



Rare Diseases Working Group

IgG4-RD Initiative Meeting Summary

The Alliance for Patient Access hosted its inaugural meeting of the IgG4-RD Initiative on March 30 and April 1, 2023. The IgG4-RD Initiative is part of AfPA's Rare Diseases Working Group. The in-person event convened health care providers and other stakeholders to discuss policies and access barriers that affect people living with IgG4-RD.

IgG4-RD is a rare disease that can affect multiple organ systems. Patients may not have any symptoms for months or years before they receive a diagnosis; meanwhile, patients can experience organ damage even before they develop symptoms. There are currently several treatments used off-label to manage the disease, but innovative treatments specifically for IgG4-RD patients are under development. The Rare Diseases Working Group and its IgG4-RD initiative look forward to ensuring that patients can access these new treatments when they become available.

Utilization Management

Utilization management tactics disrupt the physician-patient relationship and delay access to care, often leading to further disease progression. For IgG4-RD patients, potential new therapies may mean additional access barriers that must be addressed to ensure patients can benefit from FDA-approved treatments. Policymakers should prioritize policies that limit utilization management practices to ensure appropriate patient access.

Prior Authorization

Prior authorization often delays patient care to necessary treatment. Clinicians noted that these processes require additional staffing to meet insurer demands and take away from clinical hours to see patients. For IgG4-RD patients, time is of the essence in accessing appropriate care, making prior authorization a significant barrier.

Co-Pay Accumulators

Rare disease patients may use co-pay cards to help cover their high medication costs. These cards have traditionally helped patients afford their medication and contributed toward a patient's annual insurance deductible. Some health plans, however, may implement co-pay accumulator programs, which do not apply the card's value toward a patient's annual deductible, leaving patients with unexpected out-of-pocket costs of hundreds, or even thousands, of dollars.

Step Therapy

Rare disease patients are often subject to weeks- or months-long step therapy for newer medications. Under step therapy, patients must first try and fail insurer-preferred medications before accessing the medication their provider prescribes. The barrier hurts patients, who may face significant delays or worsening conditions. As innovative, FDA-approved therapies become available, insurer-led step therapy through older, off-label therapies may become a problem.

Non-Medical Switching

IgG4-RD patients and their providers make thoughtful choices when developing a care plan. Stable patients, however, may be surprised when they go to the pharmacy counter and discover they have been switched by their insurer to a different prescription because of cost considerations. This experience is known as non-medical switching. The practice undermines the patient-physician relationship and places care decisions in insurers' hands.



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Rare Disease Access Barriers

Diagnostic Odyssey

IgG4-RD patients, like other rare disease patients, can face a long diagnostic journey. Patients with rare diseases often visit several specialists, sometimes over the course of months or even years, and undergo multiple diagnostic procedures before receiving a diagnosis. A lack of knowledge about IgG4-RD among providers can lead to diagnosing patients incorrectly with cancer or other autoimmune conditions, while a lack of patient support can leave patients with few places to go for information.

Geographic Barriers

IgG4-RD specialists and clinicians who are knowledgeable about the disease are often located in large, metropolitan areas. This can make exams and treatment difficult for patients who have to travel frequently to see their provider. Clinicians expressed that it also puts an additional burden on patients and caregivers who do not have the financial resources to travel for care. This barrier also prolongs the time to a correct diagnosis.

Mental Health

Mental health is a primary concern among IgG4-RD patients. The IgG4-RD patient community lacks a formal support group, and many patients feel that no one understands their condition. Clinicians noted that patients often feel lonely and isolated. The long period of time to reach a diagnosis and small pool of IgG4-RD specialists also causes frustration for patients.

Telehealth

Telehealth services evolved and expanded during the pandemic. Because many IgG4-RD patients do not live near their provider, however, increased access to telehealth services is still needed to improve care.

Discriminatory Value Metrics

The Institute for Clinical and Economic Review (ICER) is a non-governmental body that makes determinations on a medication's value. ICER's narrow view of value discounts what's important to patients and their providers. ICER's use of the quality-adjusted life year, or the QALY, is also problematic, as the discriminatory metric devalues older patients and those with chronic diseases. As pharmacy benefit managers and health plans often use ICER's analysis to make medication and coverage decisions, their determinations can pose a barrier for rare disease patients who need access to innovative new treatments.

While barriers can be daunting, clinician advocacy can help. It is important to equip clinicians with the tools to advocate for their patients and stand up for access to new therapies.

Next Steps

The launch of the IgG4-RD Initiative is just the start. The working group is ready to engage with policymakers, develop ways to improve access to care and support advocacy for the IgG4-RD patient community. Further materials will be developed to discuss value, access to care, the disease itself and policies that can ensure that patients can benefit from new therapies.



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