

# RHEUMATIC DISEASES IN AMERICA:

CONFRONTING THE CHALLENGE



AMERICAN COLLEGE  
of RHEUMATOLOGY  
*Empowering Rheumatology Professionals*



# Rheumatic Disease in America: Confronting the Challenge

*This paper aims to educate patients, families, policymakers, and the public about rheumatic diseases, their impact on society and the health care workers who treat individuals living with these diseases.*

## I. Rheumatology 101

### WHAT IS A RHEUMATIC DISEASE?

Rheumatic diseases are autoimmune, inflammatory, and degenerative diseases that affect a person's joints, muscles, bones, and organs. There are more than 100 rheumatic diseases and conditions, including more commonly known diseases like osteoarthritis, rheumatoid arthritis, lupus, and gout.

Rheumatic diseases are not just “aches and pains,” nor are they a normal part of aging. They affect individuals of all ages – including children – and often strike adults in the prime of their lives. Rheumatic diseases can be debilitating and, if not properly treated, life-threatening.

Rheumatic diseases can result from one's own internal defense system, the immune system, producing antibodies and attacking one's healthy tissue of joints, muscles, bones, and organs, causing pain and inflammation that can lead to disability and even death.

## TYPES OF RHEUMATIC DISEASES

There are dozens of autoimmune rheumatic diseases. Some of the most common include:

- > **rheumatoid arthritis (RA)**
- > **lupus**
- > **gout**
- > **scleroderma**
- > **juvenile idiopathic arthritis**
- > **psoriatic arthritis**
- > **ankylosing spondylitis**
- > **Sjögren's syndrome**
- > **polymyalgia rheumatica**
- > **systemic vasculitis  
(including giant cell arteritis)**

# HOW RHEUMATIC DISEASES AFFECT THE BODY

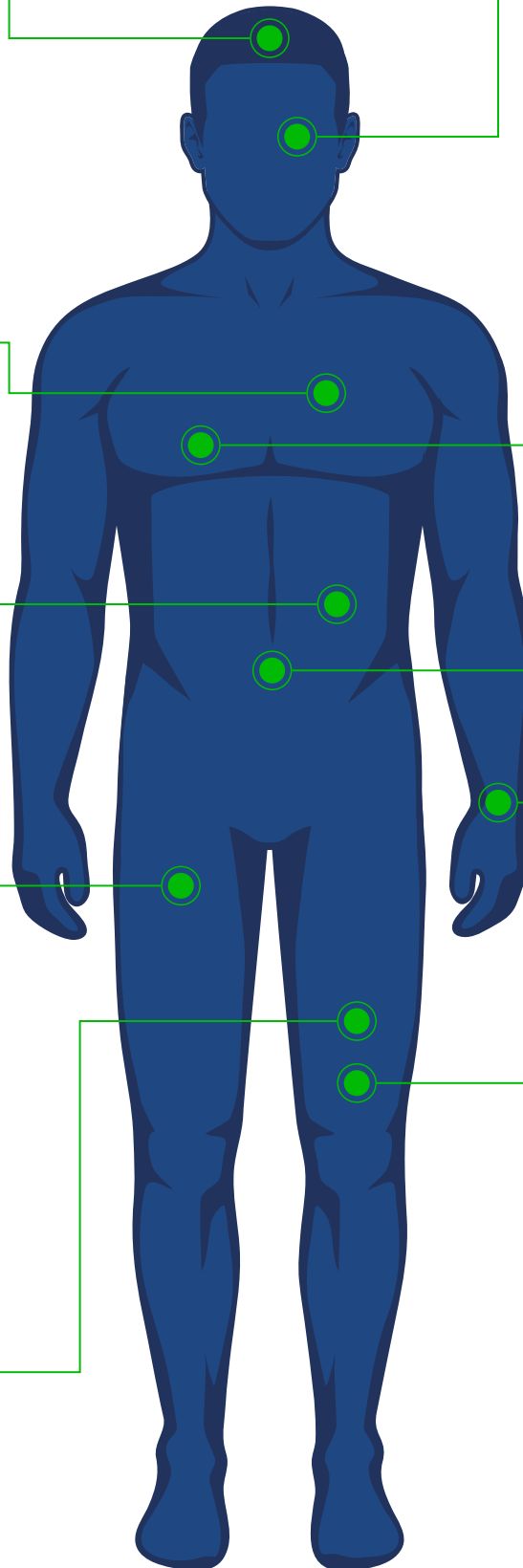
**NERVOUS SYSTEM:** Many rheumatic diseases can cause neuropathy or damage to nerve fibers by a variety of mechanisms. Strokes are also more frequent in patients suffering from several rheumatic diseases including lupus, rheumatoid arthritis, and giant cell arteritis.<sup>1</sup>

