- Coding
- *Payment*
- *Coverage*

Reimbursement Coding

Diagnoses & Inpatient Procedures

ICD-10

- International Classification of Diseases- 10th Revision
- Developed by the World Health Organization (WHO)
- The US developed a code set based on the ICDs for medical diagnoses and inpatient procedures

Inpatient Services

DRG

- Diagnosis Related Groups
- Used for inpatient services
- Classifies hospital cases in groups with other cases expected to have similar hospital resource costs

Medical Procedures and Services

HCPCS

HCPCS Level I

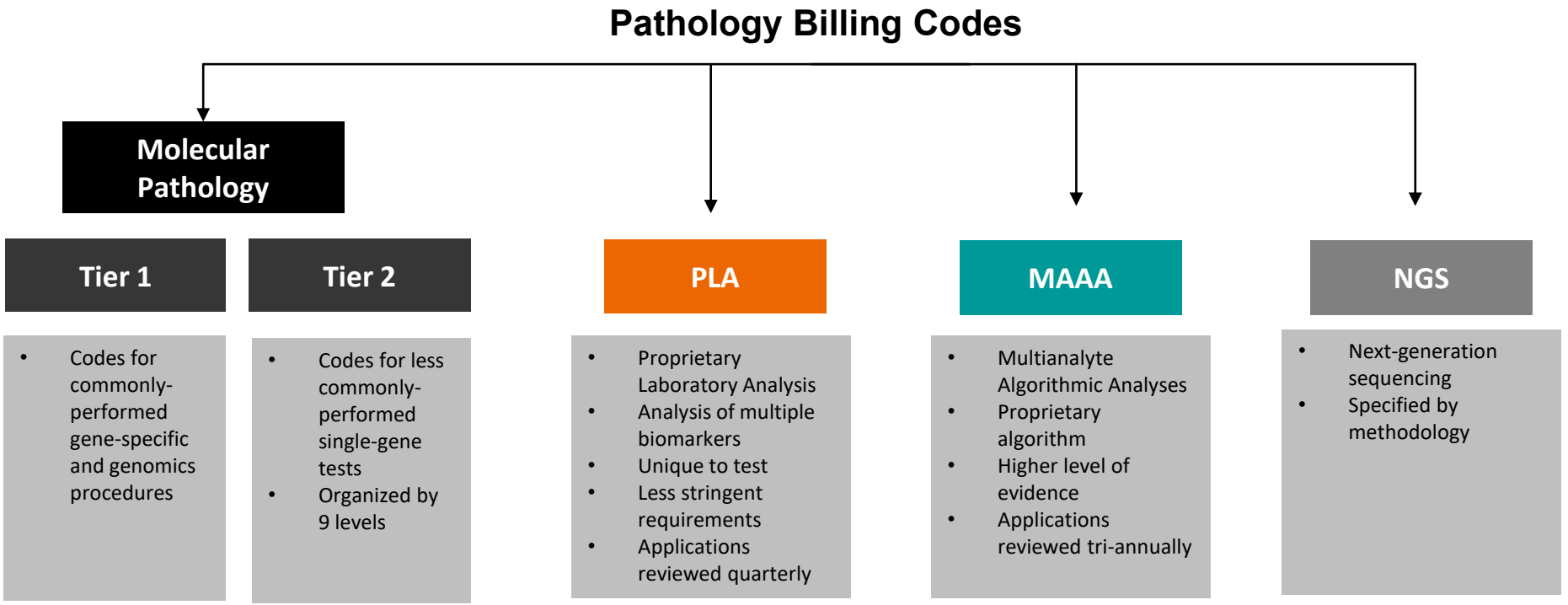
- Identical to Common Procedural Technologies codes (CPT)
- Developed by American Medical Association
- Describe physician procedures /services

