Non-Binary Coverage Decisions: *Matching to Diagnostic Tests*

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Driving Business Advantage

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Services

Procedures

Drugs

Diagnostic Tests

DME/Supplies

Binary Coverage Decision

Non-Binary Coverage Decision

Services

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Non-Binary Coverage Decision

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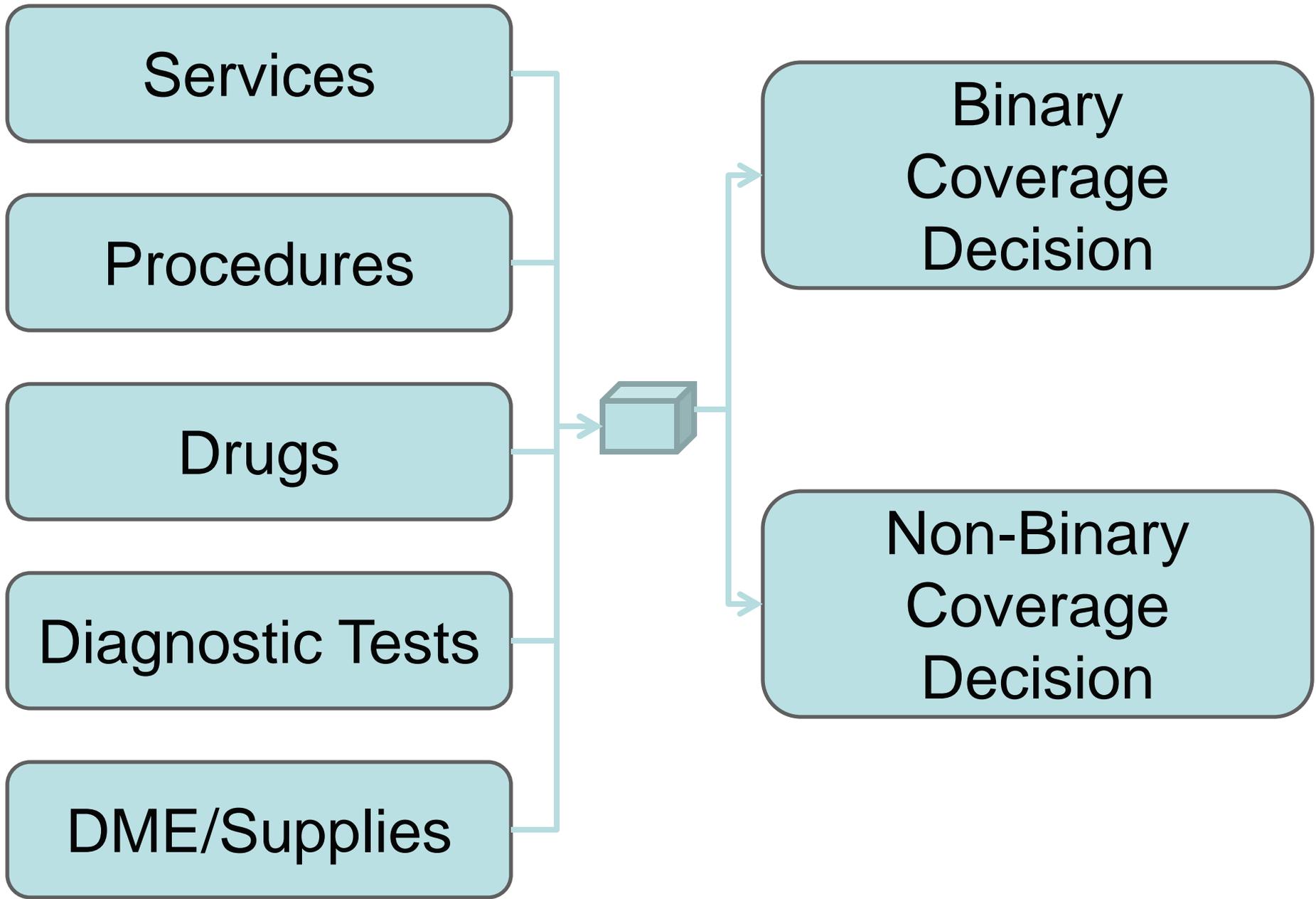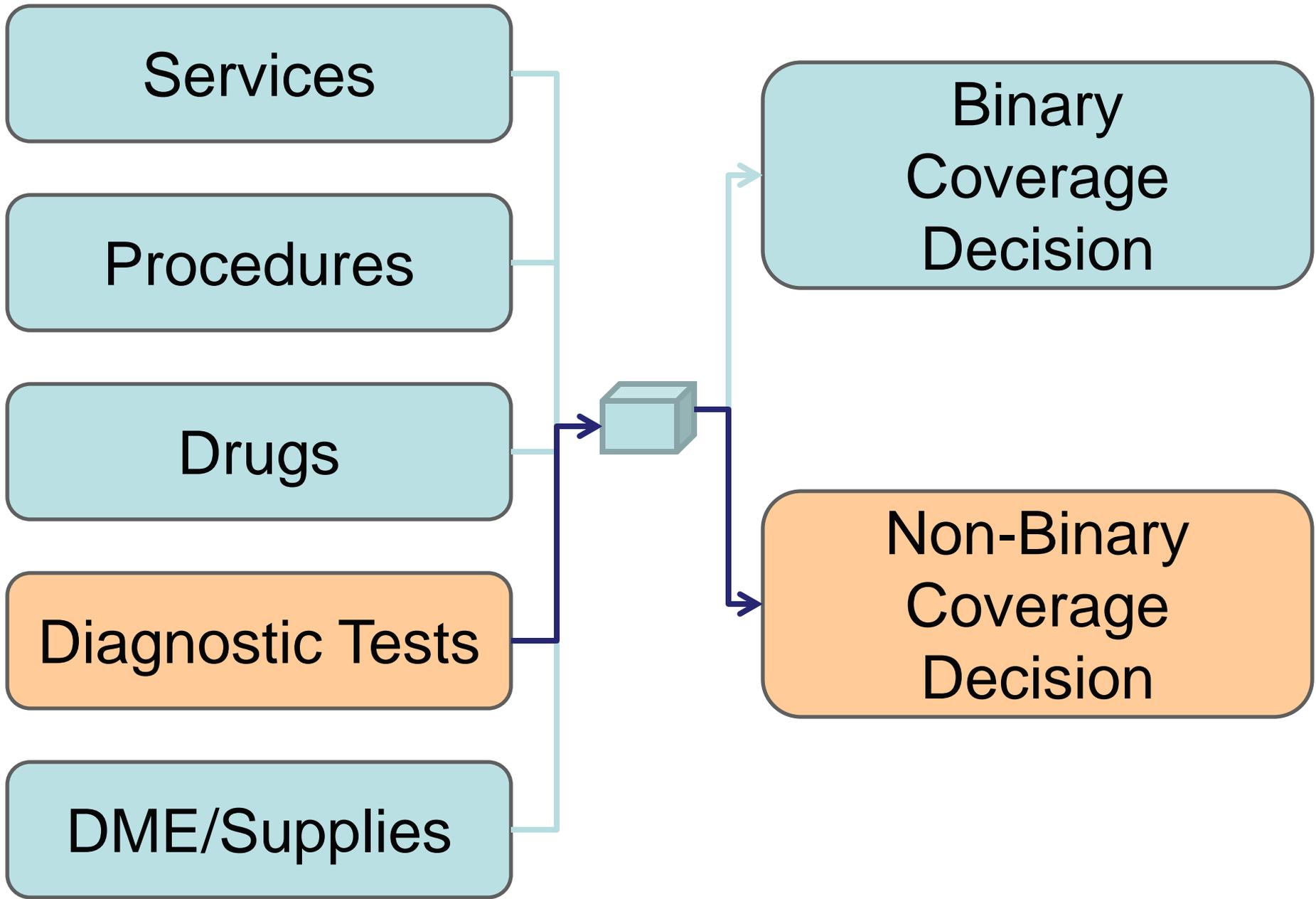
There is a century-old bias that diagnostic tests are over-used.

