Objectives

- How does Anthem – WellPoint develop medical policy and guidelines
- Comparative Effectiveness Research
- Research versus Standard of Care
35 Million Members Across the United States,
1 in every 9 Americans covered by WellPoint Plans
A Tale of Health Care in Our Nation

“It was the best of times…”

Unprecedented advances in medical technology, treatments, and pharmaceuticals can improve population health

It was the worst of times…”

The state of public health, unsustainable health care costs, the quality of medical care delivered and access to services challenge clinical care and overall health

From “A Tale of Two Cities”
By Charles Dickens
Health Care Reform

“This legislation will not fix everything that ails our health care system, but it moves us decisively in the right direction”

- #1 in health expenditures; 37th in overall health
- 50 million citizens uninsured
- Aging population
- 50% have chronic conditions
- New biological therapies and technologies and devices drive clinical care and cost
- $40B investment in information technology
- New reimbursement models to pay for quality, value, and outcomes
- ~$1 trillion health reform costs added to current $2.4 trillion
Advancing Health Care Quality and Safety Through Evidence-Based Care

To recognize true value of treatments, drugs and devices they must be proven to advance health outcomes

Evaluate new technologies to establish evidence-based medical policy

Determine “what works” through comparative effectiveness and outcomes research

Translate clinical research into clinical action

Close gaps in care and provide information at the time of care
Medical Policy and Technology Assessment Committee (MPTAC)

- Multi-disciplinary group including:
  - External physicians representing diverse medical specialties, clinical practice environments and geographic locations
  - Internal WellPoint medical directors

- Serves as primary medical policy decision-making body

- Two subcommittees: Hematology/Oncology and Behavioral Health

- Meets quarterly
Medical Policy Considerations

In evaluating the medical necessity or investigational status of new or existing technologies and/or procedures the MPTAC (and its applicable subcommittees) may include, but not limit their consideration, to the following additional information:

- Electronic literature searches, which are conducted and collated results are provided to the committee members;

- Independent technology evaluation programs and materials published by professional associations, such as:
  - technology assessment entities such as the Agency for Healthcare Research and Quality (AHRQ), and the Blue Cross Blue Shield Association TEC;
  - appropriate government regulatory bodies; AND
  - medical specialty societies and associations.
Medical Policy Considerations, continued

- All medical policies are reviewed at least annually and more often when appropriate.

- Federal and State law, as well as contract language, take precedence over medical policy and must be considered first in determining eligibility for coverage.

- Preventive health guidelines and immunization policies recommended by ACIP/CDC are adopted by WellPoint as medically necessary services.
Outcomes Research and Comparative Effectiveness Research

“Real World” Research Drives Quality, Cost Effective Care

Integrated data sources for outcomes research and analysis
Collaborative research relationships with premier academic centers
More than 110 research projects underway
  ▪ Breast cancer, asthma, rheumatoid arthritis, low back pain, multiple sclerosis
What Is Comparative Effectiveness?

- **Institute Of Medicine Definition:**
  
  - *CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.*

- **US Health and Human Services Definition:**

  - *Comparative effectiveness research is conducting and synthesizing of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings.*

- **RAND Definition:**

  - *Comparative effectiveness research examines the degree to which alternative treatments for the same health problem produce equivalent or different health outcomes. The products of comparative effectiveness research can be used in a variety of ways, including to provide information to physicians and patients in choosing appropriate treatments, as well as input into insurance benefit design, coverage determination, and payment.*
Comparative Effectiveness Research: Primary and Reviews

- There are two ways investigators find evidence for comparative effectiveness research (CER):
  - Primary Research: Conducting studies that create new evidence
  - Reviews: Reviewing existing clinical trials, clinical studies, other research

- The U.S. Agency for Healthcare Quality and Research and its Effective Healthcare Program along with other government and non-government entities provide support to both types of Research
Characteristics of Comparative Effectiveness Research – From the Institute Of Medicine

- Directly informs clinical or health policy decision
- Compares at least 2 alternatives, each with potential to be best practice
- Results at population and subgroup level
- Measures outcomes important to patients
- Methods and data sources appropriate for the decision of interest
- Conducted in real world settings
How Is Comparative Effectiveness Used

- Inform patient decisions
- Inform clinician recommendations and decisions
- Inform clinical guideline development
- Identify future research priorities
- Inform policy, including coverage deliberations
CER informs physician patient health care decision-making

CER does not make care decisions

Enable better informed decision-making

- Compare risks, benefits, and effectiveness of available treatment options
- What is best for a patient’s health and financial status?

Create true health care choices

Translate clinical evidence into action

- Disseminate clear information to public
- Provide decision-support to physicians
Comparative Effectiveness
Treatment Options and Risks/Benefits

• Facts on Back Pain
  ▪ 9 of 10 Americans experience back pain at least once in lifetime
  ▪ #1 reason for lost productivity
  ▪ $90B spent nationally on back pain treatment
  ▪ Most back pain resolves within six weeks independent of treatment

• Studied of 172,000 Anthem Members in 6 States:
  ▪ $18 million spent on 1,000 back pain surgeries within first 6 weeks
  ▪ 35,000 unnecessary imaging procedures within first 6 weeks
  ▪ Care was dependent on specialist physician who initially treated member; specialists performed more procedures

• Value and Benefits
  ▪ Back pain program with American Academy of Family Physicians
  ▪ Opportunity for new payment models including bundling of payments
  ▪ Educate members/physicians on alternative treatment options
The Need for Comparative Effectiveness Research Numerous Other Examples Present and Past

Do new treatments, tests, and technologies lead to improvement in health outcomes and quality of life?

