

# *The Case for Coverage*

An Evidence-Based Resource Guide

JUNE 2024

# *Dear ALS Community,*

Advocates play a critical role in making ALS livable for everyone, everywhere. That is why The ALS Association works every day to empower more than 40,000 advocates across the country to fight for public policies that supported research into developing treatments and cures for ALS, enhance access to the full range of health care needs of people living with ALS, and reduce or delay the harms of living with ALS.

The ALS Association advocates for public policy reforms at the federal, state, and local levels. Our advocates reach out to policymakers in statehouses across the country, in the White House and the halls of Congress in Washington, D.C., in federal agencies like the Food and Drug Administration, and with state regulatory agencies like state insurance commissioners who oversee organizations that offer health insurance.

Advocacy also takes place with other entities, like the health insurers who develop health insurance plans that govern your access to the health care you need.

This resource guide is intended to empower you to reach out to health insurers to educate them about the range of health care needs of people living with ALS – things like approved treatments, durable medical equipment, clinical care, and home health care – and show them ways that insurers can reduce barriers to care.

Too many people living with ALS who have health insurance are unable to get the medical care, equipment, and services they need or they too often face lengthy delays. This is due to insurance plans not covering certain types of care or requiring prior authorization before accessing care. Because insurers are failing people living with ALS, we need you to meet with insurance plans to secure many changes to the way insurance plans are designed so they better serve all people with ALS.

As an advocate, you may choose to meet with health insurance plan administrators to promote increased access to specific services you think should be more accessible. This might include expanding access to specialists, adding coverage for home modifications that insurance currently does not cover, or providing easier access to a specific piece of equipment.

This resource guide was designed to arm you with the evidence you need to craft a compelling case that better insurance coverage for the full range of health care needs leads to better health outcomes for people living with ALS, and also a healthier bottom line for insurers.

For more information on how to do this important advocacy work, please contact [advocacy@als.org](mailto:advocacy@als.org).

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# Introduction

This Resource Guide has information to support you in your efforts to educate people designing and administering health insurance plans about the health care needs of people living with ALS. The evidence included in this guide can be used to advocate for improvements to health insurance coverage and payment policies so they can better meet the needs of people with ALS across their disease journey. To support those efforts, this Resource Guide has:

- **Information to share with health insurance plan** about the range of health care needs that arise for people living with ALS, including treatments, supports, services, and equipment.
- **Data and evidence** illustrating the medical necessity of care, treatments, supports, services, and equipment needed.
- **Examples of how and why** health insurance processes and procedures, such as prior authorizations and claims denials, can cause harm to individuals with ALS and their caregivers.

## Using This Resource Guide

The top section of each page has key information for you to relay during your meetings with health insurers.

- The first section (**pages 3-7**) outlines the types of care that people living with ALS require and the barriers most often faced in accessing that care.
- The next section (**pages 8-11**) examines the negative impacts that occur when people living with ALS do not get the full range of health care services they need.

As you read these sections, consider how this information will help support your assertion that these services are necessary and need to be more accessible to people living with ALS.

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The first appendix page, titled [“Best Practices for ALS Coverage” \(page 14-15\)](#), is printable and you can bring it to your meetings with health insurance plan or email it to attendees. It has summary information outlining coverage gaps people living with ALS face, as well as specific actions that insurers can take to address those gaps. Other appendices have reference materials. The page titled [“What is ALS?” \(page 16\)](#) includes statistics on ALS to present background information on the disease. Refer to the [glossary \(page 19\)](#) to become familiar with health insurance and health care-related terms used in this guide. The citations and references pages display sources for the information presented in this guide. Citing medical journals and academic literature will give your message extra credibility because it is backed by research.

While this guide contains information to support health insurer-wide changes to coverage policies rather than appeals for specific individual patient denials, we know that many of you frequently appeal denials for yourself, a loved one, or your patients. We have included information on how to appeal denials in the page titled [“Appealing Denials” \(page 18\)](#).

# Employ Evidence To Talk With Health Insurers

Understanding how health insurers think about their roles will help you to ask them to reconsider the evidence and the impact of their policy decisions for ALS care. It is important to frame your message to persuade your audience. Anecdotal evidence and patient stories alone are not usually convincing enough to justify coverage of items.

## HEALTH INSURER MINDSETS & ENCOURAGING OPENNESS TO YOUR PERSPECTIVE

### 1 They regularly review and update their coverage policies to reflect new clinical evidence. They:

- Look for evidence in medical journals to ensure they cover treatments and services that are effective and aligned with current medical guidance and practice.
- Desire valid evidence that a service is medically necessary and worth the cost.
- Focus on evidence from clinical trials or other peer-reviewed documents.

**ENCOURAGE OPENNESS:** Ask them how they can reconsider the evidence with you to come to a shared understanding.

### 2 They are fiscally minded. They:

- Balance fiscal constraints and accelerating health care costs.
- Focus on paying for care that is effective and necessary.

**ENCOURAGE OPENNESS:** Ask them how to best look at costs from the perspective of avoiding more costly care over the disease trajectory.

