Meeting Your Customer

THE WHO, WHAT AND WHERE OF PAYMENT

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Goals for today:

- Describe the context for coverage/payment of drugs, devices and diagnostics
- Identify the major decision makers
- Help frame key questions for going beyond regulatory approval to payment

Ask yourself

- Who is my customer?
- What do they need to know about my product?
- Where will my product be used?

WHO

Type of payor drives data collection and positioning

- Government programs
  - Medicare
  - Medicaid
- Insured
  - Exchanges
  - Individual
  - Small group
- Self-insured (ERISA) employers

Payor type is determined by demographics and socio-economic status

	Medicaid/ SCHIP	Medicare	Exch/Ind	Small Group	Self-insured
Age	Families Children	Usually >64	Adults and families	Adults and families	Adults and families
Employment	Low wage, not employed	retired	Self-employed, part-time	Full time employed	Full time employed
Disability	Adults who cannot work	SSDI, renal disease	Partially disabled or with chronic disease	Healthy working population	Healthy working population
Economic status	Low	variable	variable	Low middle class to higher wage earners	Low middle class to higher wage earners

Certain conditions are more likely for some payors

- Cancer: Children and older adults
  - SCHIP
  - Medicare
- Multiple sclerosis: middle aged adults
  - Commercial insurance
  - Disability e.g. Medicare
- Acute trauma: young adults
  - Commercial insurance
  - Uninsured
- Mental health: schizophrenia
  - Medicare and Medicaid
  - Commercial insurance

Medicaid

- Federal and state combined program
- Focuses on low income families
- Details vary by state
- Generally low or no copays for medical visits or drugs
- Drug and DME coverage is generally good
- Important payor for Obstetrics and neonatal care

Medicare

- Federal program for care for those >/=65
- Also includes end-stage renal disease
- Part A and B cover medical visits and hospitalizations and DME
- Part D covers drugs
- A majority of beneficiaries also have supplement plans that help with deductibles and copays

State and Federal Exchanges

- Now cover over 17M people
- Plans include both medical and pharmacy coverage
- Very similar to commercial plans in terms of coverage and utilization management

WHAT

Coverage decisions depend on plan rules

- Excluded categories
- Drug evaluation and formulary placement
- Device evaluation
- Diagnostics

Exclusions: insurance

- Medically necessary procedures
- FDA approved drugs that treat medical conditions
- FDA approved vaccines as recommended by ACIP

What's in

- Medical foods
- Services that are not strictly healthcare or not performed by a licensed medical professional
- Cosmetic procedures unless required following trauma, oncology surgery
- Travel related services or vaccines

What's out

What is a formulary?

- List of covered drugs
- Tiers refer to copays/coinsurance
- Utilization management refers to rules that must be followed for the member to receive coverage

Pharmacy Clinical Policy Bulletins
Aetna Non-Medicare Prescription Drug Plan

Subject: Immunological Agents - Immunosuppressants

Status	Drug	PR	PR-QL	PR-AL	ST	M EX‡
Biological Response Modifier-Tumor Necrosis Factor (TNF) Inhibitors						
P	**Enbrel®** *(etanercept for subcutaneous inj)*	X				
P	**Humira®** *(adalimumab inj kit)*	X				
P	**Remicade®** *(infliximab for IV inj)*	X				
P	**Simponi® ARIA™** *(golimumab for IV inj)*	X				
NP	**Simponi®** *(golimumab subcutaneous inj)*	X				
FE	**Cimzia ®** *(certolizumab pegol for inj kit)*	X				X
Biological Response Modifier-Interleukin-Inhibitors						
P	**Stelara®** *(ustekinumab inj)*	X				
NP	**Actemra®** *(tocilizumab for IV/ SQ soln)*	X				
NP	**Kineret®** *(anakinra subcutaneous inj)*	X				
Biological Response Modifier-Fusion Protein						

I. Precertification Criteria

Under some plans, including plans that use an open or closed formulary, **Actemra, Amevive, Cimzia, Cosentyx, Enbrel, Entyvio, Humira, Kineret, Orencia, Otezla, Remicade, Rituxan, Simponi, Simponi ARIA, Stelara, Xeljanz,** and **Xolair** are subject to precertification. If precertification requirements apply Aetna considers these drugs to be medically necessary for those members who meet the following precertification criteria:

For **Enbrel**

A documented Diagnosis of one of the following:

