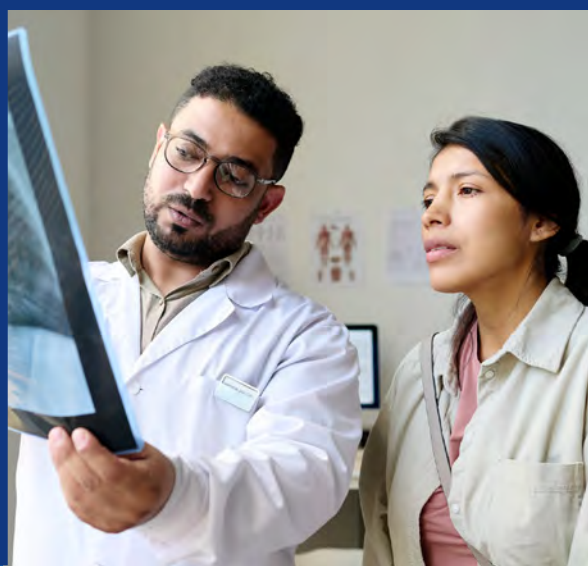
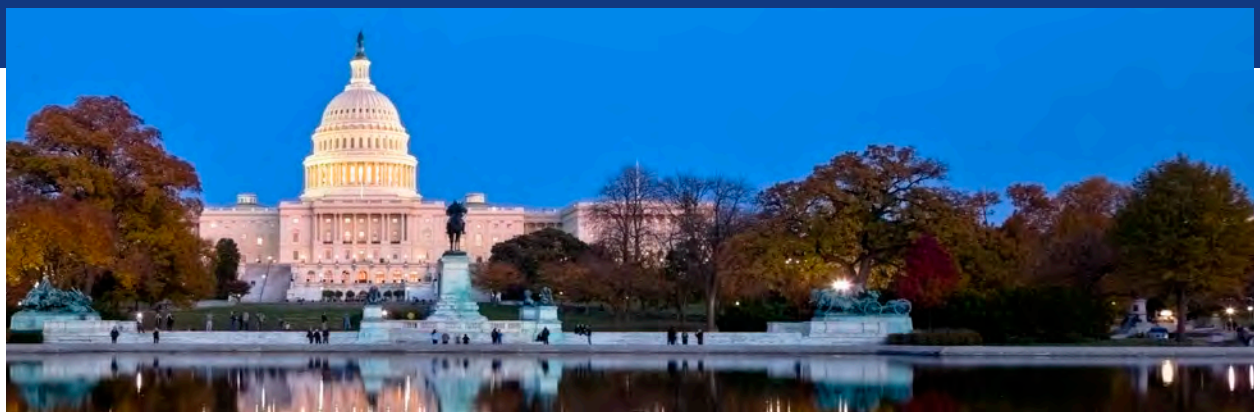
Access to Care for COPD and Lung Cancer Patients Under Current Essential Health Benefit Standards



American Lung Association®

Executive Summary



The Affordable Care Act (ACA) established 10 categories of essential health benefits (EHBs) that health plans in the individual and small group markets and Medicaid expansion plans must cover. EHBs are designed to ensure that patients have access to comprehensive healthcare coverage that includes the emergency services, preventive services, prescription drugs, and other critical treatments and services that they need. In 2013, the Secretary of Health and Human Services (HHS) issued regulations implementing standards for EHB which included a process for each state to select their own benchmark plan, supplemented by federal standards in a few specific coverage areas.

Over a decade later, changes to the benchmarking process and federal standards for EHB have been limited. The Lung Association commissioned a review of EHB benchmark plans and silver plans offered in the ACA marketplaces in five states to determine whether those benchmark and silver plans provided access to the treatments and services that patients with COPD and lung cancer would need to treat their conditions.

Key findings include:

- **Lack of Transparency:** In multiple areas, both benchmark plans and silver plans lacked key details to determine whether they met the standard of care for COPD and lung cancer.
- **Failure to Keep Up with Medical Advancement:** In the past decade, comprehensive biomarker testing has connected patients with lung cancer with targeted therapies that drastically improve their prognosis, yet none of the benchmark plans provided guidance on biomarker testing.

