Financial Aspects of Genetic Testing

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Dualism

Objectives

- By the end of this session, attendees will be able to:
  - Objective 1: Define Common insurance terms including types of insurance.
  - Objective 2: Review the perspectives of stakeholders, e.g. laboratories, payors, patients and providers, on common problems seen in payment for genetic testing.
  - Objective 3:Understand ways a practitioner can improve their chances of approval.

Agenda

- Topic 1-The Payors

  Topic 2- The Tests

  Topic 3-The Doctors

  Topic 4- The Members/Patients

Understanding Insurance Co. Behavior

- Engaged in a constant cat & mouse game with Labs & Providers
  - Labs add unspecified codes for unspecified work
  - Labs stack codes
  - Labs change tests (and double the prices) unexpectedly
  - Providers who are not qualified to order these tests order them

Payor Principles*

No payor wants to get between a kid with a medical condition and genetic testing

Or an adult with cancer

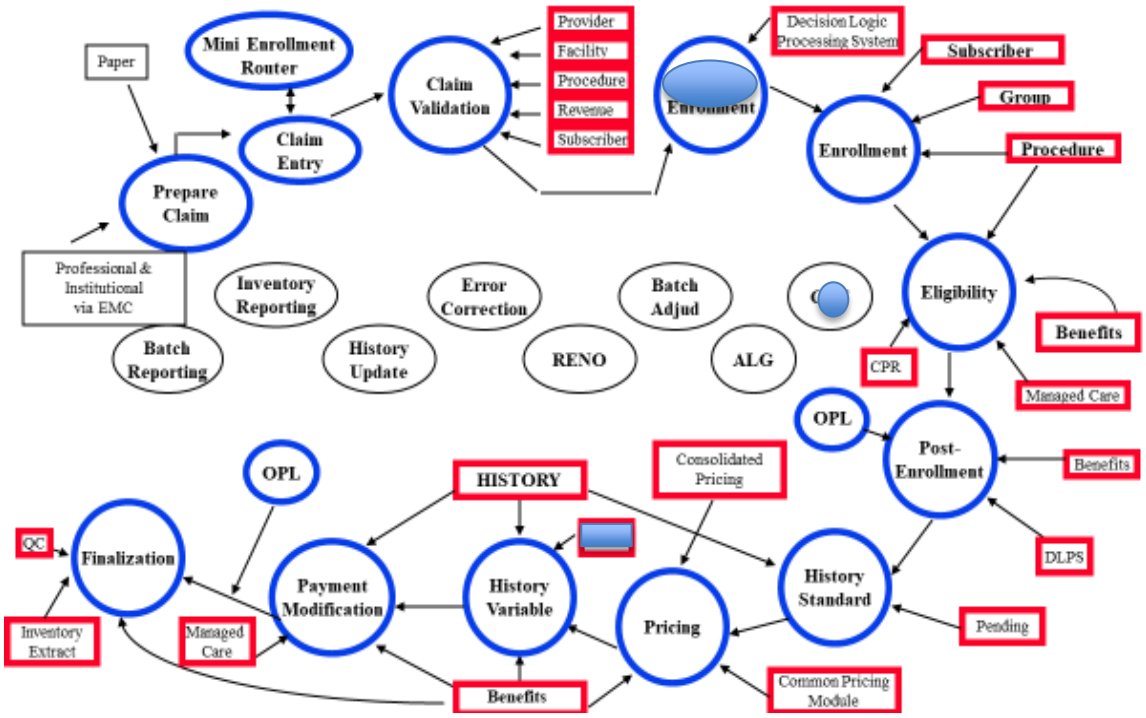
Good genetic testing gets swept up with bad genetic testing because of a lack of codes

