COVERAGE AT THE FOREFRONT OF GENETIC TESTING

A LOOK AT RECENT PAYER ACTIVITY FOR NEXT GENERATION SEQUENCING, EXPANDED CARRIER TESTING, AND COMPREHENSIVE GENETIC TESTING.

Significant improvements in the efficiency of testing multiple genes has increased both the number of labs offering tests and the complexity of payers' reimbursement rules. Payer coverage and the payment landscape for genetic testing present a number of challenges for providers and labs that perform these newer tests.

In this study, Policy Reporter looked at the policies of select payers to review coverage trends for expanded carrier testing, whole exome and whole genome sequencing, and comprehensive testing.

PARAMETERS - DOCUMENTS REVIEWED

3 TYPES OF TESTING

CARRIER SCREENING **NEXT-GEN SEQUENCING** **COMPREHENSIVE TESTING**

PARAMETERS	CARRIER SCREENING	NEXT-GEN SEQUENCING	COMPREHENSIVE TESTING
NUMBER OF PAYERS:	49	12	65
TOTAL POLICIES REVIEWED	86	24	125
COMMERCIAL	47	12	57
MEDICARE	9	6	21
MEDICAID	22	4	42
CPT® CODES	105	182	0
COVERED LIVES	131,465,704	10,801,491	143,640,537

COMMERCIAL
- INDIVIDUAL
- LARGE GROUP
- SMALL GROUP
- SELF FUNDED/EMPLOYER SPONSORED

MEDICARE
- MEDICARE ADVANTAGE
- MEDICARE PART D

MEDICAID
- MANAGED MEDICAID
- MEDICARE-MEDICAID DUAL-ELIGIBLES
- CHIP

EXPANDED CARRIER SCREENING (ECS)

Carrier screening is a type of genetic test that is used to determine whether an asymptomatic person is a carrier for a specific genetic disorder. It is primarily used before or during pregnancy to determine the risks of having a child with a genetic disorder. Carrier screening may be targeted based on ethnicity, as certain genetic disorders are most common in people of a particular ethnic group or race.

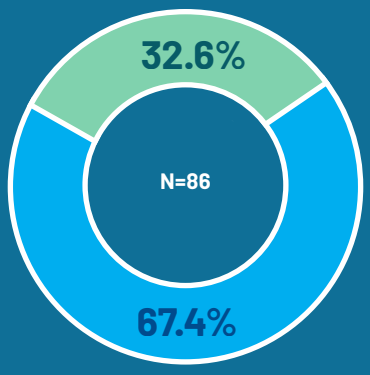
Expanded carrier screening refers to the practice of simultaneously screening for a large number of conditions in a pan ethnic approach (i.e., without regard to race or ethnicity). It is covered far less often than targeted carrier testing because payers perceive a limited utility in the test, in part from a lack of standardized recommendations for which disorders to screen as well as the risk of identifying variations of unknown significance. However, expanded carrier screening may be an appealing option for prospective parents who are unsure of their heritage.

IN 86 POLICIES REVIEWED ACROSS 49 COMMERCIAL AND GOVERNMENT PAYERS

11%

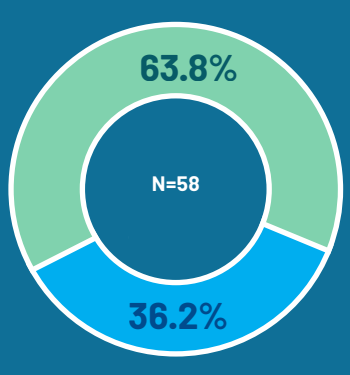
OF TOTAL LIVES ARE COVERED FOR EXPANDED CARRIER SCREENING

ECS COVERAGE BY PERCENTAGE OF POLICIES



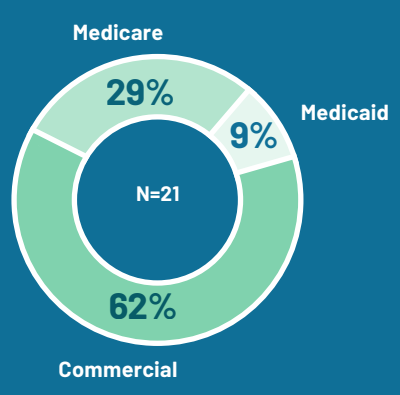
Policies with no mention of expanded carrier testing

