A Payer's Perspective

How Do We Decide What We Pay For?

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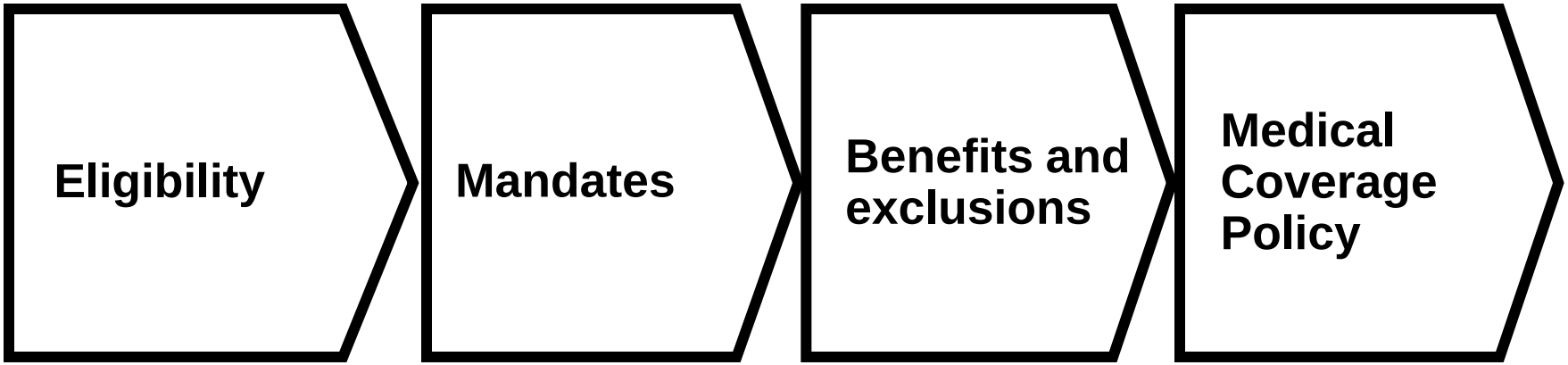
Hierarchy of coverage determination



Benefit determination: Who is covering?

- **Medicare**
- **Medicaid**
- **ASO (administrative services only)**
- **TPA (3rd party administration)**
- **Fully-funded (traditional)**

Benefit determination: Who is covered?

Eligibility

- **A patient must be primary with this plan**
- **Medicare: primary payer / secondary payer**
- **Medicaid: primary payer / secondary payer**

- If Medicare is primary, Medicare coverage rules apply
  - See National Coverage Determination (NCD) and Local Coverage Determination (LCD), if any
  - Commercial plans will refer you to your Medicare Fiscal Intermediary for coverage determinations
- If Medicare is secondary, commercial plan rules apply

Benefit determination: What must be covered?

Mandates

- **State and federal mandates trump the benefit plan**
- **Many states have a cancer clinical trial mandate**
- **Some states have a BMT specific mandate**
- **Mandated by PPACA effective 2014:**
  - **Essential Healthcare Benefits (EHB)**
  - **PPACA clinical trial mandate**

- State mandates only apply to fully insured plans
- State mandates do not apply to ERISA plans (self-funded employer groups). Most large employers are self-funded, at least partially
- PPACA mandates do not apply to “Grandfathered” plans

Benefit determination: What must be covered?

EHB

Essential health benefits must include items and services within the following 10 categories:

- **ambulatory patient services;**
- **emergency services;**
- **hospitalization;**
- **maternity and newborn care;**
- **mental health and substance use disorder services;**
- **prescription drugs;**
- **rehabilitative and habilitative services and devices;**
- **laboratory services;**
- **preventive and wellness services and**
- **chronic disease management; and**
- **pediatric services, including oral and vision care.**

Benefit determination: What must be covered?

Patient Protection and Affordable Care Act (PPACA) requirements

- Standard benefit plans cover Routine Patient Care Costs/Services related to a clinical trial
- Trial is a phase I, II, III or IV clinical trial conducted in relation to the prevention, detection or treatment of cancer or other life-threatening condition
- Services not considered Routine Patient Care Costs/Services are not covered:
  - the investigational drug, device, item, or service itself
  - provided solely to satisfy data collection and analysis needs
  - not used in the direct clinical management of the individual
  - a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
  - provided by the research sponsors free of charge for any person enrolled in the trial

Benefit determination: Plan design

Benefits and exclusions

- **Inclusions (those services that are covered)**
- **Exclusions (specifically not covered)**
- **Contingency clauses for life-threatening conditions?**
- **Designated Networks for high-cost services?**

- Self-funded employers can and do create benefits and exclusions not supported by available science.
- Their plan document is the governing benefit plan

Benefit determination: Plan design

Covered Health Service

Those health services, including services, supplies, or pharmaceutical products, determine to be all of the following:

- Medically necessary
- Described as a Covered Health Service in the Plan
- Not otherwise excluded in the Plan

Exclusion

Experimental or Investigational and Unproven Services are excluded.

