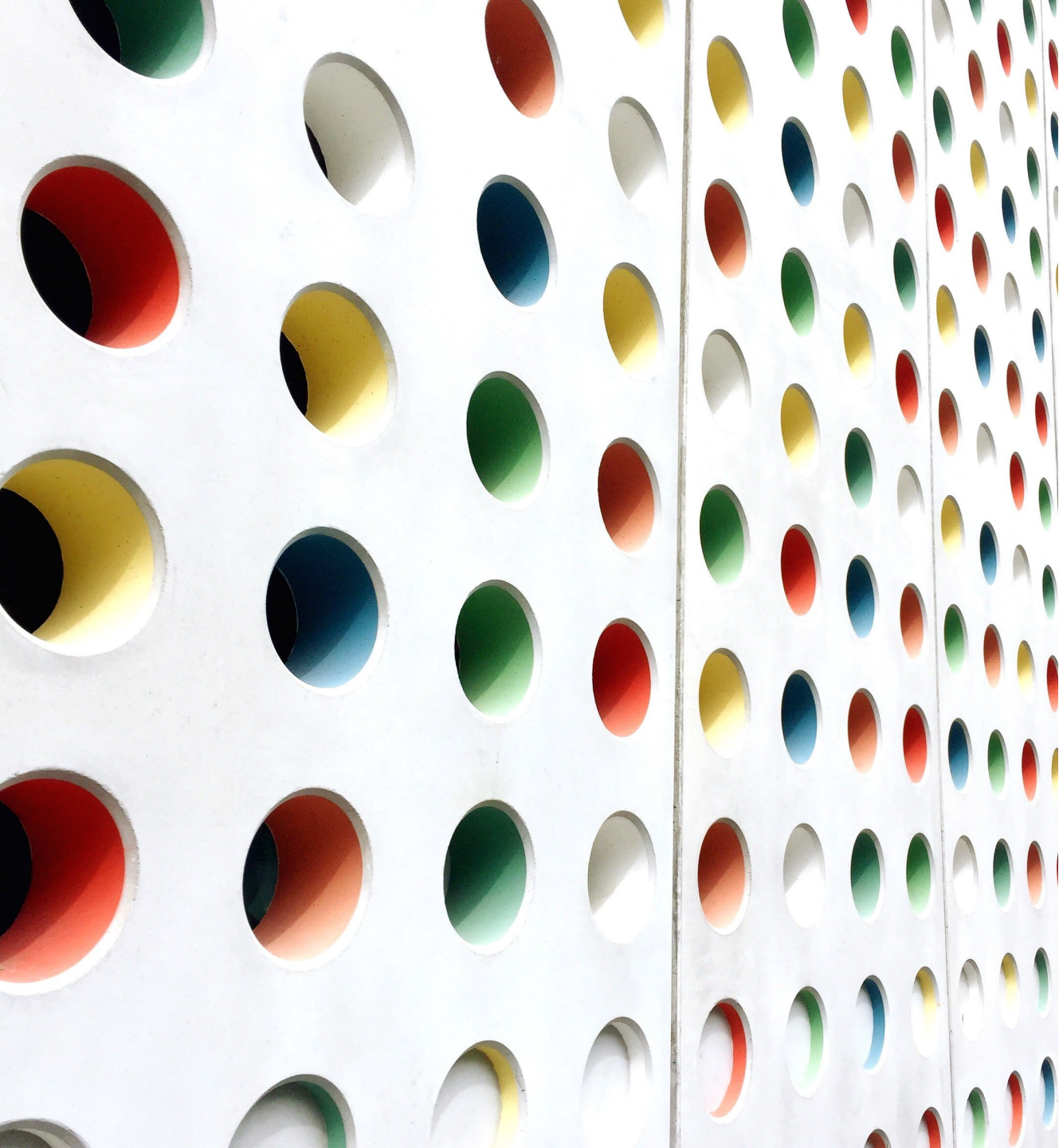


Medicare Local and National Coverage:

Evolving Access to Genomic Testing

Bruce Quinn MD PhD
Bruce Quinn Associates LLC
Los Angeles and San Francisco
bruce@brucequinn.com

NASEM October 4, 2022 *Deck available*

Overview: Medicare & Genomics

- 1) No copays for genomic testing; Fee schedules public
- 2) Coverage Decision Layers: National vs Local
- 3) All Part B payment data becomes public, by code and by lab
  - Recently, fraud is so rampant as to substantially distort national data
  - High usage of “unlisted code” also distorts data
- 4) National coverage decisions in Genomics
- 5) Local coverage decisions in Genomics
- 6) Coverage reform efforts
- 7) Coverage by Regulation

No Copays, Public Fee Schedules

1 No Copays
2 Natl Local
3 Public Data
4 NCDs
5 LCDs
6 Reform?
7 Regulation?

Not just preventive tests, but all laboratory tests, **don't have copays**

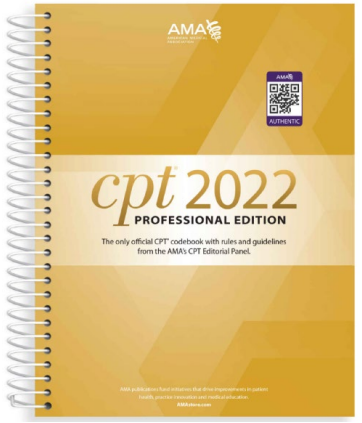
Fee schedules are public

Use AMA CPT Codes (5 digit codes; 1900 of them for lab tests; created by AMA)

- 638 codes for genomics (October 2022). *(Plus molec microbiol 112).*
- *Multiple "classes" of codes (out of scope today)*

Price levels are initially set by Medicare ("crosswalk" price or "gapfill" price)

Every three years a national survey of commercial insurance prices **resets** the Medicare price ("PAMA" price surveys, a 2014 law)