**HEART:** Chronic inflammation associated with many rheumatic diseases can lead to increased risk of cardiovascular disease. People with rheumatoid arthritis have a significantly higher heart attack risk after diagnosis.<sup>2</sup> Additionally, having lupus greatly increases a person's risk of developing cardiovascular disease and suffering from a heart attack.<sup>3</sup>

**KIDNEYS:** People with rheumatoid arthritis are at a significantly higher risk of developing chronic kidney disease than the general population and have a one in four chance of developing kidney disease compared with a one in five chance for people who don't have the disease.<sup>4</sup>

**MUSCLES AND TENDONS:** Muscle atrophy, weakness, and stiffness are frequent symptoms of most rheumatic diseases.

**BLOOD:** Anemia occurs in many rheumatic diseases including lupus, rheumatoid arthritis and vasculitis.



**EYES:** The eyes are dry, irritated and inflamed with Sjögren's syndrome. More severe eye complications can be found in juvenile idiopathic arthritis and giant cell arteritis – both of which can lead to decreased or complete loss of vision.

**LUNGS:** One in 10 people with rheumatoid arthritis will develop serious lung complications over the course of their disease due to damage to the lung tissue.<sup>5</sup> People with scleroderma have an even higher risk for lung disease and can develop pulmonary fibrosis, a scarring of the lungs, which can lead to life-threatening breathing complications.<sup>6</sup>

**GASTROINTESTINAL TRACT:** Chronic bowel inflammation can be a sign of a whole body illness. Diseases such as Crohn's Disease and ulcerative colitis are associated with joint, eye, and skin inflammation.

**JOINTS:** Rheumatoid arthritis, osteoarthritis, juvenile idiopathic arthritis, and many other types of rheumatic diseases predominantly affect a person's joints.

**SKIN:** Psoriatic arthritis is a rheumatic disease that occurs in some patients who have psoriasis, which is a chronic skin condition. Many other rheumatic diseases may cause serious damage to the skin, including lupus and scleroderma.



## THE ROLE OF THE RHEUMATOLOGIST & RHEUMATOLOGY INTERPROFESSIONAL TEAM

Rheumatologists are doctors specially trained to diagnose, manage and treat arthritis and rheumatic diseases. These specialists have a deep understanding of the physical, mental, economic, and societal impacts of rheumatic diseases and are skilled at recognizing and treating the wide array of rheumatic disease symptoms that can affect almost any organ in the body. Just as an oncologist treats cancer and cardiologists care for the heart, rheumatologists are trained to facilitate appropriate treatment for rheumatic disease with the goal of dramatically improving a patient's prognosis and quality of life.

Effective management of rheumatic disease requires more than just the expertise of a single specialist – it is a collaborative effort between the patient and a diverse group of health professionals including advanced practice clinicians (nurse practitioners, physician assistants, advanced practice registered nurses), primary care physicians, physical and occupational therapists, pharmacists, psychologists, and social workers. The job of this multidisciplinary team is to assess and manage the patient's symptoms and the effects on physical, psychological, and social functioning, as well as to support patient care by addressing health and practical concerns in the home and workplace.