- Active non-axial psoriatic arthritis **AND** a documented failure to methotrexate, of if methotrexate is contraindicated or not tolerated, to another non-biologic disease-modifying anti-rheumatic drug (DMARD)
- Active axial psoriatic arthritis and an inadequate response to 2 or more NSAIDs
- Adult Moderate to Severe Active Rheumatoid Arthritis
- Ankylosing spondylitis **AND** a documented failure of two or more non-steroidal anti-inflammatory drugs (NSAID) (e.g. naproxen, ibuprofen, meloxicam)
- Behcet's Disease **AND** documented refractory to glucocorticoids and azathioprine
- Chronic Moderate to Severe Plaque psoriasis in adults aged 18 years and older **AND** documented to be a candidate for systemic therapy or phototherapy when the following selection criteria are met:
    - 10 % or more body surface area is affected by plaque psoriasis (or 5 percent or more of body surface area if psoriasis involves sensitive areas (hands, feet, face, or genitals)) or member has a Psoriasis Area and Severity Index (PASI) score of 10 or more **AND**
    - Member has failed to adequately respond to or is intolerant to a 3-month trial of one of the following phototherapies (unless contraindicated)
        - Psoralens (methoxsalen, trioxsalen) with UVA light (PUVA)
        - UVB with coal tar or dithranol
        - UVB (standard or narrow-band)
- Juvenile Moderate to Severe Active Rheumatoid Arthritis in patients ages 2 and older
- Reactive Arthritis **AND** a documented failure of all the following: NSAIDS, methotrexate, steroids, and sulfasalazine

In health systems throughout the world, HTA plays an essential role in supporting decision making

HTA is a multidisciplinary field that addresses the clinical, economic, organizational, social, legal, and ethical impacts of a health technology, considering its specific healthcare context as well as available alternatives. The scope and methods of HTA may be adapted to the needs of a particular health system, but HTA processes and methods should be transparent, systematic, and rigorous.