	A	B	C	D
1	2022 Clinical Diagnostic Laboratory Fee Schedule			
2	HCPCS	RATE	SHORTDESC	
3	81212	$ 440.00	Brca1&2 185&5385&6174 vrnt	Brca1 (brca1, dna repair associated
4	81215	$ 375.25	Brca1 gene known famil vrnt	Brca1 (brca1, dna repair associated
5	81216	$ 185.12	Brca2 gene full seq alys	Brca2 (brca2, dna repair associated
6	81217	$ 375.25	Brca2 gene known famil vrnt	Brca2 (brca2, dna repair associated
7	81218	$ 241.90	Cebpa gene full sequence	Cebpa (ccaat/enhancer binding prot
8	81219	$ 121.63	Calr gene com variants	Calr (calreticulin) (eg, myeloprolifera
9	81220	$ 556.60	Cftr gene com variants	Cftr (cystic fibrosis transmembrane
10	81221	$ 97.22	Cftr gene known fam variants	Cftr (cystic fibrosis transmembrane
11	81222	$ 435.07	Cftr gene dup/delet variants	Cftr (cystic fibrosis transmembrane
12	81223	$ 499.00	Cftr gene full sequence	Cftr (cystic fibrosis transmembrane
13	81224	$ 168.75	Cftr gene intron poly t	Cftr (cystic fibrosis transmembrane
14	81225	$ 291.36	Cyp2c19 gene com variants	Cyp2c19 (cytochrome p450, family
15	81226	$ 450.91	Cyp2d6 gene com variants	Cyp2d6 (cytochrome p450, family 2
16	81227	$ 174.81	Cyp2c9 gene com variants	Cyp2c9 (cytochrome p450, family 2
17	81228	$ 900.00	Cytog alys chrml abnr cgh	Cytogenomic (genome-wide) analys
18	81229	$1,160.00	Cytog alys chrml abnr snpcgh	Cytogenomic (genome-wide) analys
19	81230	$ 174.81	Cyp3a4 gene common variants	Cyp3a4 (cytochrome p450 family 3
20	81231	$ 174.81	Cyp3a5 gene common variants	Cyp3a5 (cytochrome p450 family 3

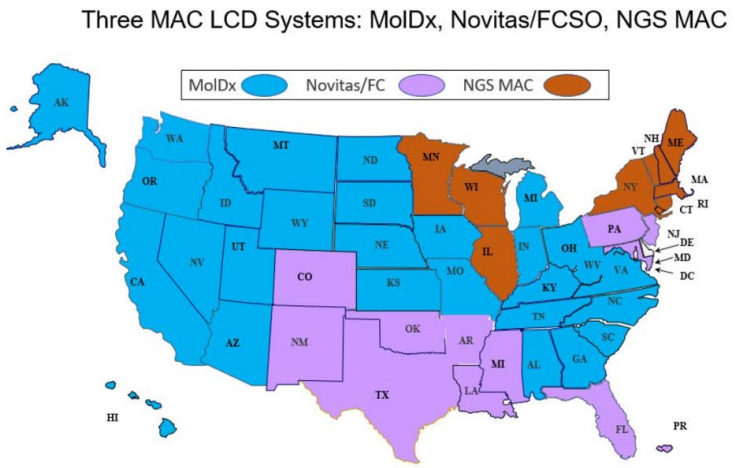
Genomics: National Decisions; 3 Local Policy Geographies

1 No Copays
2 Natl Local
3 Public Data
4 NCDs
5 LCDs
6 Reform?
7 Regulation?

There are a handful of important national coverage decisions (NCDs) in genomics.

This is where lectures usually start.

Most coverage decisions are local and fall into one of three geographic policy systems:



Medicare Part B Data Rapidly Becomes Public

1 No Copays
2 Natl Local
3 Public Data
4 NCDs
5 LCDs
6 Reform?
7 Regulation?

CY2020 data by nation and by state (by CPT code) was be released in November 2021

CY2020 data by CPT code and each lab (or doctor) was released in July 2022

CY 2021 data (national; and by state) will be released soon, in November 2022

- National: https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-National-Summary-Data-File/Overview
- State: https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-Carrier-Summary-Data-File/Overview
- Provider: https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-provider-and-service

Top 15 Codes, 2022, Including COVID

	Code		Services	Dollars Allowed		$2,499,080,834
1	U0003&04	COVID PCR	9,021,988	$900,355,873	36%	36%
2	81479	MISC MOLEC TEST	138,822	$290,906,564	12%	48%
3	81528	COLOGUARD	413,272	$210,298,026	8%	56%
4	81408	TIER II LEVEL 9	103,903	$207,027,810	8%	64%
5	87798	MICROB PCR OTH	85,338,357	$181,127,908	7%	72%
5	81162	BRCA	46,788	$77,568,416	3%	75%
6	81519	ONCOTYPE	20,028	$77,514,500	3%	78%
7	0037U	FND MED FMI	22,147	$40,366,543	2%	79%
8	81404	TIER II LEVEL 5	147,039	$34,814,185	1%	81%
9	81407	TIER II LEVEL 8	41,329	$33,958,728	1%	82%
10	81599	MISC MULTI ANALYTE	4,738	$31,586,809	1%	83%
11	81405	Tier II LEVEL 6	104,825	$29,098,713	1%	85%
12	81406	TIER II LEVEL 7	102,850	$24,981,566	1%	86%
13	81490	Crescendo test	29,733	$22,579,560	1%	87%
14	81595	Allomap	6,969	$22,240,800	1%	87%
15	81545	Tumor 5-50 Genes	6,178	$21,181,437	1%	88%

Top 15 Codes, 2022, Exclude COVID;
Proprietary Codes are 42%

	Code		Services	Dollars Allowed		$1,598,724,961	
2	81479	MISC MOLEC TEST	138,822	$290,906,564	18%	18%	18%
3	**81528**	**COLOGUARD**	413,272	$210,298,026	13%	31%	13%
4	81408	TIER II LEVEL 9	103,903	$207,027,810	13%	44%	
5	87798	MICROB PCR OTH	85,338,357	$181,127,908	11%	56%	
5	81162	BRCA	46,788	$77,568,416	5%	60%	
6	**81519**	**ONCOTYPE**	20,028	$77,514,500	5%	65%	5%
7	**0037U**	**FND MED FMI**	22,147	$40,366,543	3%	68%	3%
8	81404	TIER II LEVEL 5	147,039	$34,814,185	2%	70%	
9	81407	TIER II LEVEL 8	41,329	$33,958,728	2%	72%	
10	81599	MISC MULTI ANALYTE	4,738	$31,586,809	2%	74%	
11	81405	Tier II LEVEL 6	104,825	$29,098,713	2%	76%	
12	81406	TIER II LEVEL 7	102,850	$24,981,566	2%	78%	
13	**81490**	**Crescendo test**	29,733	$22,579,560	1%	79%	1%
14	**81595**	**Allomap**	6,969	$22,240,800	1%	80%	1%
15	81545	Tumor 5-50 Genes	6,178	$21,181,437	1%	82%	
							42%

Heavily Abused Codes (32% of payments)