### 3 They focus on medical necessity. They:

- Employ prior authorizations a tool to reduce unnecessary or inappropriate care.
- Desire to cover care that is necessary.
- See prior authorizations as useful tools and less of delaying receipt of medical necessary care or burdensome, stressful and discomfoting to people with ALS and their caregivers.

**ENCOURAGE OPENNESS:** Ask them how to work together to explore other ways to assess medical necessity while still moving forward care in a timely manner.

As you develop talking points for your meetings with health insurers using information from this resource guide, focus on proving the medical necessity of care and illustrating ways that prior authorizations, denials and delays can increase, rather than reduce, costs.

## UNDERSTANDING HEALTH INSURERS

Health insurers can have many different health plan offerings. Coverage of a drug or service, and associated prior authorization requirements or copay amounts, may be in place across all the plans that they offer or they may apply only to a subset of plans. As you schedule advocacy meetings, you may likely meet with representatives from health plans rather than executives from health insurers as a whole.

# Needed Care and Services

## Symptom Treatment & Where to Receive Support

Specialized, multidisciplinary care that extends and improves quality of life for people living with ALS<sup>1</sup>. To ensure that someone living with ALS has the full range of care they need throughout the course of their disease, a health insurer would cover care, therapies, and equipment from providers for all medical issues listed in the table below:

Issue	Treatments	Providers
Disease management	Medications	Neurologist Primary care Nursing
Swallowing and dysphagia	Feeding tube Formula Swallowing exercises	Gastroenterologist Dietician Speech-language pathologist
Breathing	Ventilation Cough assist Suction	Pulmonologist Respiratory therapist
Mobility	Wheelchair and accessories Splints/orthotics Ramps Four-wheeled walker Lift Hospital bed	Physical therapist Occupational therapist Nursing
Communication	Communication devices	Speech therapist Occupational therapist
Emotional support	Counseling and support	Psychologist Social worker Palliative care Hospice care

/ In this document, we will use the term “care” to include this full range of clinician visits, medications, equipment, and supplies.

# Medications for Treatment

The progressive nature of ALS and delays in receiving medications can affect a person's disease trajectory. Many people with ALS report difficulty getting their health insurer to pay for needed medications. Some people have reported that health insurers impose coverage restrictions that do not align with FDA approved labeled indications and clinical need.

While there is currently no cure for ALS, there are several FDA-approved medications to help slow disease progression.

## **RILUZOLE**

(RIHL-you-zahl)

Riluzole (Rilutek, Exservan, Tiglutik) is taken orally and may increase life expectancy by 3-6 months<sup>2</sup>

## **RADICAVA<sup>®</sup>**

(rah-dih-KAH-vah)

Oral or intravenous Radicava (edaravone) helps reduce the decline in daily functioning<sup>3</sup>

## **NUEDEXTA**

(new-DEK-stuh)

(dextromethorphan HBr and quinidine sulfate) is taken orally and helps alleviate symptoms of Pseudobulbar Affect (PBA)<sup>4</sup>

## **QALSODY<sup>®</sup>**

(cal-SAHD-ee)

Qalsody (tofersen) helps prevent production of toxic SOD1 proteins which damage the nervous system<sup>5</sup>

## **GUIDELINE 1**

**The FDA has approved prescription of ALS medications for all people with ALS, not only those with limited disease progression.**

According to a 2023 ALS Association survey, health insurers often restrict access to medications only to patients with little disease progression (based on lung or motor function), leaving people with more advanced ALS without access to treatments that could benefit them. This survey found that 64% of ALS clinic staff said stage of ALS is a factor in Relyvrio denials, with 81% saying it is a factor in Oral Radicava denials. The label indication for each medication says that all people diagnosed with ALS can use these medications irrespective of their stage of disease.

***“ALSFRS score, time on onset, or respiratory status should not matter in getting drug approvals. The ALS drugs are approved by the FDA for all ALS patients despite where they are at in the disease.”***

- ALS clinic staff member

## Medications for Treatment - Continued

### GUIDELINE 2

The FDA-approved ALS medications treat ALS in separate ways, and they can be taken in combination. They are not “similarly acting” medications and are never appropriate for step-therapy.

Health insurers often use **step-therapy**, also known as **fail-first**, to manage medications that people can take. Step-therapy requires proof that less expensive medications do not work before approving more expensive medications. Health insurers believe this helps ensure people take the least expensive medication that will still work.

Sometimes, health insurers use step-therapy for ALS medications, **creating a barrier to the full range of available medications**. Many health insurers require proof that riluzole is ineffective or results in bad side effects before they will grant authorization for other ALS medications, which is not appropriate because currently available ALS medications are not substitutes for one another. While step-therapy is appropriate for similar-acting medications, **ALS medications are not similarly acting** as they target different components of the disease.

Many people who participated in clinical trials for Relyvrio and tofersen were taking other medications during the clinical studies with no negative effects. Researchers are also looking into whether taking a combination of medications could be more beneficial than taking one. It is **safe and medically appropriate** to take multiple medications at the same time, not sequentially, for the treatment of ALS.