- **Barriers to Accessing Recommended Treatments:** Certain recommended medications for both COPD and lung cancer were not covered by all plans and included barriers like prior authorization, quantity limits, and placement on specialty tiers. Additionally, some plans had visit limits for pulmonary rehabilitation that compromised access to the standard of care.
- **Lack of Oversight and Enforcement:** Both the benchmark plans and all but one state's silver plans were not consistently covering tobacco cessation treatment, a preventive service required to be covered under the current EHB standards.

These gaps demonstrate a clear need to update and better enforce current EHB standards to ensure that patients have access to guidelines-based care. In 2022, the Biden administration released a request for information on EHB. As the administration continues to explore this issue, the Lung Association offers the following policy recommendations to address the gaps found in this analysis:

- **Conduct a comprehensive review of EHB standards.** HHS should establish a regular, evidence-based process that incorporates input from patients and other stakeholders on gaps in the current EHB framework.
- **Update coverage requirements in areas where there have been important changes in science and medicine since 2013.** This should include additional guidance on biomarker testing under the laboratory services category of EHB.
- **Strengthen the prescription drug standard.** The EHB standard should require coverage of a minimum of two drugs per US Pharmacopeia (USP) class and category or the number covered by the benchmark plan, whichever is greater, as well as "all or substantially all" drugs in certain specified classes, similar to the approach adopted in Medicare Part D.
- **Restrict limits on evidence-based care.** Any utilization management or other limits on treatments and services must be guidelines-based and not used to arbitrarily restrict access to EHB treatments and services.
- **Improve oversight and enforcement of existing EHB standards.** Greater resources are needed to ensure that plans meet existing coverage standards, especially for preventive care like tobacco cessation.

Introduction

The Affordable Care Act (ACA) established 10 categories of essential health benefits (EHBs) that health plans in the individual and small group markets and Medicaid expansion plans must cover.[1] EHBs are vital for patients with and at risk for lung disease to access the comprehensive care that they need. These standards have expanded access to preventive services like lung cancer screening and tobacco cessation, prescription medications, habilitative and rehabilitative care like pulmonary rehabilitation, and many other important treatments and services (see below).

10 Essential Health Benefits

1. Ambulatory patient services
2. Hospitalization
3. Mental health and substance use disorder services including behavioral health treatment
4. Rehabilitative and habilitative services and devices
5. Preventive and wellness services and chronic disease management
6. Emergency services
7. Maternity and newborn care
8. Prescription drugs
9. Laboratory services
10. Pediatric services, including oral and vision care

1. Certain health insurance policies purchased on or before March 23, 2010 that have "grandfathered" status do not have to comply with these requirements.

In 2013, the Secretary of Health and Human Services (HHS) issued regulations implementing standards for EHB which included a process for each state to select their own benchmark plan.[1] States could choose from a number of options – the three largest small group plans in their state, the three largest state employee plans in their state, the three largest federal employee health plans, or the health maintenance organization plan in the state with the largest commercial, non-Medicaid enrollment. The state benchmark plan then served as a guide for insurers in each state to design their plans for the individual and small group markets, including those sold through the ACA's exchanges. Insurers also had to design their plans to comply with additional federal standards in certain coverage areas, such as preventive services and prescription drugs.

Currently, the state benchmark process relies on benefit designs that are more than five years old.

Currently, the state benchmark process relies on benefit designs that are more than five years old. Additionally, lessons learned from the implementation of these standards over the past decade, as well as changes in science and medicine, have highlighted areas of needed improvement. In 2022, the Biden administration released a request for information on EHB and the American Lung Association submitted detailed comments identifying some of the gaps in the current EHB standards that make it harder for patients with lung disease to access the care that they need.[2]

In 2023, the Lung Association commissioned Avalere to assess whether there are gaps in EHB benchmark plans, as well as in the individual market coverage sold through the ACA's exchanges based on those benchmark plans, that impede access to care for individuals with COPD and lung cancer. Avalere conducted a comparative analysis of EHB for 2023 silver plans on the ACA exchanges within the largest ZIP codes for five states: Louisiana (70726), Maryland (20906), Michigan (48197), New Mexico (87121), and Pennsylvania (19120). This study examined whether the selected states' EHB benchmark plans provided sufficient guidance and whether silver plans offered sufficient coverage to meet the standard of care for individuals with lung cancer or COPD.

