THE Sumaira FOUNDATION

NAVIGATING INSURANCE & ACCESS BARRIERS

A Guide for NMOSD Patients & Caregivers

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HOW TO USE THIS GUIDE

Neuromyelitis optica spectrum disorder (NMOSD) is a rare neuroimmune condition in which the immune system attacks cells in the central nervous system (CNS), mistaking them for foreign invaders. Common symptoms include vision loss, color vision deficiency, paralysis, paraparesis, weakness, numbness, spasticity, vomiting, hiccups, and bladder/bowel dysfunction.

The antibody associated with NMOSD is called **aquaporin-4 (AQP4)**. More than half of the patients living with NMOSD are AQP4 positive.

If you or your loved one has been diagnosed with NMOSD, your doctor may recommend one of four treatments approved by the U.S. Food and Drug Administration (FDA):

			
Enspryng®	**Soliris®**	**Ultomiris®**	**Uplizna®**

Getting prescribed one of these medicines is an important step forward. But before you can begin treatment, **most health insurance plans require prior authorization.**

The process can be confusing, frustrating, and sometimes slow. This guide will help you:

- **Understand how insurance works**
- **Know what steps are required before you can start treatment**
- **Learn what to do if your insurance denies coverage**
- **Find resources for financial help and support**

You do not have to read this entire guide at once. Start with the section that matches where you are in the process. Although this was guide created for NMOSD patients and caregiver, tips within this resource are applicable to all rare diseases with an FDA-approved treatment.

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COMMON INSURANCE TERMS — General Insurance Basics

Coinsurance – Your share of the cost, usually a percentage, after your deductible is met (e.g., you pay 20%, your plan pays 80%).

Copayment (Copay) – A fixed amount you pay at the time of care (like $25 for a doctor's visit or $10 for a prescription).

Deductible – The amount you pay out-of-pocket each year before your insurance begins covering most services.

Explanation of Benefits (EOB) – A statement you receive after care that shows what was billed, what insurance covered, and what you owe.

Formulary – The approved list of medicines your plan will cover, often split into "tiers" that affect how much you'll pay.

Network – A group of doctors, hospitals, and pharmacies that contract with your insurance plan. Using "in-network" providers usually costs you less.

Out-of-Pocket Maximum – The total amount you'll pay in a year for covered services. Once you hit this limit, your insurance covers 100%.

Out-of-Network Provider – A provider not contracted with your insurance. Care here often costs more, and sometimes isn't covered at all.

Premium – The regular payment you make (usually monthly) to keep your insurance coverage active.

Tiered Drugs – The way insurance plans group medicines by cost:

- **Tier 1**: Lowest cost-sharing tier, usually reserved for preferred generic drugs.
- **Tier 2**: A medium-cost tier containing other generic drugs or lower-cost brand-name drugs.
- **Tier 3**: A high-cost tier, typically featuring brand-name drugs.
- **Tier 4: (Specialty Tier):** The highest-cost tier, often containing non-preferred brand-name or specialty drugs.

COMMON INSURANCE TERMS - Access to Treatment Terms

Appeal – A formal request to your insurance company to reconsider a denial of coverage.

Benefit Limitation – Restrictions your plan may have, like a maximum number of physical therapy sessions per year.

Case Management – Support services (often by a nurse or advocate assigned through your insurance) to help you coordinate complex care.

External Appeal – A review by an independent third party, outside your insurance company, if an internal appeal is denied.

Explanation of Denial – A written notice that explains why your claim, service, or prescription wasn't covered.

Internal Appeal – Your insurer's own review of their denial, usually triggered when you or your provider challenge their decision.

Prior Authorization (Preauthorization) – A requirement that your doctor get approval from your insurance before you can start a certain test, treatment, or medication.

Medical Necessity – A standard your insurance uses to decide if a treatment is essential for your condition.

Step Therapy (Fail-First Policy) – When your plan requires you to try a lower-cost option before approving the one your doctor recommends.

Utilization Review – The process your insurer uses to check whether the service requested meets its medical necessity rules.

COMMON INSURANCE TERMS - Other Helpful Terms

Allowed Amount – The maximum your insurance will pay for a covered service; anything above this may be billed to you if the provider is out-of-network.

Coordination of Benefits (COB) – Rules for how costs are split if you're covered by more than one insurance plan (e.g., through work and a spouse).

Enrollment Date – The day your insurance coverage officially starts.