Policies mentioning expanded carrier testing

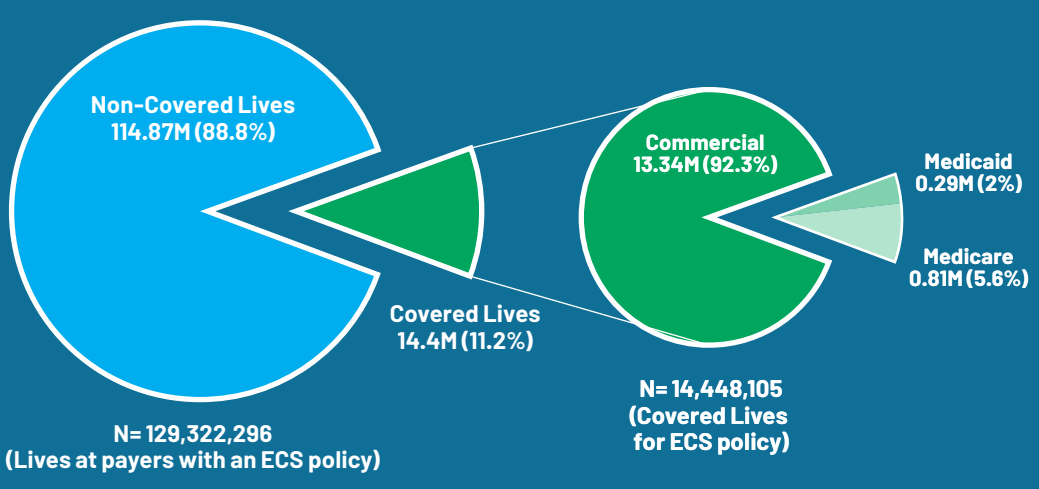


Policies not covering expanded carrier testing

Policies covering expanded carrier testing



ECS COVERED LIVES BY PAYER PLAN TYPE



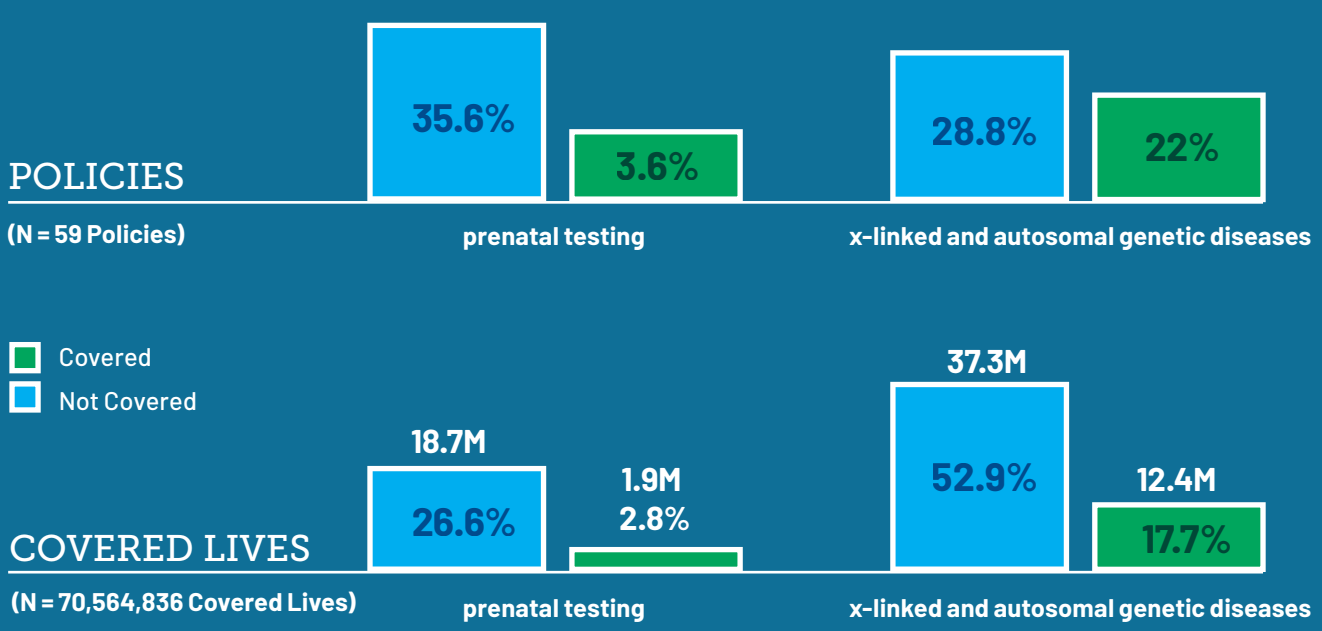
OVER

90%

OF THE 14M PEOPLE COVERED FOR ECS HAVE COMMERCIAL INSURANCE

ECS COVERAGE BY POLICY CATEGORY

Most policies categorize expanded carrier testing applications into two categories - prenatal testing and x-linked and autosomal genetic diseases



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NEXT GENERATION SEQUENCING

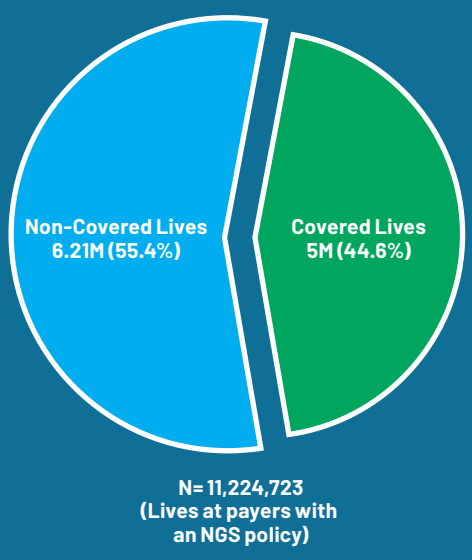
The National Cancer Institute defines next generation sequencing (NGS) as a high-throughput method used to determine a portion of the nucleotide sequence of an individual's genome. Since its first introduction in 2000, NGS, also known as