Methodology

Based on clinical expertise, national standards, and guidance to develop treatment protocols, Avalere created a standard of care for COPD and lung cancer patients. The treatment protocols included details on the severity of the condition, symptoms experienced, smoking history, schedule of treatments, drug coverage, and services required (Table 1 and 2).

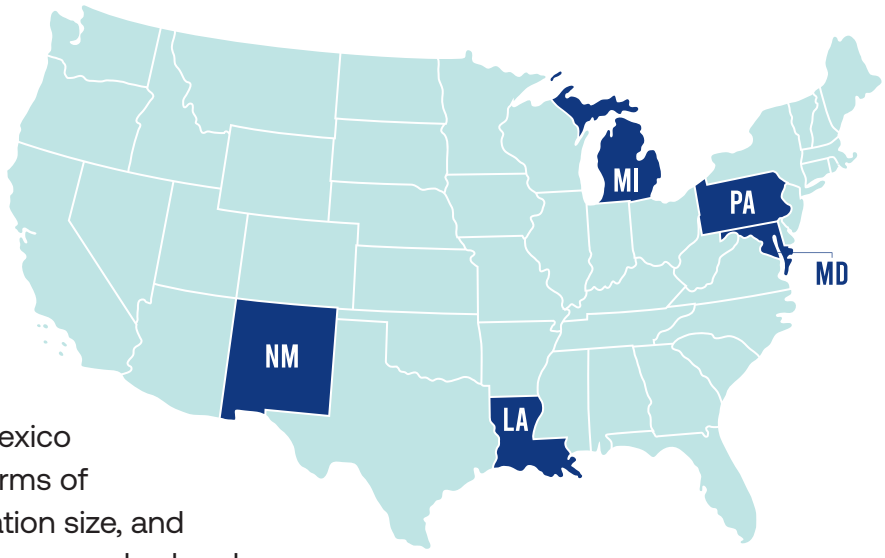
Table 1 – Standard of Care for COPD

Hypothetical Patient Overview	A 59-year-old male was diagnosed with moderate to severe COPD last year and a history of smoking (30 pack year). The patient is up to date with routine vaccinations, including the COVID-19 vaccine.	
Diagnostic Overview	The patient would require hospitalization due to COPD exacerbation. The discharge summary includes the following description: patient arrived with a persistent, nonproductive cough; Chest computerized tomography (CT) shows moderate consolidation constant with chronic bronchitis.	
Drug Utilization Overview	The patient is currently prescribed varenicline, albuterol (rescue inhaler), and a COPD maintenance therapy medication.	
Service Utilization	**Frequency of Visit**	**Schedule**
Medical Services		
Routine Primary Care Provider Visits	4	Jan, June, July, Nov
Specialist Visit (Pulmonologist)	2	Feb, July
Hospitalization (5 days)	1	July
Pulmonary Rehab Visits	24	July – Dec
Diagnostic Services		
Pulse Oximetry	5	Jan, Feb, June, July, Nov
Arterial Blood Gas Testing	1 (Additional tests as needed)	July
Spirometry Testing	1 (Additional tests as needed)	July
Chest X-Ray	1 (Additional tests as needed)	July
Sputum Culture	1 (Additional tests as needed)	July
Electrocardiogram (EKG) – Annual	1 (Additional tests as needed)	Jan
Preventive Services		
Tobacco Cessation Services	—	Continuing weeks: 1 mg twice daily for a total of 24 weeks
COVID-19 Immunization	—	2 doses