HCPCS Level II

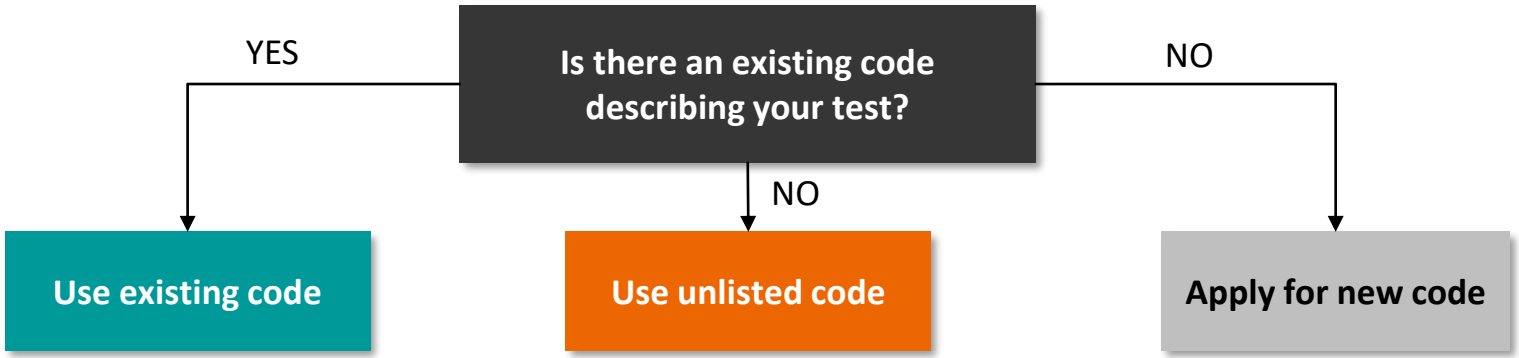
- Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)

CPT codes used for DX testing

Pathology CPT Codes



Securing a Reimbursement Code

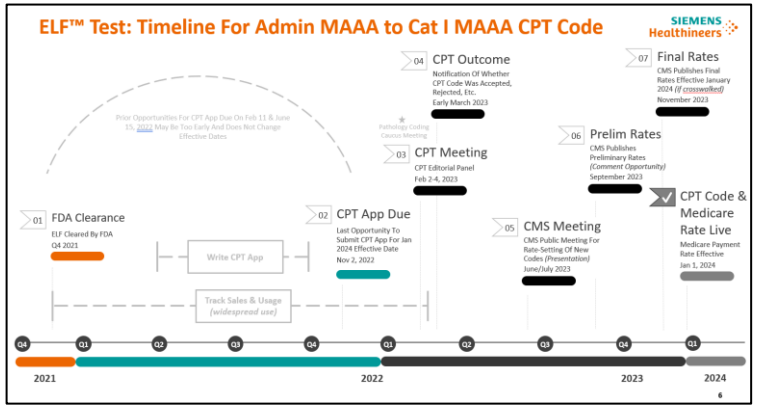


- If an existing code is appropriate for test, customers can bill this code
- Payment rate will already be set without option to change

- Additional reporting requirements to support claim submission
- No associated payment rate

