CYSTIC FIBROSIS FOUNDATION®

October 27, 2021

Ms. Susan Philip
Deputy Director, Health Care Delivery Systems
P.O. Box 997413, MS 8100
Sacramento, CA 95899-7413

RE: California CCS and GHPP Coverage of Hypertonic Saline

Dear Deputy Susan Philip,

On behalf of the approximately 2,500 people in California with cystic fibrosis (CF), we write to urge California Children's Services (CCS) and Genetically Handicapped Persons Program (GHPP) to add coverage for inhaled hypertonic saline solution, a critical component of CF care. It is our understanding that CCS and GHPP only provide coverage for Sodium Chloride injected solution and not inhaled hypertonic saline solution, and we have concerns about CF patients' inability to access this medically necessary therapy.

Cystic fibrosis (CF) is a life-threatening genetic disease that affects 30,000 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. CCS and GHPP are crucial sources of coverage for many people with CF, including nearly 800 children and over 400 adults in California. CCS and GHPP serve as both primary and secondary sources 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 the 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]

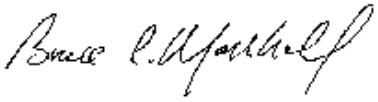
Please see the attached 2013 CF Pulmonary Guidelines and the 2016 Clinical Guidelines for Preschoolers with CF, both of which recommend the use of hypertonic saline as part of the CF care regimen.

Coverage of hypertonic saline
Coverage of these products aligns closely with your goals to provide quality care to CCS and GHPP beneficiaries in your state and, by doing so, reduces the risk for infections and costly antibiotic use. To put the cost in perspective, nebulized hypertonic saline typically can cost up to $60 in out-of-pocket costs. The risk of skipping first line therapies, including hypertonic saline, can ultimately cost thousands of dollars for hospitalizations. Therefore, we urge California to add coverage for inhaled hypertonic saline for beneficiaries covered in California Children's Services and California's Genetically Handicapped Persons Program.

The Cystic Fibrosis Foundation appreciates your commitment to ensuring access to vital treatments for people with CF in California. 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, Sr. Coordinator, at srosenthal@cff.org or 301-841-2631 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
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cc: Autumn Boylan, Integrated Systems Deputy
Richard Nelson, Integrated Systems Branch Chief
Barbara Sasaki, Special Populations Unit Chief
Shelly Taunk, Special Programs Branch-Clinical Assurance Division Chief

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[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.
[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.