# Wheelchairs & Essential Components

People with ALS eventually lose their ability to walk. The time it takes to receive power wheelchairs, features, and attachments – sometimes several months – can mean a person living with ALS is unable to continue working or caring for themselves. One way health insurers seek to contain costs is by limiting coverage and payment for high-cost durable medical equipment, like power wheelchairs; these restrictions adversely impacts people living with ALS. The timing and nature of this loss of functioning is different for every patient. Basing wheelchair and essential component (sometimes called “accessory”) coverage on standard timelines and symptoms at time of assessment can have multiple unintended consequences.

**Having timely access to a wheelchair and essential components is critical to maintaining as many activities of daily living as possible.** For example, Medicare will only cover one power mobility device **every five years, while the currently average life expectancy of someone with ALS is two to five years.** This fast-progression means that people first being outfitted for a wheelchair need to get a model with more features that will meet their future needs as their symptoms progress.

At the same time, insurers often limit coverage only to features needed at the time of purchase. This may force a decision either to get a wheelchair now that will not be appropriate in the future or go without a wheelchair until their function decreases further. **This can increase the risks of falls and other harms often treated in emergency departments at a high cost.** Also, limiting payment can create a financial barrier for a person with ALS who would need to use their own money or go without the feature.

**Powered seat elevation systems** help reduce the risks of falls and allows a person with ALS to care for their hygiene, which can prevent costly, avoidable medical complications. **Using clinical evidence, CMS determined it is a reasonable and necessary feature for a person with ALS; it is now covered for Medicare recipients.**

**Medically necessary features** such as power tilt, recline, seat elevation, and elevating leg platforms **may not be covered by health insurers.** However, many individuals need these features for daily living, paid employment, and improved quality of life. Other features allow for repositioning for circulation and ease of breathing. These features also act as “baseline safety features” for people with ALS and their caregivers. It may allow caregivers to aid without bending over and risking back injuries or a fall themselves.



In a study of patients using a power wheelchair, 73% said they started using it at the right time but 20% said they **should have started using it sooner.**



On average it takes between **1 to 4.5 months** to receive a power wheelchair, from evaluation to delivery.

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***“Covering mobility equipment doesn’t just improve independence, it reduces the risk of injuries. If you fall, you can end up in the hospital with a fracture.”***

- Care Professional

# Respiratory Equipment

People with ALS lose the ability to breathe on their own because ALS causes weakness in muscles, including those involved in breathing. As such, people with ALS need **access to appropriate ventilation and airway clearance equipment**, supplies, and skilled respiratory therapists to support longevity and quality of life. **Respiratory failure is the leading cause of death for people with ALS.**

Respiratory equipment is often **subject to prior authorizations**, delaying access to medically necessary equipment. In a 2023 ALS Association survey, ALS care professionals said 77% of bi-level respiratory devices are often or sometimes not paid for without prior authorization or appeals, 64% for airway clearance equipment and 59% for home ventilators.

Coverage and payment for respiratory support may be limited to those with weaker respiratory muscles or worse oxygen and carbon dioxide levels. People may experience difficulty breathing but still receive a denial from their health insurer due to these thresholds. Those struggling to breathe need **quicker approval** and **broader access**.

## As ALS progresses, most people will require respiratory supports that may include:

- / Non-invasive Ventilation (NIV)
- / Suction Machine to remove secretions
- / Invasive Ventilation (tracheostomy)
- / Mechanical Cough Assistance Device or High-frequency Chest Wall Oscillation (HFCWO) Device to facilitate airway clearance
- / Life support devices that include back-up battery power and pressure/volume controls/alarms

## THE IMPORTANCE OF NON-INVASIVE VENTILATION TO PROLONG LIFE

Non-invasive ventilation (NIV) provides breathing support to people via a mask or mouthpiece. Studies show **NIV increases longevity when initiated early** in the disease progression when lung function is as high as 80% predicted FVC (the amount of air you can exhale compared to other people of the same age, height, and sex)<sup>6</sup>. Insurers tend to **reimburse later in the disease progression** when FVC is below 50% predicted.

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***“People with ALS need help getting air in and getting carbon dioxide out. Without assistance, they’re more lethargic and have shortness of breath, which can be really scary.”***

- Care Professional



# Impact of Denials

When people are denied care or delayed in receiving it due to lengthy prior authorization processes or needing to appeal denials, it negatively impacts them, their loved ones, and their medical providers.



## IMPACTS ON PATIENTS

A 2021 nationwide American Medical Association survey detailed the impact prior authorizations have on physicians and their ability to care for their patients. Even when eventually approved, prior authorization requirements delay people from getting care when they need it. **But the adverse consequence is even greater when authorization is denied.** Out of surveyed physicians:

**93%** of physicians claim prior authorizations delay necessary care

**82%** report patients abandoning treatment because of prior authorizations

**91%** claim negative impact on clinical outcomes

**34%** report serious health complications because of prior authorizations, including hospitalization, life-threatening events, or permanent disability/bodily damage



## IMPACTS ON ALS CLINICS

Providers and office staff working at ALS clinics face health insurance-related challenges daily, spending a significant amount of time **filing prior authorization requests and claims appeals on behalf of their patients.** This includes time completing forms, gathering patients' medical charts, and attending peer-to-peer reviews with insurers to discuss patients' conditions.