- Requires new code application
- Must propose associated payment rate

Applying for a New Code



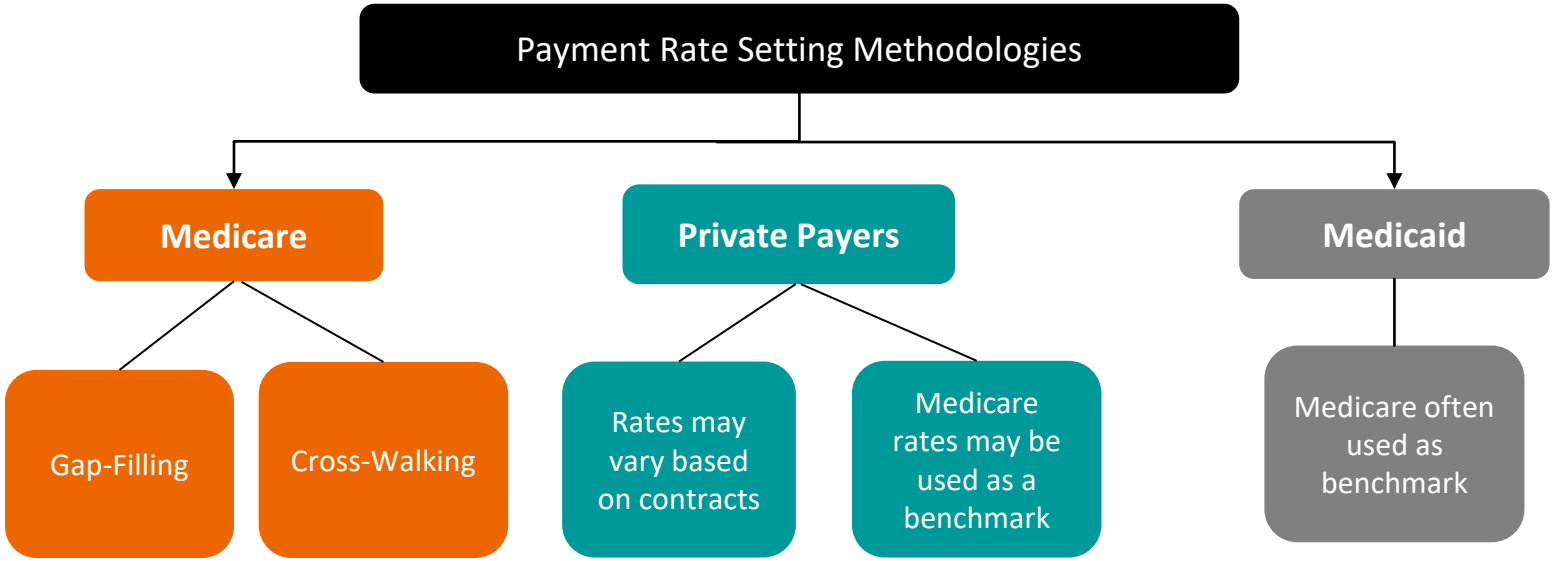
Securing a new Category 1 CPT code can take 12-18 months

Category 1 Code Criteria

- Data: Clinical validity data demonstrating testing accuracy and impact on clinical care
- Volume: Sufficient testing volume to demonstrate utilization in relevant clinical community

- *Coding*
- Payment
- *Coverage*

Rate-Setting Methodologies Vary by Payer Type



Medicare Clinical Laboratory Fee Schedule

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Clinical Lab Fee Schedule

YEAR	HCPCS	MOD	EFF_DATE	INDICATO	RATE2022	SHORTDESC	LONGDESC
2022	0001U		20220101	N	720	Rbc dna hea 35 ag 11 bld grp	Red blood cell typing
2022	0002M		20220101	N	503.4	Liver dis 10 assays w/ash	Molecular pathology test for liver disease, including alcohol liver disease
2022	0002U		20220101	N	25	Onc clrct 3 ur metab alg plp	Measurement of substances in urine to predict likelihood of polyps in large
2022	0003M		20220101	N	503.4	Liver dis 10 assays w/nash	Molecular pathology test for liver disease, including non-alcohol liver disease
2022	0003U		20220101	N	950	Onc ovar 5 prtn ser alg scor	Measurement of proteins associated with ovarian cancer in serum
2022	0004M		20220101	N	79	Scoliosis dna alys	Molecular pathology test for genetic analysis of curved spine deformity
2022	0005U		20220101	N	760	Onco prst8 3 gene ur alg	Test for detecting genes associated with prostate cancer in urine
2022	0006M		20220101	N	150	Onc hep gene risk classifier	Molecular pathology test for genetic analysis of liver tumor (HeproDX)

- Medicare Clinical Lab Fee Schedule (CLFS) publishes payment rates for all laboratory dx tests annually
- New rates are determined annually during the summer during the CLFS Annual Public Meeting
- CLFS Medicare rates are often used as a benchmark for payment by other payers

