

Optimizing the Management of Fibromyalgia

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We are pleased to introduce you to this supplemental publication of *The American Journal of Managed Care* on optimizing the treatment of fibromyalgia. The goal of this supplement is to educate and inform managed care practitioners and decision makers on the burden and impact of fibromyalgia. We will also discuss current evidence and strategies to improve clinical and economic outcomes associated with fibromyalgia treatment.

Fibromyalgia is a common and expensive pain syndrome. This disorder affects an estimated 10 million people in the United States and approximately 3% to 6% of the world's population.¹ It is a chronic, persistent disorder and results in significant negative impact on patient health-related quality of life.^{2,4} The diagnostic criteria for fibromyalgia have been defined by the 1990 American College of Rheumatology operational criteria as widespread pain above and below the waist for at least 6 months including the axial spine, characterized by the presence of at least 11 or more out of 18 well-defined tender points.⁵ Fibromyalgia is actually more common than rheumatoid arthritis with an estimated prevalence of 2% to 3%.^{6,7} The prevalence in women ranges from 3.4% to 10.5%, as compared with only 0.5% in men.⁶ Fibromyalgia is also costly,⁸ as shown in the first article in this supplement evaluating healthcare utilization and costs between subjects with newly diagnosed and without fibromyalgia using an administrative claims database from a large US health plan.

Patients with fibromyalgia are often underdiagnosed and undertreated. It takes an average of 5 years for a patient to be diagnosed with fibromyalgia.⁹ By the time of the diagnosis, the average fibromyalgia patient is incurring 25 visits and utilizing 11 prescriptions per year, compared with 12 visits and 4.5 prescriptions per year in controls as reported in a study in the United Kingdom.¹⁰ It is, therefore, important to look at the impact of a fibromyalgia diagnosis on healthcare resource use in the United States to inform decision makers. In the second article, patterns of healthcare utilization and costs prior to and following an initial diagnosis of fibromyalgia are characterized using a database capturing claims across numerous US health plans.

While various medications are used to manage painful symptoms associated with fibromyalgia, there are currently only 3 medications approved by the US Food and Drug Administration (FDA) for the management of fibromyalgia: pregabalin approved in 2007, duloxetine approved in 2008, and milnacipran approved in 2009.¹¹⁻¹³ Contributing to the complexity of managing fibromyalgia is the use of short-acting opioids, which have been shown to be among the most commonly used pain-related medications in fibromyalgia. In an analysis of fibromyalgia patients aged 18 years and older initiating pregabalin, 62% had used a short-acting opioid and 16% had used a long-acting opioid in the prior 6 months.¹⁴ Despite recommendations against the use of strong opioids,¹⁵ these agents continue to be widely used in clinical practice. Thus, the availability of FDA-approved nonopioid alternatives such as pregabalin is important for addressing challenges in managing fibromyalgia. Our third article discusses the efficacy and safety/tolerability of pregabalin in the management of fibromyalgia, reviewing data from 2 pivotal phase 3 trials.

Another concern is the difference in management and treatment between older and younger patients. We know that the prevalence of fibromyalgia increases with age,⁶ with the highest prevalence in those aged 60 to 79 years. Our fourth article studies older patients with fibromyalgia who have been prescribed pregabalin and characterizes their comorbidities, burden, pain-related medication use, and healthcare resource use using a large US claims database.

Despite the availability of 3 FDA-approved medicines, some formularies have restricted access to these medications, preferring a trial of tricyclic antidepressants, muscle relaxants, or generic medications. Such restrictions may, in fact, be counterproductive. A Medicaid study demonstrated that the probability of opioid use was 6.5% higher and total healthcare costs of diabetic peripheral neuropathy/postherpetic neuralgia were \$418 higher in states with restrictions on pregabalin versus formularies without those restrictions.¹⁶ Our fifth article discusses a hypothetical model comparing costs to US health plans of fibromyalgia under scenarios of prior authorization versus no prior authorization using national market share data for pregabalin and alternative treatments, published drug costs, cost of prior authorization adjudication

and patient copayments. These data show that prior authorization may not be cost-effective.

We hope that you take the time to read this supplement. We also hope that you find the information contained within both informative and helpful. Our goal is to provide you with the most up-to-date research, treatment options, and recommendations for management of fibromyalgia.

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