Benefit determination: Plan design

Definition of Experimental and Investigational

Medical, surgical, diagnostic, psychiatric, substance abuse or other health care services, technologies, supplies, treatments, procedures, drug therapies, medications or devices that are:

- Not approved by the FDA to be lawfully marketed for the proposed use

  - (and not identified in the *American Hospital Formulary Service* or the *United States Pharmacopoeia Dispensing Information* as appropriate for the proposed use)

- Subject to review and approval by *any* institutional review board for the proposed use.

  - (Devices which are FDA approved under the *Humanitarian Use Device* exemption are not considered to be Experimental or Investigational)

- The subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trial set forth in the FDA regulations

Benefit determination: Medically necessary?

Medical Coverage Policy

- **Evidence based**
- **Not based solely on expert opinion**
- **Consistent with standard of care**
- **Final step in the benefit determination process**

- **Policy is based primarily on Clinical Superiority**
- **Cost-effectiveness is not considered in policy formation, but may impact sequence of administration**

Medical Coverage Policy

"Clinically Superior"

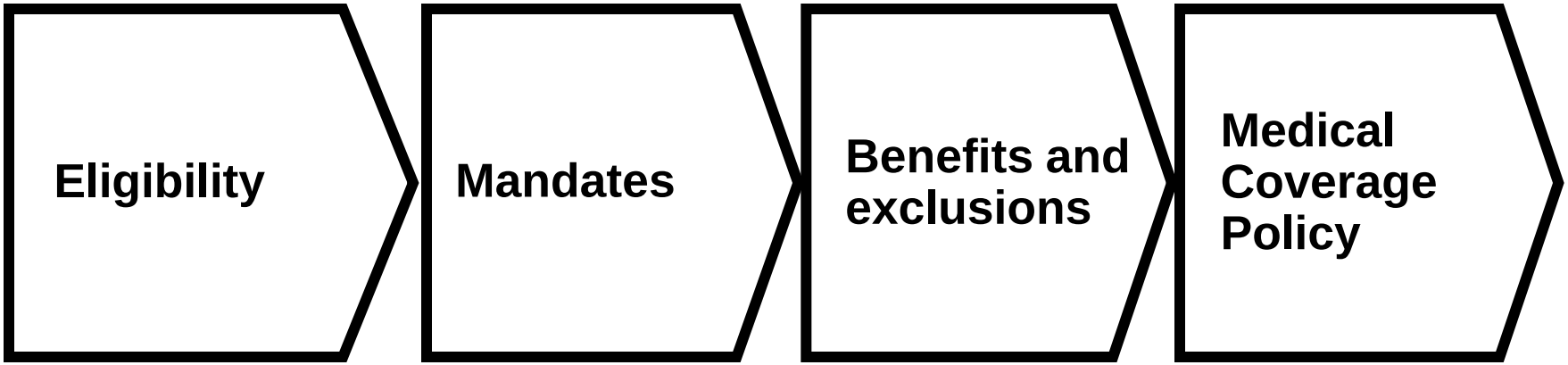
- **The subject health care technology is shown to provide a significant therapeutic advantage in a substantial portion of the target populations when compared to alternative therapies:**
  - **Greater effectiveness in a substantial portion of the target populations than alternative therapies**
    - **(generally, this would require direct comparative clinical evidence)**
  - **Greater safety in a substantial portion of the target populations**
    - **(in some cases, this would require direct comparative clinical evidence) or**
  - **In unusual cases, where neither greater effectiveness nor greater safety has been shown, a demonstration that the technology otherwise makes a major contribution to patient care.**

Medical Coverage Policy

Medical Coverage Policy developmental hierarchy in descending order of importance:

- Statistically robust, well-designed randomized controlled trials
- Statistically robust, well-designed cohort studies
- Large, multi-site observational studies
- Single-site observational studies
- In the absence of incontrovertible scientific evidence, medical policies may be based upon national consensus statements by recognized authorities.
  - National guidelines and consensus statements, e.g., USPSTF, NIH clinical statements, AHRQ clinical statements
  - Evidence-based nationally recognized clinical guidelines
  - CMS National Coverage Decisions (NCDs)
  - Clinical position papers of professional specialty societies when their statements are based upon referenced clinical evidence
  - Expert opinion using Cochrane grading

Hierarchy of coverage determination



Thank you!

Questions?