

Breath of Fresh Care Improving Asthma Patients' Access to Innovative Treatments



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Asthma and inhalers are closely intertwined in the minds of most Americans, even those without any personal connection to the widespread respiratory condition. Far fewer are aware of powerful new options that can significantly improve a patient's relationship with their asthma.

With the help of diagnostic tools and treatment options, including biologics, health care professionals can in fact begin to personalize asthma care to each individual patient. Low awareness among patients and health care professionals, however, limits the benefit these approaches can provide patients. When patients are prescribed tests and innovative treatments, they often can't access them. Health plan barriers like prior authorization, step therapy and non-medical switching prevent patients from receiving the best treatment and achieving optimal health.

More and better treatment options are within asthma patients' reach. Clearing away barriers to cutting-edge care will allow millions of Americans suffering from the disease to finally breathe easier.



The Progress of Asthma Diagnosis and Treatments

Asthma can threaten patients with everything from school absences to death. Because the condition attacks a vital biological function – breathing – patients must be diagnosed and treated sooner rather than later. The disease has no cure, so ideal treatment plans tend to have two elements:

1. Quick-relief medications taken during asthma flares
2. Longer-term medications to prevent flares and manage symptoms over time

Without treatment, asthma patients suffer frequent episodes of shortness of breath, coughing and wheezing, and even permanent lung damage. During flares, a patient’s airways constrict and can make breathing difficult and painful.¹

Some patients are triggered by allergies; others suffer on a more regular basis.² Children are more vulnerable to asthma than adults. In fact, asthma is the most common chronic

disease among kids.³ And African Americans are disproportionately represented among the 4,000 U.S. asthma deaths every year.⁴

Pulmonary medicine has come a long way from the medicated “asthma cigarettes” and ignitable “asthma powders” of the 19th century. Rescue inhalers, first introduced in the 1950s, have been the most common quick-relief treatment for decades.⁵

But improving patient outcomes also requires ongoing education.

Asthma patients today have options beyond an inhaler, especially when it comes to proactively managing their condition over the long term.

There are new medications and new tools, and existing tests can offer great insight when covered by health plans. Patients with severe asthma in particular can benefit immensely from these innovations – but only if they know about them.

Innovations in Asthma Treatment

The most game-changing development in the fight against asthma this century has been biologics, medications derived from natural, living molecules.⁶ The first anti-asthma biologic, omalizumab, was approved by the Food and Drug Administration in 2003. And as the science has advanced, so have patients' options. Five more biologics have come to clinic since then.⁷ These treatments have radically changed how patients can manage their asthma.

Each biologic fights asthma in a different way, offering patients a variety of options based on their individual needs and biochemistry. Different medications are best suited to different patients.

Biologics are controlling asthma symptoms and improving asthma patients' quality of life. Innovation has developed biologics to target different types of asthma. As a result, complete control could very easily transition from the goal to the standard.



Diagnostics & Specialty Care

The level of care that biologics offer asthma patients largely relies on diagnostic tests. For the first time, biomarker testing can begin to reveal the genetic cause of a patient's asthma. Health care professionals can better select the biologic that specifically targets the specific type of asthma. The information provided by diagnostic tests can help clinicians and patients identify what treatment path will lead to optimal health outcomes.

Asthma control, in many cases, depends on access to these diagnostic tests.

Yet biomarker testing for asthma patients isn't currently the standard of care. While tests continue to be developed, many health care professionals and patients don't have access to them.⁸

There are several reasons patients may not be tested and start treatment with a biologic.

Factors such as age, socioeconomic standing and type of insurance can all influence a patient's likelihood of accessing the right testing and treatment to best manage their condition.⁹



Treatment Access Challenges

Barriers to advanced asthma care can have a harmful impact on patients' disease management and health outcomes.

Pharmacy Benefit Managers

Pharmacy benefit managers, for example, can pose a serious problem for asthma patients. These organizations determine a health plan's formulary and potential utilization management requirements, impacting what treatments receive coverage.

In many cases, unfortunately, decisions on what to include in a formulary list aren't made based on patient savings. These decisions are based on what drugs will financially benefit the pharmacy benefit manager and health plan. New and innovative asthma treatments may be excluded from formulary lists by pharmacy benefit managers because they are deemed too expensive.

And in instances where these treatments are included on a formulary, patients may have to bear a heavy financial burden or face significant utilization management.

Utilization Management

Bureaucratic health plan obstructions can also get in the way of treatment access. A common example of these obstructions is utilization management.

One tactic is prior authorization, which requires clinicians to request and receive approval from insurance companies before they can prescribe certain medications. Patients must wait for their treatment to be approved. Delays can be lengthy, especially if a treatment is denied. All the while, asthma patients must go without treatment and risk severe health episodes.

Excessive request for medical records is the newest coverage diversion that stems from prior authorization. Some requests for records are reasonable, but in many instances treatment is delayed while insurance companies ask for medical records that have little to do with the reason the medication was prescribed.

Another delay tactic is called step therapy. This occurs when insurance companies refuse to cover more expensive or newer treatments until patients try one or more medications that the health plan prefers.