A 2022 ALS Focus survey of people with ALS and their caregivers found that 76% relied on nurses, doctors, or other medical staff to help them submit prior authorizations or claim appeals. This takes providers' **time away from their patients** and leads to burnout among healthcare workers.



## IMPACTS ON CAREGIVERS OF PEOPLE WITH ALS

Caregivers face an increased burden when their loved ones are unable to access the medical care they need. When equipment that could make a person with ALS more independent or that makes providing care safer and more efficient is denied, it takes more time and physical effort to provide care. This increases the **risk of caregivers getting injured** or inadvertently hurting the person with ALS.



***“My wife, who cares for me, has health problems. Insurance only covers a manual hospital bed, but she would have hurt herself raising and lowering it. So I had to pay out of pocket for an electric one.”***

- Person with ALS

# What People With ALS Say About Denials

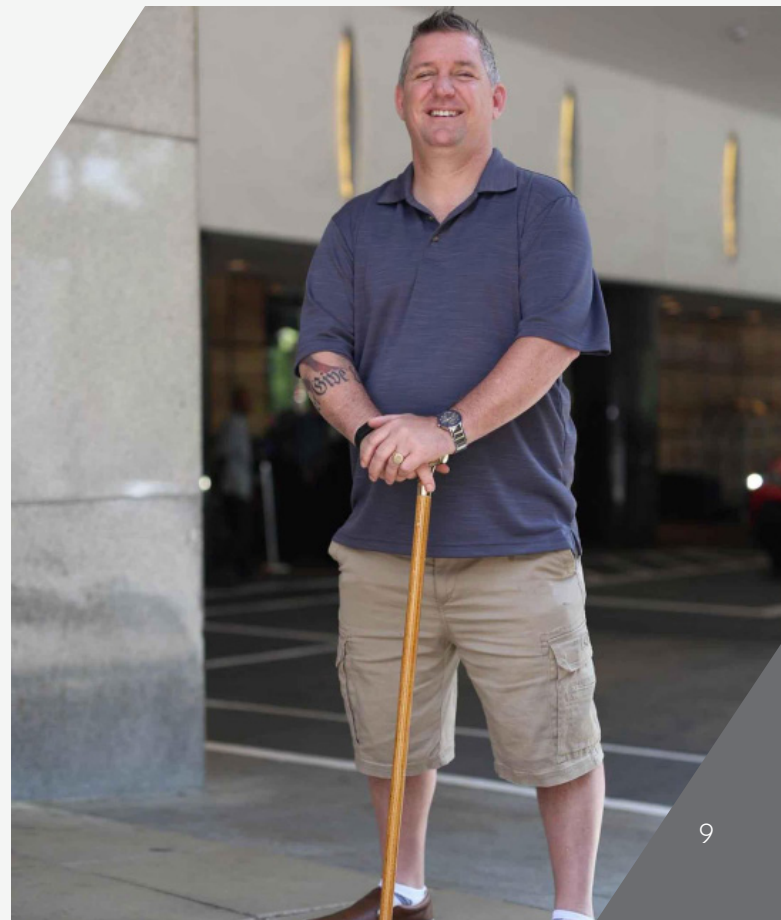
*“People with ALS know there are medicines that could slow their disease. It’s a stressful, helpless feeling to wait and wonder if you’ll get something that can help you.”*

*“I don’t bother to submit claims anymore, I just pay out of pocket since I’m lucky enough to afford it. Insurance makes it so hard to get things approved, they probably hope people like me give up.”*

*“We lose so many abilities. If there is some equipment that can help me remain independent for longer, that means so much to me. Insurance companies don’t understand this is about basic human dignity.”*

*“When I needed a new prescription for my medication, it was denied because I’m not showing signs of improving. Doesn’t my insurance realize that’s not what an ALS medication is designed to do?”*

*“I was assessed for which features I would need for my power wheelchair, but at the same time advised to limit the features so insurance would pay for it. Why is there a disconnect between what my physician says I need versus what my insurance will cover?”*



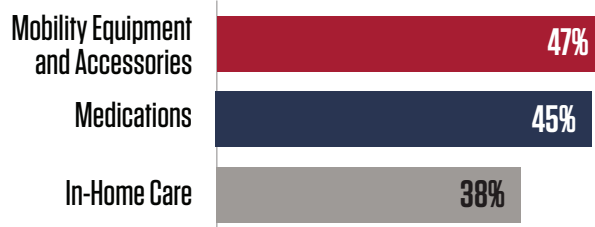
# Where Coverage Can Be Improved

Other survey data demonstrate how claims denials and prior authorization requirements impact access to services and increase financial burdens on people living with ALS.

Denials are seen across the spectrum of care that people with ALS need, though some treatments, equipment, and services are more frequently denied than others. A 2022 ALS Focus survey of people with ALS and caregivers asked about experiences with denied claims and prior authorizations. The survey found that **36% of people with ALS have faced denied claims and/or prior authorization requirements.**

While it is possible to appeal a denied claim or prior authorization, these processes create barriers to timely receipt of medical care. If not covered, it creates a financial barrier for a person who would need to use their own money or go without the care they need. **Seventy percent of people with ALS who appealed a denial said it took more than one month to resolve**, with 36% saying it took at least four months.