Starting point: DOJ indictments

Then find: Code patterns used by indicted labs

- Which is: Labs that bill 80% and up in Tier 2 codes, esp. 81408 for which 2 tests per patient were paid at $2000 each or $4000 per patient
- Labs billing heavily in Tier 2 codes often tied to telemedicine fraud (per DOJ indictments or guilty pleas or convictions)
- Often names like "ABC Lab" or "Best Lab"
- Then, troll CMS lab claims records for matching labs billing high proportion of code 81408; well known labs are completely absent (LabCorp, Quest, etc)

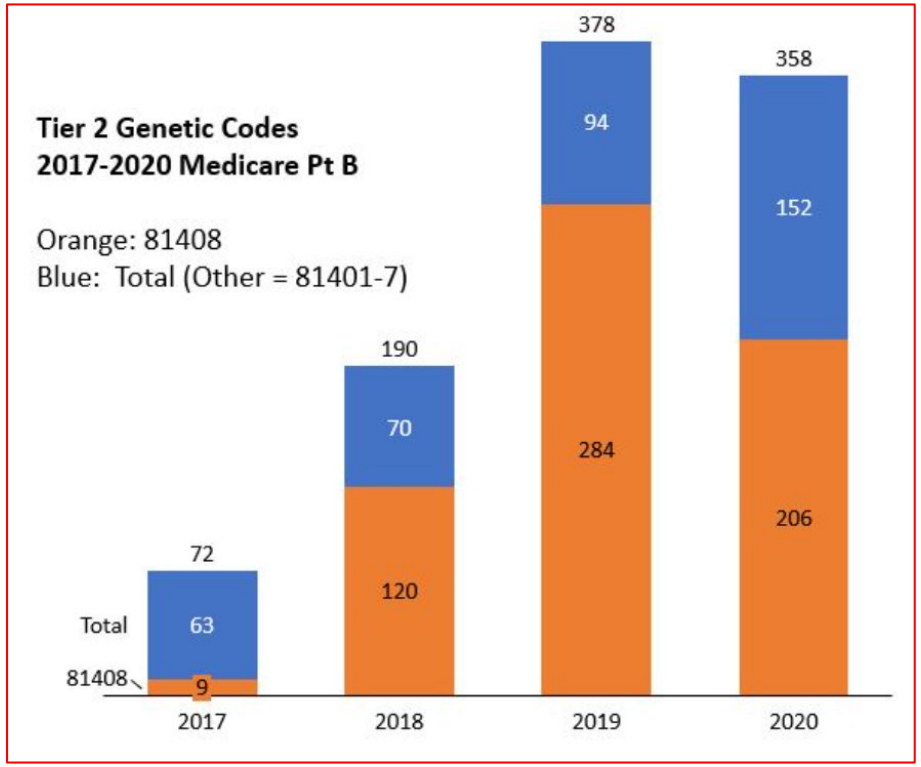
Top 15 Codes, 2022, w/o COVID;
HEAVILY ABUSED CODES, 32%

	Code		Services	Dollars Allowed		$1,598,724,961	$511,008,911
2	81479	MISC MOLEC TEST	138,822	$290,906,564	18%	18%	
3	81528	COLOGUARD	413,272	$210,298,026	13%	31%	
4	81408	TIER II LEVEL 9	103,903	$207,027,810	13%	44%	13%
5	87798	MICROB PCR OTH	85,338,357	$181,127,908	11%	56%	11%
5	81162	BRCA	46,788	$77,568,416	5%	60%	
6	81519	ONCOTYPE	20,028	$77,514,500	5%	65%	
7	0037U	FND MED FMI	22,147	$40,366,543	3%	68%	
8	81404	TIER II LEVEL 5	147,039	$34,814,185	2%	70%	2%
9	81407	TIER II LEVEL 8	41,329	$33,958,728	2%	72%	2%
10	81599	MISC MULTI ANALYTE	4,738	$31,586,809	2%	74%	
11	81405	TIER II LEVEL 6	104,825	$29,098,713	2%	76%	2%
12	81406	TIER II LEVEL 7	102,850	$24,981,566	2%	78%	2%
13	81490	Crescendo test	29,733	$22,579,560	1%	79%	
14	81595	Allomap	6,969	$22,240,800	1%	80%	
15	81545	Tumor 5-50 Genes	6,178	$21,181,437	1%	82%	
							32%

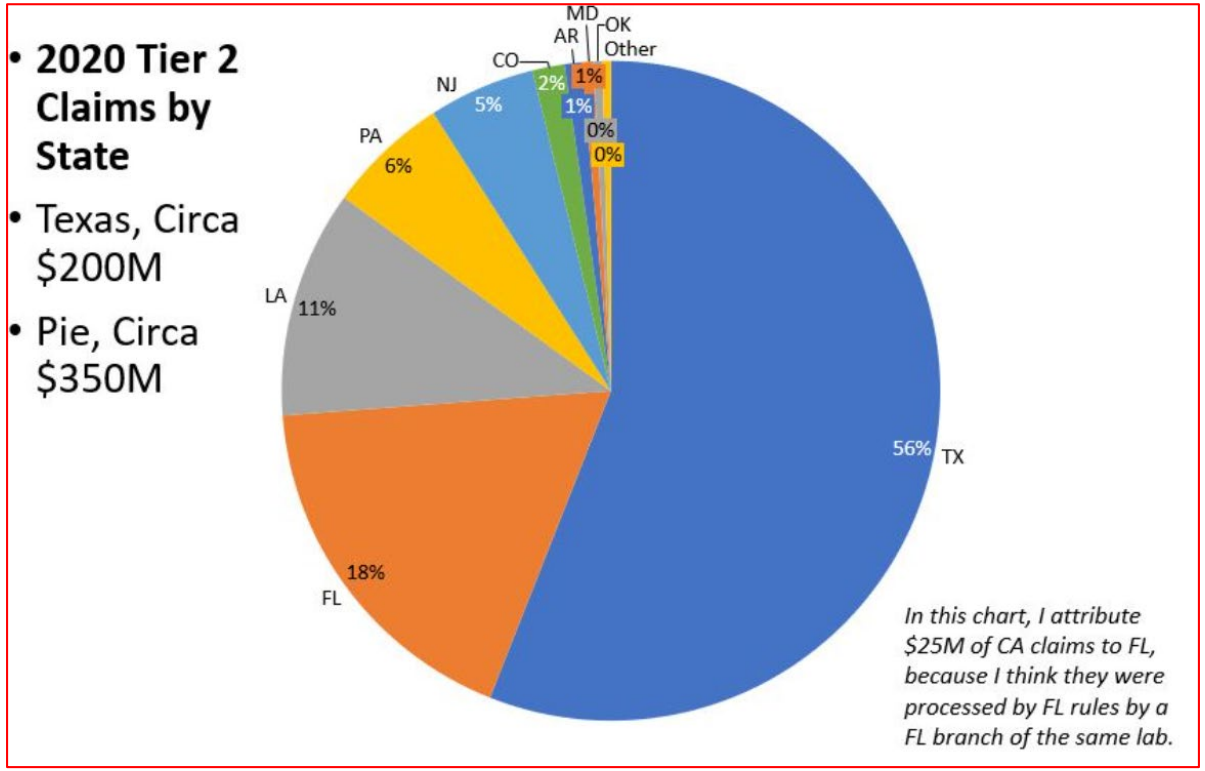
Quick Peek:
Proprietary Tests 61% (w/o “yellow tests”)