Establishing a Payment Rate on the CLFS

Medicare CLFS Rate-Setting Methods

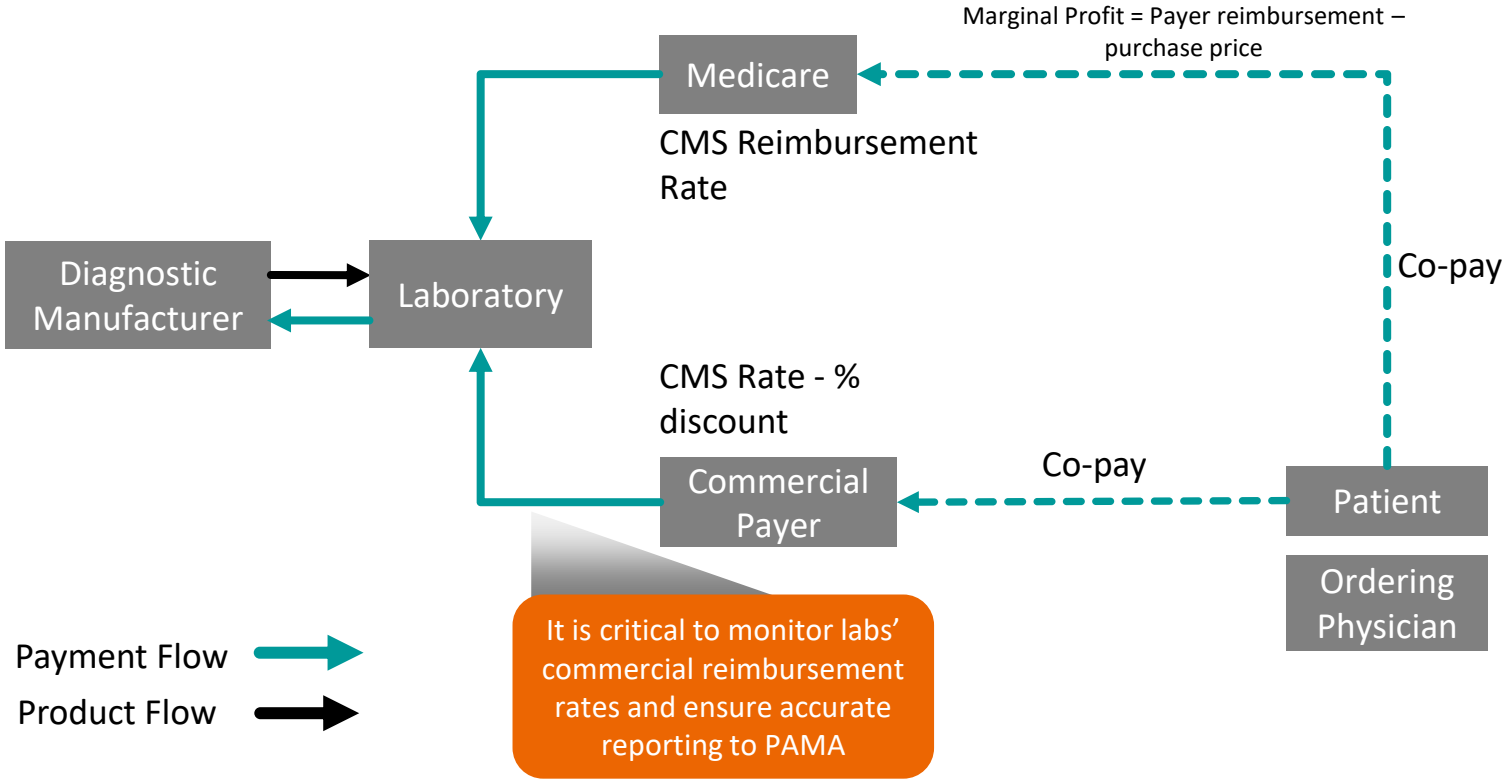
Cross-Walking

- Can use when a new test is similar to an existing test with an associated payment rate
- Existing payment rate can be applied for

Gap-Filling

- When comparable test is not available, MACs determine rate using charges, resource utilization, discounts
- CMS sets National Limitation Amount (NLA) after a year using median payment rate

