



April 24, 2023

North Carolina General Assembly
Legislative Building
16 West Jones Street
Raleigh, NC 27601

Dear Honorable Members of the North Carolina House of Representatives,

On behalf of the nearly 1100 people with cystic fibrosis (CF) in North Carolina, we are writing to express our support for HB 649, which makes several important reforms to the prior authorization (PA) process. PAs can delay access to critical CF therapies and the Cystic Fibrosis Foundation supports efforts to minimize the administrative burden PAs impose on patients and their providers, enhance efficiency of the process, promote transparency of PA requirements, and ensure PA determinations are rooted in evidence.

Cystic fibrosis is a life-threatening genetic disease that causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to serious infections. CF care is grounded in evidence-based clinical guidelines and as a complex, multi-system disease, CF requires an intensive treatment regimen including multiple medications. For people with CF, it is not uncommon to take seven therapies every day, and as many as twenty.¹ Many medications are taken year after year, and in most cases, for life. While these therapies are helping people live longer, healthier lives, we also know patients often encounter barriers to accessing them.

Prior authorizations are one of the obstacles people with CF must navigate when accessing care. These requirements can delay the start or continuation of needed treatments, which can lead to adverse health outcomes. Specifically, since CF is a progressive disease, interruptions in care put people with CF at risk of irreversible lung damage and costly hospitalizations. PAs can also cause significant administrative burden for CF providers and are often redundant for medications that people with CF must take indefinitely to maintain their health. For instance, in a CF Foundation survey of CF care teams, 58 percent of providers reported spending 20 percent or more of their time on PAs in 2016. This arduous process diverts valuable time and resources away from direct patient care.

We appreciate North Carolina's attention to this issue and support the following provisions in HB 649:

Medications for Chronic Diseases

PA requirements present a unique set of challenges for people with CF and other lifelong, chronic diseases who must adhere to intensive, ongoing treatment plans. Recognizing that these patients take the same drugs for most of their lives, we appreciate that HB 649 exempts drugs and therapies used to treat chronic and long-term care conditions from repeat authorizations and requires insurers to honor a prior authorization approval for the duration of the treatment. Eliminating unnecessary repeat

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2680350/>

authorizations will help promote immediate and consistent access to life-saving therapies for people with CF, and significantly reduce administrative burden for CF care teams.

Gold Carding

To further reduce administrative burden and delays in care, HB 649 exempts providers from prior authorization requirements if 80 percent of their requests were approved in the preceding 12 months, a practice known as gold carding. Once a provider obtains an exemption, they would be exempt from having to request a PA for that healthcare service for at least the next year. Because cystic fibrosis requires highly specialized care and treatment, the vast majority of people with CF receive care at a CF Foundation-accredited care center which provide quality, specialized CF care that is based in clinical guidelines. If members of a CF care team received an exemption, that care center could spend more time on patient care instead of paperwork and, most importantly, people with CF could avoid delays in care.

Response Times and Continuity of Care

HB 649 requires health plans to respond to all prior authorization requests within 48 hours for non-urgent services or 24 hours for urgent services, thereby ensuring timely access to treatments. Also included in the bill is a continuity of care provision that protects patients from experiencing care delays when there are changes in coverage for a given treatment or when patients switch health plans. As stated previously, CF maintenance requires many chronic medications, and gaps in therapy put people with CF at increased risk of costly hospitalizations and negative health outcomes. We support efforts to reduce delays in care and ensure people have timely access to their necessary medications.

Transparency for Prior Authorization Requirements

The CF Foundation applauds the provisions of HB 649 to increase transparency for PAs, specifically the intent to require insurers to maintain a complete list of services that require PA, publicly share data on approvals and denials, and mandate PA requirements and criteria — and changes to these policies — are easily accessible and clearly articulated. People with CF take many medications every day, many of which require prior authorizations. Each additional prior authorization can further exacerbate the administrative burden on both people with CF and care teams as they navigate the criteria required to obtain these medications. Increasing the availability of information on prior authorization requirements and processes at the point-of-care will help reduce the administrative burden of these policies and streamline the process for care teams.

Evidence-Based Review

One of the purposes of prior authorization is to verify the clinical appropriateness of a service, so it is crucial that insurers use evidence-based criteria when developing prior authorization requirements. CF treatments have very clear indications established by the Food and Drug Administration and it is essential that prior authorization criteria reflect the data and label approval. To that end, HB 649 requires insurers to review their prior authorization criteria annually and ensure that their criteria reflect current medical and scientific evidence. Additionally, PA denials must be made by a medical doctor who specializes in managing the medical condition or has experience providing the requested service.

The Foundation appreciates that PA policies were adopted to ensure patients only receive medically necessary care, and we understand the challenge insurers face in managing medication utilization and cost. However, utilization management cannot come at the expense of delays in patient access to

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needed care. HB 649 provides an opportunity to make prior authorization processes more transparent, efficient, and evidence-based, allowing for timely access to appropriate treatments.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary B. Dwight". The signature is fluid and cursive, with a large initial "M" and "D".

Mary B. Dwight

Chief Policy & Advocacy Officer

Senior Vice President, Policy & Advocacy

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