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What Employers Need to Know About Biomarker Testing

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Greater Philadelphia Business Coalition on Health

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Oncology Spend Has Doubled Since 2013 and Is Expected to Reach \$240B by 2023

\$240B

Expected Annual Spend
in Oncology in 2023

64%

of growth in spending is
attributed to the launch
of new medicines

2X

US spending on
oncology more than
doubled from 2013-2019

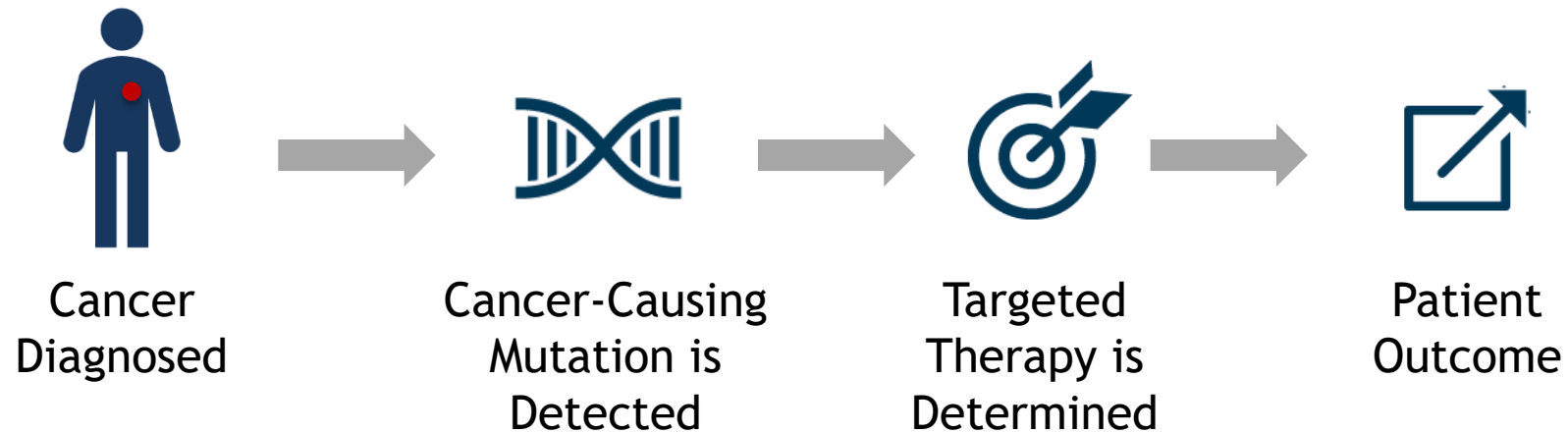
>12%

of employer healthcare
spend is on cancer treatment
costs and growing

**The Right Testing Can Ensure Patients Are Started on The
Right Treatment at the Right Time And Eliminate Waste**

Biomarker Testing Is Helping Cancer Care Evolve From Treating Based on Site of Cancer to Treating Based on Cancer Mutation

The Pathway of Biomarker Testing /



Access to biomarker testing can help physicians and patients select the correct pathway of treatment and ensure the patient gets the right drug at the right time while saving money and providing better outcomes

Determining A Treatment for A Specific Cancer Type Is One of Many Uses of Biomarker Testing

Biomarker testing provides value to patients by measuring the presence or absence of a disease or condition to better determine the best path forward for the patient

