



The rates of autoimmune diseases and conditions in the United States are rising—and women are disproportionately affected. Specifically, [80% of patients](#) diagnosed with autoimmune disorders are women, though gender ratios differ among individual diseases. Sex differences also influence symptom manifestation and severity. While the causes of many autoimmune diseases remain unknown, sex chromosomes and hormonal changes play an important role.

WHAT ARE AUTOIMMUNE AND IMMUNE-MEDIATED DISEASES?

Autoimmune diseases are a group of more than 80 chronic and often disabling diseases that develop when the immune system mistakenly attacks the body's own healthy organs, tissues, and cells. Autoimmune diseases are characterized by antigen presence, whereas immune-mediated inflammatory diseases do not have an

identified antibody. Some autoimmune and immune-mediated diseases (e.g., type 1 diabetes, rheumatoid arthritis, inflammatory bowel disease) are more common, whereas others (e.g., Kawasaki disease, Asherson's syndrome) are rare and can be difficult to diagnose.

Timely diagnosis and treatment are critical for improving health outcomes, yet are often negatively impacted by utilization management programs, such as prior authorization and step therapy, that can lead to delays in care and disease progression.

“EVERY BARRIER TO COVERAGE MEANS DELAYS, AND FOR PEOPLE WITH AUTOIMMUNE DISEASES, DELAYS MEAN POORER HEALTH OUTCOMES, GREATER DISABILITY, AND HEALTH LOSSES THAT CANNOT BE REGAINED.”

**-Molly Murray, President and CEO,
Autoimmune Association**

WHAT IS UTILIZATION MANAGEMENT?

Utilization management (UM), sometimes called utilization review, is [defined as](#) “the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities under the provisions of the applicable health benefits plan.” Types of UM include:



Prior authorization (PA) – a process used by some health insurance companies that requires the review and approval of a specific procedure, service, or drug before it is prescribed



Step therapy – or “fail first” – is a policy implemented by an insurance company that requires a patient to try and “fail” a lower-cost treatment before the treatment that a clinician originally prescribed or recommended

WHAT ROLE DO INSURANCE POLICIES PLAY IN PATIENT OUTCOMES?

Generally, autoimmune diseases cannot be cured, so treatment focuses on managing symptoms and slowing the progression and negative impacts of the disease. Finding an effective treatment quickly is key for improving not only health outcomes but also quality of life.

The National Pharmaceutical Council's (NPC) 2022 [The Myth of Average](#) report revealed that “a patient’s coverage for a prescribed medication is likely to vary substantially based on their insurer,” with variation in the consistency, volume, and types of evidence cited by major commercial payers in their coverage policies. Too often, coverage decisions are made outside of clinical and economic evidence and [without a holistic review](#) of disease burden, including consideration of the caregiver burden that disproportionately affects women’s health and quality of life.



Approximately one-third of coverage decisions made by the largest U.S. commercial health plans are more restrictive than the FDA label. ¹

UM policy decisions are often designed with a one-size-fits-most approach, overlooking patient-centered care. For patients – who experience different types and severity of symptoms, responses to treatments, and have different needs – delays in care can be devastating, resulting in disease progression and higher costs over time.

“THOUGH HEALTH PLANS MIGHT SEE SHORT-TERM DRUG COST SAVINGS WITH UM, THOSE GAINS MAY BE LOST TO LONG-TERM INCREASES IN HOSPITALIZATIONS OR TREATMENTS FOR MANAGING WORSENING CONDITIONS.”

- National Pharmaceutical Council

WHAT IS THE IMPACT OF UM ON PATIENTS AND PROVIDERS?

PA IMPACTS ON PROVIDING CARE

A 2021 American Medical Association (AMA) prior authorization physician [survey](#) found that:

- 93% of physicians report care delays while waiting for PA approval
- 91% of physicians report that PA has a somewhat or significant negative impact on clinical outcomes
- 88% of physicians describe the burden associated with PA as high or extremely high
- 82% of physicians report that PA can lead to treatment abandonment
- Physicians and their staff spend an average of 13 hours (almost two business days) completing PA requests
- Practices, complete, on average, 41 PAs per week
- 30% said that PA criteria are rarely or never evidence-based
- Two in five physicians have staff who work exclusively on PA

STEP THERAPY IMPACT ON PATIENT OUTCOMES

A 2019 [PharmacoEconomics](#) study that examined treatment outcomes of people with rheumatoid arthritis (RA) and psoriatic arthritis (PsA) – two types of immune-mediated inflammatory diseases – found that:

- Among the patients with plan-level access restrictions to a certain class of biologic and synthetic drugs, 70% of those with RA and 79% of those with PsA were in plans that required step therapy, with or without PA, versus plans that required just PA.
- There was 27% reduced medical adherence for PsA patients whose plans had step therapy requirements, and the likelihood of treatment effectiveness was 25% lower.
- RA patient plans that required step therapy had 17% lower odds of treatment effectiveness and 18% lower medication adherence.
- RA patients with restricted access plans were 3x as likely to be admitted to the hospital because of an infection and almost 2x as likely to visit the emergency room during the study period.
- More people whose plans included access restrictions filled prescriptions for glucocorticoids and nonsteroidal anti-inflammatories than those without access restrictions, potentially pointing to poorly managed disease.

[1] Chambers JD, Kim DD, Pope EF, Graff JS, Wilkinson CL, Neumann PJ. Specialty Drug Coverage Varies Across Commercial Health Plans In The US. Health Aff (Millwood). 2018 Jul;37(7):1041-1047. doi: 10.1377/hlthaff.2017.1553. PMID: 29985695.