massively parallel sequencing, has rapidly evolved to become both faster (results in under a day) and more affordable (the August 2019 report from the National Human Genome Research Institute put the cost of sequencing a complete human genome at 942 USD).

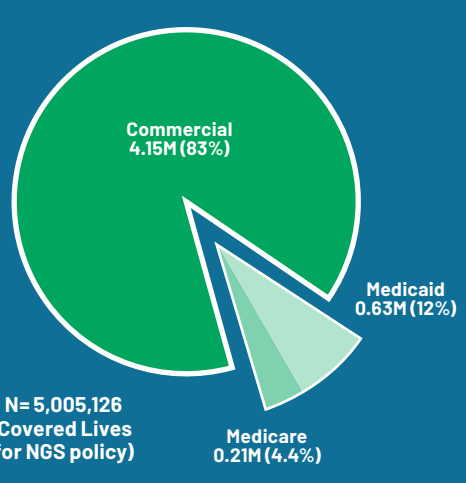
CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

Medicare doesn't generally offer guidance on comprehensive genetic testing, with the exception of National Coverage Determination 90.2 Next Generation Sequencing (NGS). In this policy, CMS provides coverage guidance specific to 2 different types of cancer: Somatic (acquired) and Germline (inherited) and leaves it to the Medicare Administrative Contractors (MACs) to determine coverage for other types of genetic testing, including RNA sequencing, and protein analysis. The table below summarizes NGS coverage from CMS.