Determine optimal treatment for specific mutational driver of the cancer

Monitor response to treatment

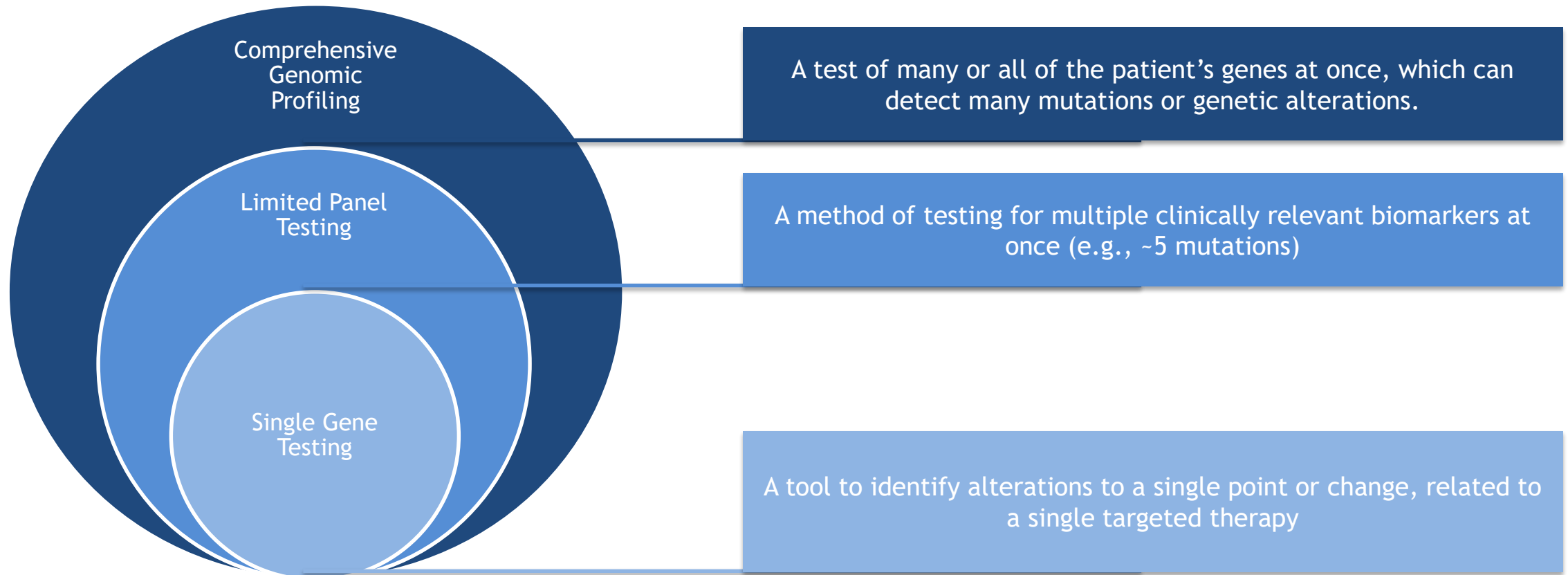
Predict or monitor cancer recurrence

Determine the presence of cancer earlier for proper diagnosis

Today's Discussion

Biomarker Tests Can Be Done Through Various Methods And Cover Different Numbers of Gene Mutations

Types of Biomarker Tests



FDA. Precision Medicine. Available [here](#).

Dana-Farber Cancer Institute. What is a Biomarker? 2018. Available [here](#).

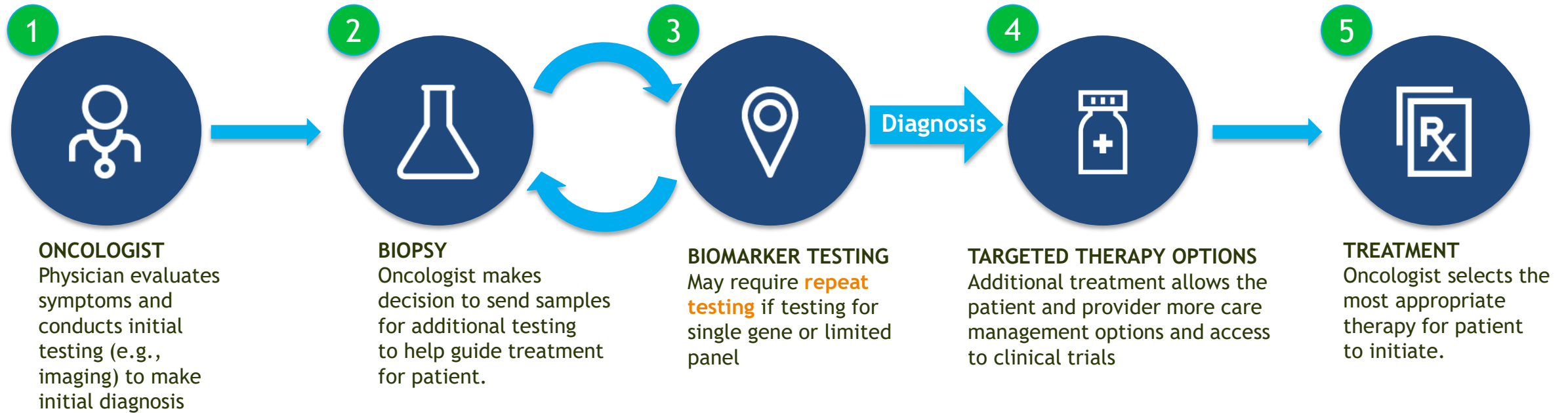
Foundation Medicine. What is Comprehensive Genomic Profiling. Available [here](#).



