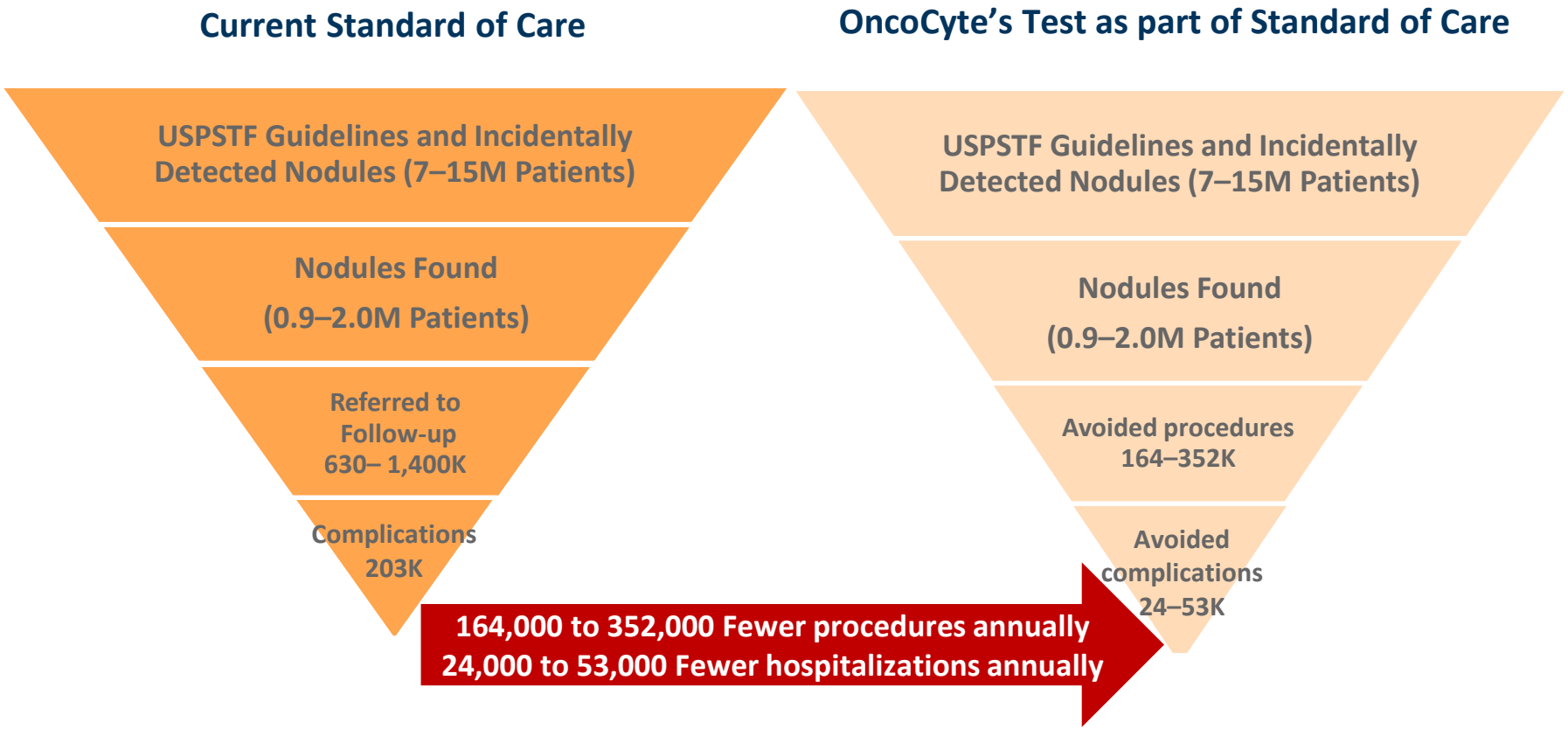
High clinical utility – the potential for fewer risky procedures and significant cost savings

OncoCyte's test could result in $2.2B to $4.7B in annual U.S. cost savings



Intended use – Confirmatory test first launch, Lung-RADS 3 and 4

Assumptions: 15M patients screened, 13% positive results, molecular diagnostic with 65% specificity (OncoCyte test may have higher or lower specificity); all Lung RADS 3-4 referred to downstream procedures including repeat LDCTs, PET scans, bronchoscopies, surgical biopsies, with 15% complications and associated hospitalization costs. 65% physician compliance with test results. Cost savings does not reflect cost of diagnostic.

