

## FOCUS ON:

## Market Access &amp; HTA

## The Role of HTAs in U.S. Payers' Medical Policy Making

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### Introduction

Technology assessment in health care is a multidisciplinary field of policy analysis. It encompasses the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.<sup>1</sup> Given this comprehensive definition, the importance of, and

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the interest in, health technology assessment (HTA) is relevant throughout the world; however,

the extent to which decision-makers rely on HTA to make coverage and reimbursement decisions varies from country to country. An example is U.S. payers' view of HTAs for medical policy making which is substantially different from that of ex-U.S. reimbursement and market access authorities.

### Leading U.S. HTA Bodies

In the U.S., both government-funded and private entities generate HTAs. The major government-sponsored HTAs with national application are generated by:

- *The Agency for Healthcare Research and Quality (AHRQ)*, is the lead federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. As one of 12 agencies within the Department of Health and Human Services, AHRQ supports health services research that will improve the quality of health care and promote evidence-based decision-making.<sup>2</sup>

- *The Centers for Medicare and Medicaid Services (CMS)*, the federal agency that administers health care benefits for 46 million Medicare beneficiaries, which includes the elderly (ages 65 and older), the disabled, and those with end-stage renal disease (ESRD). CMS also coordinates the state-administered Medicaid program that covers nearly 60 million low-income recipients.<sup>3</sup> CMS defines its mission as follows: "To ensure effective, up-to-date health care coverage and to promote quality care for beneficiaries."<sup>4</sup>

Private companies responsible for generating HTAs in the U.S. include:

- *ECRI Institute*, an independent nonprofit organization whose mission is to benefit patient care by promoting the highest standards of safety, quality, and cost-effectiveness in health care.<sup>5</sup>
- *Hayes, Inc.*, an independent health technology research and consulting company dedicated to promoting better health outcomes. Hayes performs unbiased, evidence-based health care technology assessments of the safety and efficacy of new, emerging, and controversial health technologies and evaluates the impact of these technologies on health care quality, utilization, and cost.<sup>6</sup>
- *Blue Cross and Blue Shield Technology Evaluation Center (BCBSA TEC)*, which defines its mission as follows: "...to provide healthcare decision makers with timely, objective and scientifically rigorous assessments that synthesize the available evidence on the diagnosis, treatment, management and prevention of disease."<sup>7</sup>

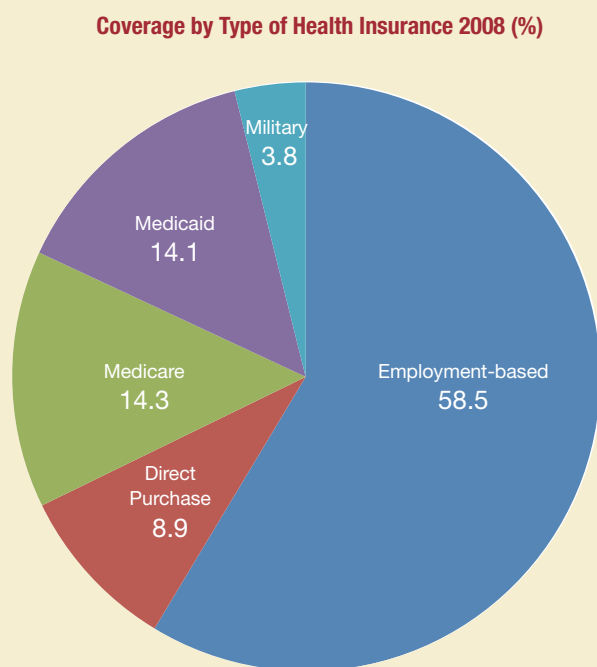
The evidence-based research reports generated by both government and private entities are accessible to U.S. payers through public access or on a paid or subscription basis.

With the exception of HTAs generated by CMS that result in National Coverage Determinations

(NCD), all other HTAs are evidence-based opinions that payers may apply as needed to their covered populations. CMS's NCDs are binding upon all Medicare contractors for the Medicare populations they serve, but are not applicable to other populations unless adopted by other government or private payers.