## MOST FREQUENTLY DENIED CARE



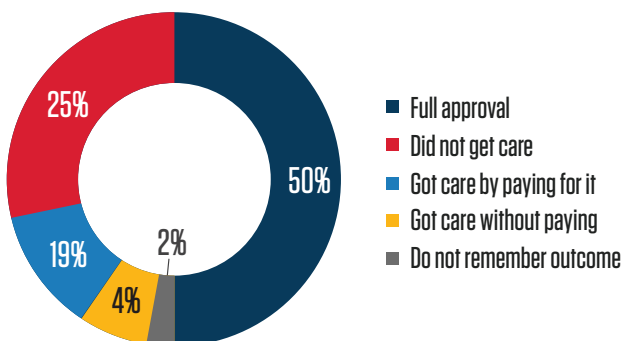
## WHAT ALS CLINICS ARE SAYING

Clinic staff report on denials and delays for certain medications and equipment

Service/treatment option	% clinic staff who said it is denied at least some of the time	% said it takes at least 1 month between the request and the patient receiving it
Oral Radicava	86%	74%
Power wheelchairs	60%	89%
Home ventilators	57%	31%

## WHAT IS THE OUTCOME OF APPEALED DENIALS?

Of the 2022 ALS Focus survey respondents who had to appeal a denied prior authorization or claim, 25% did not end up getting the care they needed. Another 19% got care but had to pay for part or all of the cost out-of-pocket.



***“We don’t order things our patients don’t need. Denials don’t help anyone.”***

- ALS Clinic Physician

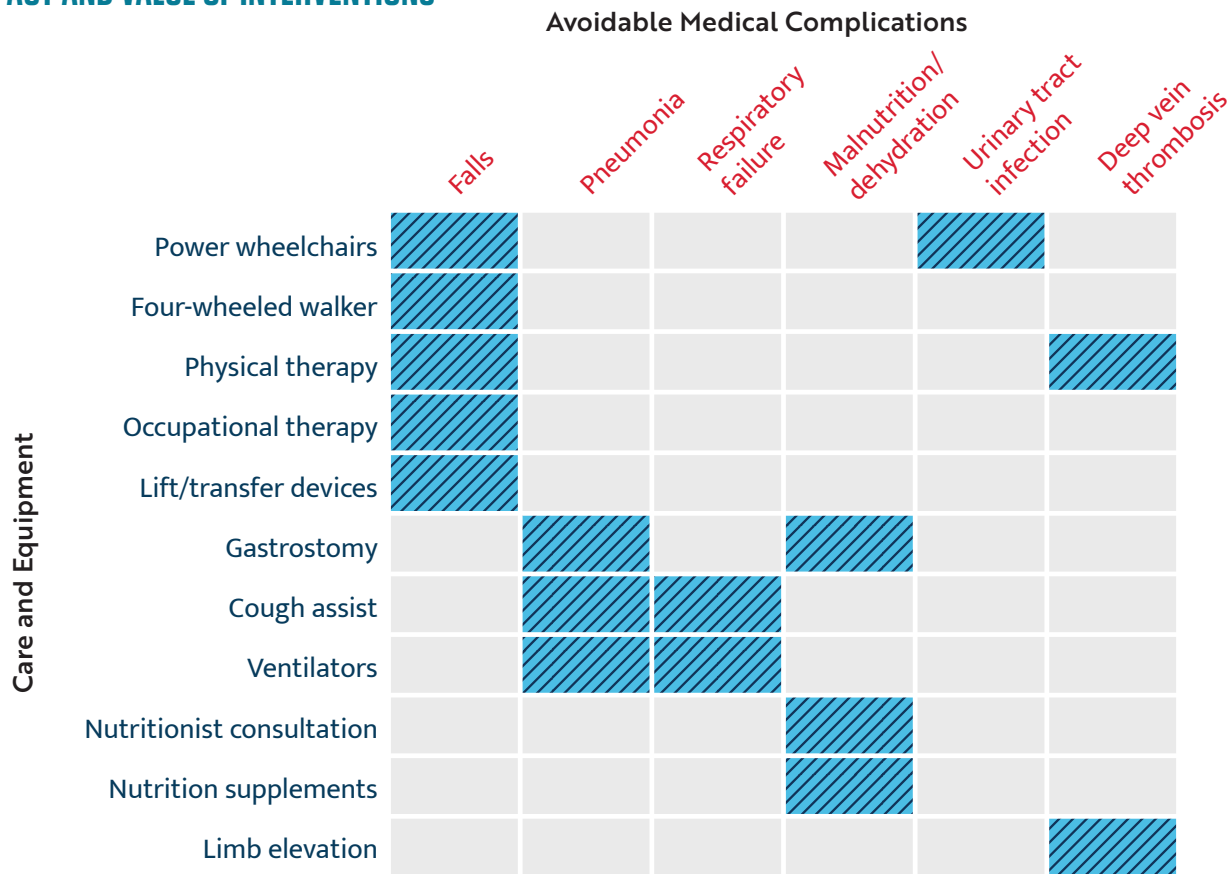
***“We want to spend our limited time doing things that make us happy with family and friends. We don’t want to waste time fighting insurance companies.”***

- Person with ALS

# Preventing Medical Complications

Several of the leading causes of injury and hospitalizations for people with ALS are preventable through increased access to needed services and equipment. Restricting access to certain services and equipment can lead to higher spending on avoidable costs<sup>7, 8, 9, 10, 11, 12, 13, 14</sup>. It is important that health insurers consider how the provision of certain care and equipment in a timely manner can prevent more expensive care in the future. Without needed care and equipment, people with ALS risk further medical complications. Not only do these complications decrease quality and length of life, but they also often result in expensive emergency room visits or hospital stays.

