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This article will address:
1) Health Technology Assessment (HTA):
   a) An Overview
   b) ISPOR HTA Special Interest Group Project Objectives
2) HTA Forum:
   a) ISPOR Global Health Care Systems: Website Resource
   c) The U.S. Health Care System Decision Model and Reimbursement Roadmap

Health Technology Assessment (HTA)
An Overview
Health Technology Assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technology. Its main purpose is to inform technology-related policymaking in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods [1]. HTA studies the medical, social, ethical and economic implications of development, diffusion and use of a health technology. Health technologies include pharmaceuticals, medical devices, diagnostics and biotechnology products. HTA can be used as a tool in decision-making and policy-making to bridge the gap between research, clinical practice and public policy.

The critical components of pharmacoeconomic (economic) and outcomes research studies include not only validated methods and research standards (in accordance with current global standards in HTA principles), but also interpretation, communication and use of this evidence in designing clinical trials and making reimbursement decisions.

It is important for outcomes researchers to consider reimbursement guidelines and the impact of clinical and economic endpoints in protocol design and understand the decision-making process. It is equally important that health care decision makers are knowledgeable of outcomes research methods and understand the value of outcomes research study results in health care decision-making. By its presence or absence, reimbursement for a new drug, medical device or diagnostic product can dramatically affect patient access and quality of care.

Bringing New Products and Technologies to Global Markets
In support of its global mission to promote the science of pharmacoeconomics (health economics) and outcomes research and facilitate the translation of this research into useful information for health care decision-makers (www.ispor.org), ISPOR established Special Interest Groups to contribute to international health technology assessment and reimbursement research standards and methods, and create a forum for communication between researchers, payers and the scientific and academic communities at large. The Special Interest Group co-chairs and leadership teams share a commitment to excellence in health care through the establishment of good business practices in health economics, outcomes research and reimbursement.

ISPOR HTA Special Interest Group Project Objectives
Since 2006, the HTA Special Interest Group has embarked on an initiative to develop a comprehensive tool that defines the decision maker, decision-making process, reimbursement process and requirements for bringing new products to global markets.

The ISPOR HTA Special Interest Group has two primary initiatives, which are stated in the following objectives:

1) To develop a country-specific roadmap of health care reimbursement systems and requirements for pharmaceutical products.
2) To develop and validate a decision-making model that defines the decision maker(s), influencers and the steps in the decision-making process for coverage and payment of new pharmaceutical products in countries around the world.

We are developing the following Reimbursement Roadmaps and Decision-Making Models at this time.

Countries:
1) Australia  11) Italy
2) Austria   12) Netherlands
3) Canada  13) N.Ireland
4) China    14) Poland
5) Denmark  15) Scotland
6) England  16) Spain
7) France   17) Sweden
8) Germany  18) Taiwan
9) Greece  19) USA
10) Hungary 19) Wales

As these countries are completed and validated, they will be posted on the ISPOR website (www.ispor.org). New countries will continue to be added to this assessment with a goal of completing all countries that are represented by ISPOR membership. The Global Reimbursement Roadmap and Decision-Making Models include the following components:

I. Background
   a. Description of health care system (Introduction)
II. Decision-Makers and Influencers
   a. Description of Decision-Makers and Influencers, Reimbursement and HTA Organizations
III. Decision-Making Process
   a. Specific details related to decision-making process for reimbursement and pricing approval of pharmaceuticals
IV. Reimbursement and Pricing Process
V. Data Requirements
   a. Health Technology Assessment, Health Economic Analysis, Budget Impact, etc.
VI. Acronyms

VII. Suggested Reading

VIII. Useful Links

HTA FORUM
ISPOR Global Health Care Systems: Website Resources
Global Roadmap: http://www.ispor.org/HTARoadMaps/Default.asp
Decision-Making Models: http://www.ispor.org/HTARoadMaps/USHPass


Figure 1. Decision Model Framework

Country

*Leading Payer Organization

LEVEL 1

Model defines:
- Decision Maker(s)
- Evaluators / Advisors
- Brief description of primary factors that support decision-making process for coverage & payment of pharmaceutical products.

LEVEL 2

Supporting text describes:
- How Decision Maker functions,
- History,
- Leadership structure,
- Steps involved in decision-making process,
- Geographic coverage

*Leading Payer Organization: Top 3 payer groups covering majority of population.

Figure 2. Level 1 Model Structure

Country

*Leading Payer Organization

Key Decision Maker (Primary and Secondary)

Evaluator / Advisor (Person / Organization)

Step 1

Step 2

Step 3

Step 4

Not Approved

Approved

Formulary or Approved Products List

*Leading Payer Organization: Top 3 payer groups covering majority of population.

Figure 3. The U.S. Health Care System: Decision Model and Reimbursement Roadmap

United States

Decision Makers

Public / Governmental

Medicare
Medicaid
VA & DoD / Tricare
SCHIP

Private

BCBSA (39 companies)
Large MCOs:
- Aetna, CIGNA, Humana,
- WellPoint, United Healthcare
Regional MCOs

Employers

Fully/Partially Insured or Self-Insured

Evaluators / Advisors

AHRQ, EPCs and DECIDE Network, UHC, VA and DoD: Internal HTA Programs

CQIN or Coordinated Clinical Interventions

Use HTA of Health Plans

*Leading Payer Organization: Top 3 payer groups covering majority of population.