Table 2 – Standard of Care for Lung Cancer

Hypothetical Patient Overview	A 60-year-old female and former smoker (20 pack year).	
Diagnostic Overview	The patient received a diagnostic computed tomography (CT) scan following the low dose computed tomography (LDCT) scan, revealing a large mass (4 cm) in the left lung with lymph node involvement. A needle biopsy confirmed non-squamous adenocarcinoma of the lung, and her positron emission tomography (PET) scan and CT was consistent with extensive bone metastases. The patient was diagnosed with ROS1 fusion gene adenocarcinoma, confirmed by next-generation sequencing (NGS) testing, also known as biomarker testing.	
Drug Utilization Overview	The patient was placed on targeted oral therapy with crizotinib, which resulted in disease stabilization through the end of the year.	
Service Utilization	**Frequency of Visit**	**Schedule**
Medical Services		
Routine Primary Care Provider Visits	1	Jan
Specialist Visit (Oncologist)	14	Jan–Dec
Specialist Visit (Cardiologist)	6	Jan, Mar, May, July, Sept, Nov
Pulmonary Rehab Visits	24	July–Dec
Diagnostic Services – Labs		
Bloodwork – Comprehensive Metabolic Panel and Complete Blood Count	12	Jan–Dec
Bloodwork – Liver Panel	2	Jan–Feb
Diagnostic Services – Scans		
Electrocardiogram (EKG)	6	Jan, Mar, May, July, Sept, Nov
PET Scan	6	Jan, Mar, May, July, Sept, Nov
CT Scan	6	Jan, Mar, May, July, Sept, Nov
Needle Biopsy	1	Jan
NGS Test (including ROS1)	1	Jan
Preventive Services		
LDCT Scan	1	Jan

Selection of States & Approach to Selecting Plans



Avalere and the Lung Association selected five states (state-based and federal exchanges) with diverse and expansive populations to offer a range of variations among state plan benefits and descriptions. The chosen states (Louisiana, Maryland, Michigan, New Mexico and Pennsylvania) vary in terms of type of marketplace, population size, and demographics. Next, Avalere researched and categorized silver plans within the most populous ZIP codes of each state based on the availability of services and treatments for COPD and lung cancer patients.

EHB Benchmark and Silver Plan Analysis

Avalere assessed whether the states' EHB benchmark plans covered each treatment or service outlined in the standard of care for each condition in the analysis. Avalere also completed a separate and similar analysis to determine whether the state silver plans met the state EHB benchmark plan and/or the standard of care. Avalere then evaluated and categorized each treatment or service outlined in the standard of care into the following groupings.

The state EHB benchmark plans included the following categories:

- Meets the Standard of Care
- Does Not Meet the Standard of Care
- Coverage Details Not Specified

The silver plans in each state included the following categories:

- Meets Benchmark
- Exceeds Benchmark
- Does Not Meet Benchmark
- Coverage Details Not Specified

Next, Avalere calculated the proportion of state EHB benchmark plans that met the standard of care, did not meet the standard of care, or did not provide sufficient coverage details ("benchmark details were not specified"). Avalere calculated the proportion of silver plans in each state that met the benchmark plan, exceeded the benchmark plan, did not meet the meet benchmark plan, or the coverage details were not specified. Lastly, Avalere conducted a qualitative review of the silver plans that met the state benchmark plan but did not meet the standard of care.

Formulary Analysis

Avalere evaluated the coverage, tiering and utilization management for each prescription drug included in the standard of care for COPD and lung cancer.[2] There are Food and Drug Administration (FDA) approved treatments for COPD and lung cancer that were not listed in the standard of care and not included in this analysis. Avalere assessed brand and generic coverage, limited to the availability of drugs within the formulary database.

Most health plans have a prescription drug formulary that indicates which brand and generic drugs the health plan will cover and the cost sharing requirements for the patient. Plan formularies assign prescription drugs to tiers, which designate each drug's coverage, commonly noted as preferred, non-preferred, or specialty. Preferred tiers are associated with lower cost sharing for the patient compared to non-preferred and specialty tiers.

2. Avalere partners with Clarivate™ to obtain formulary data and pharmacy lives covered across all payer types. Specific data included herein are derived from the Fingertip Analytics© of Clarivate. All rights reserved. Data current as of February 2023.

Results

Avalere utilized the standard of care for COPD and lung cancer to conduct research across the five states included in this analysis. Avalere located state benchmark plans and identified coverage based on the standard of care for both conditions. The standard of care for COPD and lung cancer patients included inpatient and outpatient care, specialist visits, diagnostic testing, prescription drug coverage, and preventive services.

Avalere researched available plans in the most populous ZIP codes across five states. Federal exchange plan summaries were more accessible via internet searches in comparison to state-based exchange plans. Additionally, a considerable number of complete plan brochures were not available for download across all five states. Most plan brochures that were available did not provide coverage details on types of specialists or specific information on inpatient services and treatments.