# THE IMPORTANCE OF PROPER TREATMENT

Early intervention and appropriate treatment of a rheumatic disease enhances a person’s ability to work and carry out daily responsibilities. It also reduces many of the downstream costs and health impact of dealing with disability, surgeries, and organ damage. Rheumatologists and rheumatology health professionals also have the ability and experience to prescribe vital biologic medications, many of which have only become available in the last few decades. While these treatments can be highly effective, they also come with potentially dangerous side effects and should be prescribed by a rheumatology health professional. Due to their advanced and specialized education and training – as well as their dedication to understanding and utilizing the latest advancements in treatment – rheumatology health professionals are the best equipped specialists to prescribe the appropriate medications for each particular rheumatic disease and to monitor for and respond to potential side effects.

Rheumatology health professionals also understand that treatment priorities begin with the patient, resulting in a treatment plan that will best control the disease and its symptoms, and improve functioning.

## THE WINDOW OF OPPORTUNITY

The first few months after the onset of rheumatic disease symptoms, known within the rheumatology community as the “window of opportunity,” is a crucial time period for patients to get treatment in order to diminish the long-term complications of their rheumatic disease. Research shows that early and aggressive treatment, especially within the first 12 weeks of disease onset, can prevent damage to joints and other organs, improve long-term function and increase the likelihood of achieving disease remission.<sup>7</sup> Medical costs, disability, and work limitations due to rheumatic diseases can all be reduced with early treatment.



# II. Rheumatic Diseases: Prevalence & Impact

Rheumatic diseases are common. According to the Centers for Disease Control and Prevention (CDC) an estimated 54 million U.S. adults – or 1 in 4 – have a doctor-diagnosed rheumatic disease.<sup>8</sup> A recent study suggests the number of Americans living with rheumatic diseases could be as high as 91 million – or 1 in 3 Americans – when accounting for symptoms reported by undiagnosed individuals.<sup>9</sup> Furthermore, there are an estimated 300,000 children in the U.S. with juvenile arthritis who require specialized care from a pediatric rheumatologist.<sup>10</sup>

Rheumatic diseases are the leading cause of disability in the United States<sup>11</sup> and are a more frequent cause of activity limitation than heart disease, cancer, or diabetes.<sup>12</sup>

**\$304  
BILLION**

Total cost of  
rheumatic  
disease in the  
United States

## ECONOMIC TOLL

The economic toll of rheumatic disease is also significant. According to the latest federal estimates, rheumatic diseases generate \$140 billion in medical costs each year, along with an additional estimated \$164 billion in lost wages and productivity when degenerative conditions like osteoarthritis are included.<sup>13</sup> This combined figure of \$304 billion is greater than the cost of cancer in the United States.<sup>14</sup> One study found that nearly one-third of people with rheumatoid arthritis stopped working within five years of their diagnosis.<sup>15</sup> Many others living with rheumatic disease have had to not only alter their working hours, but also change their job or pursue a different career altogether.

## HEALTH DISPARITIES

Rheumatic disease does not affect all Americans equally. Approximately 1 in 12 women will develop an autoimmune or inflammatory rheumatic disease in their lifetime compared to 1 in 20 men.<sup>16</sup> Women are also 2 to 3 times more likely to be diagnosed with rheumatoid arthritis<sup>17</sup> and 9 out of 10 people who have lupus are women.<sup>18</sup>

Black, Latino and Indigenous Americans have a significantly higher prevalence of arthritis-attributable activity limitations than non-

Hispanic whites despite all groups having a similar overall prevalence of arthritis.<sup>19</sup>

Veterans also have a significantly higher prevalence of rheumatic disease, particularly arthritis – likely the result of joint damage sustained during military training and deployment. Data show 1 in 3 veterans are diagnosed with arthritis, compared to 1 in 5 members of the general population.<sup>20</sup> Arthritis is also the second leading cause of discharge from the U.S. Army.<sup>21</sup>

# III. Emerging Trends in Rheumatology

Rheumatology is a constantly changing field of medicine. This section will discuss emerging trends in the treatment of rheumatic diseases and what this means for patients, their families, and the public.