- Artificial Intervertebral Discs (AIDs)
  - Is there significant clinical advantage of AIDs to spinal fusion or is it comparable?
  - Over what time period will the device perform?

- Bone Marrow Transplantation for Breast Cancer Treatment
  - 1988 – 1998 Federal and State mandatory coverage
  - 30,000 procedures and $5 Billion in medical costs
  - Eventually research showed no difference in survival and lower quality of life.
Medical Policy Transparency

• All policies available via Plan websites
• Accessible by network physicians
• Includes background, coding, and definitions
• Detailed rationale
• References to:
  • Peer-reviewed journals
  • Other authoritative publications
• Comprehensive revision history

Medical Policy

| Subject: | Positron Emission Tomography (PET) and PET/CT Fusion |
| Document #: | RAD.00002 |
| Status: | Revised (Coding updated 10/01/2011) |
| Current Effective Date: | 07/13/2011 |
| Last Review Date: | 05/19/2011 |

Description/Scope

Positron Emission Tomography (PET) is an imaging modality that produces an image of the body's soft structures, including metabolic and/or chemical information. The CT scan produces an image of body structures, including bone and tissue. The PET/CT fusion combines the two images to show both hard structures, such as bone, and soft structures, such as growing tissue or tumors. This document addresses the use of PET scans and PET/CT fusion.

Note: For information related to the use of PET scans using gamma cameras, please see RAD.00040 PET Scanning Using Gamma Cameras.
Medical Policies

- Administrative (6)
- Ancillary (4)
- Behavioral Health (3)
- Durable Medical Equipment (14)
- Genetics (22)
- Laboratory (9)
- Medicine (49)

- Orthotics – Prosthetics (1)
- Prescription Drugs (24)
- Radiology (40)
- Rehabilitation
- Surgery (98)
- Transplant (24)
## PRESCRIPTION DRUGS

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## RADIOLGY

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Cardiology

The first study: Every other MRI is paid for by insurance and the intervening MRIs are paid for by the study. Are the SOC vs research charges subjective (how should they be determined?). It appears that they are dictated by a coordinator or PI.
Cardiology

Second study: Kids have a cardiac device implanted and are typically seen clinically 1 month, 6 month and then annually after the procedure. This study (sponsored by the device manufacturer) follows the patients for 5 years with the one and 6 month visits being the most critical end points. The sponsor does not pay for anything but provides the device. The procedure and all follow up visit procedures [ECHO, EKG, Chest Xray (CXR)] are considered SOC. However, the chest x-rays are not routinely ordered for many of the patients. When the participants’ cardiologist is asked to order a CXR, they ask questions and the PI explains why the order is "necessary". It seems that although CXRs CAN be ordered for this dx as SOC, it is not always necessary. So 14 of my 15 patients did not have an CXR ordered originally (clinically), but when asked to be ordered (for the study requirement) they were billed and paid for as SOC. Many questions can be raised for this one.
Surgical:

Third study: Brief synopsis of study: Surgical implantation of the HemiBridge™ spinal clip for correction (at least that's the idea) of main thoracic spinal curve for patients diagnosed with idiopathic scoliosis.

Current treatment for idiopathic scoliosis: Observation, physical therapy, chiropractic manipulation, external bracing, or fusion surgery (usually once the severity of the curve progresses to 41-50 deg).

Two main challenges presented themselves while preparing the study for subject enrollment. They are outlined below:

1) Billing patients with insurance and self-pay patients the same for standard of care procedures – keeping the study equitable across the board.
2) Establishing standard of care vs. research procedures for this study.
   a) When does standard of care treatment stop and research treatment begin for the study? That is the main question.
   b) Non-research patients with idiopathic scoliosis are followed every 6 months by Orthopedics with clinic visit and x-ray films, until progression of the curve deems a different follow-up pattern, or treatment regimen. So a 6 month follow-up pattern is considered standard of care for patients with this diagnosis.
   c) The study requires a similar follow-up schedule once the patient is 6 months out from surgery.
   d) However, patients who undergo the study’s surgical procedure have a curve of 25 - 40 deg. Surgical intervention is usually (meaning standard of care) not proposed until curve progression is >40 deg.
Pediatric Cancer:
Research – i.e. Interventions or treatment not customarily part of the standard of practice for a specific diagnosis:

1. Blood specimen for host genomics prior to therapy -- even if done at the same time as an otherwise routine venipuncture (the specimen is research, though the risk is minimal because of the standard of practice medical need for the venipuncture anyway).
2. New drug research pharmacokinetics blood draws
3. Bone age studies in patients enrolled on phase I anti-angiogenic small molecule or antibody clinical research regimens; if the indication is licensed then probably not
4. Functional MR/language mapping in patients receiving CNS toxic therapies
Pediatric Cancer:

Standard of practice – i.e. used for therapeutic decision making regardless of treatment; usually treatment is altered based upon these results:

1. PET imaging early response in lymphoma  
2. Marrow early response in leukemia  

Of course defining an absolute "standard of practice" is difficult and a bit of a moving target. Larger centers have generally used newer technology routinely for safety and precision in treatment.