Health Insurance Marketplace – The online portal where you can compare and buy health plans, often with financial help if you qualify.

Insurance Card – The card you receive from your plan with important information like your policy number, copays, and insurer's phone number.

Insurance Plan Types:

- **Health Maintenance Organization (HMO)**: requires patients to choose a primary care doctor and get referrals to see specialists; only covers in-network care (except emergencies). Usually has lower premiums.

- **Preferred Provider Organization (PPO)**: Lets patients see specialists without referrals and offers some out-of-network coverage, though at a higher cost. Usually has higher premiums but more flexibility.

- **Self-Insured/Self-Funded Plan**: An employer, not the insurance company, pays for care but an insurer still manages the plan. These plans may have more flexibility, and HR/benefits teams can sometimes help get approvals overturned.

FDA-APPROVED TREATMENTS FOR NMOSD

Until a few years ago, there were no treatments made specifically for NMOSD. Today, there are four medicines approved by the U.S. Food and Drug Administration (FDA). These medicines have been shown in clinical trials to reduce relapses, lower the risk of disability, and give patients more control over their disease.

Medicine	How It Works	How It's Given	How Often	Eligibility Notes	Insurance Considerations
UPLIZNA® inebilizumab-cdon **(inebilizumab)**	Targets and reduces B-cells that drive NMOSD relapses	Intravenous infusion (hospital/clinic)	Every 6 months (after 2 starting doses, 2 weeks apart)	Approved for adults with NMOSD antibody positive	Often requires proof of diagnosis and history of relapses; neurologist must prescribe
ENSPRYNG® **(satralizumab)**	Blocks IL-6, a protein that causes inflammation in NMOSD	Self-injection under the skin	Every 4 weeks (after 3 loading doses)	Approved for adults with NMOSD antibody positive	Insurance may require positive aquaporin-4 antibody test; sometimes step therapy rules apply
SOLIRIS® (eculizumab) **(eculizumab)**	Blocks the complement system (part of immune response)	Intravenous infusion (hospital/clinic)	Every 2 weeks (after 4 loading doses)	Approved for adults with NMOSD antibody positive	Vaccines *may* be required before insurance will allow treatment to start
ULTOMIRIS® (ravulizumab-cwvz) **(ravulizumab)**	Longer-acting complement inhibitor, similar to Solrirs	Intravenous infusion (hospital/clinic)	Every 8 weeks (after 2 starting doses)	Approved for adults with NMOSD antibody positive	Vaccines *may* be required before insurance will allow treatment to start

FDA-APPROVED TREATMENTS FOR NMOSD

What Insurance Looks For in Eligibility

Insurance companies often use “coverage policies” to decide if you qualify. These policies may include:

- A confirmed diagnosis of NMOSD
- Proof of AQP4 antibody positivity (especially for complement inhibitors)
- A history of at least one relapse
- Evidence that the treatment is being prescribed by a **neurologist** or a doctor experienced with NMOSD

Key Takeaways for Patients and Caregivers

- **Antibody status matters:** Insurance companies often use antibody test results (AQP4) to decide coverage, especially for Soliris and Ultomiris.
- **Route of administration differs:** Some patients may prefer home injections (Enspryng), while others may prefer less frequent infusions (Ultomiris, Uplizna).
- **Insurance paperwork is similar:** For all four, you will almost always need prior authorization and documentation from your doctor.
- **Step therapy may apply:** Some insurers require patients to try (and fail) a preferred, lower-cost treatment before covering other options like Soliris, Ultomiris, or Enspryng.
- **Vaccines may be required:** Complement inhibitors (Soliris and Ultomiris) require certain vaccines before insurance will allow treatment to start.

PRIOR AUTHORIZATIONS 101

When your doctor prescribes a treatment for NMOSD, the next big step is usually something called a **prior authorization**.

This is how your insurance company double-checks that:

- The treatment is medically necessary for you, and
- It fits their rules for coverage

What Happens During Prior Authorization

Step #1: Your Doctor Submits Paperwork

- **What's included in a prior authorization request:**
  - Documentation of your NMOSD diagnosis
  - Test results (like aquaporin-4 antibody testing)
  - Your history of relapses or hospitalizations
  - Previous treatments you tried and why they were not effective
  - A letter of medical necessity written by your doctor
  - Your diagnosis (often anti-AQP4 antibody test results), history of relapses, MRI findings, and treatments you've already tried.

