
**A Payer Perspective on
Improving Evidence for Decision Making:
Future Strategies for U.S. Technology
Assessment**

**The Health Industry
Forum**

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Overview

- **The Health Benefits Framework**
- **The Current Process for Medical Policy in WellPoint**
- **Some Key Gaps**

The WellPoint Mission

“Improve the lives of the people we serve and the health of our communities”

Improve health outcomes, including the support of useful technologies while maintaining affordability

The Health Benefits Framework

The Legal Framework:

The Benefit Plan Documents

The Practitioner/Provider Contracts

A Settlement Agreement

The Regulatory Framework

The Claim and UM Environment

The Current Process

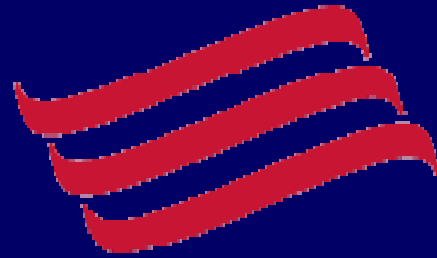
- Determine if the technology or procedure is able to be identified in a claim or reasonable clinical certification process, estimate the cost of review, and the legal and regulatory environment and then,
- Review the clinical evidence supporting improvement in clinical outcomes for a medical necessity determination.
- Limited cost benefit analysis regarding the clinical outcome

Devices to Market

- CDRH cleared 2,617 510(k) submissions for products with prior uses.
- CDRH approved 38 new PMA's in 2005.
- CDRH recalled 437 devices in 2005.
- In 2004, the agency received 51 original PMAs compared to 54 in 2003. Similarly, the FDA received 226 IDEs in 2004 compared to 242 in 2003.
- WellPoint currently has between 250 and 300 medical policies.
- Since the onset of development of CPT category III codes there have been a total of 161 created.

Current Key Gaps In Creation of Medical Policy

- FDA approval process for devices – only safety and efficacy without evaluation regarding clinical outcomes
- The evolution of a device
- Lack of a formal process for procedures
- A proliferation of diagnostic tests (imaging and lab) and the knowledge gap in evidence for clinical improvement
- 161 Category III CPT codes, the hospital claim form and prompt payment



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