## BIOSIMILAR MEDICATIONS

In recent years, a new type of treatment has emerged for patients who use biologics: biosimilars. Biosimilars are copies of biologic drugs that are intended to work in the same way as their reference biologic. In order to be approved by the FDA, a biosimilar product must demonstrate no clinically meaningful differences from its reference biologic in terms of safety and effectiveness.<sup>22</sup>

It is important to note that biosimilars are not the same thing as generic drugs. All generic drugs contain all the same active ingredients, are chemically the same and can be expected to work the *exact same way* as the original medication.

By contrast, biosimilars are not exact copies of their reference products. This is because, while biosimilars are made from the same starting materials and according to a similar manufacturing process as their reference product, they are ultimately living cells and can be expected to have slight variations from batch to batch. These slight differences could cause the drug to interact with the body's immune system in a different way from the original biologic.<sup>23,24</sup> That's why it is very important that biosimilars go through rigorous clinical trials to prove they are safe and effective.

## BIOSIMILARS & RHEUMATOLOGY

Several biosimilar drugs have already been approved in the United States to treat rheumatic diseases and more are expected to enter the market over the next few years. These drugs treat disease including rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis.

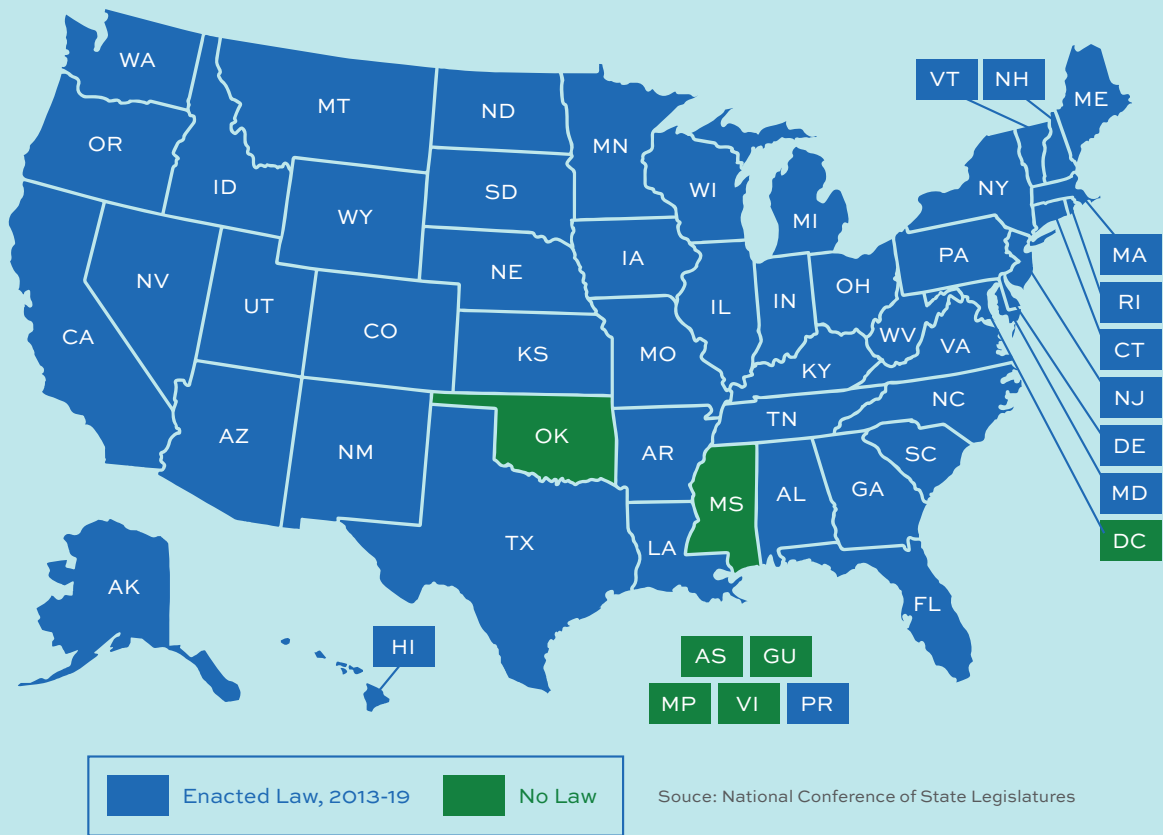
Currently, a patient must be prescribed a biosimilar by name in order to receive one. However, the FDA could decide – after it feels there is enough clinical evidence the biosimilar will work exactly like the original biologic in any given patient – that some biosimilars are interchangeable with their reference products. This means pharmacists will be able to substitute a biologic with a biosimilar without the