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Impact of Biomarker Testing on Patient Care

Targeted Treatment Start Requires Characterization of Tumor and May Need Several Tests If Testing for Single Genes



Single Gene Tests and Small Panels Can Have Considerable Limitations Leading To Inefficiency and Missed Mutations

Single-Gene testing looks for mutational changes within one single gene to detect cancer, but have considerable limitations with can lead to:

Inconclusive Results

- Requires additional testing
- Delays diagnosis
- Delays treatment start

Incomplete Information

- Increases potential for missed mutations
- Results in potential use of wrong therapy

Extra Procedures

- Risk of Re-Biopsy as multiple tests exhaust tumor tissue⁽¹⁾

A panel of several clinically appropriate tests or CGP can test for many different things at once, avoiding many of these issues

(1): Tissue insufficiency is an ongoing issue, and many insurers currently will only pay for blood sample biopsy if solid tissue is insufficient.

Comprehensive Genomic Profiling (CGP) Can Provide More Patient Insights and Improve Patient Outcomes

Access to CGP, when indicated, can improve the outcomes of patients in multiple ways, including:



Patient Centric Care

Biomarker testing helps physicians form deeper insight into a patient's condition so they can determine the best individualized care plan sooner, as well as open up new treatment options.



Reduced Toxicity

Targeted therapies may present fewer and less severe side effects vs. traditional drugs.

Potential for reduced emergency room visit and inpatient admission due to toxicity.



Improved Quality of life

Patients are spared unnecessary procedure or prescriptions.

Decrease loss associated with absenteeism and presenteeism.



Access to new Information

Ability to appropriately counsel patients regarding the availability of clinical trials.



Reduced Overall Cost

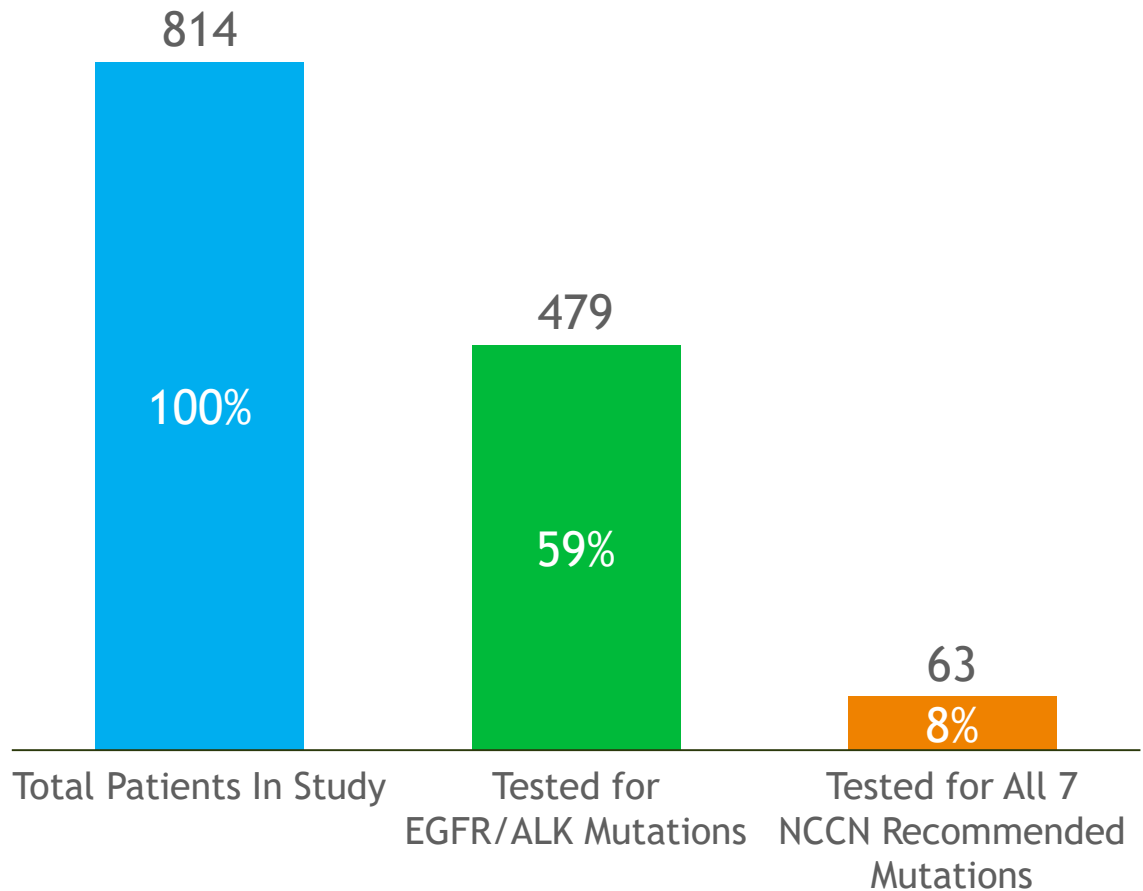
Spending money upfront on a CGP test can save money in the long run by reducing spend on inappropriate/ ineffective treatments.