## IMPACT AND VALUE OF INTERVENTIONS



Here is an example of how to interpret this chart: “Access to a power wheelchair can help prevent UTIs.”

**“People don’t know how hard it is living with ALS. If they fall they could end up in the emergency room. They can get urinary tract infections if they can’t use the toilet by themselves. Not everyone has someone around who can help them.”**

- ALS Clinic Physician



# Conclusion

The evidence in this resource guide will support you in helping make ALS livable for everybody, everywhere, while we continue as a global community to advance the search for cures.

Knowing that health insurers regularly review and update their coverage policies to reflect new clinical evidence means we can encourage their openness to updating their policies to ensure they cover the full range of health care needs of people living with ALS. It also provides an important opportunity to convince them that better coverage can help extend life for people living with ALS.

Knowing that health insurers focus on costs, the evidence in this resource guide empowers you to have conversations with health insurance administrators to educate them about the many reasons that covering the full range of health care needs to make ALS livable is fiscally sound.

Knowing that health insurers focus on medical necessity means you have the opportunity to explain how covering the full range of health care services needed to treat ALS leads to better health outcomes.

Beyond cost savings and improved health outcomes, we know that these coverage changes also will advance and enhance quality of life for people living with ALS and their caregivers.

You have the power to help ensure that people living with ALS in your community have access to the health care they need, when they need it, without having to navigate unnecessary, costly and burdensome barriers. The result: more health insurance plans that readily meet the needs of people living with ALS and more members of our community whose lives are more livable.

For more information on how to start this conversation with health insurance administrators, go to **[WEBSITE LINK TO COME]**

# *Appendix*





# Best Practices for ALS Coverage

## About ALS

ALS is a progressive neurodegenerative disease. People with ALS will require several types of equipment and care from many specialists and therapists. Access to these is important to prevent complications such as falls, malnutrition, pneumonia, respiratory failure, infections and bed sores – all of which can lead to costly hospitalizations or emergency department visits. The best health outcomes are secured when a person living with ALS receives their care at a multidisciplinary clinic and can access care, supports, services, and equipment in a timely manner.

## Frequent Access Issues

**Difficulty accessing FDA-approved medications.** Health insurers impose step-therapy (also known as fail-first) before approving newer medications, but evidence shows ALS medications are safe when taken together. They have different mechanisms of action and target different underlying issues. It may even be beneficial to take multiple ALS medications contemporaneously. Others receive medication coverage denials due to disease progression, even though the FDA has approved the drugs for all people with ALS irrespective of their state of disease.

**Limitations on respiratory equipment.** Coverage policies often restrict ventilation equipment to those with lower lung capacity, despite published evidence of increased survival and slower decline for those starting ventilation earlier. Providing non-invasive ventilation support at an early stage improve longevity.

**Denials for power wheelchairs and safety features.** ALS is a quickly progressive, degenerative disease, and over time, people will need many features for safety and quality of life. Access issues arise due to policies that limit how often someone can get a new power wheelchair or policies denying payment for features not yet needed at the time of purchase, even if those features will eventually be necessary. People with ALS live two to five years after diagnosis, though health insurers pay for wheelchairs once every five years.

**Reduced access to specialists and therapists.** There is often limited coverage of physical and occupational therapy despite the benefits of therapy in slowing decline. Prior authorizations for visits to specialists necessary to treat ALS, such as pulmonologists or gastroenterologists, create delays in accessing medically necessary care that can help maintain activities of daily living.

## Outcomes

Many of the leading causes of hospitalization and emergency department visits in people with ALS – falls, pneumonia, respiratory failure, and malnutrition – are preventable by the timely provision of medications, equipment, and outpatient care.

Insurers spend significant amounts of resources processing prior authorization requests and denial appeals.



## *Best Practices for ALS Coverage - Continued*

We understand that insurers rely on prior authorizations and denials to manage costs and prevent unnecessary spending. However, there are changes insurers can make to simplify processes to ensure people with ALS obtain medically needed care in a timely manner.

