Treatment Stability in NMOSD

Abbreviations

AEs, adverse events; **AQP4**, aquaporin-4; **ARR**, annualized relapse rate; **FDA**, Food and Drug Administration; **IgG**, immunoglobulin G; **IPND**, International Panel for Neuromyelitis Optica Diagnosis; **IVIG**, intravenous immunoglobulin; **NMOSD**, neuromyelitis optica spectrum disorder.

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Are your patients with NMOSD stable?

Current definitions of disease stability may miss treatment-related complications, such as hypogammaglobulinemia and recurrent infections, which may increase the risk of hospitalizations and/or trigger relapse.¹⁻⁶



There are 4 FDA-approved treatments for anti-AQP4 antibody-positive NMOSD in the US³

- However, many patients are prescribed off-label treatments, which can offer certain benefits but may also have critical limitations when used long term⁷⁻⁹
- Treatments like immunosuppressants have not all been studied in placebo-controlled trials.
 Use of off-label therapies is based largely on case studies, retrospective studies, and expert opinion⁷

Key Considerations With Off-Label B-Cell Depleting Treatment

- Off-label B-cell depleting therapy has been commonly used to treat NMOSD⁵
- In a retrospective, observational study using charts (January 2010-June 2021) from 111 patients with anti-AQP4 antibody-positive NMOSD, according to the 2015 IPND criteria, who received off-label B-cell depleting therapy^{5,a}:

Off-Label B-Cell Depletion

- 28% of patients had ≥1 relapse during treatment
- Median ARR decreased from 1.1 to 0 pre- to post-treatment
- 43% of patients developed infections
- 16% of patients experienced hypogammaglobulinemia (IgG <600 mg/dL)^b
- 41% of patients experienced at least 1 infusion reaction

Key Considerations With Other Off-Label Treatment

Corticosteroids

- Widely available and low cost⁸
- Adverse events may include infections, diabetes mellitus, weight gain, Cushing's syndrome, and osteoporosis^{3,7}

Other Immunosuppressants

- Various studies reported reduction in median ARR from pre-treatment to post-treatment^{10,11,c,d}
- Various studies showed: 37% to 61% relapse-free rate^{10-12,ce}
- Possible side effects may include malignancies; lymphoproliferative disorders; bone marrow depression with anemia; leukopenia and/or thrombocytopenia; elevation of liver enzymes; nausea; vomiting; diarrhea; sepsis; and bacterial, viral, or fungal infections^{3,7}

^aThe median duration of treatment with rituximab was 3.7 years (range: 0.5-13.2 years). ⁵
^bLaboratory values within 1 month of steroid treatment were excluded. ⁵
^cBased on a chart review and telephone follow-up study of 99 patients with NMOSD, of which 70 patients were assessed. ¹⁰
^cBased on a retrospective review of medical records of 103 anti-AQP4 antibody-positive patients with NMOSD. ¹¹
^cBased on a retrospective review of 3 centers that treated 58 patients with NMOSD. ¹²

Discuss potential signs of treatment-related complications and disease instability with your NMOSD patients³

Relapse symptoms		Notes based on discussion with patient
Has anything changed in your daily activities? Are there any activities that to perform $\!\!\!\!\!^{\mathrm{13}}$	t have become more difficult or that you are no longer able	
Have you experienced any new or worsening symptoms in any of the following areas ¹³⁻¹⁶ :		
 Vision problems, such as blurred vision, vision loss, or pain with eye movement? 	 Issues with bladder or bowel control, such as urgency, incontinence, or constipation? 	
 Weakness, numbness, or tingling in your limbs? 	· Pain or headache?	
Difficulty with walking or needing increased walking assistance?Falls or loss of balance? How often?	 Persistent nausea/uncontrollable vomiting or persistent hiccups? 	
Infections		
Have you had any recent infections, such as urinary tract infections, respiratory infections, or other infections? If so, how often and has the frequency changed (eg, more than before starting treatment)? ^{3,5}		
Have you been treated with antibiotics, antivirals, or antifungals in the past 6-12 months? If so, how often and has the frequency changed (eg, more than before starting treatment)? ^{3,5,7}		
Have you visited any urgent care facilities, emergency rooms, or specialists (eg, pulmonologists or infectious disease doctors) for symptoms like fever, cough, or pain? If so, how often and has the frequency changed (eg, more than before starting treatment)? ^{3,5}		
Hypogammaglobulinemia		
Have your laboratory tests ever shown low immunoglobulin levels or have you needed IVIG or other immune support? ¹⁻³		
Infusion reactions and other AEs		
How was your last infusion? Did you experience any problems during or after your infusion? ^{3,5,7}		
Examples include itching, headache, rash, or fever		
Did you need to adjust your schedule or take time off after your infusion? ^{3,5,7}		
Have you experienced any other side effects or adverse events since beg	inning treatment? ^{3,5}	

The questions included in this list are not exhaustive. Health care professionals should exercise their clinical judgment and discretion when engaging in discussions with patients and assessing relapses.

Consider a therapy change for patients who have experienced signs or symptoms of relapse or adverse events in the chart above^{3,17}