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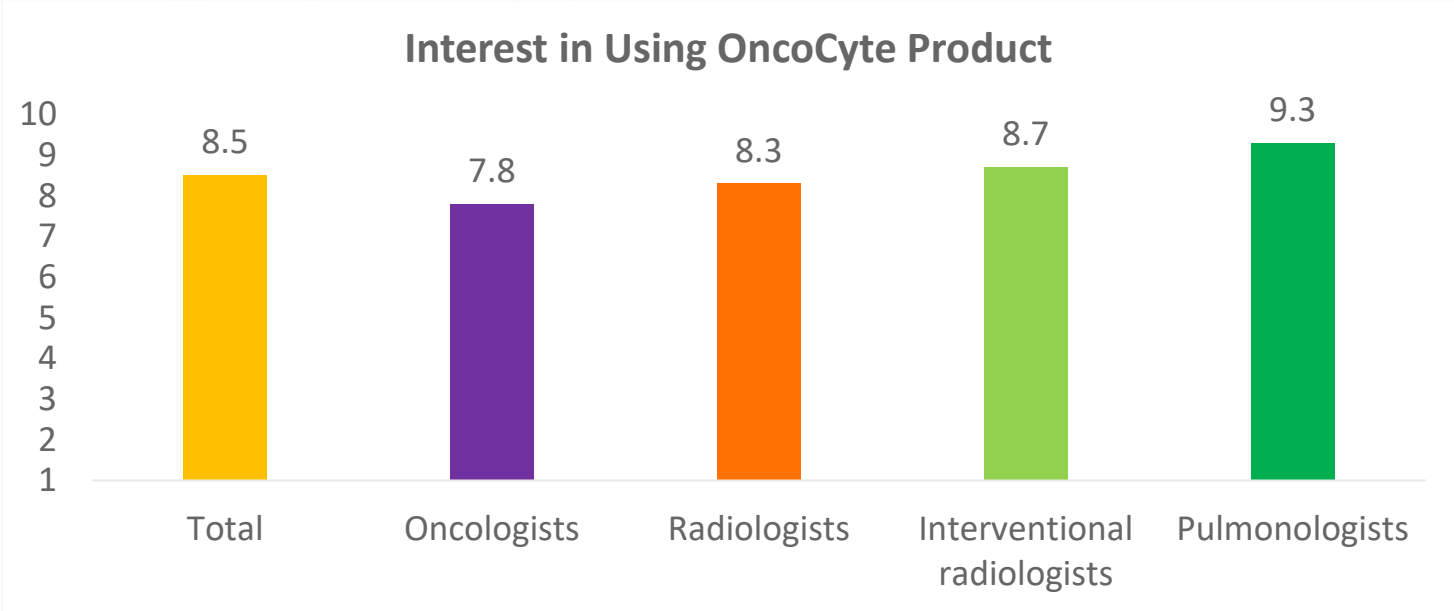
Physicians in target specialties express highest level of interest



- Interest in using the OncoCyte test is very high (mean rating of 8.5 out of 10)
- Highest interest with pulmonologists and interventional radiologists
- Reasons provided for high ratings:
  - ✓ Useful for smaller nodules with high risk factors
  - ✓ Provides additional accuracy and benefit
  - ✓ Avoid biopsies
  - ✓ Non-invasive blood test
  - ✓ Provides clinical utility

Results of (30) in-depth, clinician interviews fielded in September/October 2015. Question asks: On a scale from 1-10 where 10 is very interested, how interested would you be in utilizing Test X?

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Reimbursement strategy has three key components

Coding

- MAAA Ensured status allows value based pricing
- Pursue CDLT status
- Launch with unlisted code
- Obtain unique CPT code when have CMS coverage

