance, usefulness, or medical benefits of the item or service to the Medicare population.”⁵⁶ Note that by statute, Medicare is not permitted to consider cost.

External requests to initiate the NCD review process must be made by formal request, but federal rules emphasize the importance of informal discussions with CMS prior to filing a formal request to avoid unnecessary delays. A formal NCD request must include all of the following elements:⁵⁷

- ▶ Be submitted in writing (email or hard copy)
- ▶ Clearly identify the statutorily-defined benefit category the requestor believes the benefit belongs in,
- ▶ Be accompanied by sufficient supporting evidence
- ▶ Provide relevance, usefulness, or medical benefits of the item or service to the Medicare population
- ▶ Fully explain the design, purpose, and method of using the item or service

Once CMS opens the review process, it publishes a tracking sheet on its website to provide public notice and usually opens a 30-day public comment period. CMS then begins a formal evidence review process and issues a proposed decision within six months of the beginning of the NCD review. Reviews can take up to nine months if a technology assessment or meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) is needed.⁵⁸

CMS may refer a topic to the MEDCAC when CMS would like independent expert advice in making decisions or to address broad, significant issues relevant to coverage determinations. “MEDCAC has provided expertise

and input to help CMS consider the appropriateness of a framework for the evaluation of diagnostic tests; in assessing the strength of the evidence for multi-factorial, non-invasive, “lifestyle” modifying interventions to treat cardiac disease; or in clarifying what constitutes the standard of care in wound therapy. CMS may also make use of the MEDCAC for horizon scanning to help identify developing technologies that may be appropriate for Medicare coverage.” CMS will refer a matter to the MEDCAC when there is not enough available evidence, when available evidence is inconclusive, or if CMS believes the NCD process would be better informed by a broader deliberation that includes patient advocates.⁵⁹

Within six to nine months, and after a rigorous review of the evidence, Medicare will issue a final determination: either to issue an NCD and cover the benefit, to issue a non-coverage NCD, to issue an NCD with limitations, or to issue a decision that no NCD is required. NCDs with and without limitations, and non-NCDs apply to the entire Medicare population. After a decision is issued, there is another 30-day comment period, followed by a final NCD and decision memorandum no later than 60 days after the end of the comment period.

If no NCD is required, local Medicare Administrative Contractors (MAC), of which there are 12 for the entire country, are then granted authority to make the coverage determination, known as a local coverage determination (LCD).⁶⁰ The LCD process is similar to the NCD process, but decisions apply only to states covered by the jurisdiction of the local MAC in question. As a result, there is some regional variation as to which services Medicare covers.

While the NCD process requires a rigorous review of evidence and is intended to be evidence-driven and politically neutral, some suggest there have been instances when it has been influenced by interest groups, leading to coverage of services with no proven health benefit.⁶¹

One study found that coverage determinations between 2008-2012 were 20 times less likely to be positive than those made in 1999-2002.⁶² Other studies have looked more closely at evidence-based medicine⁶³ and coverage determination in Medicare as well as the variation in local coverage determinations.⁶⁴

US Department of Veterans Affairs: Well-Defined Standards

Federal regulations that govern medical benefits packages for veterans specify the hospital, outpatient, and extended care services that constitute the “medical benefits package.”⁶⁵ The regulations note that the package of basic and preventive care “will be provided to individuals only if it is determined by appropriate health-care professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice.”⁶⁶ Determination of necessary care is based on the following definitions:

- ▶ **Promote health.** Enhance the quality of life or daily functional level of the veteran, identify a predisposition for development of a condition or early onset of disease which can be partly or totally ameliorated by monitoring or early diagnosis and treatment, and prevent future disease
- ▶ **Preserve health.** Maintain the current quality of life or daily functional level of the veteran, prevent the progression of disease, cure disease, or extend life span.
- ▶ **Restore health.** Restore the quality of life or daily functional level that has been lost due to illness or injury

A key strength of the VA’s coverage guidance is that it defines a standard by which to assess whether an item or service should be covered.

Canada’s Medicare

Canada’s single payer system, known as Medicare, makes coverage determinations in much the same way that the Medicaid system of the US does in that the national program delegates to the provinces the authority to make coverage determinations. Specifically, the Canadian government gives block grant money to individual provinces and territories and requires that they cover very broad categories of health services and hospital services while leaving the details of the specific treatments up to the individual provinces and territories. Provinces also have the discretion to cover additional services, such as the country’s national prescription drug program, ambulance services, and optometric services, and they may choose to cover them fully or partially.⁶⁷

The UK's National Health Service: A Focus on Cost-Effectiveness

The National Institute for Health and Care Excellence (NICE) was established in 1999 by the National Health Service (NHS) to evaluate drugs and other treatments. NICE is charged with making recommendations and “technology appraisals” on medicines, medical devices, diagnostic techniques, surgical procedures, and health promotion activities. Recommendations are based both on clinical evidence and on a cost effectiveness analysis (CEA).⁶⁸ These recommendations drive coverage determinations by NHS, but NICE guidance is not mandatory.

NICE does not have a rigid CEA requirement, but in general believes those interventions with an Incremental Cost-Effectiveness Ratio (ICER) of less than £20,000 per Quality-Adjusted Life Years gained are considered to be cost effective. Interventions with an ICER above £20,000 necessitate more careful consideration, and those above £30,000 would require a very strong case for inclusion in coverage.⁶⁹

Topics for an appraisal are generally identified by the National Institute for Health Research Horizon Scanning Centre at the University of Birmingham, and can be brought to the Institute's attention by the public. In addition, companies can suggest technologies for consideration through UKPharmaScan.

The national process as a whole is strengthened by the incorporation of both clinical evidence and cost effectiveness criteria in the coverage recommendation process.

Endnotes

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