FOR	Somatic (acquired) Cancer	Germline (inherited) Cancer
NGS is reasonable and medically necessary and nationally covered for a patient	With recurrent, relapsed, refractory, metastatic, or advanced stage II or IV cancer AND Not been previously tested with the same NGS test for the same cancer genetic content AND Is seeking further cancer treatment	Ovarian or Breast Cancer AND A clinical indication for germline testing for hereditary breast or ovarian cancer AND A risk factor for germline breast or ovarian cancer AND Not been previously tested with the same germline test using NGS for the same germline genetic content
And the lab test using NGS must have:	FDA approval or clearance as a companion in vitro diagnostic AND FDA-approved or cleared indication for use in that patient's cancer AND Results provided to the treating physician for the patient using a report template to specify treatment options	FDA approval or clearance AND Results provided to the treating physician for the patient using a report template to specify treatment options
Non-Covered Indication	Any patient NOT meeting the requirements above	
MACs may determine coverage	Recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer AND Not previously tested with same test using NGS for the same cancer genetic content AND Seeking further cancer treatment	Any cancer diagnosis AND A clinical indication for germline cancer AND A risk factor for germline cancer AND Not been previously tested with the same germline test using NGS for the same germline genetic content

NGS COVERED LIVES BY PAYER PLAN TYPE



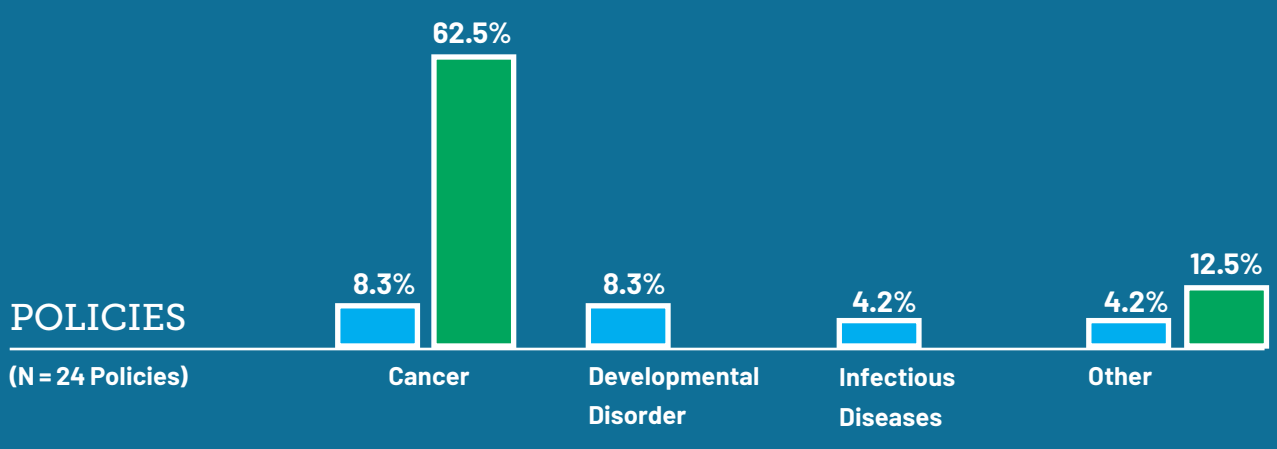


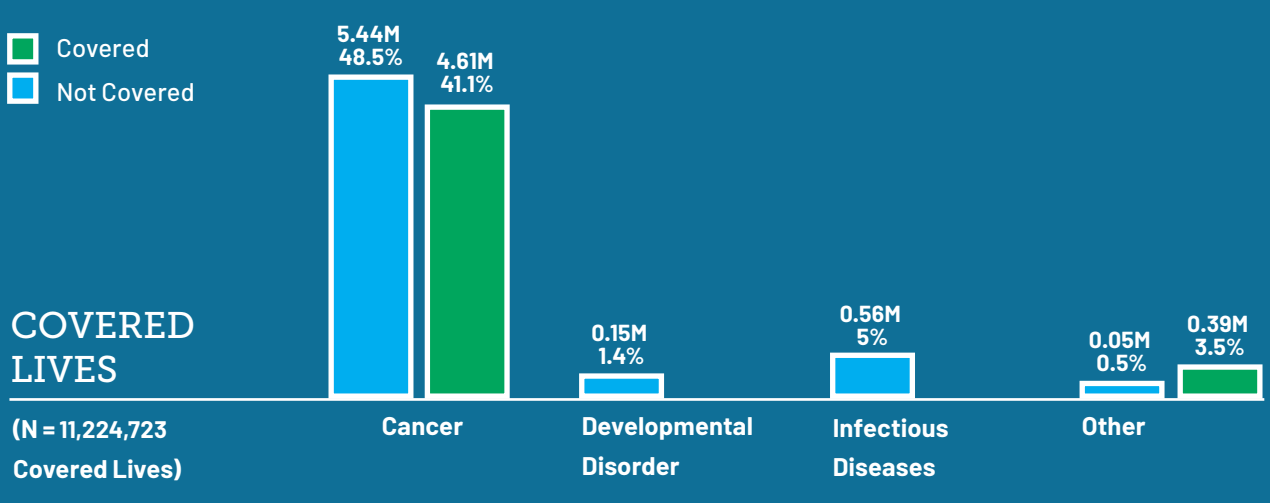
IN 24 POLICIES REVIEWED ACROSS 12 COMMERCIAL AND GOVERNMENT PAYERS

44.6%

OF TOTAL LIVES ARE COVERED FOR NGS FOR AT LEAST ONE INDICATION

NGS COVERAGE BY INDICATION





OTHER INDICATIONS

- Sequence variants and/or deletions/duplications of the genes
- Hereditary connective tissue disorders
- Germline multi-gene panels

Commercial payers are much more likely to cover NGS than are government payers, with a focus on coverage for oncology diagnoses that help steer patients to appropriate precision medicine.

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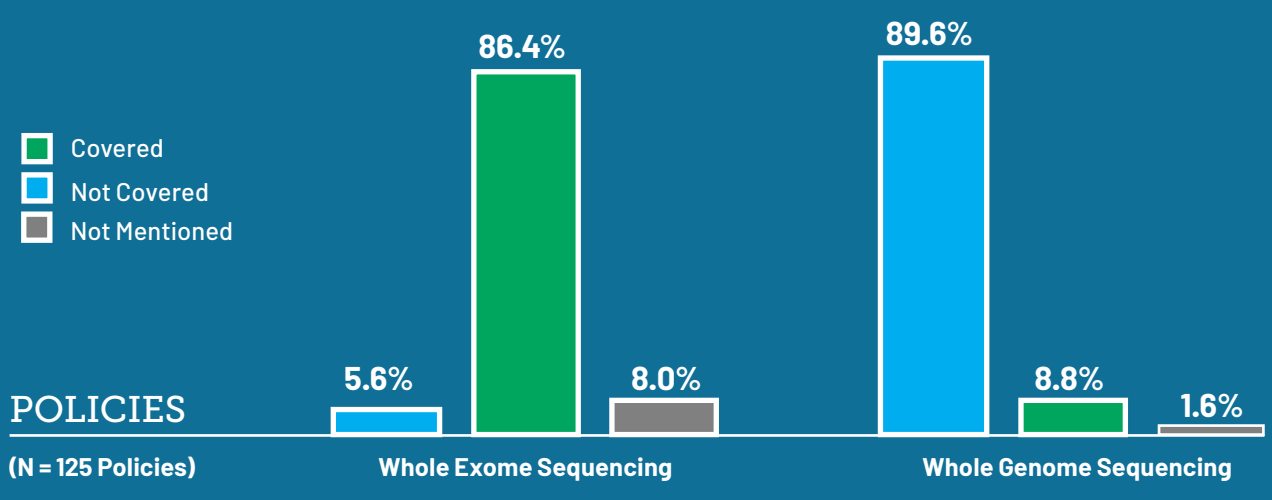
COMPREHENSIVE TESTING

Comprehensive genetic testing can diagnose disease states beyond oncology, and is now possible but is not necessarily covered by payers. Policies differentiate between whole exome and whole genome sequencing.

