

Covering Genomic Tests

Why isn't it easy?

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It's easier when...

- Clear and <u>consistent scientific evidence</u> support clinical utility; and
- Risks of medical misadventure are known, measurable and acknowledged; and
- Physicians consistently <u>use it where it fits</u> in the overall management scheme; and
- A <u>standard nomenclature and taxonomy</u> exist; and
- All relevant components are consistently and precisely identifiable in a claims stream; and
- There is agreement on the <u>valuation</u> of the technology.

Evidence Base

- Immature: stops well short of clinical utility –
 at times short of analytic validity.
- Not Holistic: challenged to incorporate other "knowns" and comorbidities.

Medical Misadventure

- Lack of readily available clinical sentry posts how does a physician intuitively come to suspect the result is wrong?
- How does managing a perceived risk affect other unrecognized risks?

Where Does it Fit?

- Test young a lifetime to manage risk but little personal priority
- Test old is there a point where your genome is less relevant
- Self identification of family risk and origin is challenging, may be prone to bias

What Test Done?

- Multiple platforms
- Multiple vendors
- Multiple indications

What is the true reference standard?

What Test Billed?

- Stacking codes
- CPT codes

What is it Worth?

- Resource basis?
- Whose effort are we counting?
- Clinical utility basis what is the incremental value of the information?