CGP: Comprehensive Genomic Profiling
Ginsburg GS, Phillips KA. Precision Medicine: From Science To Value. Health Aff (Millwood).

2018;37(5):694-701. Available [here](#).

Despite the Known Benefits, Evidence-Based Biomarker Testing is Not Performed Routinely

Guideline Adherence for Biomarker Testing in Advanced NSCLC in the Community Setting¹



- Effective implementation of precision medicine in oncology relies on biomarker testing that is inclusive of all-guideline recommended mutations.
- In a study of advanced Lung cancer in the community setting, only 8% of patients received testing for all genes recommended by NCCN guidelines
- Lack of guideline-recommended testing likely results in patients erroneously offered ineffective and expensive therapies

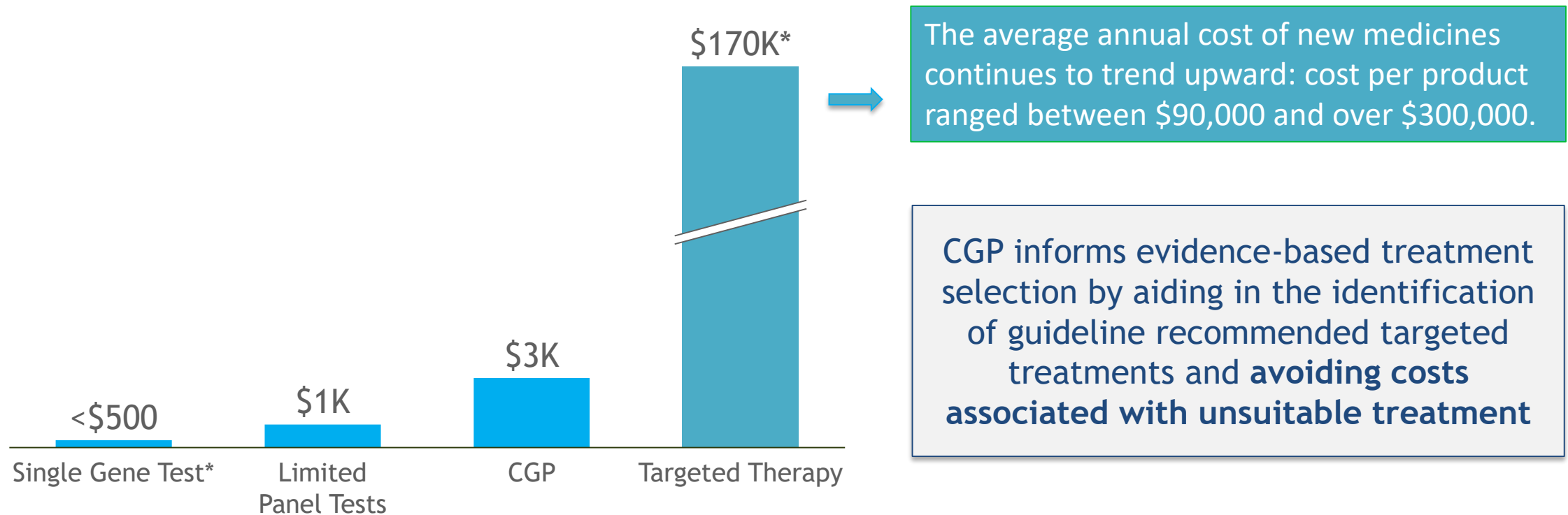


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Benefit Design & Coverage Considerations

While More Expensive Than Single Gene/Limited Panel Tests, CGP Provides Better Insights to Guide Cancer Treatments

Average Cost per Test Type vs. Average-Annual Cost for Targeted Therapy