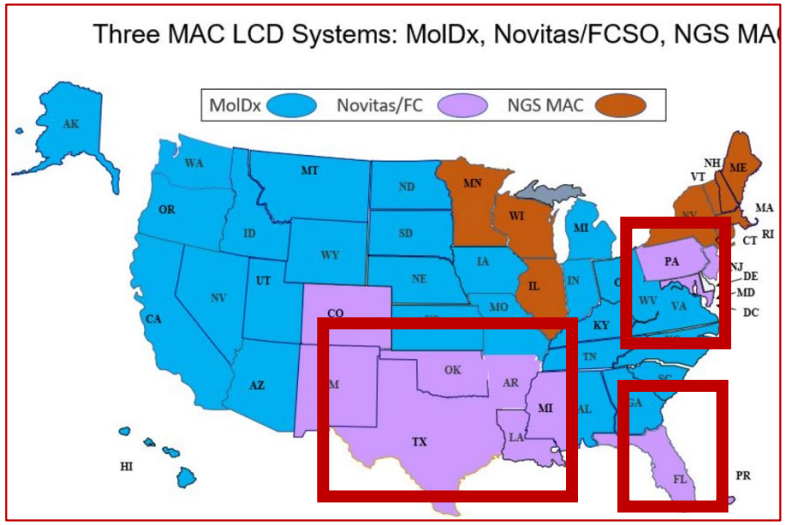
	Code		Services	Dollars Allowed		$1,087,716,050	
2	81479	MISC MOLEC TEST	138,822	$290,906,564	27%	27%	27%
3	**81528**	**COLOGUARD**	413,272	$210,298,026	19%	46%	19%
4	81408	TIER II LEVEL 9	103,903		0%	46%	
5	87798	MICROB PCR OTH	85,338,357		0%	46%	
5	81162	BRCA	46,788	$77,568,416	7%	53%	
6	**81519**	**ONCOTYPE**	20,028	$77,514,500	7%	60%	7%
7	**0037U**	**FND MED FMI**	22,147	$40,366,543	4%	64%	4%
8	81404	TIER II LEVEL 5	147,039		0%	64%	
9	81407	TIER II LEVEL 8	41,329		0%	64%	
10	81599	MISC MULTI ANALYTE	4,738	$31,586,809	3%	67%	
11	81405	Tier II LEVEL 6	104,825		0%	67%	
12	81406	TIER II LEVEL 7	102,850		0%	67%	
13	**81490**	**Crescendo test**	29,733	$22,579,560	2%	69%	2%
14	**81595**	**Allomap**	6,969	$22,240,800	2%	71%	2%
15	81545	Tumor 5-50 Genes	6,178	$21,181,437	2%	73%	
							61%

Heavily Abused Codes

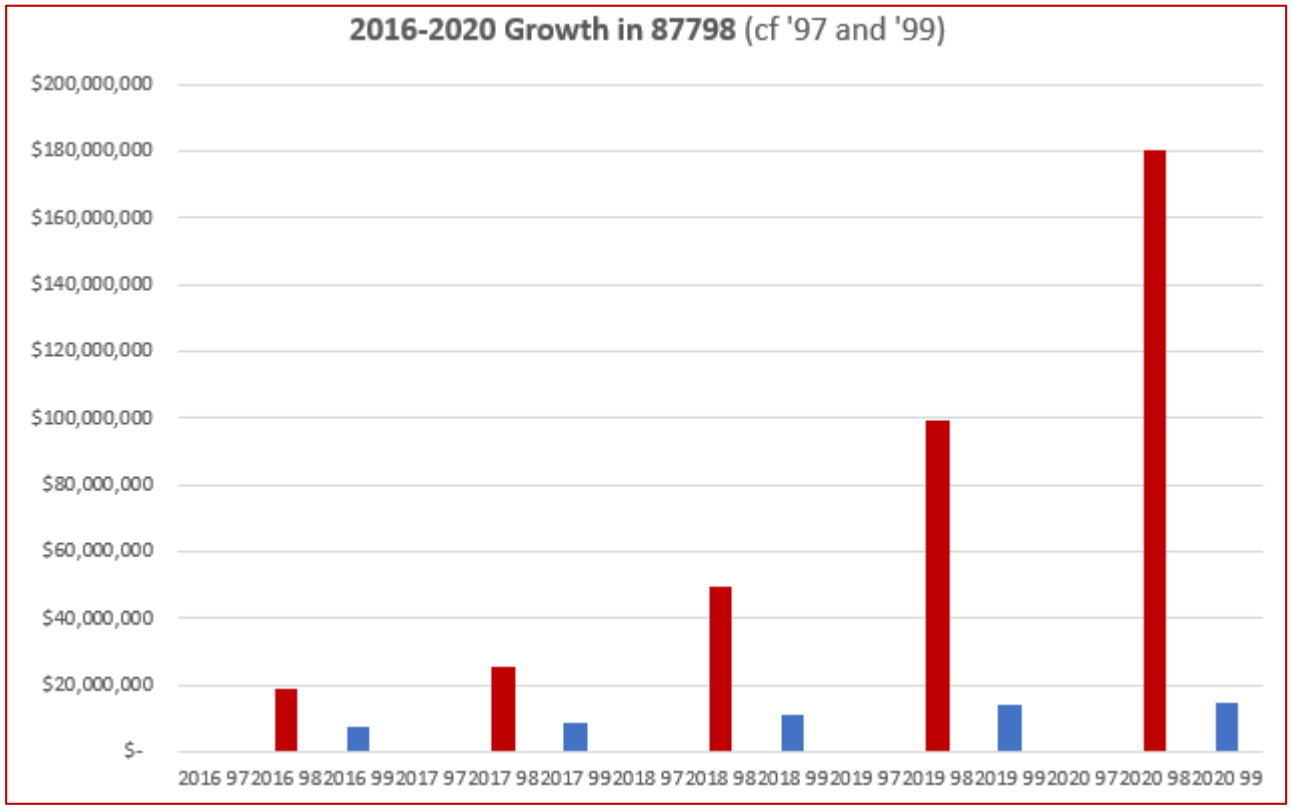


- Massive growth 2018, 2019, 2020
- **+$705M** *over 2017 base rate* for Tier 2 codes (mostly 81408, 81407)