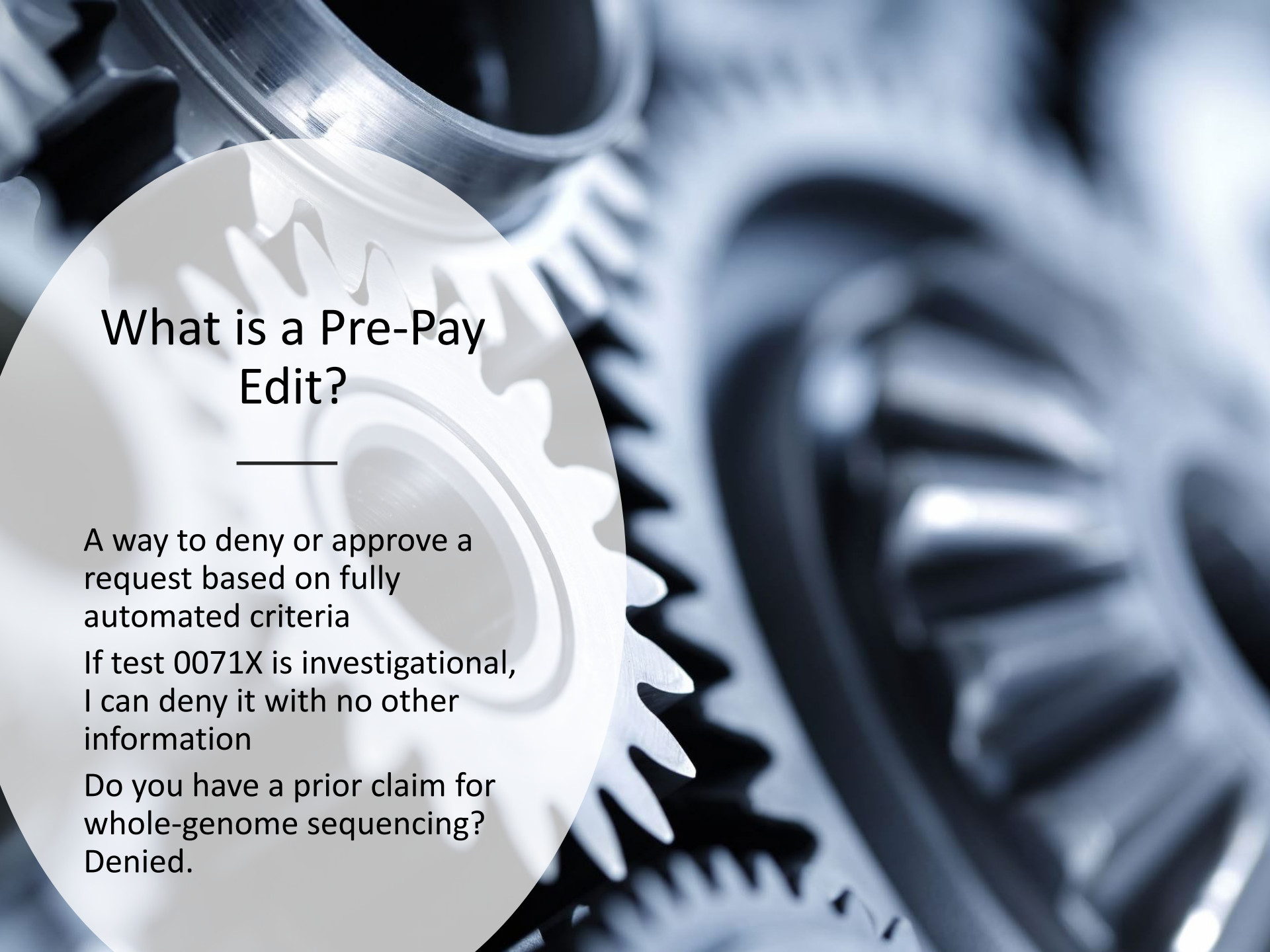
Payors hate getting defrauded

*Yes, they exist

Step 1: Claims

1. Verification of Demographics
   - Wrong company?
2. Verification of Benefits
- Does the member have
- Is this service covered?
3. Verification of Responsibility
- Are we primary or secondary?
4. Pre-pay edits
- Approve
- Deny
- Pend for Review





What is a Pre-Pay Edit?

A way to deny or approve a request based on fully automated criteria

If test 0071X is investigational, I can deny it with no other information

Do you have a prior claim for whole-genome sequencing? Denied.

Step 2: Medical Review

The process varies by company, but the structure is basically the same

Step 1- In-house review

Peer-to-peer*

Step 2- Appeal

Step 3- Appeal to either same-specialty reviewer or an IRO (Independent Review Organization)

Ask the person on the phone what's available

*If you appeal before a peer to peer, you lose that peer to peer

Step 3: Peer-to Peer

When discussing a case with a Medical Director, you can argue either the policy or that a test is medically necessary.

- Medical Policy Criteria
  - Usually, you can Google the company's name and the test you're looking for
  - Must be publicly available

Step 4: Appeals

- There is no formal difference in review between an initial request and an appeal
  - But most Medical Directors will give an appeal more scrutiny
- Letters of Medical Necessity *can* help
  - Not when they are clearly from the lab
  - Not when they are 10 pages long
  - Not when they are antagonistic

Knowledge Claims

Why is everything Investigational/Experimental?