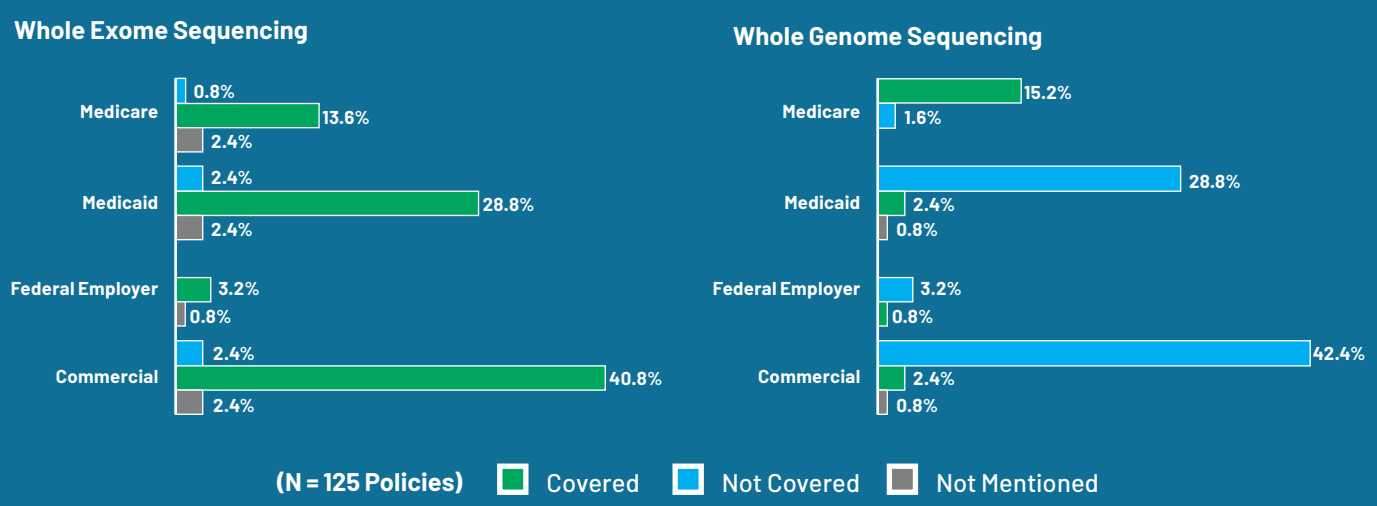
Whole exome sequencing (WES) is a laboratory test used to determine the nucleotide arrangement of the protein-coding regions of the genome. The exome encompasses only 1-2% of the complete DNA sequence (genome), yet it contains approximately 85% of disease-causing variants.

Whole genome sequencing (WGS) determines the order of the nucleotides in the entire genome. Because the genome is so much larger, WGS is a more robust, but more expensive approach.