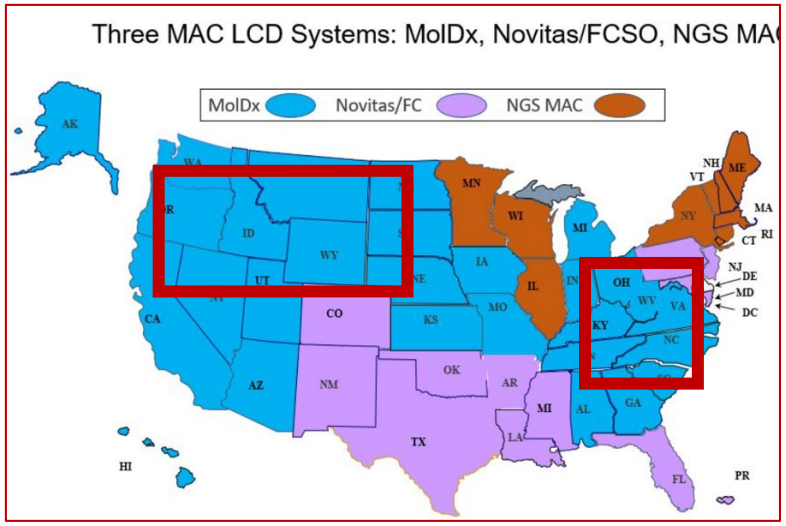


Heavily Abused Codes: 87798 “Other PCR Pathogen)



- Massive growth 2018, 2019, 2020
- +**$252M** *over base rate* for 2017 for one code 87798 (Other Microbe, PCR)

Large 87798 payments *primarily limited to* labs in “MOLDX” policy states (blue)



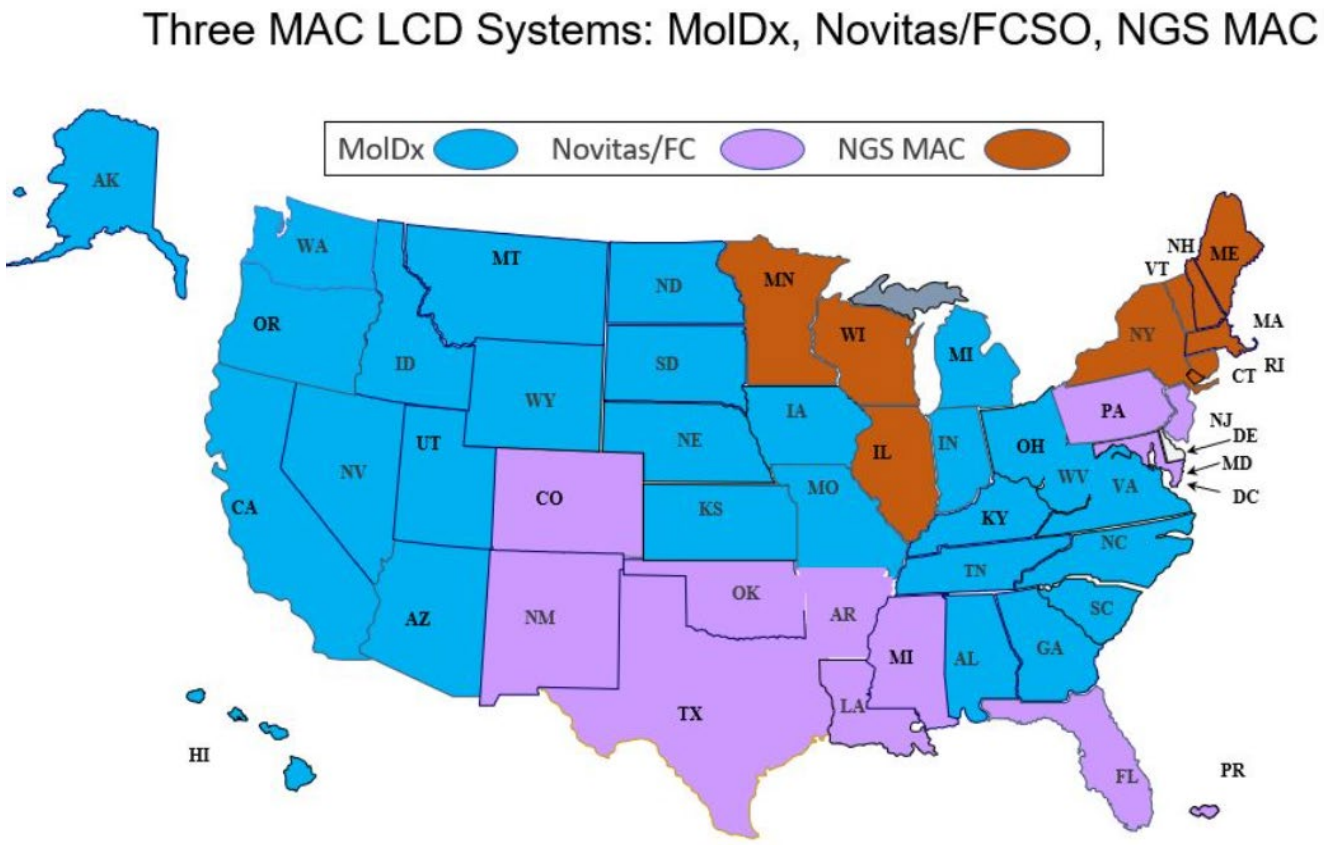
Genomics National Coverage Decisions

1 No Copays
2 Natl Local
3 Public Data
4 NCDs
5 LCDs
6 Reform?
7 Regulation?

- **2014 – Cologuard Decision**
  - Coverage of prevent service test, DNA-based fecal colon cancer screening test
- **2018 – Next Gen Sequencing in Cancer Decision**
  - Guarantees immediate coverage for all FDA-approved companion diagnostics USING "NGS"
  - Intended to incent development of FDA-approved tests
  - (*Draft decision would have banned coverage of LDT tests*)
  - *Blocks use of "same test more than once"* – since liquid biopsy recurrence tests (minimal residual disease) tests are entering use – but NCD won't be revised until there is an FDA test as an index case for NCD
- **2021 – Liquid Biopsy for Cancer Screening**
  - Automatically will cover blood-based cancer screening if 74% sensitive and 90% specific – and FDA hasn't approved such a test yet