- Payors use different sources of information for decision making
- CMS is important
- Health Technology Assessment companies are subscribed to
- Evidence-based guidelines (not consensus guidelines)
- Cultural- geneticists are first adopters, payors are conservative

Topic Two: The Tests

Lack of CPT Codes

Bill- orders a craniosynostosis panel through BIG LAB- East with United Healthcare and it's approved

Sam- orders the nearly identical panel using BIG LAB-WEST with United healthcare and it's denied

What Happened?

BIG LAB-1 18 genes

CPT: 81402- approved

- Tier 2 code representing a small-to-medium panel

BIG LAB- 2 20 genes

CPT: 81402- approved

CPT: 81479- denied

- The unspecified code is billed legitimately for additional del/dup analysis for which there is no other code
- Because 81479 was denied, the lab called the provider and stated that the test was denied for insufficient reimbursement

Why?

The test above could have been denied because:

- Different UHC Plans with different benefit structures
  - One may have strict limits on genetic testing
- Lack of clinical information or lousy notes
- Medical Director's lack of genetics knowledge
- Out-of-Network testing available In-Network
  - Rare to deny this, more likely a high co-pay then the member tells the lab "No"

Lack of CPT Codes

Huge problem in genetics

 # possible disease panels X # of labs = size of the problem

AMA invented Proprietary Laboratory Analysis (PLA) codes which labs can apply for to identify their tests separately

4 numbers then a U, e.g., 0027U

AMA just held a meeting which identified problems, no solutions

See Resources for link to AMA document

Sponsored Testing

For years, the BIG LABS have made offers to patients & doctors: Send your sample to us and we will cap your patient's out-of-pocket payment to $100.

- I used these *all* the time when I was practicing

Here's the problem

- This incentivizes people to use a lab which the payor doesn't want you to use and sometimes there's a reason for that*

*Fake Labs

- Over $1 Billion was billed through fake labs in 2018
- Some are vacant shops in strip malls
  - Either have or steal a CLIA number & provider ID
- At Highmark, we found one!
- We cover roughly 6.8M people
  - We processed 108M claims last year
  - Finding the fraudster is very difficult

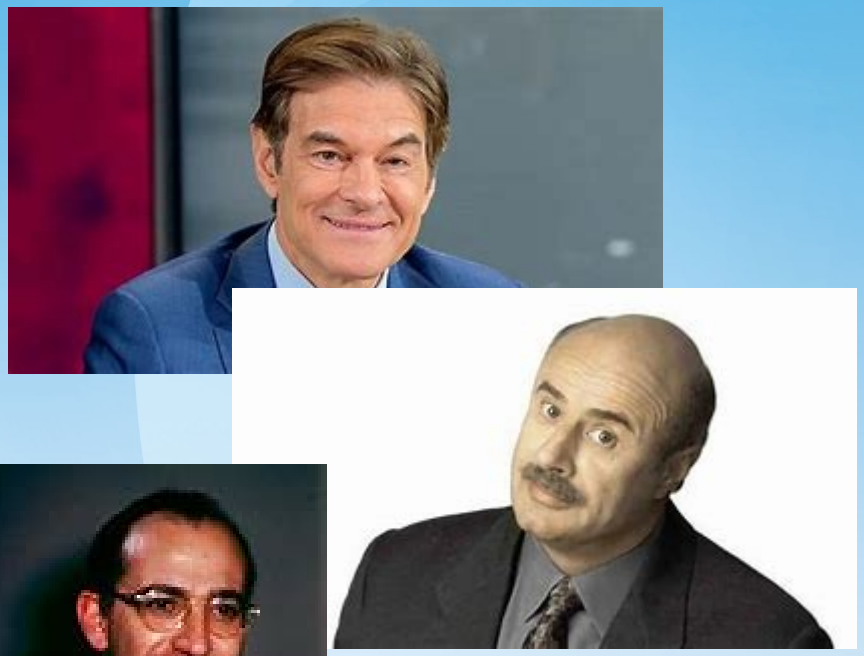
Topic Three: The Doctors

Two Very Different Providers

First Adopters

- Geneticists are taught they are better geneticists if they can recite the 15th gene for Joubert syndrome
- Labs are happy to accommodate this because reporting more genes on a panel doesn't cost much more
- Payors are suspicious that many of these genes are research, not clinical

Two Very Different Providers



Non-Geneticists

- Geneticists can no longer hold a monopoly on genetic testing
  - But not everyone is a geneticist
- Salespeople may have a lot of influence
  - Behavioral health providers who order PGx at their first visit
  - OB/Gyns order gender testing as part of NIPT
  - Neurologists who order repeat whole-genome sequencing

Lousy Clinical Notes

Good Example

I saw _____today for depression follow-up. Still recalcitrant

SLE

Continue MTX

Depression

Continue Zoloft + Abilify

Check PGx

Bad Example

I saw ____today for a routine physical exam. He was counseled about prostate cancer risk

SLE

Cont. MTx

Cont. Zoloft +Abilify

Check PGx

The Most Common Clinical Note

Topic Four: Members/Patients

The Improperly Insured

- Uninsured
- Underinsured
- Overinsured
- Primary & Secondary Insurances

The Over/Under (Insured)

What is an “Underinsured” situation?