Reimbursement Payment Flow



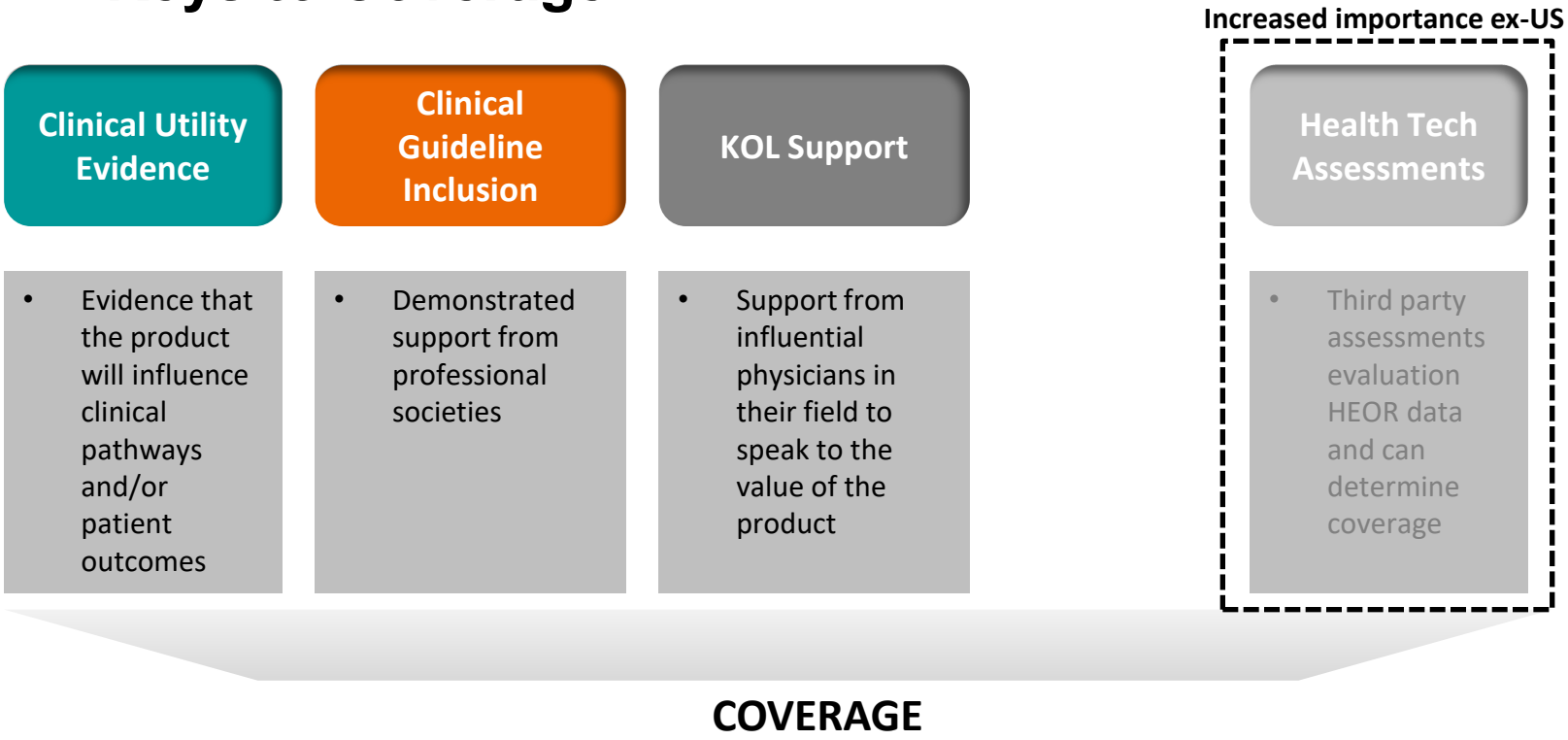
- *Coding*
- *Payment*
- Coverage

Reimbursement for Laboratory Tests

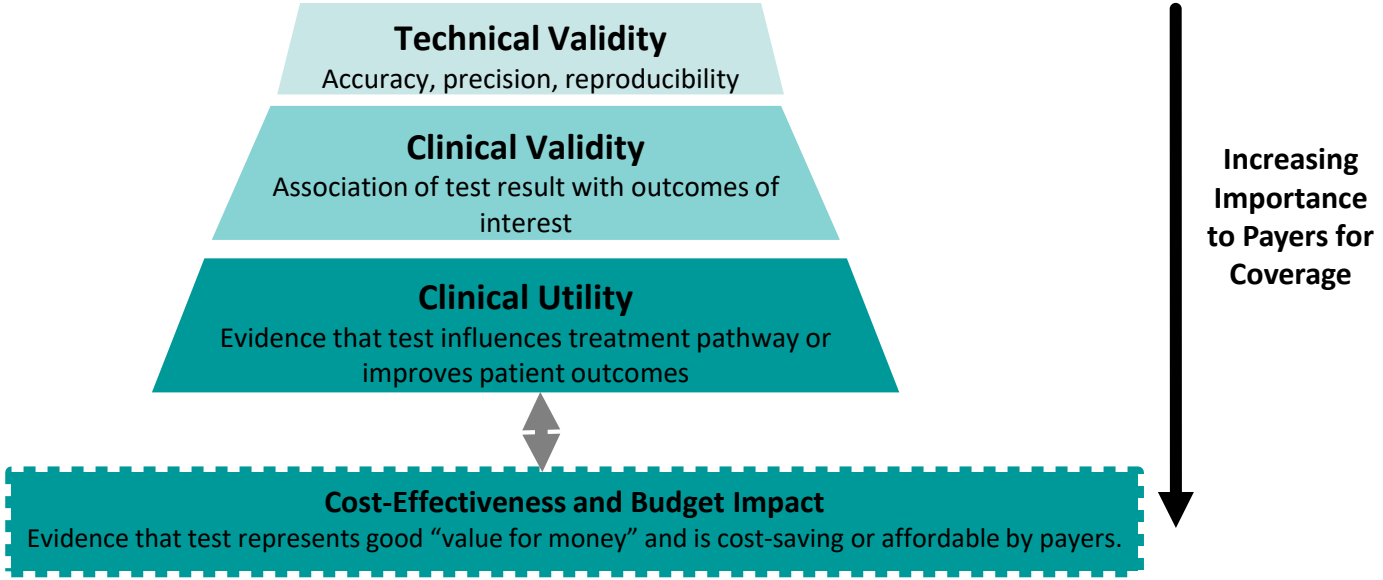
- Centers for Medicare and Medicaid Services set payment for laboratory tests on the Clinical Lab Fee Schedule (CLFS)
- CMS will reimbursement labs/physicians the payment rate for the test's respective code on the CLFS
- Physician services for laboratory tests are paid on the Medicare Physician Fee Schedule (PFS)

- Commercial payers will use the CLFS and PFS rates as benchmarks for reimbursement and typically pay a discount or premium to the schedule rates

Keys to Coverage



Evidence of Clinical Utility is Essential for Driving Payer Coverage



- Unlike pharma, RCTs are not required for lab dx regulatory approval
- Therefore, a compelling evidence plan is critical for coverage

Top Down vs. Bottom Up Coverage Strategies

Top Down Strategy

- Publishing clinical utility evidence early to shape the market for product adoption
- Actively engaging payers to develop inclusive coverage policies

Bottom Up Strategy

- Developing a strong appeals program to actively appeal denied claims
- Leveraging overturned claims to pursue positive coverage policies

Both strategies can be used throughout commercialization as stronger evidence develops

Conclusions

- **A Comprehensive Market Access Strategy Requires Alignment**
  - A successful market access strategy requires early initiative and alignment across departments i.e., regulatory, clinical marketing, R&D
- **Every Geographic Market Has Varying Market Access Requirements**
  - Some countries require health economic analyses, clinical data with specific study designs or patient populations, society support
- **Coding, Payment and Coverage Should be Considered Together**
  - Coding, payment and coverage should be considered in synchronicity
- **Clinical Evidence is Key**
  - Payers will require high levels of clinical outcomes data to determine coverage. However, diagnostics do not need this level of data for regulatory approval, creating an added hurdle
  - Clinical evidence generation will likely require the most resources and needs to be considered during product development
- **Successful Coverage is an Enduring Process**
  - Manufacturers need to continually consider evidence generation to secure positive coverage and defend coverage as new competitors arrive in the market