Genomics Local Coverage Decisions = 3 Zones

1 No Copays
2 Natl Local
3 Public Data
4 NCDs
5 LCDs
6 Reform?
7 Regulation?

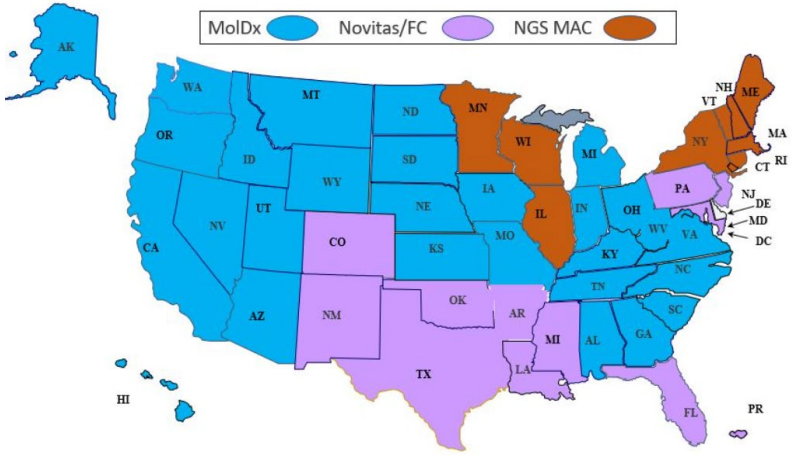


Three Zones Behave Very Differently!

1 No Copays
2 Natl Local
3 Public Data
4 NCDs
5 LCDs
6 Reform?
7 Regulation?

- NGS MAC system (BROWN)
  - Under local decisions, Far less payments per capita or per million benes than other MACs
  - However, about 'zero' highly suspicious payments
  - DO pay two of the biggest, FDA approved, nationally covered tests (Cologuard WI, Foundation Medicine MA)
- NOVITAS SYSTEM (PURPLE)
  - Battered by high abnormal payments
  - Rolling out some VERY strict draft LCDs
    - Cardiology – No Genes Allowed
    - Cancer – Only Guideline-Endorsed Tests Allowed
- MOLDX SYSTEM (BLUE)
  - In 2018, payments were more normal, handled about 80% of LCD-based payments
  - Very elaborate body of policies, rules, tech assessments, databases, etc. "MolDx ology"
  - Early coverage of comprehensive genomic profiling in solid tumors, and of minimal residual disease testing in cancer

Three MAC LCD Systems: MolDx, Novitas/FCSO, NGS MAC



Reform and Regulation

1 No Copays
2 Natl Local
3 Public Data
4 NCDs
5 LCDs
6 Reform?
7 Regulation?

❑Trump Proposal - MCIT

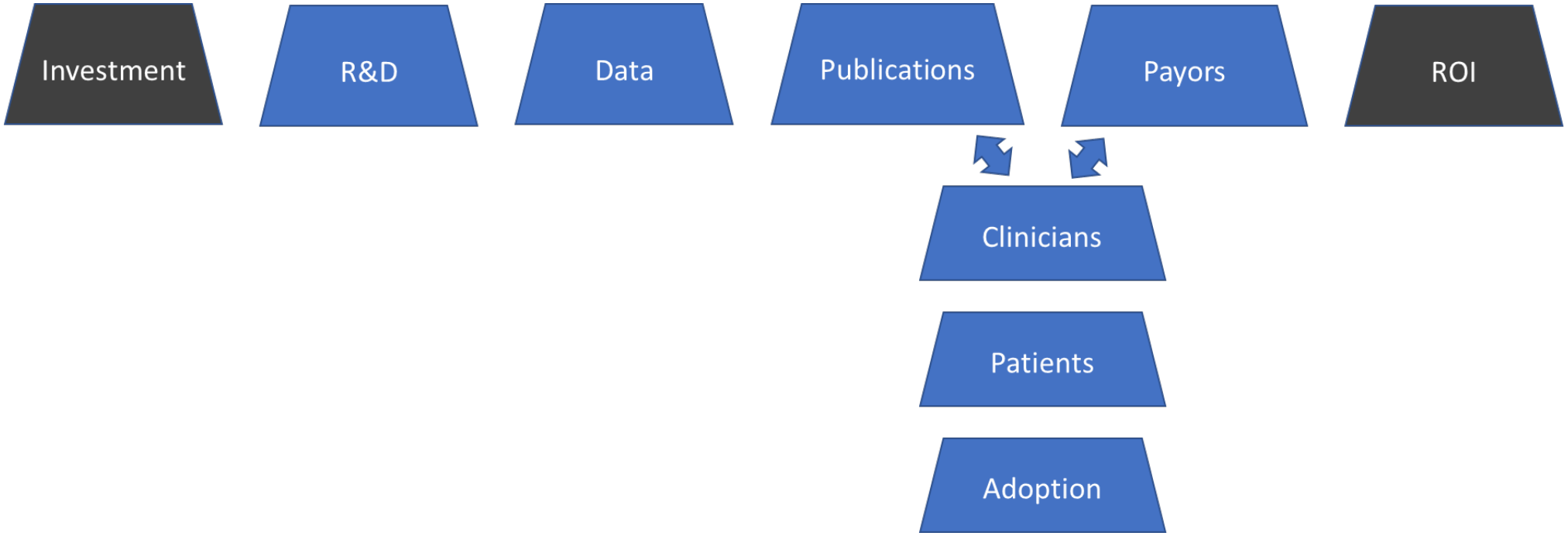
- Medicare Coverage for Innovative Technology
- FDA breakthrough devices get 4 years coverage
- Canceled by Biden Administration

❑Transitional Coverage for Emerging Technology (TCET)