MEDICINE AND THE REIGN OF TECHNOLOGY

STANLEY JOEL REISER

1978

A Parisian physician touring American hospitals in *1912* reported his surprise at the number of laboratory tests routinely requested…they seemed, "Like the Lord's rain, to descend from heaven on the just and the unjust in the most impartial fashion…"

In the *1940s*, Harrison noted "the present day tendency towards a five-minute history followed by a five-day barrage of special tests in the hope that the diagnostic rabbit may emerge from the laboratory hat."

Studies in the *1970s* found that many laboratory tests ordered by doctors yielded little information that was new or useful.
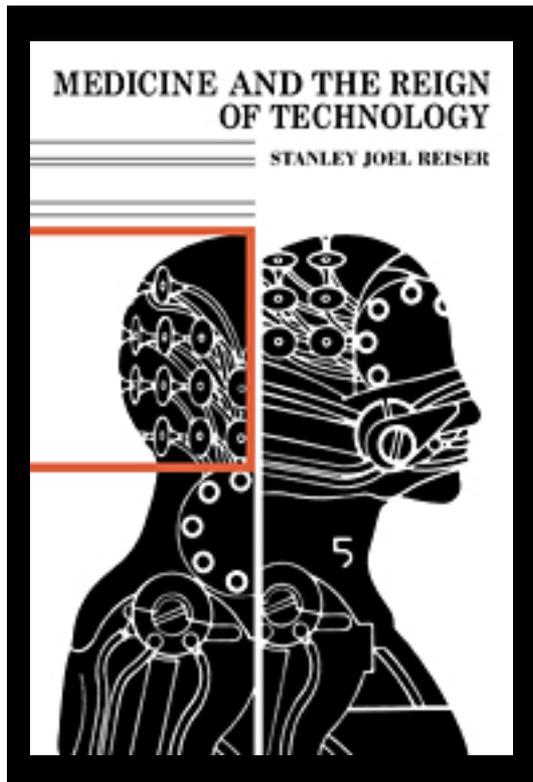
Problems with Evidence for Diagnostic Tests

- Technology Assessments and Diagnostic Tests
  - AHRQ/BRCA
  - Highest ratings for Double blinded RCT
  - RCT → Causality
  - RCT should pivot on diagnostic test
  - Lack of outcome data
  - Comparative advantage difficult & confusing to access

^ Causes of Problems with Evidence for Diagnostic Tests

AHRQ/BRCA	→	• Evidence that BRCA is assoc. with breast cancer is, at best, "fair" (?!)
DBL BLIND RCT	→	• Generally *impossible* to do blinded RCT with Dx: Use mock lab reports in one arm (?!)
RCT→Causality	→	• RCTs help establish causality. But Dx test may hinge on "correlation," *e.g. Troponin does not cause MI*
RCT Pivots on Test	→	• Statistical dilemma with equipoise • RCT Pivots on Test: "Diagnostics are like Herceptin" (next slide)
Lack of Outcome Data	→	• Real world considerations (e.g. one PET scan mfgr & a breast cancer trial) • FDA: Validate & approve test before clinical trials (outside of Combi. Dx.)

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"Diagnostic Tests are Like Herceptin"

