



October 31, 2022

Amir Bassiri
Acting Medicaid Director
Office of Health Insurance Programs
New York State Department of Health
One Commerce Plaza
Albany, NY 12210

RE: New York Medicaid Coverage of Hypertonic Saline

Dear Mr. Bassiri,

On behalf of over 1,600 people in New York with cystic fibrosis (CF), we write to urge New York Medicaid to add coverage for inhaled hypertonic saline solution, a critical component of CF care. It is our understanding that New York Medicaid no longer provides coverage for Sodium Chloride Inhalation Solution 7% and CF clinicians in the state have recently expressed concerns about their patients' inability to access this medically necessary therapy.

Cystic fibrosis (CF) is a life-threatening genetic disease that affects close to 40,000 children and adults in the United States. CF causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to life-threatening infections. As a complex, multi-system condition, CF requires targeted, specialized treatment and medications. Medicaid is a crucial source of coverage for many people with CF, including half of children and one-fourth of adults in New York. Medicaid serves as both a primary and secondary source of insurance for people with CF, providing access to vital care and treatments—including inhaled hypertonic saline—to help people with CF maintain their health and well-being.

Inhaled hypertonic saline

Mucociliary clearance is an essential component of CF care and CF pulmonary guidelines recommend use of hypertonic saline in individuals ages 6 and up.¹ Specifically, treatment with mucolytic products—including inhaled hypertonic saline solution—is shown to help clear mucus from the lungs, resulting in fewer lung infections, improved lung function, and better quality of life for people with CF.² Long-term clinical trials also found that people who were treated with inhaled hypertonic saline experienced a reduction in antibiotic use for pulmonary exacerbations and subsequently missed fewer days of work and school due to illness.³ Additionally, the 2016 Clinical Guidelines for Preschoolers with Cystic Fibrosis recommends hypertonic saline be offered to patients based on individual circumstance.⁴ Further studies of this age group, released in both 2018 and 2019, conclude that use of hypertonic saline is safe, well-tolerated, and resulted in improved lung clearance for both infants with CF and children aged 3-6 years with CF.^{5,6}

Please see the attached 2013 CF Pulmonary Guidelines and the 2016 Clinical Guidelines for Preschoolers with CF, both of which recommend the use of hypertonic saline as part of the CF care regimen.

Medicaid coverage of hypertonic saline

Several state Medicaid programs, including California, Colorado and Illinois, cover hypertonic saline and receive federal matching funds. We have found in conversations that some states have confusion about a state's ability to cover hypertonic saline and draw federal match; we are happy to assist in clarifying any clinical or financial concerns. To put the cost in perspective, nebulized hypertonic saline typically accounts for approximately \$60 per month in out-of-pocket costs. The risk of skipping first line therapies, like hypertonic saline, can ultimately cost thousands of dollars for hospitalizations.

Most importantly, we believe that coverage of these products aligns closely with your goals to provide appropriate care to Medicaid beneficiaries in your state. Therefore, we urge New York Medicaid to add coverage for inhaled hypertonic saline for beneficiaries covered in Medicaid fee-for-service, as well as for those enrolled in Medicaid Managed Care Plans (MMC).

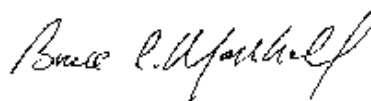
The Cystic Fibrosis Foundation appreciates your commitment to ensuring access to vital treatments for people with CF in New York. We would be happy to connect you with our clinician partners at local CF care centers to further discuss hypertonic saline and its use in CF care. Please contact Sage Rosenthal, State Policy Specialist, at srosenthal@cff.org if you have any questions.

Please let us know how we can be a resource to you going forward. Thank you for your attention to this important issue.

Sincerely,



Mary B. Dwight
Senior Vice President of Policy & Advocacy
Cystic Fibrosis Foundation



Bruce C. Marshall, MD
Senior Vice President of Clinical Affairs
Cystic Fibrosis Foundation

¹ Mogayzel, Peter, Jr., Naureckas, Edward, et al. Cystic Fibrosis Pulmonary Guidelines. American Journal of Respiratory and Critical Care Medicine, Vol. 187, 2013.

² *ibid*

³ Elkins MR, Robinson M, Rose BR, et al. A controlled trial of long-term inhaled hypertonic saline in patients with cystic fibrosis. N Engl J Med 2006;354:229–240.

⁴ Lahiri, Thomas, Hampstead, Sarah E., et al. Clinical Practice Guidelines From the Cystic Fibrosis Foundation for Preschoolers With Cystic Fibrosis. Pediatrics, Vol. 137, 2016.

⁵ Ratjen F, Davis SD, Stanojevic S, et al. Inhaled hypertonic saline in preschool children with cystic fibrosis (SHIP): a multicentre, randomised, double-blind, placebo-controlled trial. Lancet Respir Med 2019; published online June 6. [http://dx.doi.org/10.1016/S2213-2600\(19\)30187-0](http://dx.doi.org/10.1016/S2213-2600(19)30187-0).

⁶ Stahl, Mirjam, Wielp, Mark O., et al. Preventive Inhalation of Hypertonic Saline in Infants with Cystic Fibrosis (PRESIS). American Journal of Respiratory and Critical Care Medicine. Volume 199. 2018.