### **Opportunities to Reduce Denial/Prior Authorization Costs**

- 1 Review data on prior authorizations for ALS patients.**

Prior authorizations create administrative costs for insurers, which is only worth it if they save more money in medical spending. By examining prior authorizations related to members with ALS, health insurers can see which ones rarely result in denials. Sunsetting prior authorization requirements for members living with ALS that do not lead to savings in medical spending would be advantageous for both insurer and member.
- 2 Bring ALS specialists into the prior authorization/appeals review process.**

ALS is a rare disease, and not all physicians are familiar with the full range of health care required to treat people living with ALS. Health insurers should rely on neurologists, gastroenterologists, and pulmonologists with experience treating ALS for such reviews rather than primary care doctors or specialists expert in other diseases. This can help lead to more timely, accurate, and appropriate coverage decisions and fewer appeals.
- 3 Create a streamlined “gold card” process for approving orders from trusted physicians.**

If there is confidence that a provider is only prescribing care that is medically necessary, there could be a simplified way to approve care. Assigning a “gold card” status to providers whose orders rarely result in denials is one way to ensure that members get the care they really need without delay. These providers may include ALS clinics or other expert ALS care providers who fully understand the variation in medical needs at different stages of the disease.



## What is ALS?

Amyotrophic Lateral Sclerosis (ALS) is a fatal neurodegenerative disease in which a person's brain loses connection with their muscles. People with ALS lose their ability to walk, talk, eat, and eventually breathe.

ALS usually occurs in people between the ages of 40 and 70, but it can affect anyone at any time. Although there is not yet a cure or treatment that halts ALS, scientists have made significant progress in understanding what causes ALS.

## Facts about ALS



**5000+** people in the US are diagnosed every year



**10%** of cases occur where there is family history



**2-5 years** is the average life expectancy



Every **90** minutes someone is diagnosed, and someone passes away from ALS

### DIAGNOSIS

**Difficult to diagnose.** ALS is often diagnosed by ruling out other diseases, which may take months or years.

### OUTCOMES

**Progressive loss of muscle control.** ALS Gradually prohibits the ability to:

- Speak
- Grasp objects
- Swallow
- Move
- Walk
- Breathe

## About The ALS Association



The ALS Association is dedicated to fighting ALS on every front. The Association leads the way in global research, care services, public education, and public policy. The Association's nationwide network of chapters provides comprehensive patient services and supports to the ALS community. The Association strives to serve, advocate for, and empower people affected by ALS to live their lives to the fullest as well as help discover treatments and a cure to ALS.

# Acknowledgements

Thanks to those who participated in research informing this Resource Guide: People with ALS and their caregivers, ALS clinicians, clinic coordinators, ALS Association care services team members, and Chief Medical Officers and proxies for these experts. We also thank the working group members from The ALS Association and Venable, LLP who collaborated for a year to develop this Guide, and our research partners at Mathematica for collecting, analyzing, and compiling a wealth of data for this project with the rigor needed to make the important case for covering ALS care. The ALS Association exercised complete authority over the process, content, and methodology in preparing this Resource Guide without any outside influence.

## RESOURCE GUIDE UPDATES

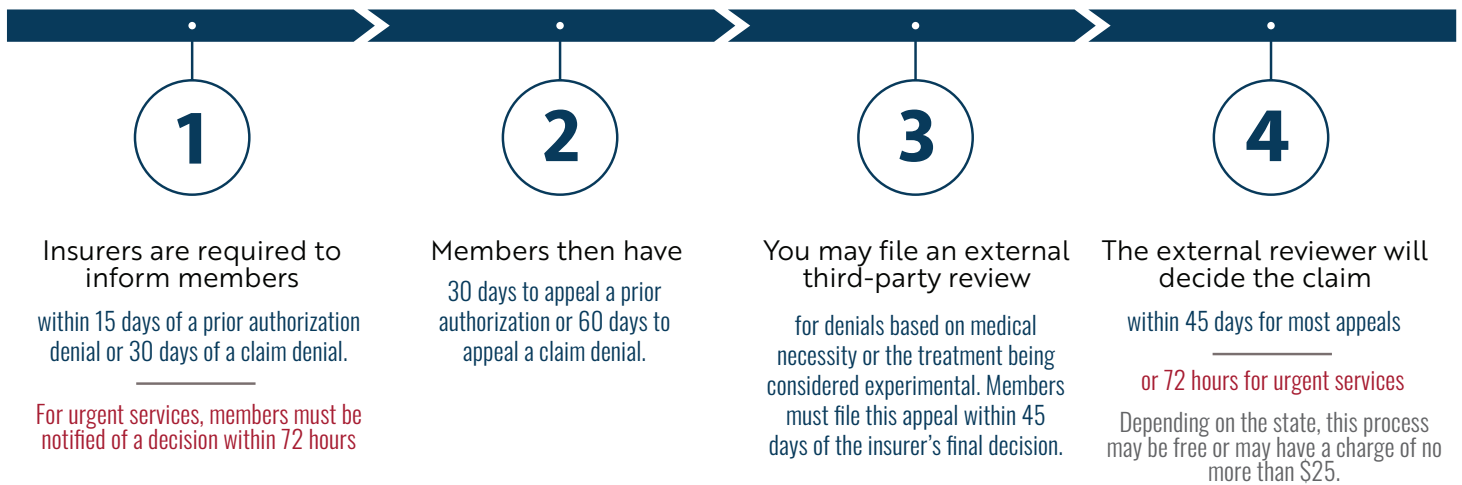
There have been swift and significant medical advancements in the treatment of ALS. The ALS Association carefully reviews all relevant materials and ensures that this resource guide is kept up-to-date with the latest information. As of May 2023, it is current, but we encourage you to check back regularly for updates.