| 200 Women with Breast Cancer | 200 Women with Breast Cancer | 200 Patients |

| 100 Control | 100 Herceptin | Herceptest | 100 w/o Test | 100 w/ Test |

| 30 Her2+ | Controls | Enriched Population | 30% Change Dx |

| 50% Live Longer | 50% Live Longer | 50% Live Longer |

| 100 | 85 | **15** | 100 | 50 | **50** | 100 | 85 | **15** |
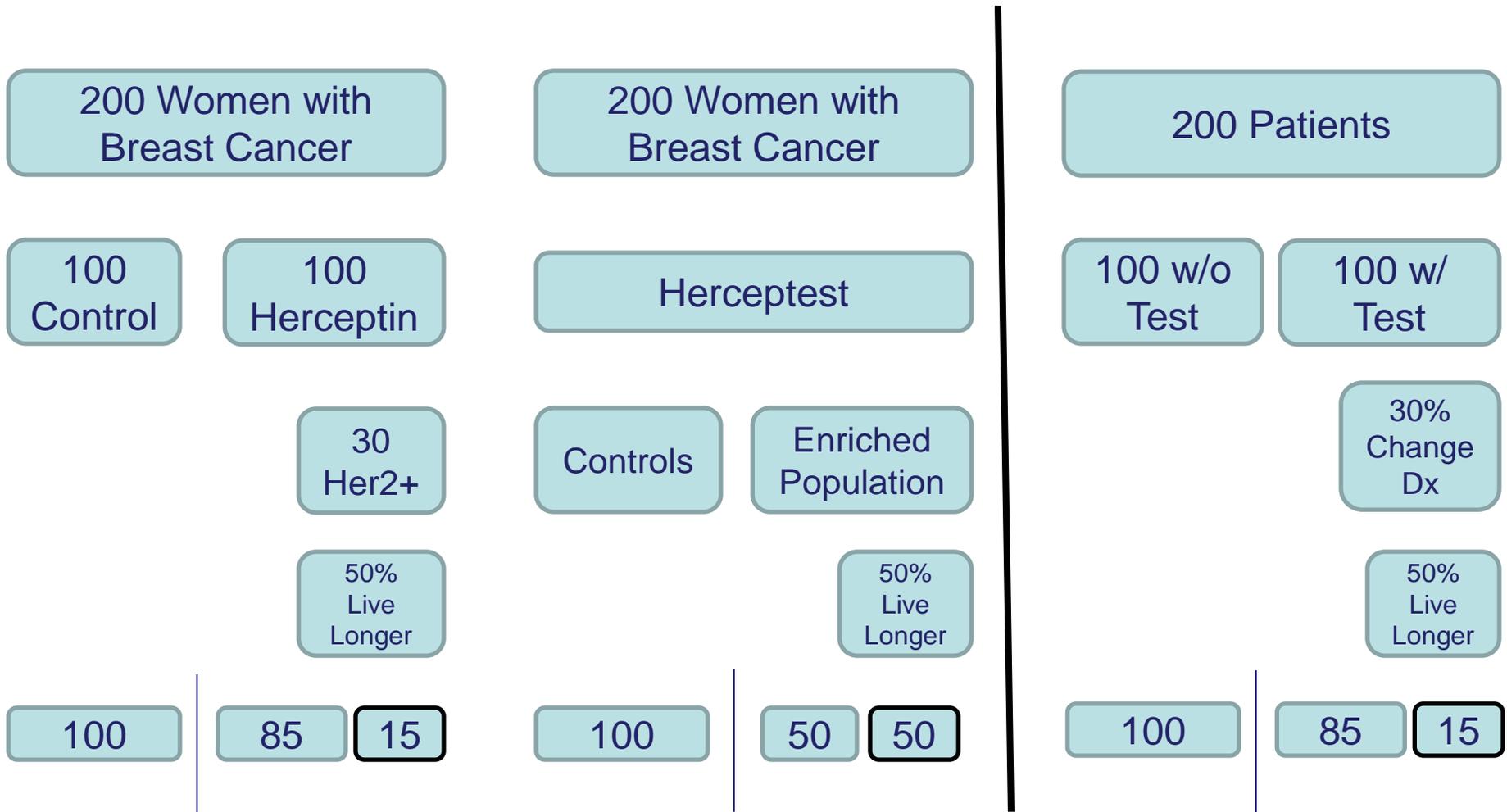
(Illustrative Numbers Only)

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│    Services     │─────┐                         │     Binary      │
└─────────────────┘     │                         │    Coverage     │
                        │                         │    Decision     │
┌─────────────────┐     │                         └─────────────────┘
│   Procedures    │─────┤
└─────────────────┘     │
                        │
┌─────────────────┐     │
│      Drugs      │─────┤
└─────────────────┘     │
                        │                         ┌─────────────────┐
┌─────────────────┐     │                         │   Non-Binary    │
│ Diagnostic Tests│─────┤                         │    Coverage     │
└─────────────────┘     │                         │    Decision     │
                        │                         └─────────────────┘
┌─────────────────┐     │
│  DME/Supplies   │─────┘
└─────────────────┘
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Services