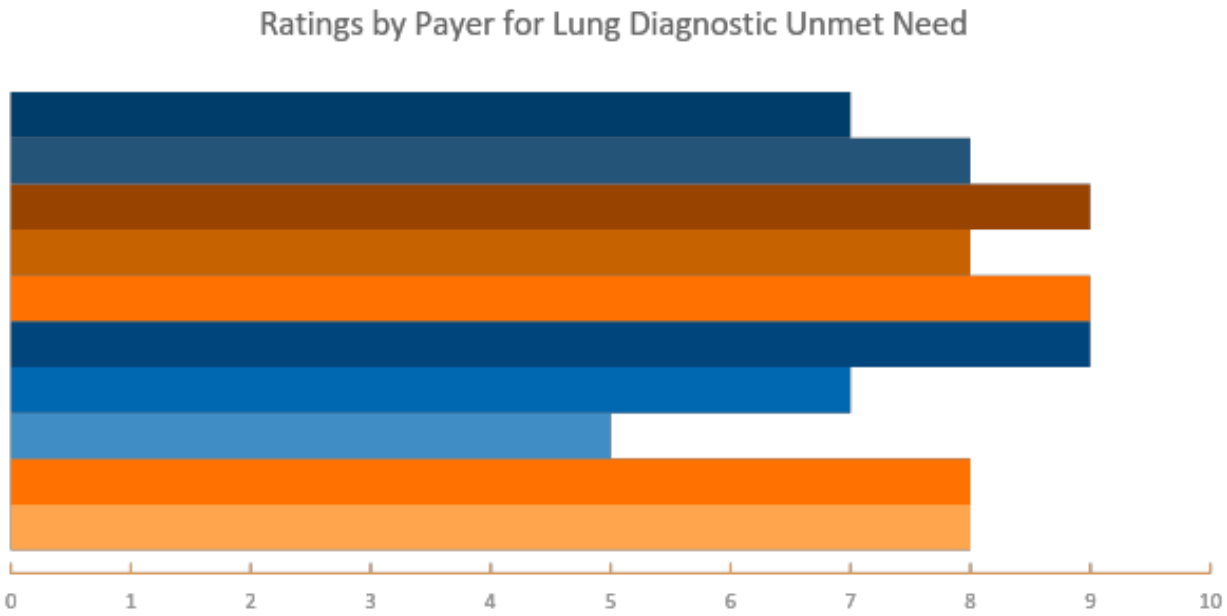
Coverage

- MolDx has clear pathway to coverage
- Develop and implement a strong evidence and publication plan
- Clearly demonstrate analytical and clinical validation, clinical utility and cost savings to health care system
- Obtain CMS coverage 2-3 years after launch

Reimbursement

- List price at launch
- CMS Price set post-launch based on weighted average of commercial plans
- Pursue private payor strategy that leverages PAMA pricing guidelines
- Optimize rather than maximize in-network providers

Lung is compelling proposition for payers



"Getting tissue in lung biopsy is much more invasive for lung than other cancers"

"Am concerned with USPSTF guidelines and the high false positives (one in five) and invasiveness of biopsies"

"Not just about the expense, there is also increase morbidity and mortality with biopsies"

"High need driven by lack of good screening procedures and a clinical concern to identify patients earlier"

- Payers gave diagnostic high ratings for unmet needs
- Pricing and TPP discussion with payers very positive

Survey of (10) Commercial, Managed Medicaid and Managed Medicare payers representing 20M covered lives.
Question asks: What is your perception of the overall unmet need for certain oncology screening diagnostics or procedures.
On a scale of 1 to 10 where 1 is no unmet need and 10 is significant unmet need for an improved screening procedure/diagnostic.

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Key to coverage is strong clinical validation and clinical utility studies

- OncoCyte's strategy is to achieve the highest level (IA) of evidence
- Previewed clinical protocol designs with payers (November 2016)
  - 10 Payers
  - Public and commercial
  - 77M Covered lives

MolDx Coverage Pathway

Coverage Probability

MolDx Level of Evidence	Clinical Trial Design Principal Study	Clinical Trial Design Secondary Study
Highest IA	Randomized, Prospective (PCT)	Randomized Prospective or Retrospective (PCT, PRT)
IB	PCT`	Prospective Observational Studies (POS) or Retrospective Data Modeling (RDM)
IIA	PRT	POS or RDM
IIB (minimum requirement)	POS	POS or RDM

Conclusion: Successful trials should result in positive coverage decisions.

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Focused reimbursement strategy enables value-based pricing

Value-based pricing creates list price

- OncoCyte test is MAAA
- Full list price for the first six months of Medicare coverage

Optimize private-payer coverage

- Contracting strategy focused on maintaining value-based pricing
- Patient assistance program

PAMA Ensures maintenance of value-based pricing

- Medicare price determined every 12–36 months based on weighted commercial median