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Comparative Efficacy & Evaluation for Medical Devices

What is the Healthplan Point of View?

Fiona Wilmot, M.D., M.P.H

Medical Director of Policy, Transplant, Pharmacy and
Therapeutics

Blue Shield of California

Agenda

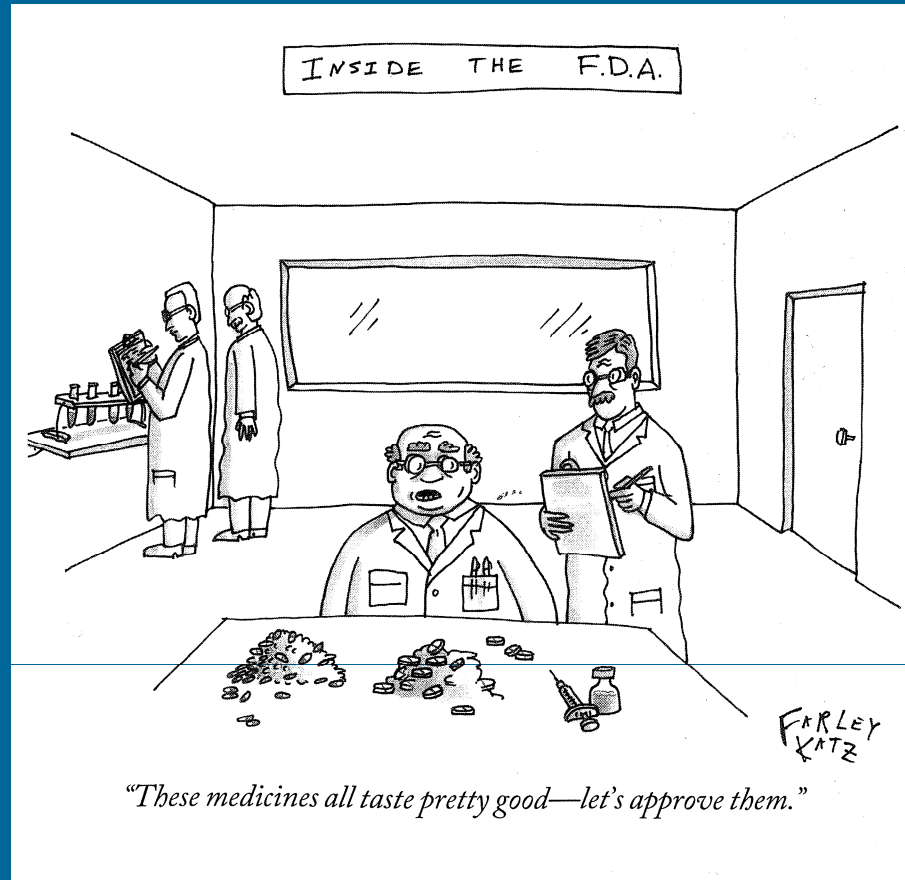
What I will talk about:

- Brief Overview of Technology Assessment at Blue Shield of California.
- Is comparative effectiveness a consideration?
- What about 'alternative' coverage strategies (CED), P4P, 'formularies; will they get us where we want to go?
- Challenges



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Inside the FDA



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Medical Policy Committee --Using Evidence-Based Medicine (EBM)

- EBM is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.
- The practice of using EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research.



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Criteria

- The technology must have final approval from the appropriate government regulatory bodies.
- The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.
- The technology must improve the net health outcomes.
- The technology must be as beneficial as any established alternatives.
- The improvement must be attainable outside the investigational settings.



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**California Technology Assessment
Forum (CTAF)**

www.ctaf.org

Meets 3 times per year
12-15 reviews/yr

**BCBSA Technology Evaluation
Center**

www.bcbs.com

Meets 3 times per year
12+ reviews /year

BCBSA Medical Policy Panel

[internal website](#)

Meets monthly
Updates full library (300+) annually

BSC Medical Policy Committee

www.blueshieldca.com

Meets 4-5 times per year
Reviews/updates 20+ policies/mtg.



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Limitations

1. Paucity of data

- RCT limited; expensive, lengthy, may squelch innovation

2. Comparative data almost non existent

- Not required for approval
- No 'upside' for manufacturers
- How do you factor operator skill?

3. Do alternatives fill the gap or is this just 'lowering the bar'

- CED – can you get good data for registries?
- Does this just further reduce incentive development of good data?

4. What is the role of Healthplan (individual or employer sponsored)



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Examples

1. Treatments for Prostate Cancer

- Watchful waiting
- Surgeries
- Radiation therapies (3D Conf, IMRT, Proton)

2. Treatments for Back Pain

- Conservative (medications, PT, stretching, alternative therapies)
- Surgeries (including use of devices)

3. Vagal Nerve Stimulation for treatment of resistant depression

- Current data does not support
- User population diverse, acutely and chronically ill, few options



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Challenges

- **Who should be deciding which 'data' best and making 'coverage' decisions**
- **Member/Provider Expectation (DTC advertising, Internet)**
- **Regulator Pressure, bias towards action/ innovation and action (newest is best, better to do something than nothing)**



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Questions?



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