Supported in part by



# Appealing Denials

What to do if your health insurance claim or request for prior authorization of a service, medication, or equipment is denied



## Best Practices for Insurance Appeals



### Keep all documents related to your appeal

This includes letters you or your physician sent along with the appeal form, medical records submitted, Explanations of Benefits received from the plan, and notes taken during any phone calls with the insurer's customer service.



### Submit medical records or a letter from your physician

In order to prove medical necessity, be sure to submit medical records showing your current condition including test results and physician notes. A letter from your physician can also document your current condition and why the service or treatment is needed. If prior treatments have failed, submitting proof of this may help navigate step-therapy requirements.



### Request help with your appeal if needed

Your state's Consumer Assistance Program or insurance department (found at <http://content.naic.org/state-insurance-departments>) can help file the appeal.

# Glossary

<b>ALS</b>	Amyotrophic lateral sclerosis.
<b>ALSFRS</b>	ALS Functional Rating Scale (ALSFRS); a scale to evaluate functions, such as speech and walking ability, in individuals with ALS which can be used to monitor disease progression over time.
<b>Claim</b>	A request for payment that you or your health care provider submits to your health insurer when you get items or services you think are covered.
<b>Forced vital capacity</b>	A measure of how much air you can forcibly exhale from your lungs.
<b>Health insurer</b>	A company that offers one or more health plans for purchase, including group health plans and individual coverage policies.
<b>Health insurance plan or health plan</b>	A contract where a person is entitled to receive a defined set of health care items or services in exchange for payment. This payment may be paid by an individual or employer.
<b>Maximal inspiratory pressure</b>	A measure of the strength of muscles used to inhale.
<b>Medicare</b>	A federal health insurance program for people 65 and older and certain younger people with disabilities. It also covers people with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a transplant, sometimes called ESRD).
<b>Multidisciplinary ALS care</b>	The provision of care to the ALS patient and their family by a range of health care disciplines and support services. This may include neurologists, respiratory therapists, gastroenterologists, rehabilitation, and/or palliative care, allied health care professionals in physiotherapy, occupational therapists, speech and language pathology, nutrition and social work, nurses, genetic counselors, psychologists, and neuropsychologists.
<b>Prior authorization</b>	A decision by your health insurer or plan that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary. Sometimes called prior authorization, prior approval or precertification. Your health insurance or plan may require preauthorization for certain services before you receive them, except in an emergency. Preauthorization isn't a promise your health insurance or plan will cover the cost.

# End Notes

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# Other Helpful Resources

## MEDICATIONS

### Radicava:

- <https://www.als.org/navigating-als/living-with-als/fda-approved-drugs/edaravone#how-work>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5737249/>

### Riluzole:

- <https://www.med.umich.edu/llibr/Neurology/ALS/RiluzoleHandout.pdf>

### Relyvrio:

- <https://www.nejm.org/doi/full/10.1056/NEJMoa1916945>
- <https://www.npr.org/sections/health-shots/2020/09/02/908874110/drug-combination-slows-progression-of-als-and-could-mark-new-era-in-treatment>

### Qalsody:

- <https://investors.biogen.com/news-releases/news-release-details/fda-grants-accelerated-approval-qalsodytm-tofersen-sod1-als>

## VENTILATION EQUIPMENT

- <https://pubmed.ncbi.nlm.nih.gov/15947331/>
- [https://journals.lww.com/ajpmr/Abstract/2010/05000/At\\_Home\\_and\\_on\\_Demand\\_Mechanical\\_Cough\\_Assistance.7.aspx](https://journals.lww.com/ajpmr/Abstract/2010/05000/At_Home_and_on_Demand_Mechanical_Cough_Assistance.7.aspx)
- <https://thorax.bmj.com/content/thoraxjnl/66/11/948.full.pdf>
- <https://jamanetwork.com/journals/jamaneurology/article-abstract/2782747>
- <https://www.sciencedirect.com/science/article/pii/S152605420900075X>
- [https://journals.lww.com/homehealthcareonline/fulltext/2012/03000/the\\_management\\_of\\_respiratory\\_insufficiency\\_in.9.aspx](https://journals.lww.com/homehealthcareonline/fulltext/2012/03000/the_management_of_respiratory_insufficiency_in.9.aspx)

## PHYSICAL, SPEECH, AND OCCUPATIONAL THERAPY

- <https://www.alsclinic.pitt.edu/patient-issues/occupational-and-physical-therapy>
- <https://pubmed.ncbi.nlm.nih.gov/33546507/>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4433000/>

## TELEHEALTH VISITS

- <https://www.sciencedirect.com/science/article/abs/pii/S1047965120301078?via%3DiHub>
- <https://onlinelibrary.wiley.com/doi/abs/10.1002/mus.26838>

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- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2077622/>
- <https://content.iospress.com/download/neurorehabilitation/nre182531?id=neurorehabilitation%2Fnr182531>