- High-deductible plan sold to someone who can’t pay the deductible
- Most state Medicaid plans- smaller pie to slice
- “Grandfathered” plans- weak plans which were in effect prior to ObamaCare & “Grandfathered”
  - These are rare but Trump allowed sale of short-term products
- Good insurance sold to someone who can’t navigate it*

*Vast majority of US population

Workarounds for Underinsured Patients

High-deductible plans- wait until the end of the year

Grandfathered plans or plans without a genetic testing benefit (extremely rare)- give up

Medicaid- Adjust your expectations. They won't pay for WGS which might be cheaper in the long run but take the microarray and argue for a panel

Workarounds for Well-Insured Patients

- Perform a P2P
  - This is the best way to 1) get your test approved and 2) avoids having your patient act
- Take over the patient's appeal rights
  - Your legal department should have a template
- Know your regions primary insurers in-network labs
  - Painful but if you know to send Myriad to Cigna and Ambry to Aetna then your approval rates will be higher

Federal Programs

- Medicare- has extensive coverage of tests for cancer detection & treatment
  - Tighter criteria for hereditary cancer
  - Hard to find and read their policies
- VA- whole ‘nother world
  - Well respected for their genomic research

Secondary Insurance

Secondary insurance should cover costs one's primary insurance does not.

Common Examples:

- Primary private insurance (UHC) with secondary Medicaid for a child with severe neurologic injury who has a parent who works
- Primary private insurance (Highmark) with secondary Medicare A (hospitalization) for a person on dialysis who works.
- Primary Medicare with Medicaid secondary- common for disabled persons with lower incomes

Managing Secondary Insurance

The Best way: submit all co-pays to the secondary to decrease out-of-pocket costs

Pitfalls

- A provider submits to the secondary first
- The primary does not approve a particular service. Then there is controversy between the policies on whether the secondary will pay if the claim meets their criteria. Chaos ensues.

What about the Over-Insured?

Why did Obama try to get rid of “Platinum Plans?”

- Having too much insurance leads to moral hazard
- The over-insured are more likely to over-access healthcare
- Plans which require reasonable co-pays, co-insurance and/or deductibles do not diminish healthcare uptake

Brook, Robert H., Emmett B. Keeler, Kathleen N. Lohr, Joseph P. Newhouse, John E. Ware, William H. Rogers, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Patricia Camp, Caren Kamberg, Arleen Leibowitz, Joan Keesey, and David Reboussin, The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate. Santa Monica, CA: RAND Corporation, 2006. https://www.rand.org/pubs/research_briefs/RB9174.ht

Patients- Patience

- It is not fair that genetic testing is not available equally
  - Lower income people have poorer access
- Sometimes this takes awhile
  - It takes on average 104 days from prior authorization request to sample collection for exome sequencing

Lee G, et al Factors Associated with the time to complete clinical exome sequencing in a pediatric patient population. *GIM;* 2022

Conclusions

Hopefully, at this point I've

- Improved the status of insurance companies in your hearts
- Shown how Good genetic testing gets swept up with Bad testing (or coding & billing)
- Demonstrated competing interests between provider, payor, and laboratory
- Explained that not everyone is acting in good faith all the time

TipSheet

Easy Do's	Easy Don'ts
Look at the medical policies of your most frequent payors	Try to memorize details of a particular plan
Lots of Peer-to-peers	Be difficult during peer-to-peers
Letter of Medical Necessity Or Attach clinic notes & clinical guidelines	Letter of Medical Necessity Include primary literature, especially case reports unless your request is a Hail Mary

Resources and References

Lab Quality: Diagnostic Quality Assurance Pilot | Tapestry Networks

Also see: Center for Genomic Interpretation run by Julie Eggington

Genetics Value Assessment: Center for Translational and Policy Research on Personalized Medicine (UCSF) run by Kathryn Phillips

Fraud in Genetics: Healthcare Fraud Prevention Partnership White Paper, July 2020, copies available at TTP@gdit.com

Value Assessment of Rare Disease Drugs: Ollendorf D, Chapman R, Pearson S. Evaluating and Valuing Drugs for Rare Conditions: No Easy Answers. Value in Health 21 (2018) 547-52.