IMPACTS OF HEALTH TECHNOLOGY

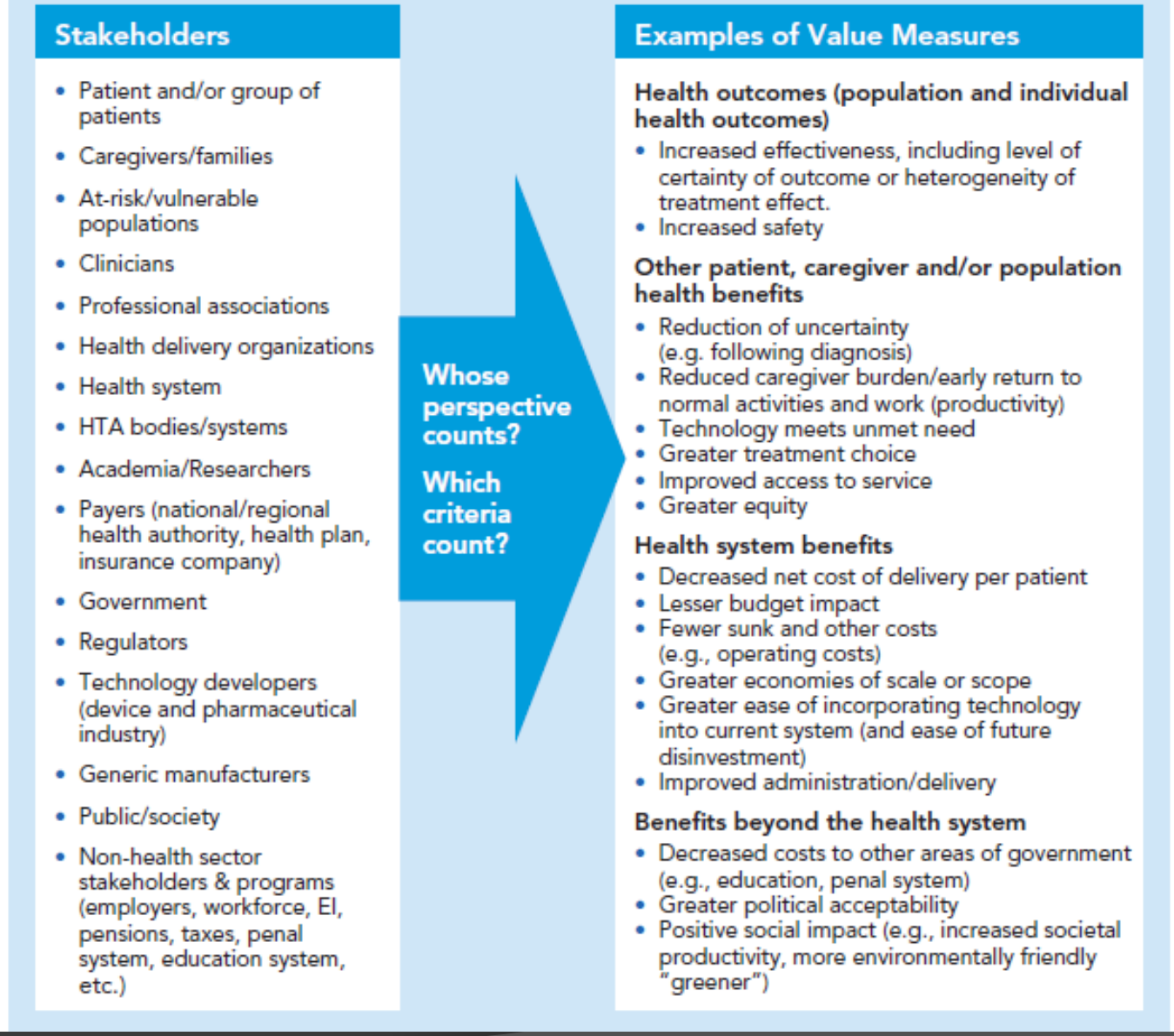
- CLINICAL
- ECONOMIC
- ORGANIZATIONAL
- SOCIAL
- LEGAL
- ETHICAL

Defining value

Value can be generally defined as:

- A fair return or equivalent in goods, services, or money for something exchanged
- The monetary worth of something (e.g., market price)
- The relative worth, utility, or importance (e.g., a good value at the price, the value of base stealing in baseball).

Table 1. Overview of stakeholders and examples of criteria for assessing technology value



Drug Evaluation

IMPACTS OF HEALTH TECHNOLOGY

- CLINICAL
- ECONOMIC
- ORGANIZATIONAL
- SOCIAL
- LEGAL
- ETHICAL

- Efficacy
- Safety
- Quality of Life
- Cost-effectiveness and cost-benefit
- Utilization and guidelines
- Alternatives/CER
- Patient acceptance
- Equity/fairness and social good

Device Evaluation

IMPACTS OF HEALTH TECHNOLOGY

- CLINICAL
- ECONOMIC
- ORGANIZATIONAL
- SOCIAL
- LEGAL
- ETHICAL

- Beyond 510k
- Outcomes
- Comparative effectiveness
- Longer term safety and effectiveness/replacement data

Diagnostics

- Site of care
  - Lab
  - MD office
  - Hospital
- Most large payors want members to use lab partners (e.g. Quest)
- Beyond just measuring payors are looking for evidence
  - Result will change therapy/decision
  - Doing test will change patient outcomes

WHERE

Setting for use of the technology determines who the decision makers will be

Hospital
- Hospital is the usual decision maker
- Tools used in hospital are hospital responsibility
- Many costs are bundled in DRG and other rates
- Payors may pay directly for implanted devices but not always

Outpatient
- Facility is the usual decision maker
- Tools are part of the bundled rate
- Drugs or implantable devices that are the primary treatment may buy and bill and therefore billed directly to the payor

Home
- Health plan is the usual decision maker
- Devices: DME rules may apply
- Drugs: buy and bill for some and outpatient pharmacy for others

Pharmacy/lab
- Health plan is the usual decision maker
- May be supplied via retail, mail or specialty
- Labs may be done by providers or at stand-alone labs

Summary

Decision Rules

- Payor is determined by the patient characteristics
  - Demographics
  - Socio-Economic status
- Coverage is determined by the payor
  - HTA (clinical and economic assessment)
  - Exclusion and inclusion (benefit design and plan language)
  - UM Programs (conditions for coverage)
- Decision making is determined by the setting for use of the product
  - Hospital
  - Outpatient

Links

- http://ctinnovations.com/
- http://www.htai.org/
- http://www.pcori.org/
- http://www.eunethta.eu/
- http://www.icer-review.org/
- http://www.nhlbi.nih.gov.sibr

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Thank You