Table 3 – State EHB Benchmark Plans and Silver Plans in Most Populous ZIP Codes of Five States[3]

State	ZIP Code	County/ Parish	Number of Silver Plans	Qualitative Assessment
Louisiana	70726	Livingston	18	The state benchmark plan did not meet the standard of care for COPD due to gaps in tobacco cessation. The state benchmark plan did not provide specific details to determine coverage of lung cancer screening or biomarker testing.
Maryland	20906	Montgomery	10	The state benchmark plan did not meet the standard of care for COPD because the plan limited pulmonary rehabilitation benefits. The state benchmark plan did not provide specific details to determine coverage for biomarker testing.
Michigan	48197	Washtenaw	36	The state benchmark plan included all services and treatments included in the standard of care for COPD. The state benchmark plan did not include specific details to determine coverage for biomarker testing.
New Mexico	87121	Bernalillo	7	The state benchmark plan met the standard of care for all services and treatments included in the standard of care for COPD. The state benchmark plan did not include specific details to determine coverage for biomarker testing.
Pennsylvania	19120	Philadelphia	26	The state benchmark plan met the standard of care for all services and treatments included in the standard of care for COPD. The state benchmark plan did not meet the standard of care for lung cancer because it did not specify lung cancer screening or reference the USPSTF. The state benchmark plan also did not provide sufficient details to determine coverage for biomarker testing.

3. EHB benchmark plan types varied across states, which included plans from the largest small group product to the largest health maintenance organization plan in a state. Small group plans were either a preferred provider organization, health maintenance organization, or point of service plan.

Evaluation of State EHB Benchmark Plans to the Standard of Care

Table 3 provides an overview of the benchmark plan analysis for each state. The standard of care for COPD included pulmonary rehabilitation, an evidence-based program of education and exercise for patients with COPD and other lung diseases designed to improve lung function, reduce symptom severity and improve quality of life. Maryland's benchmark plan did not meet the standard of care for pulmonary rehabilitation because the plan limited the number of visits and did not cover maintenance programs. The program limited members to "one program per lifetime."

The standard of care for COPD also included tobacco cessation. The US Preventive Services Task Force (USPSTF) recommends behavioral interventions (counseling) and FDA-approved medications for adults who use tobacco products, and plans are legally required to cover both. Louisiana's benchmark plan did not meet the standard of care for tobacco cessation coverage, as the plan excluded all tobacco cessation programs, supplies, and drugs. The exception was bupropion, which was the only covered drug for tobacco cessation. The benchmark plan also included language indicating that tobacco cessation programs and drugs are not considered medically necessary. The benchmark plan did not mention tobacco cessation counseling. Louisiana's benchmark plan drug formulary provided contradictory information and listed varenicline as a covered drug for tobacco cessation. Additionally, benchmark plans in Maryland, Michigan, and Pennsylvania only specified coverage of pharmacotherapy for tobacco cessation treatment. The plans did not provide additional details to determine whether individual or group counseling services were covered.

The standard of care for lung cancer included biomarker testing, which allows doctors to identify abnormalities in a cancer cell's DNA and determine the best course of treatment for patients with lung cancer. However, none of the states' EHB benchmark plans provided sufficient details to determine coverage of biomarker testing for lung cancer patients. Additionally, USPSTF recommends annual lung cancer screening for individuals at high risk for lung cancer based on their age and smoking history. Louisiana's benchmark plan did not provide sufficient detail to determine whether lung cancer screenings were covered. The benchmark plan coverage document lists other cancer screenings but does not specifically list lung cancer screening. Pennsylvania's benchmark plan also did not specify lung cancer screening, and there is no reference to the USPSTF guidelines.[4]

4. Plans that included references to the USPSTF were considered to have met the standard of care.

Evaluation of the State EHB Benchmark Plan to Silver Plan Coverage

Avalere assessed silver plans compared to their state's EHB benchmark plan. While silver plan coverage may have equated to "meeting the benchmark," their coverage details may not have aligned with the standard of care. Table 4 shows coverage of select treatments and services included in the standards of care for COPD and lung cancer across silver plans.