Non-medical switching, another common access barrier, forces stable patients to change medications simply because their insurance company decides to alter coverage. These decisions leave patients to face recurring symptoms and new side effects. Some lose the ability to manage their disease.

Cost Sharing

Other barriers to access impact patients at the pharmacy counter. Copay assistance diversion programs, like copay accumulators or copay maximizers, are tactics often used by insurers to prevent patient assistance resources from counting toward a patient's annual out-of-pocket deductible. When patients exhaust the copay assistance, they are often left with large out-of-pocket expenses to continue accessing their treatments.

In recent years, a new threat to patient assistance programs has emerged. Alternative funding programs are third-party vendors who work with employers



A Win for Asthma Advocates

A scenario from 2022 demonstrates how advocates can work to overcome barriers and secure access to treatments.

In late 2021, an asthma biologic called tezepelumab was approved for clinician administration. A few months later, several Medicare Administrative Contractors placed tezepelumab on a list of drugs that are self-administered by patients. The packaging for the medication didn't include instructions for patients or any information on storage, creating a serious safety risk.

Advocates urged Medicare Administrative Contractors to reverse the decision, and they were successful. Their effort eliminated a barrier for asthma patients before it could do harm.

Treatment challenges abound. But they are surmountable.

to remove certain specialty medications from coverage and instead divert patients to patient assistance programs. By giving insured patients funds that were intended for uninsured or underinsured patients, alternative funding programs risk draining critical resources for patients who need them most.

Value Considerations

Pharmacy benefit managers, insurers and even government health programs increasingly lean on algorithms developed by outside

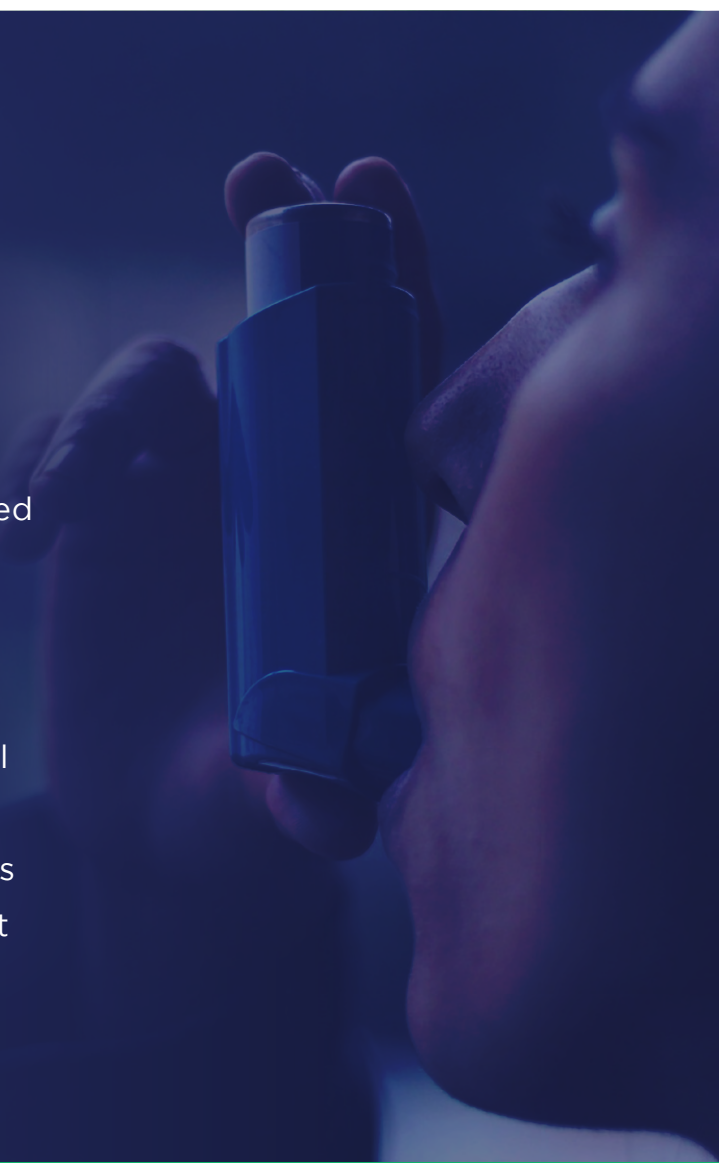
organizations like the Institute for Clinical and Economic Review to make coverage decisions. The organization includes health economists who try to determine medications' value based on patient population data.

These metrics typically result in a one-size-fits all approach, rather than recognize the unique needs of individual patients. Metrics like the quality-adjusted life year ultimately assign a price for medications that can sometimes lead to denying a patient the right care.

Conclusion

Thanks to the emergence of biologics and biomarker-identifying diagnostics, optimal health outcomes for asthma patients are within reach. But patients' access to these effective treatments and tools is still blocked by obstacles within the health care system.

Patients, health care professionals, payers and lawmakers should all work to improve policy and educate stakeholders, so that all asthma patients — not just those with the most money or best coverage — can access the personalized diagnostics and treatment options now available.



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