- **Why it matters**: insurance companies want proof that you meet the criteria for treatment.

Step #2: Your Insurance Provider Reviews the Request

- An insurance medical reviewer checks whether you meet their "coverage criteria."
- These criteria are often available on your insurance company's website under "clinical policies."
- Your insurance provider will respond within 1–3 weeks. Some states require insurers to respond within 15 business days. Expedited review may be possible if your doctor certifies that waiting could cause serious harm (decision in 72 hours).

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PRIOR AUTHORIZATIONS 101

Step #3: Your Insurance Provider Makes a Decision

- **Approved**: You will learn where the medication can be covered through a benefit investigation (e.g., infusion center, hospital, home). The prior authorization is then submitted with the chosen site of care determined by the patient and their provider to confirm approval/coverage.

- **Denied**: You'll get a letter explaining why. Common reasons include:
  - "Not medically necessary" (they want more documentation).
  - "Step therapy required" (they want you to try another medicine first).
  - "Experimental" (they haven't updated their policy for NMOSD).

What You Can Do to Help

Prior authorization is not a sign that your treatment won't be covered — it's a checkpoint. By working closely with your doctor's office and staying organized, you can help move things forward faster.

- **Stay in close contact with your doctor's office.** Ask: "Has the prior authorization been submitted yet?"

- **Make sure your information is correct.** Double-check your insurance ID number, group number, and mailing address.

- **Keep a log.** Write down the date submitted, who you spoke with, and reference numbers from the insurance company.

MY PRIOR AUTHORIZATION IS DENIED, HOW DO I APPEAL THE DECISION?

A denial does not mean the end of your treatment journey. It simply means your insurance company needs more information before agreeing to cover the medicine. Appeals are common, and it's important to work with your NMOSD specialist to ensure all important paperwork and medical history is submitted according to your insurance provider's requirements.

Why Denials Happen

Insurance companies may deny prior authorization requests for several reasons:

- Missing paperwork or incomplete medical records
- The insurance plan wants proof that you meet eligibility criteria (for example, antibody status for some medicines)
- The company believes you should try another treatment first (sometimes called "step therapy")
- They don't consider the medicine "medically necessary" based on their guidelines

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MY PRIOR AUTHORIZATION IS DENIED, HOW DO I APPEAL THE DECISION?

What to Do Next

Read the Denial Letter

Ask your doctor's office for a copy of the denial letter. This letter explains the reason and tells you the deadline to appeal.

Work with Your Doctor

Your specialist can write a **Letter of Medical Necessity** that explains:

- Your NMOSD diagnosis
- Test results (such as antibody status)
- Your history of relapses or previous treatments
- Why the prescribed medicine is the best option for you

Additional clinical notes, MRI reports, or hospital records can strengthen your case.

Submit the Appeal

- The appeal is usually submitted by your doctor or their office staff.
- Some insurance companies allow patients or caregivers to submit supporting letters as well.

Know the Timeline

- Insurance companies generally review appeals within **30 days** (for non-urgent cases) or within **72 hours** (for urgent cases).
- Ask your doctor to mark the appeal "expedited" if waiting could risk another relapse.

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MY PRIOR AUTHORIZATION IS DENIED, HOW DO I APPEAL THE DECISION?

Use Patient Support Programs

All three drug manufacturers (Amgen, Genentech, Alexion) have teams that help with appeals. They can provide sample letters, track status updates, and help with financial assistance if approval is delayed. Below is a table that lists support programs offered for all four FDA-approved treatments for NMOSD.

Medicine	Company	Program Name	Website	Phone Number
Uplizna	Amgen	Amgen By Your Side	**Amgen By Your Side**	(833) 842-8477
Enspryng	Genentech	ENSPRYNG Access Solution	**Genentech Access Solution**	(844) 677-7964
Soliris / Ultomiris	Alexion	Alexion Access Navigator / OneSource	**Alexion Access Navigator**	(888) 765-4747

MY APPEAL WAS UNSUCCESSFUL. WHAT ARE MY OTHER OPTIONS?

If your first appeal is denied, **don't panic**. There are still multiple layers of review available to you. Each step has its own requirements and timelines and knowing what to expect can help you stay on track.

Option #1: Second-Level Appeal (Internal Review)

A second-level appeal is another review within your insurance company, usually handled by a different team of doctors or specialists who are employed by your insurance company.