Table 4 – Percentage of Silver Plans in Most Populous ZIP Codes in Five States that Met the Standard of Care for Select Treatments and Services for COPD and Lung Cancer

Treatment or Service	Louisiana	Maryland	Michigan	New Mexico	Pennsylvania
Albuterol	100%	100%	100%	100%	100%
Biomarker Testing	0%	0%	0%	0%	0%
COVID-19 Vaccine	100%	100%	100%	100%	100%
Crizotinib	72%	60%	78%	100%	100%
Fluticasone Furoate, Umeclidinium & Vilanterol	100%	100%	100%	71%	75%
Lung Cancer Screening	100%	100%	100%	100%	100%
Ondansetron	100%	100%	100%	100%	100%
Prednisone	100%	100%	100%	100%	100%
Pulmonary Rehabilitation	89%	0%	100%	86%	100%
Varenicline	100%	60%	100%	100%	100%
Tobacco Cessation Counseling	28%	0%	38%	100%	28%

Beginning with pulmonary rehabilitation, all silver plans in Maryland met the state benchmark plan but did not meet the standard of care. Like the state's EHB benchmark plan, the silver plans limited pulmonary rehabilitation to "1 program per lifetime for an enrollee diagnosed with significant pulmonary disease." Additionally, four of the ten plans did not provide maintenance programs for pulmonary rehabilitation. In the other states, most silver plans met the state benchmark and either did not have quantitative visit limits or had limits that exceeded the number of visits in the standard of care; however, two silver plans reviewed in the largest ZIP code in Louisiana and one silver plan in the largest ZIP code in New Mexico did not specify the details needed to determine whether pulmonary rehabilitation services were covered.

The standards of care for both COPD and lung cancer included prescription drug coverage. Current EHB standards require coverage of only one drug per US Pharmacopeia (USP) class or the number of medications included in the USP class in the state's benchmark plan. For COPD, all plans covered either ProAir RespiClick® or albuterol hydrofluoroalkanes, the generic alternative, for rescue inhalers with quantity limits. All plans also covered prednisone without any utilization management restrictions. However, all plans did not cover fluticasone furoate, umeclidinium & vilanterol (Trelegy Ellipta®). This medication was only covered in 71% of the silver plans in New Mexico and 75% of the silver plans in Pennsylvania. Additionally, many plans covered this maintenance therapy with quantity limit restrictions, ranging from 54% of the time in Pennsylvania to 89% of the time in Louisiana.

For lung cancer, all silver plans covered ondansetron, again with quantity limits. As for the targeted therapy crizotinib (Xalkori®), coverage varied across states, and prior authorization was required. Crizotinib was covered by 60% of the silver plans in Maryland, 72% in Louisiana, 78% in Michigan, and 100% in New Mexico and Pennsylvania. Additionally, many silver plans across all states listed crizotinib on the specialty tier, ranging from 40% in Maryland to 100% in New Mexico.

Patient Story

Renee is a patient with lung cancer who received her healthcare through the ACA marketplace for two years. Renee had a positive experience with the marketplace and eventually found a suitable plan that facilitated the continuation of her cancer treatments, covering most medications and treatments. However, Renee faced significant difficulties in obtaining coverage for a crucial medication following her plan selection, a targeted immunotherapy that is very expensive when not covered through insurance. She was very fortunate to be able to afford this medication despite insurance not covering it and continued with her cancer treatment. Patients like Renee need access to all guidelines-based medications for successful management of their conditions.

Continuing with lung cancer, Avalere found that 100% of silver plans across all five states cover lung cancer screening by referencing the USPSTF, even though the state EHB benchmark plans in Louisiana and Pennsylvania did not reference the USPSTF. However, all silver plans failed to meet the standard of care based on diagnostic testing. No state silver plans listed biomarker testing in diagnostic coverage.

Finally, for tobacco cessation, Avalere found 100% of silver plans in the most populous ZIP codes in Louisiana, New Mexico, Michigan, and Pennsylvania listed varenicline in formularies. In Maryland, only 60% of the plans in the most populous ZIP code listed varenicline. The standard of care for tobacco cessation treatment for the COPD patient included varenicline. The branded product for this drug is no longer being produced. Some plan formularies continued to list the brand and others listed generic varenicline, along with other tobacco cessation treatments.[5]

The coverage of tobacco cessation counseling services was more limited. Only one state, New Mexico, provided detailed coverage for tobacco cessation counseling for all silver plans in the largest ZIP code. Only 38% of silver plans in the largest ZIP code in Michigan and 28% of silver plans in the largest ZIP codes of both Louisiana and Pennsylvania covered tobacco cessation counseling. No silver plan in the largest ZIP code in Maryland covered tobacco cessation counseling.