Procedures

Drugs

Diagnostic Tests

DME/Supplies

Binary Coverage Decision

Non-Binary Coverage Decision

Diagnostic Test

- Local Coverage
- Non Coverage NCD
- NCD with available "terms"
- Non-Binary Coverage Decision
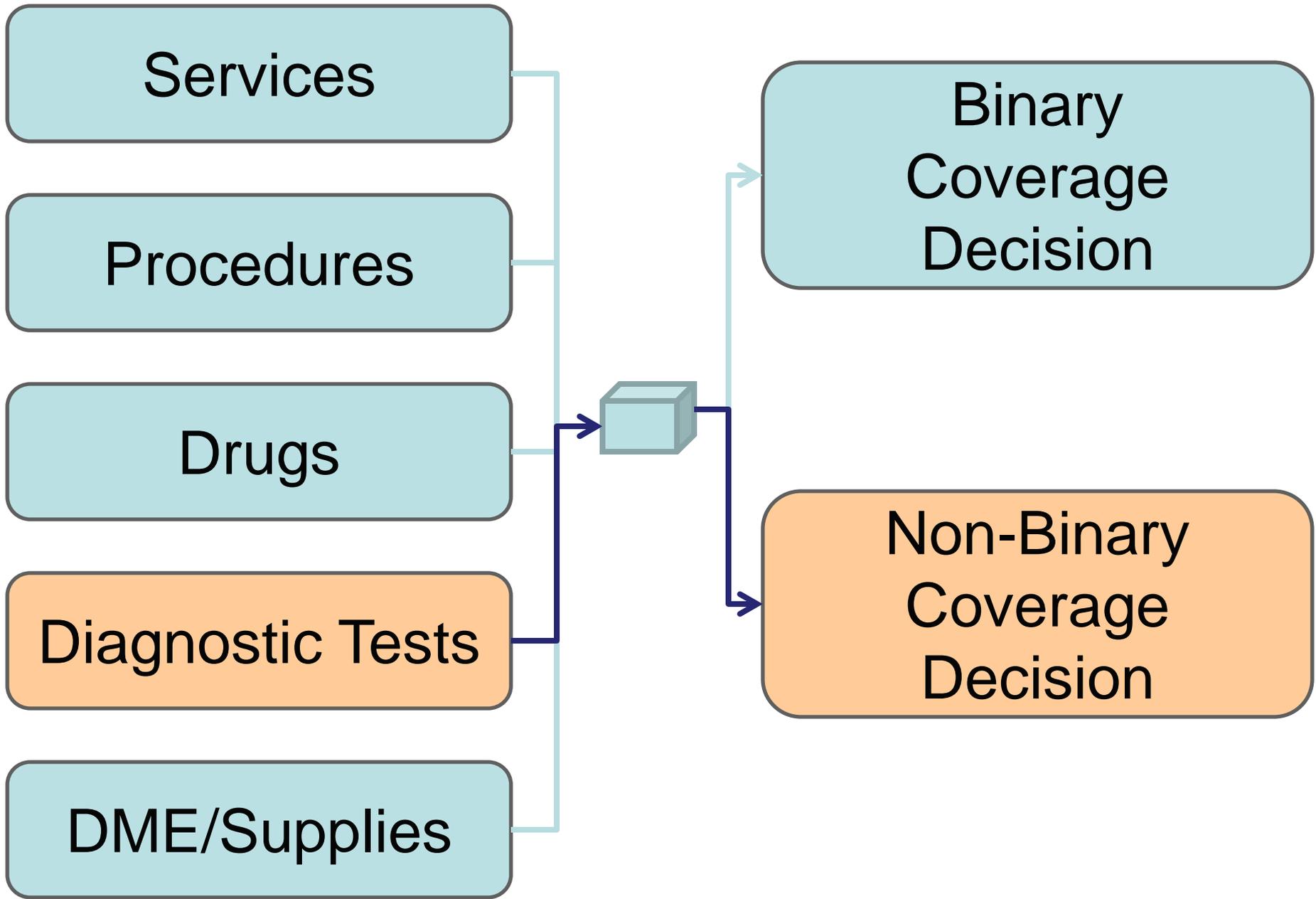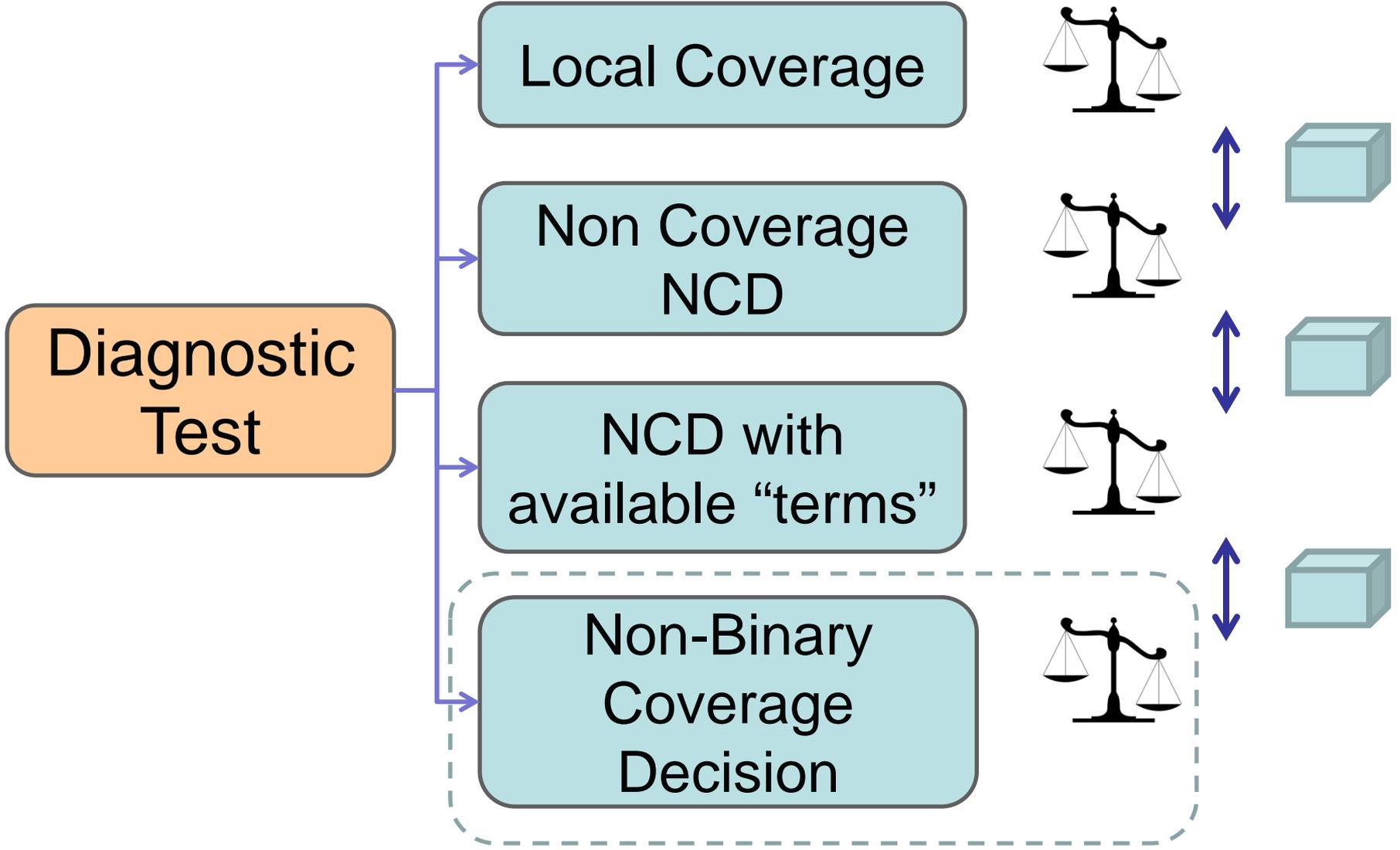
Diagnostic Test

Local Coverage
- Patient access
- Some terms of control
- Few signals as to what more is needed

Non Coverage NCD
- Likely to stop progress on this test
- Are you sure you want this – if so, OK

NCD with available "terms"
- Works when (a) the resulting access is appropriate and (b) field is fairly static (don't revisit often)

Non-Binary Coverage Decision
- Remediates some incentive problems for data
- Provides greater level of guidance than the other 3 options
- Provides patient access
- Limited by resource constraints of payers

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Non-Binary
Coverage
Decision

Real World Issue Is…Which?	?	Non Binary Coverage Decision Solution	?
Safety issues		Monitor claims for AE's (key to FDA REMs, etc)	
Usage choices		Spot check orders & records	
Decision impact		• NOPR-type registries • Spot check claims data • Best when value of clinical choice is well established	
Replicate accuracy of test in real world		Often almost impossible (requires full & extended RCT), but this varies with test	
Outcomes		Consider outcomes that "don't occur" (eg. Non-surgeries, non-chemotherapies); claims data?; sampled-records analyses	
Comparative effectiveness vis-à-vis alternate test		Probably best suited for analytic and modeling approaches not CED	