patient having to obtain a different prescription. As of May 2021, the FDA has not issued any guidance on biosimilar interchangeability.<sup>25</sup>

As more biosimilar drugs come to market, patient and provider education will continue to be crucial. Research shows that while rheumatologists generally had a good understanding and acceptance of biosimilar products, more patient education about biosimilars is needed.<sup>26</sup> A recent survey found that 29 percent of rheumatic disease patients were unsure whether they had been prescribed a biosimilar drug.<sup>27</sup>



## STATES THAT HAVE ENACTED BIOSIMILAR NOTIFICATION LAWS



## ONGOING POLICY ISSUES REGARDING BIOSIMILARS

One potential benefit of biosimilars is that they will introduce more competition into the prescription drug marketplace which could lead to lower prices. One estimate put the potential cost savings of biosimilars to be \$54 billion over ten-year period starting from 2017, however that analysis noted that actual savings will depend heavily on the evolving regulatory and competitive landscape.<sup>28</sup>

Another important issue concerning the use of biosimilars is whether pharmacists will be required to notify patients and providers if a biosimilar is substituted for a biologic after the FDA determines the two are interchangeable. Many states have considered and enacted legislation in recent years to require that patients be notified when such

substitution occurs. According to the National Conference of State Legislatures, 45 states have passed biosimilar notification laws between 2013-2019, although the laws differ significantly in the degree to which they require patient notification.<sup>29</sup>

The American College of Rheumatology strongly believes that patients and providers should be notified immediately when a substitution is made and that providers should be able to write “dispense as written” on all prescriptions (including biologics) to prevent substitution. This will ensure decision concerning which type of drug is right for an individual patient remains between the patient and their rheumatology provider.<sup>30</sup>



## TELEHEALTH & RHEUMATOLOGY

Another emerging trend in the practice of rheumatology is the increasing use of telehealth. The “tele-rheumatology” trend has been further catalyzed by the COVID-19 pandemic, where – for a time – telehealth services were the only safe option for patients in need of care.

According to a 2020 survey of rheumatic disease patients, 66 percent reported that they had a rheumatology appointment via telehealth within the past year. More than half of respondents cited the fact that patients were not being seen in the office due to COVID-19 as their primary reason for using telehealth services.

Another catalyzer of the recent uptake in telehealth usage is due to changes made by insurers and the Centers for Medicare and Medicaid Services (CMS) to allow for more flexibility for providers to offer telehealth services during the public health emergency. While many of these changes were originally meant to be temporary, there are ongoing discussions among policymakers to make some of them permanent.

**66%** of rheumatic disease patients had an appointment via telehealth in 2020

But there are many other benefits to telehealth in addition to keeping people safe during the pandemic. For example, telehealth can make rheumatology care more accessible for people with disabilities or for those who are in a nursing home. For patients living in rural areas, telehealth is a valuable option for those who would otherwise have to travel long distances to see a rheumatology health professional. Children with rheumatic diseases in particular could benefit from increased access to telehealth in that they may no longer have to miss school or extra-curricular activities to attend a rheumatology appointment.