5. This analysis focused on a specific set of drugs for review. The analysis did not include all drugs for the conditions included in this review. The analysis does not reflect a lack of coverage for any FDA approved drugs used for these conditions.

Discussion

These results reveal a number of key gaps in the design and implementation of the current EHB standards. First, a lack of transparency in both benchmark plans and silver plans makes it difficult to determine whether patients have access to guidelines-based care for COPD and lung cancer. For example, a substantial number of health plan brochures did not specifically list or enumerate coverage details for pulmonary rehabilitation services, and the number of sessions covered was not commonly listed. Similarly, preventive healthcare coverage was not always readily available in plan brochures. Details on tobacco cessation coverage, vaccination coverage and healthcare screenings required significant research. Consumers should not be expected to do extensive research to determine if critical services are covered by their plan.

A lack of transparency makes it difficult to determine whether patients have access to care.

Second, EHB standards have failed to keep up with changes in science and medicine over the past decade, including biomarker testing. In the past decade, comprehensive biomarker testing has connected patients with targeted therapies that drastically improve their prognosis. Studies show that lung cancer patients that have access to biomarker testing and are thus able to receive targeted therapy treatments have better overall chances of survival.[3] However, coverage details were not specified for biomarker testing across all state EHB benchmark plans and across all silver plans within the largest ZIP code within each state, jeopardizing patients' access to these critical medical advances.

Third, the results of this analysis indicate there are barriers to accessing certain treatments recommended for COPD and lung cancer. Certain recommended medications for both COPD and lung cancer were not covered by all plans. Additionally, many medications included barriers like prior authorization, quantity limits, and placement on specialty tiers, which typically have higher cost-sharing. Visit limits for pulmonary rehabilitation were a barrier as well. These barriers have important implications for patients. For example, research has shown that even relatively low levels of cost-sharing limit the use of necessary healthcare services.[4] Similarly, prior authorization requirements can delay patients' access to care and even lead some patients to abandon treatment.[5]

Finally, the results of this analysis suggest there are substantial gaps in the coverage of tobacco cessation treatment, especially in terms of coverage of counseling. Despite requirements to cover USPSTF-recommended preventive services, in three of the five states, only a fraction of the silver plans covered tobacco cessation counseling and in one state, there was no coverage of tobacco cessation counseling. This highlights the lack of oversight and enforcement of current EHB standards for preventive services.

Overall, the lack of transparency and gaps in access to key treatments and services across plans makes it more difficult for patients shopping for coverage to know with any certainty what is covered and to choose the optimal plan for their health needs. Ultimately, when plans do not cover these treatments and services, patients will either be forced to choose between paying more to access the care that they need or delaying recommended treatments and services, often resulting in more costly care in the future and poorer health outcomes.

Policy Recommendations

These gaps demonstrate a clear need to update and enforce current EHB standards to ensure that patients have access to evidence-based care. As policymakers continue to explore this issue, the Lung Association offers the following recommendations to address the gaps found in this analysis:

1. **Conduct a comprehensive review of EHB standards.** HHS should establish a regular, evidence-based process that incorporates input from patients and other stakeholders on gaps in the current EHB framework.

2. **Update coverage requirements in areas where there have been important changes in science and medicine since 2013.** This should include additional guidance on biomarker testing under the laboratory services category of EHB.

3. **Strengthen the prescription drug standard.** The EHB standard should require coverage of a minimum of two drugs per US Pharmacopeia (USP) class and category or the number covered by the benchmark plan, whichever is greater, as well as "all or substantially all" drugs in certain specified classes, similar to the approach adopted in Medicare Part D.

4. **Restrict limits on evidence-based care.** Any utilization management or other limits on treatments and services must be guidelines-based and not used to arbitrarily restrict access to EHB treatments and services.

5. **Improve oversight and enforcement of existing EHB standards.** Greater resources are needed to ensure that plans meet existing coverage standards, especially for preventive care like tobacco cessation.

Acknowledgments

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