Figure 4. The U.S. Health Care System Decision Model: Public/Governmental Payers

United States

Decision Makers

Medicare Coverage & Advisory Group
NCDs

Medicaid Coverage Advisory Committee
Medicaid

Fiscal Intermediaries
LCDs

OMERCs (Medical Devices)
LCDs

Agency for Health Care Research & Quality (AHRQ)

Decision Makers

Developing Evidence to Inform Decisions About Effectiveness (DICE)
Evidence-Based Practice Centers (EPCs)
U.S. Preventive Task Force (USPSTF)

Decision Makers

Formulary Review & Benefit Design Committee (FRBDC)

Decision Makers

WellPoint Pharmacy Management

WellPoint Outcomes Based Formulary™

Determine if product is safe &
Determine if product will be forwarded to FR&BD for further review.

Determine overall product value relative to their comparators

Cost: To determine placement on WellPoint Outcomes Based Formulary™

The U.S. Health Care System Reimbursement Roadmap

The United States is a multi-payer system with public and private payer organizations. Reimbursement decisions are informed by numerous inputs: clinical guidelines and standards, public/private/ independent evidence reviews, manufacturer costs and effectiveness trials and data, etc. There are many types of coverage, including mandated (Emergency Medical Treatment and Active Labor Act (EMTALA) or emergency care) and entitled government sponsored insurance (Medicare (elderly), Medicaid (low income and certain medical conditions like End Stage Renal Disease (ESRD), Veterans Administration (VA)).

In the private sector, there are two types of plans, individual and employer-sponsored. Individual plans serve retired, self-employed, unemployed and individuals who are not able to obtain insurance through an employer and are administered by private insurance companies. In employer-sponsored plans, the cost of coverage is shared between the employer and employee. Self-insured employers utilize third-party administrators to design their insurance plan. In addition, there are for-profit (United Health Group) and non-profit {Blue Cross / Blue Shield (BSBC)} insurers.

For each public and private plan, there are many plan variables. In the private sector, for example, there are Health Maintenance Organizations (HMO), Preferred Provider Organizations (PPO) and Point of Service (POS) plans with deductibles, premiums, prior authorization requests, in-network versus out-of-network, exclusions, tiers, co-payments, co-insurance and additional coverage for pharmacy, vision and dental coverage. The public sector includes Medicare, Medicaid, the State Children’s Health Insurance Plan (SCHIP) and Veterans Administration, Department of Defense and TriCare (Civilian Health and Medical Program of the Uniformed Services).
Table 1: Definitions of Plan Variables

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Deductible</td>
<td>The amount of covered healthcare expenses incurred by the insured individual that is borne by the enrollee before the insurer begins making payments. Deductible requirements vary by plan and by policy, and are in force over the course of a set period (usually one year).</td>
</tr>
<tr>
<td>Premium</td>
<td>The financial sum that must be paid periodically to purchase health insurance coverage and to keep the policy in force or active.</td>
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<tr>
<td>Prior Authorization</td>
<td>A formulary status classification that requires that the prescribing physician or pharmacists filling the prescription to call the insurance company for approval to write or fill the prescription, respectively.</td>
</tr>
<tr>
<td>Co-Payment / Co-Insurance</td>
<td>A form of cost sharing whereby the insured person pays a specified amount for the healthcare product or service.</td>
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</tbody>
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Source: ISPOR Lexicon edited by Chris L. Pashos, Eric G. Klein and Lee A. Wanke

Upon Federal Food and Drug Administration (FDA) approval, products are eligible for coverage by both public and private payers. For Center for Medicare and Medicaid Services or CMS (public), coverage decisions are made at both a national and a regional level. There are many factors that determine whether coverage will be approved, including plan and benefit type. For pharmaceutical products, coverage is dictated by the formulary. The product’s placement on the formulary (Tier 1-4) is often determined by the Pharmaceutical and Therapeutics (P&T) Committee. Tier 1 typically includes generic products. Tier 2 includes “preferred products” that have demonstrated superior efficacy or for which pharmaceutical manufacturers have negotiated rebates for use. Tier 3 is where most branded products are placed at the time of launch. Tier 4 is typically reserved for expensive specialty products and utilizes co-insurance instead of co-payment mechanisms.

Health care reform is a major factor that will have a direct impact on product reimbursement. With the rise in health care costs and an increase in the number of uninsured individuals, there will continue to be a tremendous amount of scrutiny on determining the clinical and cost-effectiveness of different products and treatments. The need for clinical and economic evidence will become even greater as physicians, patients, hospital administrators and other stakeholders determine the best option for their patient. While the debate continues regarding the future of the U.S. health care system, it is certain that any option will have a significant impact on the current system and there will be a greater requirement for pharmacoeconomic (health economic), outcomes and comparative effectiveness data.

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The following members of the HTA Special Interest Group Leadership Team should be recognized for their ongoing contributions:

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For further information, please refer to the ISPOR website at: www.ispor.org.

Reference