To start, carefully read your denial letter. It will explain your right to a second appeal and the deadline for submitting it, which is often between 30 and 60 days. **Write this deadline down and mark it clearly on your calendar so it is not missed.**

When filing this appeal, include a **new** Letter of Medical Necessity from your doctor. This should provide updated medical information, such as:

- Test results confirming your NMOSD diagnosis (for example, aquaporin-4 antibody status).
- A record of relapses or hospitalizations you've experienced.
- A list of past treatments you've tried and why they were not effective.

You may also choose to add **a personal impact statement**, describing how relapses or ongoing symptoms affect your daily life, your ability to work, or your independence.

It is helpful to ask your doctor's office to copy you on all materials sent to the insurance company so you can stay fully informed.

Timeline: Second-level appeals usually take 30–45 days. If your doctor certifies that waiting could cause serious harm, you may qualify for an "expedited" review. These are often completed in as little as 72 hours.

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MY APPEAL WAS UNSUCCESSFUL. WHAT ARE MY OTHER OPTIONS?

Option #2: External Review (Independent Review)

If your second-level appeal is denied, you may request an external review. This is conducted by an independent third party, and your insurance company does not employ the reviewer.

The importance of this step cannot be overstated: if the external reviewer decides in your favor, your insurance company is legally required to cover the treatment.

Your denial letter should include instructions for requesting an external review. In many cases, you will need to submit forms to **your state's Department of Insurance or another regulatory agency.** To search for your state's Insurance Department, refer to the **National Association of Insurance Commissioners website**. Be aware that deadlines are strict — you often have just four months from the date on your denial letter to make this request.

When submitting an external review, include:

- Updated medical documentation from your doctor.
- Copies of all denial letters and appeal submissions.
- Any additional expert opinions, such as a note from a neurologist at an NMOSD center of excellence.

Keep copies of every document you send, as missing paperwork can delay the process.

Timeline: External reviews typically take 45–60 days, though urgent cases may be reviewed in just a few days.

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MY APPEAL WAS UNSUCCESSFUL. WHAT ARE MY OTHER OPTIONS?

Option #3: State Resources

Every state has a Department of Insurance (DOI) or a similar agency that can help patients navigate appeals. These offices often provide:

Hotlines where you can speak directly to a consumer advocate.
Online complaint forms for reporting unfair insurance practices.
Guidance on how to file an external appeal.

To locate your state's DOI, search on Google for "Department of Insurance [Your State] external appeal," or visit the **National Association of Insurance Commissioner's website** and search by your state. If you need additional support identifying your DOI and point of contact, please reach out to The Sumaira Foundation to help point you in the right direction.

Option #4: Financial Assistance During the Process

Because external appeals can take weeks or even months, it is important to explore bridge or starter programs that may provide your NMOSD treatment while you are waiting. Drug manufacturers may have programs, called starter or bridge programs, that temporarily cover treatment for eligible patients until insurance approval is resolved:

In addition, independent foundations such as the **PAN Foundation**, **The Assistance Fund**, **Good Days** and the **National Organization for Rare Disorders (NORD)** sometimes offer emergency grants to help with treatment costs.

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MY APPEAL WAS UNSUCCESSFUL. WHAT ARE MY OTHER OPTIONS?

Resources to Help You Organize your Appeal Packet

Stay organized and keep a binder or digital folder with:

- Copies of all denial letters
- Copies of all prior authorizations and appeals submitted
- Letters of medical necessity from your doctor
- Personal impact statements (if you included them)
- Records of phone calls with your insurance provider (date, time, name of the person you spoke to, and a summary of your conversation)
- Copies of test results, hospital records, and treatment history

Key Takeaway

A denial does not mean the end of your journey to treatment. Each step of the appeals process is designed to give you another opportunity to demonstrate why your treatment is medically necessary. By staying persistent, keeping detailed records, and using all available support programs, you can increase your chances of success.

CONCLUSION: TAKING CHARGE OF THE INSURANCE PROCESS

Navigating insurance for NMOSD treatments can feel overwhelming, but you are not alone. With the right information, a strong partnership with your doctor, and support from advocacy organizations, you can take active steps toward accessing the treatment you need.

Remember:

- **Denials are common, but they are not the end of the road.**
- **Every layer of review is designed to give you another chance for approval.**
- **Keeping detailed records and staying persistent are the best ways to protect yourself.**
- **Financial assistance programs can provide a safety net while you work through the process.**

The Sumaira Foundation is here to guide you, answer questions and connect you with resources every step of the way.

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