OVERALL COVERAGE BY PERCENTAGE OF POLICIES

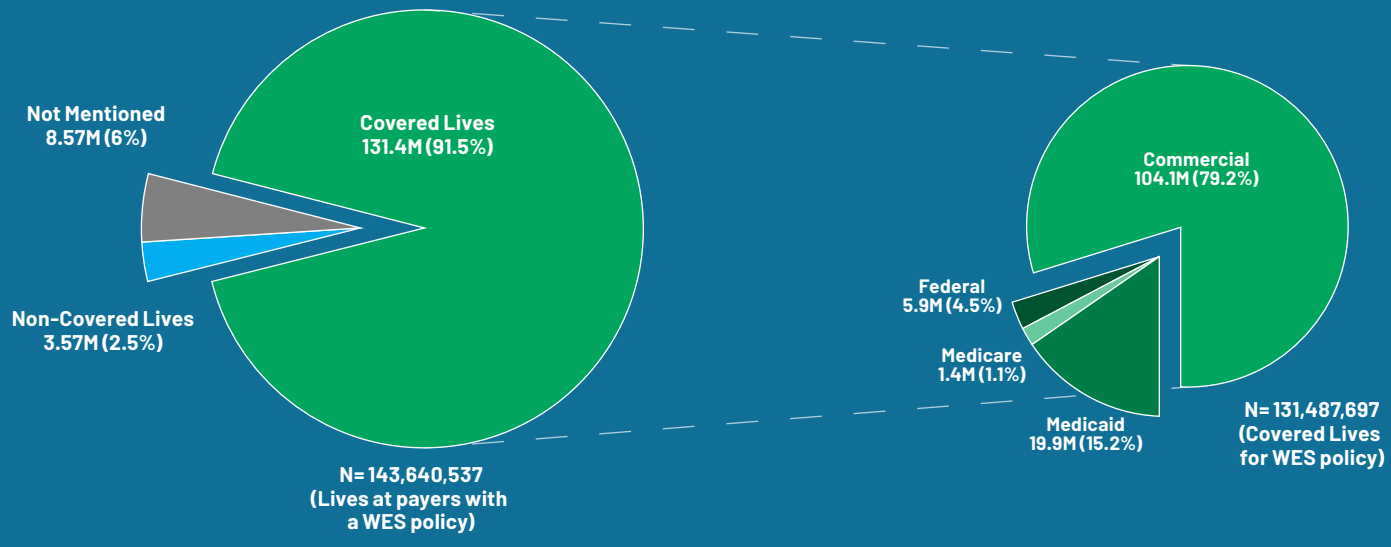


WGS & WES COVERAGE BY PAYER PLAN TYPE

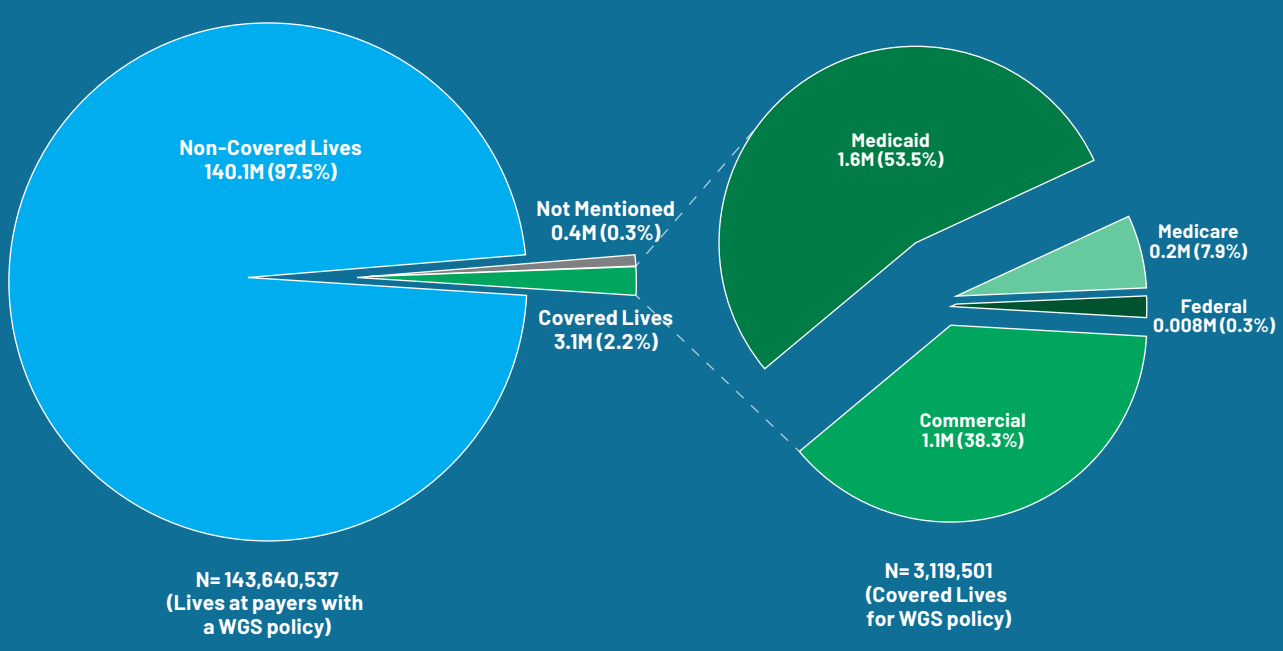


WGS & WES COVERED LIVES BY PAYER PLAN TYPE

Whole Exome Sequencing



Whole Genome Sequencing



On average, payers do not seem to consider WGS medically necessary to improve patient outcomes.

SUMMARY

As this snapshot shows, coverage and reimbursement for genetic testing is complex and inconsistent across the payer landscape. Policy Reporter keeps you up-to-date on the ever-changing payer landscape with policy updates and market trends that could dramatically impact your business.

References:

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