*Single Gene Test Cost: Medicare rate for EGFR, CPT code 81235; *The average annual cost of new medicines continues to trend upward: cost per product ranged between \$90,000 and over \$300,000. (IQVIA Report). *\$3K is the approximate Medicare rate for next generation sequencing CPT code 81455
CGP: Comprehensive Genomic Profiling
IQVIA. Global Oncology Trends 2019. Created May 2019. Accessed July 28, 2021. Available [here](#).
CMS. Clinical Laboratory Fee Schedule Files. Q3 2021. Available [here](#).

Payer Coverage Varies

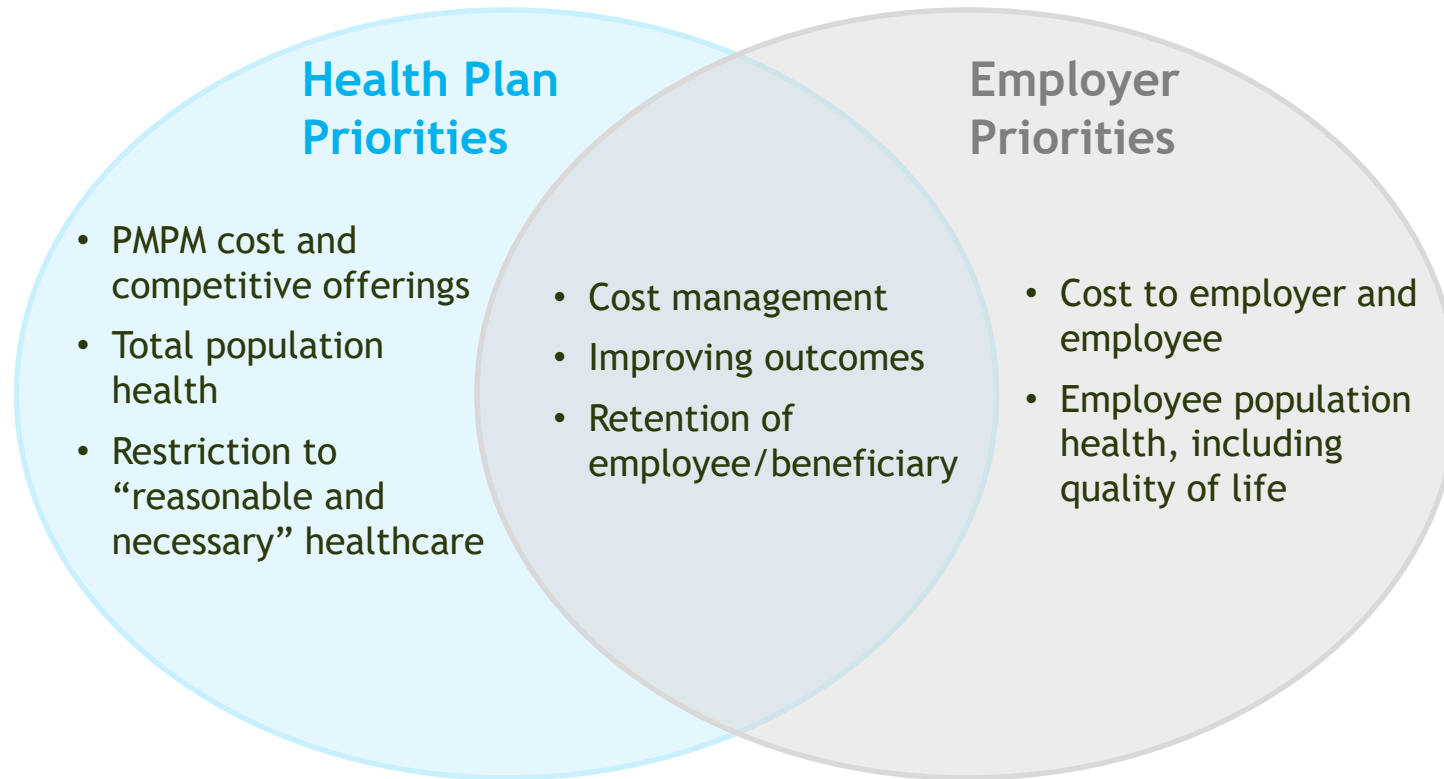
United Healthcare (link)	Limits NGS coverage to targeted panels (<50 biomarkers) or to specific FDA-approved CDx assays, but only when patient has progressed on 1L therapy and immune checkpoint inhibitor is being considered for subsequent treatment
Anthem (link)	Limits NGS coverage to targeted panels (<50 biomarkers) or to broad panels (50+ genes), but only when patient has progressed on 1L therapy and immune checkpoint inhibitor is being considered for subsequent treatment
Aetna (link)	Limits NGS coverage to targeted panels (<50 biomarkers)
Humana (link)	Limits NGS coverage to targeted panels (<50 biomarkers) or to broad panels (50+ genes), but only when patient has progressed on 1L therapy and immune checkpoint inhibitor is being considered for subsequent treatment

