A Payer’s Perspective

How Do We Decide What We Pay For?

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Hierarchy of coverage determination

- Eligibility
- Mandates
- Benefits and exclusions
- Medical Coverage Policy
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?

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
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
“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
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Thank you!

Questions?