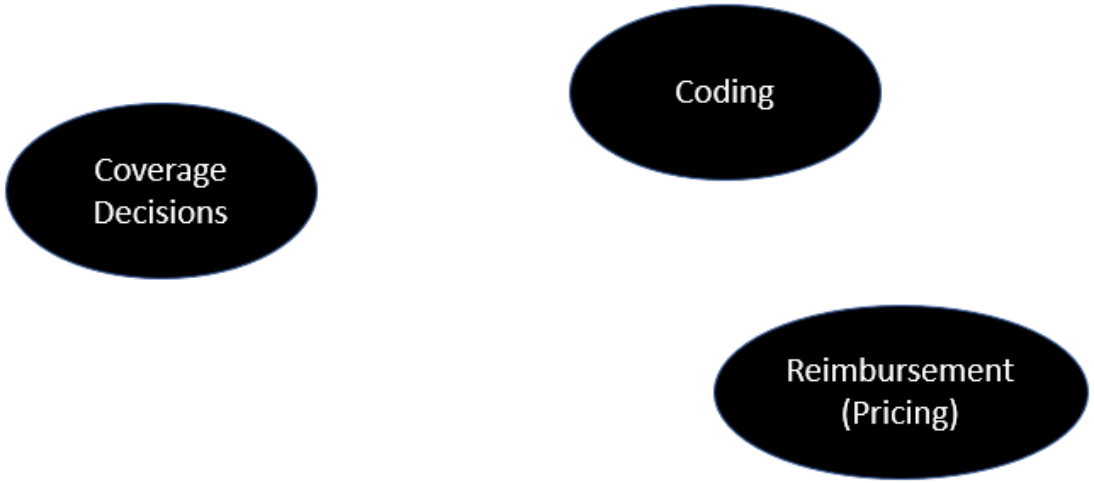
- NOT A SINGLE PROPOSAL – AT THE STAGE OF TOWN HALLS, ETC
- "WE PLAN TO DO THINGS"

- Held town halls x 2 in spring
- Have also presented decks, e.g. modernize or amplify "Coverage with Evidence Development" **CED**
- AHRQ – Recently reported on Medicare's **CED** process (see also Zeitler 2022, PMID 35981123)
- Public advisory meeting in December – on **CED** process
- Some stakeholders want **TCET** to build on "Category B Trial Coverage" which is managed by CMS staff

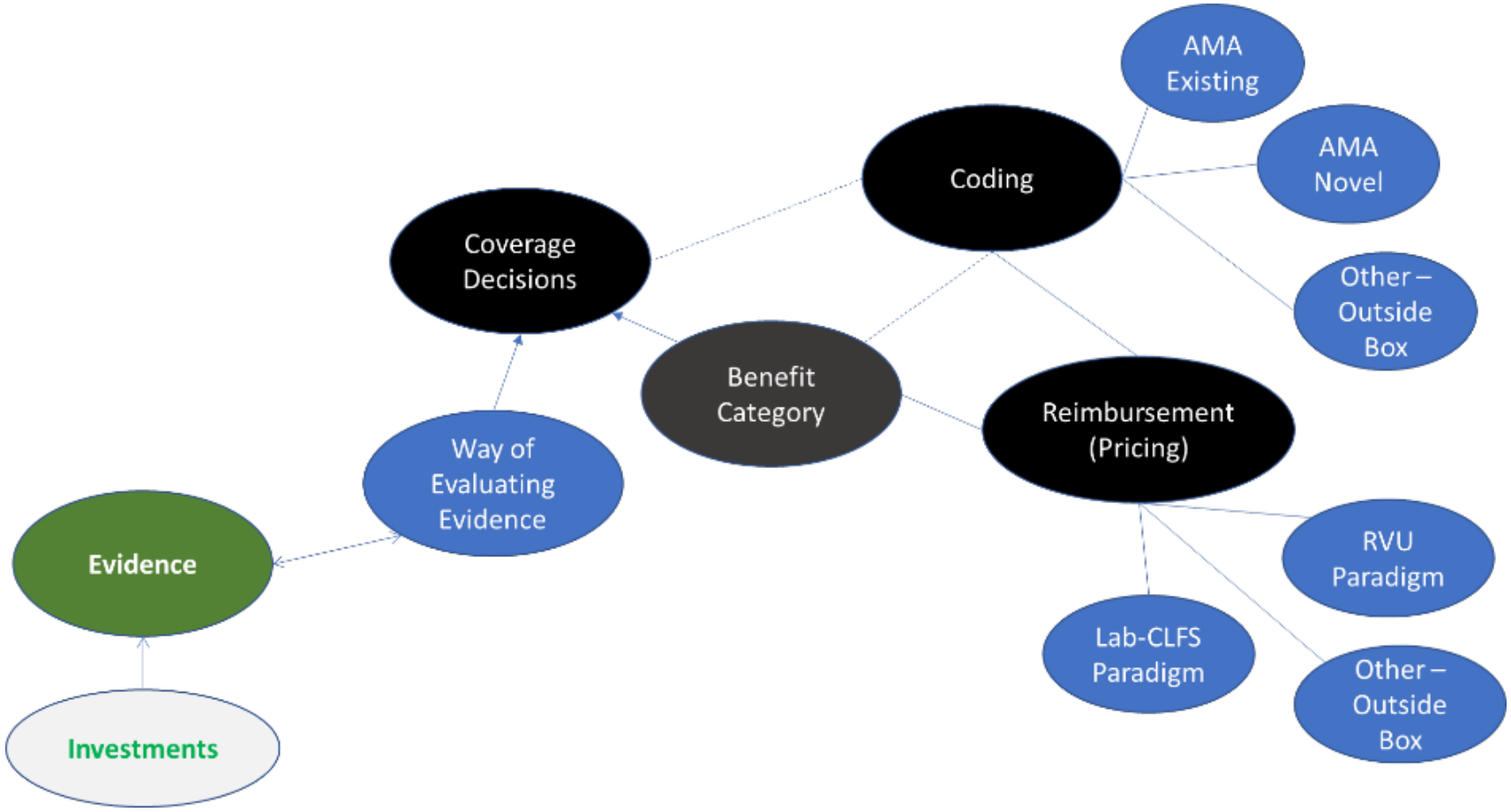
Simplest view is “linear”