Financial Support for Patients Available

- Lilly
- Sanofi

Health Plan and Employer Priorities are Often But Not Always Aligned; Greater Employer Involvement Is Critical

Effective Application of Precision Medicine Starts with Access



Employers Should Talk to Their Health Plans To Understand:

- The health plan’s biomarker testing policies
- What the plan is doing to ensure coverage for comprehensive tests that comply to medical guidelines for all recommended biomarkers
- Why they are not covering certain FDA approved products
- How to improve coverage for tests that can offer eligibility to clinical trials
- Understand what the plan is doing to reduce start of treatment delays



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Employer Toolkit

Employers Should Consider Factors Guiding Key Stakeholders When Designing Cancer Biomarker Testing Benefits

Factors Guiding Key Stakeholders

	American Cancer Society Cancer Action Network	CMS National Coverage Decision	Leading Oncology Guidelines/Drug Compendia	Health Technology Assessment Organizations
TEST/PANEL SIZE <i>[breadth of genes to support precision medicine decision making and alignment with NCCN Guidelines]</i>	✓		✓	✓
TEST QUALITY <i>[FDA approval and/or validation data]</i>	✓	✓	✓	✓
COMPANION DIAGNOSTIC STATUS <i>[FDA-approved to inform use of specific targeted therapies]</i>	✓	✓	✓	✓
CLINICAL TRIAL MATCHING <i>[ability to identify patient eligibility for clinical trials]</i>		✓	✓	

Employer Toolkit Overview

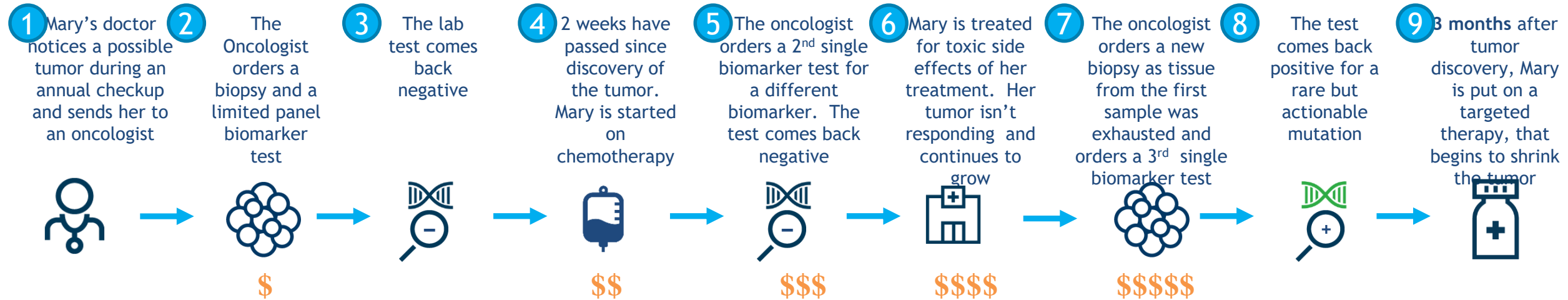
Employer Toolkit Objectives:

