Rare Diseases Working Group
IgG4-RD Initiative
2025 MEETING SUMMARY

The Alliance for Patient Access hosted its annual meeting for the IgG4-RD Initiative of its Rare Diseases Working Group on August 15-16 in Washington, DC. Clinicians convened to discuss challenges in diagnosing and managing IgG4-Related Disease, or IgG4-RD. The group focused on persistent barriers and the critical need for education on rare diseases.

LACK OF AWARENESS AND ACCESS TO SPECIALISTS

An overarching issue in the rare disease community is lack of awareness. Meeting participants emphasized a lack of awareness about IgG4-RD among both clinicians and patients. This knowledge gap even extends to insurers, resulting in utilization management policies that do not reflect the complexity of the disease. Advocacy and education efforts remain critical to improving diagnosis and curbing misinformation on IgG4-RD and biologic treatment options.

Compounding the lack of awareness is the lack of available IgG4-RD specialists. According to a clinician, "It's difficult to reach clinicians who have expertise." Telehealth services could help bridge the gap, but decreased reimbursement rates and issues with interstate licensure make it difficult for patients.

DIAGNOSTIC ODYSSEY

The most emphasized area of concern for clinicians across specialties was the difficult journey, or odyssey, to diagnosis. There is currently no specific test to diagnose IgG4-RD, and some clinicians who don't specialize in IgG4-RD expressed a lack in confidence diagnosing the disease. "It is a complex disease," said one clinician. There are broad tests that look for higher levels of IgG4-RD serum levels, but elevated levels could also indicate another disease. Clinicians expressed the need to standardize testing of IgG4-RD and stressed the proper interpretation of elevated serum levels.

TREATMENT OPTIONS AND ACCESS

Clinicians discussed the lack of appropriate treatments and access to them. The only FDA-approved treatment for IgG4-RD, inebilizumab-cdon, was recently approved in April 2025. If patients cannot obtain this treatment, long-term steroid use often becomes the fallback option. However, long-term steroid use has the potential to worsen pancreatic damage in a disease that already targets that organ.

Another challenge is that tertiary care centers often require strong evidence of IgG4-RD before accepting referrals, further delaying care. One participant said, "For academic facilities, some of the wait times are just too long."

UTILIZATION MANAGEMENT

Prior Authorization

Prior authorization continues to be a burden for clinicians treating patients with IgG4-RD. Meeting participants reported frustration with prior authorization requirements for standard treatments like steroids and generics. One clinician said, “Dealing with prior authorization takes time away from patient interaction.”

Clinicians expressed concern that payer-driven prior authorization processes are not tailored to rare diseases like IgG4-RD, where diagnostic uncertainty and treatment complexity already create strain. Another clinician said, “The patients get mad at us when their prior authorization is denied. In my own practice, I have to diffuse the anger.”

Step Therapy

Step therapy protocols are an ongoing challenge for clinicians and people with IgG4-RD. Many clinicians recalled experiences where insurers mandate that patients must first be unsuccessful with an off-label therapy before they can access the only FDA-approved treatment option for the disease. This practice is a barrier to not only clinicians but also patients, whose condition worsens during the process.

MENTAL HEALTH AND RARE DISEASE BURDEN

Misdiagnosis, uncertainty and delayed treatment continue to take a toll on mental health. One clinician said, “By the time we get to diagnosis, we have multiple psychiatric manifestations.” Addressing these issues requires both timely diagnosis and integrated psychosocial support for patients and caregivers.

NEXT STEPS

Meeting participants were eager to use their voice on behalf of their patients. They offered ideas for new educational resources and expressed interest in legislative engagement.

GET INVOLVED

To learn more about AfPA’s IgG4-RD Initiative and Rare Disease Working Group, visit **AllianceForPatientAccess.Org** or contact Isabelle Logsdon **ILogsdon@allianceforpatientaccess.org**