



# **Payer Perspectives on Molecular Diagnostics**

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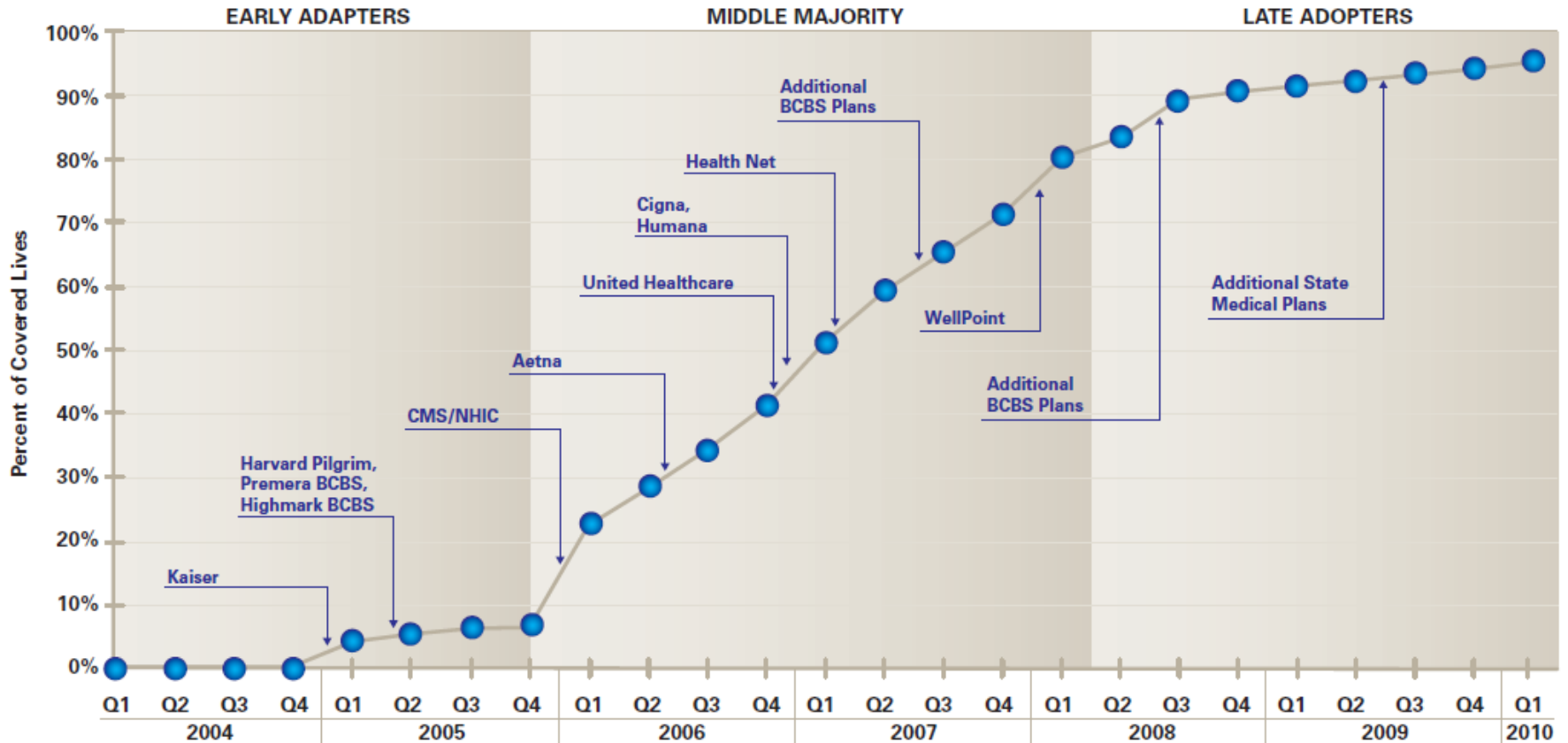
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# Novel Diagnostics Applications Across Cancer

	Risk Assessment	Screening	Diagnosis	Staging and Prognosis	Therapy Selection	Monitoring
Test Description	<ul style="list-style-type: none"> <li>Diagnostic tests to complement traditional risk factors</li> </ul>	<ul style="list-style-type: none"> <li>Applied to high-risk patients to identify disease early</li> </ul>	<ul style="list-style-type: none"> <li>Used for definitive diagnosis and general cancer typing</li> </ul>	<ul style="list-style-type: none"> <li>Assess severity and/or risk of recurrence</li> <li>Inform adjuvant chemo decision</li> </ul>	<ul style="list-style-type: none"> <li>Used to predict efficacy or safety response to specific treatments</li> </ul>	<ul style="list-style-type: none"> <li>Recurrence monitoring</li> <li>Monitoring for treatment efficacy</li> </ul>
Test Examples	<ul style="list-style-type: none"> <li>BRACAnalysis®</li> <li>COLARIS®</li> <li>MELARIS®</li> <li>deCODE Prostate Cancer™</li> </ul>	<ul style="list-style-type: none"> <li>PreGen-Plus™</li> <li>EarlyCDT-Lung™</li> </ul>	<ul style="list-style-type: none"> <li>CancerTYPE ID®</li> <li>C-kit</li> <li>OVA1™</li> <li>PathFinderTG®</li> <li>miRview™</li> </ul>	<ul style="list-style-type: none"> <li>Oncotype DX® Breast and Colon</li> <li>Previstage™</li> <li>MammaPrint™</li> <li>Prezeon™</li> <li>Adjuvant! Online</li> </ul>	<ul style="list-style-type: none"> <li>HER2/neu</li> <li>TheraScreen® K-RAS and EGFR Mutation Kits</li> <li>ResponseDx™</li> <li>VeriStrat®</li> <li>OnDose™</li> <li>ChemoFx®</li> </ul>	<ul style="list-style-type: none"> <li>CellSearch™</li> <li>BCR/ABL</li> </ul>

# ONCO TYPE DX COVERAGE TIMELINE

Positive coverage as percent of total US covered lives over time



# Coverage Inconsistencies for Example Diagnostics

Innovative Test Examples	FDA Cleared	Positive Coverage Policies			
		Aetna	Regional CMS	Cigna	Regional BCBS
AlloMap	Yes		✓		
Oncotype DX (breast cancer)	No	✓	✓	✓	✓
MammaPrint	Yes		✓		
Pathwork Tissue of Origin	Yes				
BRAC <i>Analysis</i>	No	✓	✓	✓	✓
OVA1	Yes		✓		~
KRAS (colorectal cancer)	No	✓	✓	✓	✓

# Discussion Themes

- Substantial uncertainty about test utility in many/most circumstances
- Associated costs are growing
- Coding systems have lagged the progression of this field which creates challenges for innovation, reimbursement, monitoring care, and patient utility
- Companion diagnostics/therapeutics create financial and ethical challenges