- NCTA has created an “Employer Toolkit”

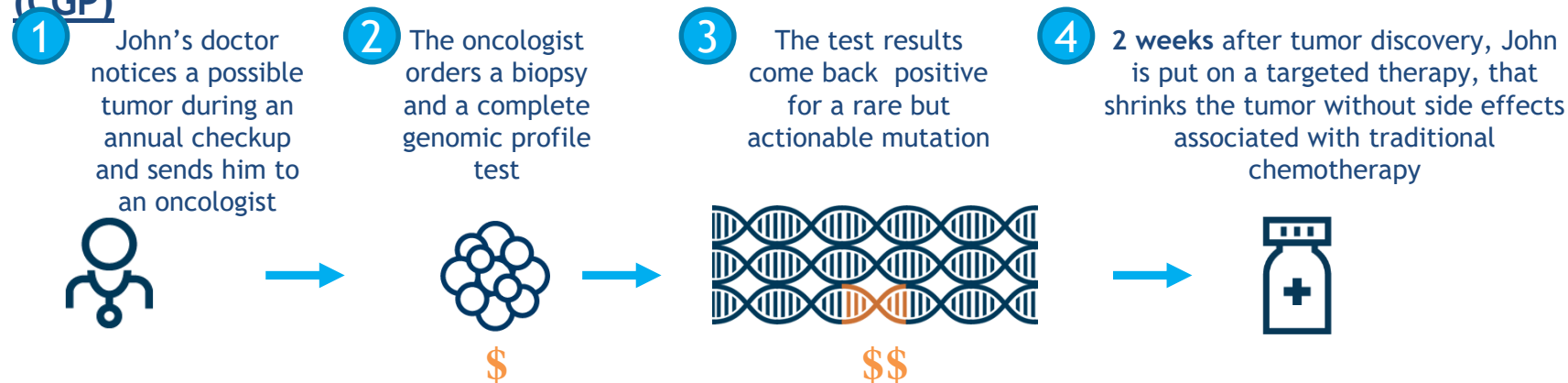


2 Journeys: Limited Panel Biomarker Testing vs. Comprehensive Genomic Profile Testing

Limited Panel Biomarker Testing



Comprehensive Genomic Profiling (CGP)



\$\$ = cumulative cost before start on targeted therapy

Legislative Activities

- Kentucky: <https://apps.legislature.ky.gov/record/23rs/hb180.html>
- Florida: <https://www.flsenate.gov/Session/Bill/2023/805>
- Oklahoma: <http://www.oklegislature.gov/BillInfo.aspx?Bill=SB513&session=2300>
- Colorado: <https://leg.colorado.gov/bills/hb23-1110>
- Ohio: <https://ohiohouse.gov/legislation/135/hb24>
- Nevada: <https://www.leg.state.nv.us/App/NELIS/REL/82nd2023/Bill/9818/Overview>

Employer Checklist

- Purpose: Checklist/action steps to empower employers to assess current coverage and inform the benefit coverage policy

Example of Checklist Questions

- 1 Does my policy cover all tests that are FDA-approved as a companion diagnostic to match patients to all FDA-approved targeted therapies and immunotherapies?
- 2 Does my policy cover tests which include all guideline-recommended genes in any given tumor type?
- 3 Does my policy cover tests inclusive of all genes which could indicate potential resistance to an FDA-approved therapy?
- 4 What is my plan doing to reduce delays in getting patient started on treatments?
- 5 Does my policy cover clinical trials? Would the plan consider covering them?

Thank you to our sponsors!



Contact Information:

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www.NCTAcancer.com for the toolkit