**Policies and guidelines concerning telehealth and rheumatology are constantly changing. For the latest, please visit the American College of Rheumatology’s resource center at:**

**[www.rheumatology.org/announcements/COVID-19-Practice-and-Advocacy](http://www.rheumatology.org/announcements/COVID-19-Practice-and-Advocacy)**

# IV. Access, Affordability, & Lifestyle Challenges For People Living with Rheumatic Diseases

## ACCESS TO TREATMENT

A growing shortage of rheumatology health professionals in many parts of the country – particularly in rural areas – combined with insurance barriers and rising drug costs make it difficult for the millions of individuals living with rheumatic diseases to receive timely care and quality treatments.

Even though as many as one-quarter to one-third of the U.S. population may be living with a rheumatic disease, there is an average of only one practicing rheumatologist for every 40,000 people. Research shows that demand for rheumatic disease care far outpaces supply. High rates of retirement within the specialty and a rapidly aging population mean that the U.S. will need thousands more adult

rheumatologists by 2030 to meet growing patient demand.<sup>31</sup>

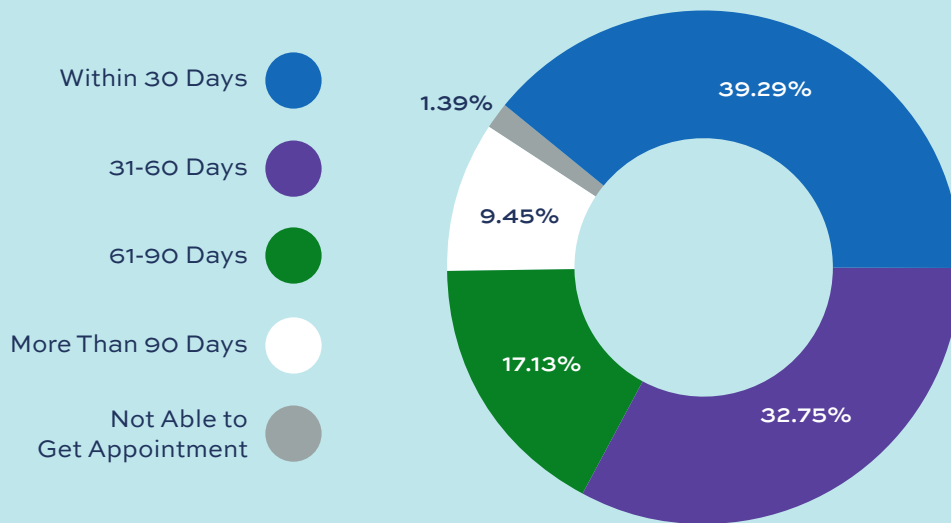
The shortage of pediatric rheumatologists is even more acute. It is estimated that there are only 300 pediatric rheumatologists currently practicing in the United States. By 2030, demand is projected to be twice the current supply.<sup>32</sup>

The rheumatology workforce shortage means that patients have to wait longer before they can access care. A recent survey of rheumatic disease patients found that 60 percent of respondents who indicated that they had been referred to seek treatment from a rheumatologist had to wait more than 30 days after referral to get an appointment – if they could get one at all.<sup>33</sup>

### U.S. RHEUMATOLOGIST SHORTAGE PROJECTED TO WORSEN OVER THE NEXT SEVERAL DECADES



## DAYS BETWEEN REFERRAL AND INITIAL RHEUMATOLOGY APPOINTMENT



Source: American College of Rheumatology, 2020 National Patient Survey

Individuals living with rheumatic disease also face barriers to accessing care from their own insurance companies. Utilization management practices such as step therapy and prior authorization make it more difficult for patients to access treatment and place additional burdens on the providers prescribing critical treatments.