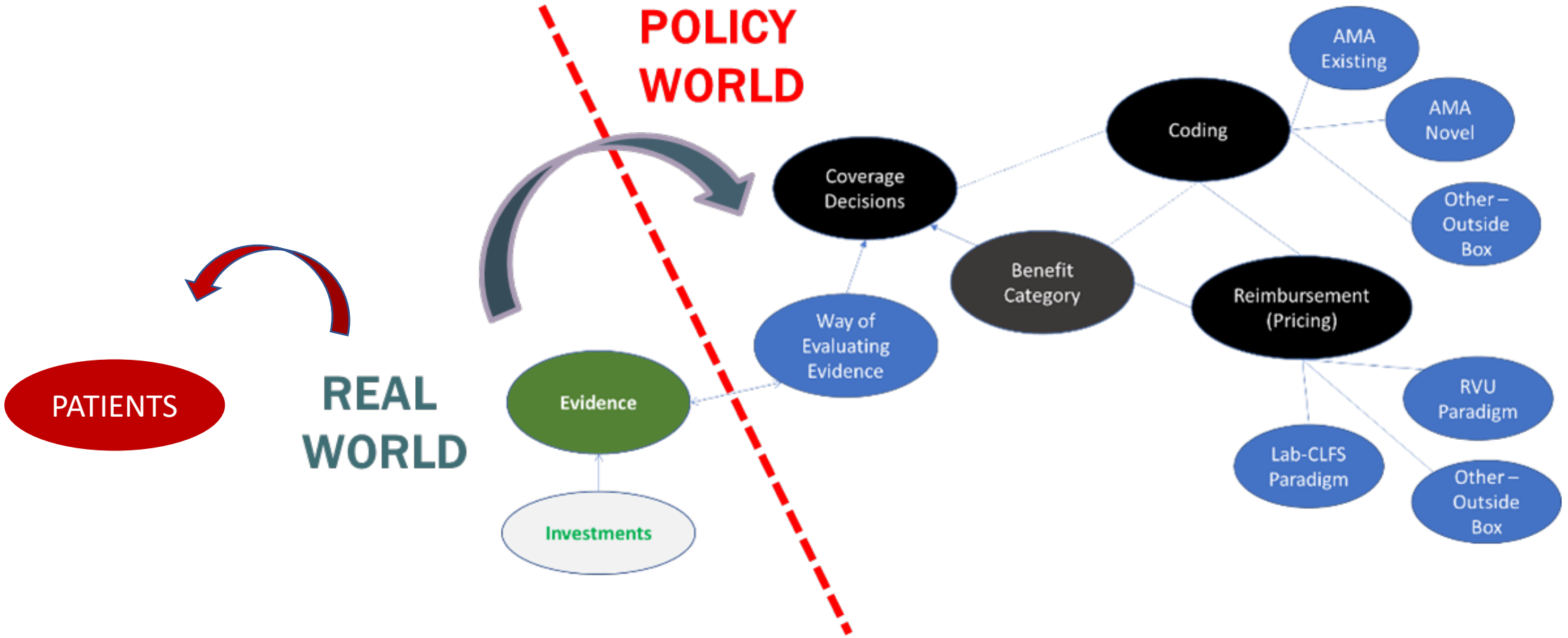
When we think of three things, “coverage, coding, payment”…



There's all this stuff going on around "C, C, P"



Of which only “evidence” is in the real world.



Questions?

BRUCE QUINN ASSOCIATES LLC

HEALTH INNOVATION MADE REAL.

Appendix

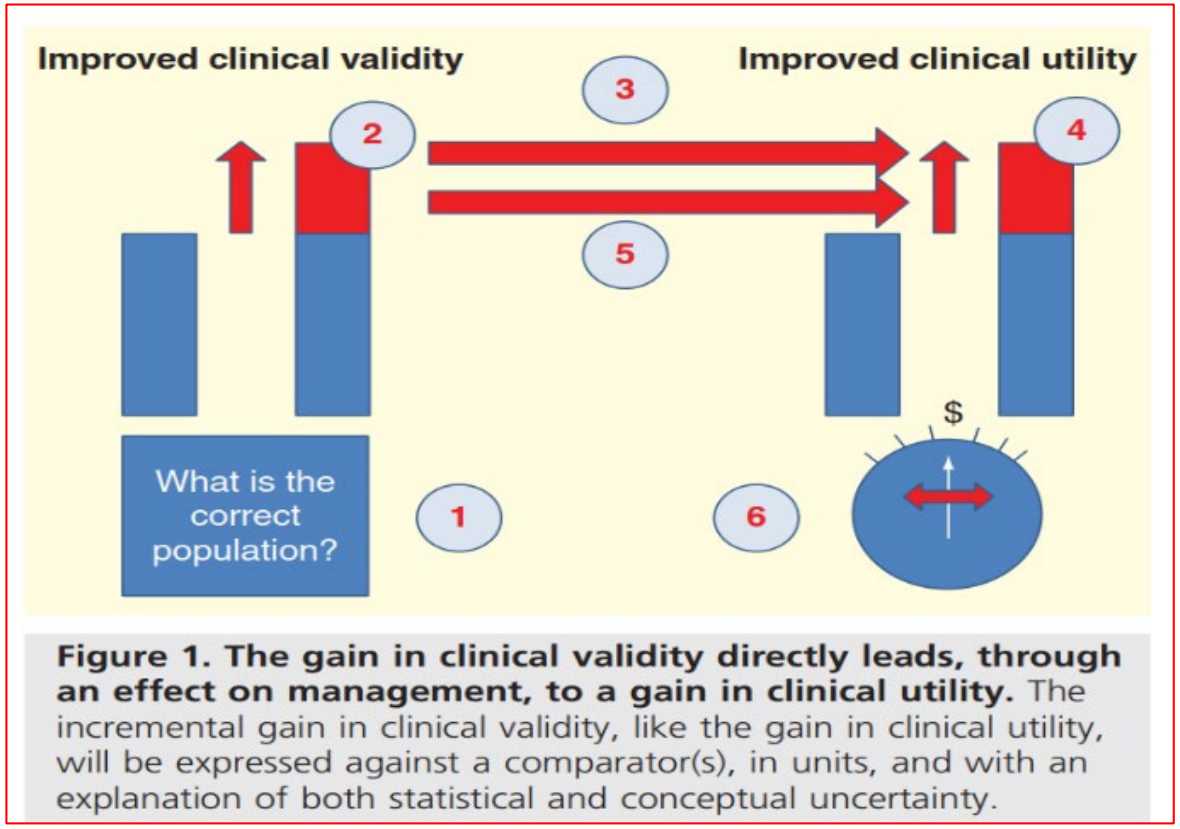


Figure 1. The gain in clinical validity directly leads, through an effect on management, to a gain in clinical utility. The incremental gain in clinical validity, like the gain in clinical utility, will be expressed against a comparator(s), in units, and with an explanation of both statistical and conceptual uncertainty.

For details see Quinn & Frueh, 2014, Expert Rev. Mol Diagn. 14:777-86

Appendix

Discoveries in Health Policy

Ideas for or from an evolving healthcare system

Thursday, February 3, 2022

Revisiting Medicare's Bizarre Construction of Date of Service Rules for Proteomic MAAA Tests

For a few years, this has been the status quo for Medicare bundling of tests based on blood or tissue samples taken in the hopsital outpatient environment (both hospital outpatient medical clinics and hospital outpatient surgical centers.) The rules are at 42 CFR 414.510.

All laboratory and pathology tests are bundled to the underlying procedure or office visit, EXCEPT for MOLECULAR PATHOLOGY tests. In practice, CMS defines molecular pathology tests as human DNA/RNA and marks these with a payable indicator in the outpatient fee schedule. Payable tests are paid by the lab that performs them

http://www.discoveriesinhealthpolicy.com/2022/02/revisiting-medicares-bizarre.html