Large payers, such as Kaiser and WellPoint, generate their own HTAs. There are also state-based initiatives, such as the Oregon Drug Effectiveness Review Project (DERP), which provides evidence reports about pharmaceuticals to policy makers within state Medicaid programs and other entities.<sup>8</sup>

**Figure 1. U.S. Payer Mix in 2008<sup>9</sup>**



### Application in Medical Policy Making

Nearly 60 percent of the U.S. population is covered by private insurance (Figure 1); however, coverage is provided by hundreds of private companies, resulting in minimal uniformity across plans. This fragmentation is due to a large extent to private payers (e.g., Aetna, BCBS) administering the benefits for employers who provide health insurance coverage to their employees. Within those insurance plans, the companies offer a myriad of benefit arrangements with covered and non-covered benefits defined in the contracted policy benefit

manuals. There can be as many variations in benefit plans and structures as there are employers in the U.S., with benefits varying even within a single plan.

This diversity among privately-insured individuals causes Medicare to be the largest single payer in the U.S. Even with Medicare, however, if there is no national coverage determination for a particular health care intervention, local Medicare contractors may each create their own local coverage determinations (LCD).

Given this fragmentation, it is not surprising that there is no one or two HTA bodies that provide the “gold standard” for coverage and non-coverage decisions in the U.S.

### One HTA to Rule Them All?

To determine how a particular payer covers a product or service in the U.S., one must access the payer’s documentation for coverage. For example, many U.S. payers use formularies—lists of covered drugs—to manage coverage of oral and/or self-administered injectable drugs under the prescription drug benefit. Formularies are often publicly accessible and will indicate whether a drug is covered or not; and if covered, whether it is “preferred” or “non-preferred” by the plan. These designations do not reference HTAs.

HTAs may be visible for physician-administered drugs and procedures, covered under a payer’s medical benefit, within medical coverage policies describing the conditions of coverage for the particular medical intervention. Medical policies describe the indications for coverage, whether the intervention is considered first-line or should appear later in the treatment plan, and may specify the site of care in which the service or product is covered. Depending on the comprehensiveness of the medical policy, HTAs may have been reviewed and referenced. It is not unusual for a medical policy to describe an intervention as “covered” yet include language in a “background” section such as the following (identifiers redacted):

- *At least a dozen systematic evidence reviews produced by independent organizations*

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*have questioned the quality of the evidence supporting the use of \_\_\_\_\_, including systematic evidence reviews published by the Cochrane Collaboration, Washington State Department of Labor and Industries, Canadian Coordinating Office for Health Technology Assessment, Australian Safety and Efficacy Register of New Interventional Procedures—Surgical, NHS Quality Improvement Scotland, Centre for Clinical Effectiveness, Agency for Healthcare Research and Quality, Technology Assessment Unit of McGill University Health Centre, Institute for Quality and Efficiency in Health Care (IQWiG), Ontario Ministry of Health and Long-Term Care, and Clinical Evidence.*

Therefore, U.S. payers may reference HTAs for global support of coverage decisions but there is no one HTA that acts as the gold standard.

### Potential for Future Application

While some payers review HTAs generated by international decision-making bodies,<sup>10</sup> this practice is not currently widespread. For the U.S., other influences, such as that resulting from recent health care reform legislation, will further enhance the importance of HTAs in decision-making. Two of these to watch as they develop are:

- **Comparative Effectiveness Research (CER)**—To help identify which health care services work best, Congress, in the American Recovery and Reinvestment Act (ARRA) of 2009, appropriated \$1.1 billion to provide strong federal support of CER. This provision in the law reflected the legislators’ belief that better decisions about the use of health care resources could improve the public’s health and reduce the costs of care. According to the legislation, CER covers “research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions.”<sup>11</sup>
- **Coverage with Evidence Development (CED)**—CMS has provided coverage for health care interventions that are being

researched in clinical trials through the CED process. CMS states, “The purpose of CED is to generate data on the utilization and impact of the item or service evaluated in the NCD, so that Medicare can a) document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; b) consider future changes in coverage for the item or service; c) generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service.”<sup>12</sup>

### Conclusion

The use of HTAs by U.S. payers for coverage decisions will continue, for the foreseeable future, to reflect HTAs conducted by individual payers with reference to, rather than reliance on, more standard HTA assessments. Even within the legislation authorizing the establishment of the Patient-Centered Outcomes Institute to conduct comparative effectiveness research, there is language restricting how findings may be used:

- *“Prohibits any findings to be construed as mandates on practice guidelines or coverage decisions and contains patient safeguards to protect against discriminatory coverage decisions by HHS (U.S. Department of Health and Human Services) based on age, disability, terminal illness, or an individual’s quality of life preference.”<sup>13</sup>*

When conducting global reimbursement assessments, it is critical to recognize that HTAs occur at the micro level in the U.S.—not the macro level. This perspective is germane to understanding that the role of HTAs in U.S. payer decision-making is uniquely its own.

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