### STEP THERAPY

Step therapy, sometimes known as “fail first,” occurs when an insurer requires a patient to first try therapies preferred by the insurance company before it agrees to cover the treatment prescribed by the patient’s doctor – even when doctors are uncertain as to whether the insurer-preferred option will be effective. According to a recent survey, 47 percent of patients receiving treatment for a rheumatic disease were subject to step therapy requirements.<sup>34</sup> Another survey found that more than half of patients who went through step therapy reported having to try two or more different drugs prior to getting the one their doctor had originally ordered.<sup>35</sup>

This can be damaging to a patient’s health. That same survey found that step therapy had to be stopped in 39 percent of cases because the drugs were ineffective and in 20 percent of cases due to worsening conditions.<sup>36</sup>

### PRIOR AUTHORIZATION

Prior authorization is an insurer tactic that requires prescribers to obtain approval from the patient’s insurance plan before the prescribed treatment can start. This time- and resource-intensive process often leads to care delays – sometimes for weeks or months. In a recent survey, 92 percent of physicians reported that prior authorization caused delays in their patients’ care, and 78 percent reported that prior authorizations sometimes led to treatment abandonment.<sup>37</sup>

Research has shown that when treatment is delayed or the patient does not return for the prescription, it can have negative consequences for the patient’s health even if authorization is ultimately granted.<sup>38</sup>

# AFFORDABILITY

Treatment affordability is another concern for people living with rheumatic disease. Many patients rely on powerful and expensive medications to manage their disease symptoms. High prescription drug prices combined with restrictive insurer practices means many patients are required to pay out of pocket for a significant portion of their specialty drug costs.

Research conducted by the American College of Rheumatology found that median annual out-of-pocket spending for patients receiving treatment for a rheumatic disease amounted to \$1,000 in 2020 – a two-fold increase from when the ACR surveyed out-of-pocket drug costs in 2019.<sup>39</sup>

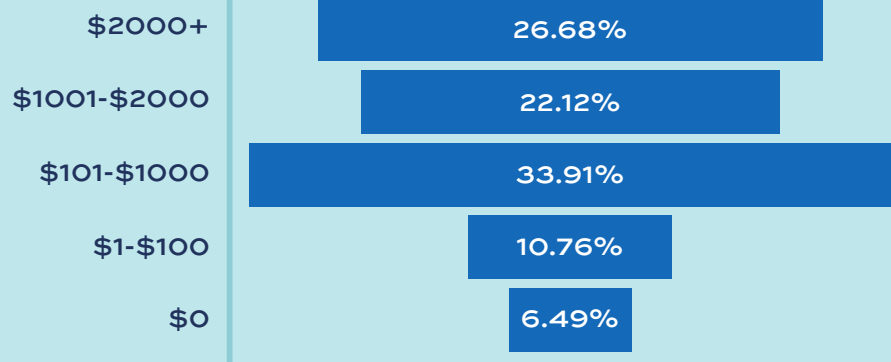
Secretive pricing practices on the part of pharmacy benefit managers (PBMs) also make it difficult for patients to afford the treatments they need. PBMs act as intermediaries between insurers, drug manufacturers, and pharmacies. Though PBMs claim to use their position to negotiate lower drug prices, they often pocket excess rebates and fees while failing to pass along the savings they negotiate to patients. An analysis of data from 19 PBMs operating in

Texas found that between 2016 and 2019, PBMs collected more than \$350 million in revenue, while passing only \$16 million in savings to plan enrollees.<sup>40</sup>

The fact that PBM's pocket a significant portion of the rebates they negotiate can also cause drug prices to rise. This is because the profit incentive motivates PBMs to demand higher rebates from manufacturers in exchange for preferred status in PBM formularies. To pay these higher rebates, drug manufactures may in turn raise their list prices.<sup>41</sup>

Several states have begun to enact legislation to hold PBMs accountable and make their pricing practices more transparent by ensuring they are subjected to fair licensing and auditing processes, requiring disclosures of discounts and rebates, and disallowing claw-back provisions from being inserted into PBM-insurer contracts. In 2018, the federal government also stepped in to ban so-called “gag clauses” that prevented pharmacists from informing patients about lower cost alternatives for affording their medications, such as when the cash price for the drug is lower than the copay with insurance.

## ANNUAL OUT-OF-POCKET TREATMENT COSTS FOR RHEUMATIC DISEASE PATIENTS



Source: American College of Rheumatology, 2020 National Patient Survey.

# ACTIVITY & LIFESTYLE CHALLENGES

Having a rheumatic disease can cause significant physical, mental and emotional strain. Even seemingly simple tasks – like cooking, getting dressed, or driving an automobile – can be difficult for those with a rheumatic disease. More than 80 percent of individuals living with a rheumatic disease reported at least one activity limitation as a result of their disease the most common of which were the ability to exercise and work.<sup>42</sup>

Keeping up with the responsibilities of daily life – from childcare to work demands to community involvement – can also be challenging when you live with one of these conditions.

Rheumatic diseases also often take a mental and emotional toll on the people who live with them and can affect a person's family, intimate, social, and business relationships. Anxiety and depression are some of the most common

co-existing conditions of rheumatic diseases, resulting from the stress of living with a chronic disease and chronic pain. Some medical studies suggest 15 percent of those with a chronic illness, such as a rheumatic disease, suffer from clinical depression; others place this figure as high as 60 percent.<sup>43</sup> In addition to depression, anxiety, and intimacy issues, rheumatic diseases can cause cognitive difficulties. These cognitive issues can affect a person's self-esteem, ability to communicate, and ability to function in work, social, and family environments.

Rheumatic diseases can be debilitating – but they don't have to be. Educating patients about the health care issues affecting rheumatologic care and providing tools that make it easy for patients to become advocates for their care can help ensure that people who are affected by rheumatic diseases receive timely and affordable care and treatments.

## About the American College of Rheumatology

*The American College of Rheumatology (ACR) is the nation's leading advocacy organization for the rheumatology care community, representing more than 7,700 U.S. rheumatologists and rheumatology health professionals who are committed to improving health care for Americans living with rheumatic diseases.*

# Additional Resources

## For Healthcare Professionals & Students:

- ▶ The American College of Rheumatology website ([www.rheumatology.org](http://www.rheumatology.org))
  - ▶ ACR Professional Learning Center
  - ▶ Clinical Treatment Guidelines
  - ▶ Position Statements
- ▶ The ACR's Lupus Initiative ([www.thelupusinitiative.org](http://www.thelupusinitiative.org))
- ▶ The ACR Legislative Action Center ([www.rheumatology.org/Advocacy/Legislative-Action-Center](http://www.rheumatology.org/Advocacy/Legislative-Action-Center))

## For Patients:

- ▶ Simple Tasks ([www.simpletasks.org](http://www.simpletasks.org))
- ▶ The Lupus Initiative ([www.thelupusinitiative.org](http://www.thelupusinitiative.org))
- ▶ ACR patient resources ([www.rheumatology.org/I-Am-A/Patient-Caregiver](http://www.rheumatology.org/I-Am-A/Patient-Caregiver))
  - ▶ ACR's Disease & Conditions and Treatments Databases
  - ▶ Patient Educational Resources & Videos

## For Advocates & Policymakers:

- ▶ Rheumatic Disease Report Card ([www.simpletasks.org/reportcard](http://www.simpletasks.org/reportcard))
- ▶ 2019 National Patient Survey ([www.simpletasks.org/survey](http://www.simpletasks.org/survey))
- ▶ 2020 National Patient Survey ([www.simpletask.org/2020-survey](http://www.simpletask.org/2020-survey))

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