Forest Research Institute, Inc.
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August 30, 2012

Reva Winkler, MD, MPH
Senior Director, Performance Measures
National Quality Forum
1030 15th Street, NW, Suite 800
Washington, DC 20005

Dear Dr. Winkler:

Forest Laboratories, Inc. (Forest) is a U.S.-based pharmaceutical company with a long track record of building partnerships and developing and marketing products that improve patient care and clinical outcomes.

Forest supports NQF's mission to improve quality of American healthcare by endorsing national consensus standards for measuring and publicly reporting on performance.

We appreciate the opportunity to participate in the National Quality Forum's appeal process for Measure 0102: *COPD: inhaled bronchodilator therapy (AMA-PCPI).* This measure does not currently include all approved standards of care. We request that Tudorza™ Pressair™ (aclidinium bromide inhalation powder) be included in the list of medications for this measure. As the measure is currently written, patient access to all new treatments may be limited as healthcare professionals may be discouraged from trying new therapeutic options. As the company who manufactures and sells Tudorza™ Pressair™ (aclidinium bromide inhalation powder), we are concerned that this will not only directly and materially impact Forest, but will also directly impact patients who suffer from Chronic Obstructive Pulmonary Disease.

Chronic Obstructive Pulmonary Disease (COPD) is a common, progressive, and debilitating lung disease characterized by persistent airflow limitation that makes it hard to breathe; it is currently the third leading cause of mortality in the US.[1] Characteristic symptoms include breathlessness, excessive production of sputum, and a chronic cough. Even with available COPD treatments, patients with COPD continue to experience bronchospasm and other COPD symptoms. Therefore, COPD patients may benefit from having access to all available COPD therapies.

On July 23, 2012, Forest Laboratories, Inc. received approval from the U.S. Food and Drug Administration (FDA) for Tudorza™ Pressair™ (aclidinium bromide inhalation powder). Tudorza ™Pressair ™ is indicated for the long-term maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema.[2] It is not indicated for the initial treatment of acute episodes of bronchospasm (i.e., rescue therapy.) Tudorza™ Pressair™ 400 mcg is inhaled (one inhalation, twice daily) long-acting anticholinergic, also referred to as a long-acting muscarinic antagonist (LAMA). Tudorza™ Pressair™ produces bronchodilation by

inhibiting acetylcholine's effect on muscarinic receptors in the airway smooth muscle in the lungs. Tudorza™ Pressair™, the second approved LAMA, has been shown in clinical studies to improve lung function (based on morning pre-dose [trough] FEV_1 and peak FEV_1), reduce dyspnea (based on the Transition Dyspnea Index [TDI]), and reduce the requirement for the use of rescue short- acting beta agonists. Inhaled medications, including Tudorza Pressair, may cause paradoxical bronchospasm. If this occurs, treatment with Tudorza Pressair should be stopped and other treatments considered. Tudorza Pressair should be used with caution in patients with narrow angle glaucoma or urinary retention. Patients should be instructed to consult a physician immediately should any signs or symptoms of narrow-angle glaucoma or prostatic hyperplasia or bladder-neck obstruction develop. Immediate hypersensitivity reactions may occur after administration of Tudorza Pressair. Given the structural similarity of the formula of atropine to aclindinium, patients with a history of hypersensivity reactions to atropine should be monitored for similar hypersensitivity reactions to Tudorza Pressair. Tudorza Pressair should be used with caution in patients with severe hypersensitivity to milk proteins. The most common adverse reactions (> or equal to 3% incidence and greater than placebo) were headache, nasopharyngitis and cough..[2]

Tudorza™ Pressair™ is administered via the Pressair™ inhaler, a preloaded, breath-actuated, multidose dry powder inhaler designed for the effective and reliable delivery of Tudorza™ Pressair™.[3,4,5,6] The Pressair™ inhaler provides accurate and consistent dose delivery of Tudorza™ Pressair™ to patients, delivering the target dose at flow rates as low as 35 L/min.[2] The Pressair™ inhaler also has several key attributes that distinguish it from other inhalers. It provides both visual and acoustic feedback to reassure patients that they have taken their medication correctly, including a colored control window that changes from green to red with an audible click on successful actuation of each dose. [2]

Given the seriousness of this disease, Forest supports measures that positively impact the healthcare of patients who suffer with COPD. We believe it is important to ensure these measures embody the best clinical practice. National Quality Forum Measure 0102: COPD: inhaled bronchodilator therapy (AMA-PCPI) is one of the NQF Pulmonary and Critical Care Measures which were endorsed on July 31, 2012. This measure was undergoing maintenance and endorsement prior to the approval of Tudorza™ Pressair™. Since NQF's goal is to ensure that measures reflect current knowledge and state-of-the-art, high quality care, we respectfully request the addition of Tudorza™ Pressair™ to the measure.

Because the Centers for Medicare & Medicaid Services (CMS) has proposed to use this measure under its Physician Quality Reporting System as an individual quality measure available for reporting via claims, registry, Electronic Health Records (EHR) or Group Practice Reporting Option (GPRO) web-interface for 2013 and beyond,[7] adherence to this measure, as it is currently written, not currently including all approved therapeutic options, has the potential to adversely impact both patients with COPD as well as Forest. We urge NQF to work with the measure developer to ensure that measure 0102 appropriately incorporates Tudorza™ Pressair™ prior to the January 1, 2013, effective date of CMS' rule.

We greatly appreciate the opportunity to submit information for your consideration. Should you have additional questions regarding Tudorza™ Pressair™ or on the information provided, please contact either Medical Information Communications at (800) 678-1605, ext.66297 or me at (201) 427-8203.

Thank you for your consideration,

Kim Thacker, MD
VP, Medical Affairs and Health Outcomes
Forest Research Institute, Inc.

References:

1. Centers for Disease Control and Prevention and National Center for Health Statistics. *National Vital Statistics Reports.* Hyattsville, MD. U.S. Department of Health and Human Services. 2012.

2. Tudorza Pressair [package insert]. St. Louis, MO: Forest Pharmaceuticals, Inc.; July 2012.

3. Block K, Folger S, Fyrnys B, Kurtz S. Delivered dose and fine particle dose of aclidinium 200 mcg via the Genuair inhaler are independent of the flow rate within the working area of the device. Presented at European Respiratory Society Annual Congress; September 18-22, 2010. Barcelona, Spain.

4. Fuhr R, Magnussen H, Singh D, de Miquel G, Caracta C, Garcia Gil E. Patient assessments of ease of use of Genuair® versus Aerolizer® and HandiHaler®. Poster presented at the European Respiratory Society Annual Congress; September 24-28, 2011. Amsterdam, The Netherlands.

5. Hass C, Engdahl K, Albert W, Setyawan J, Mateo N. Patient preferences and perceived ease of use in inhaler features: Genuair® vs other inhalers. Poster presented at the American College of Chest Physicians Annual Congress; October 30-November 4, 2010. Vancouver, BC, Canada.

6. Chrystyn H, Niederlaender C. The Genuair® inhaler: a novel, multidose dry powder inhaler. *Int J Clin Pract.* 2012 Mar;66(3):309-17.

7. See U.S. Centers for Medicare & Medicaid Services. Table 32: Proposed PQRS Individual Quality Measures Available for Reporting via Claims, Registry, EHR, or GRPO Web-Interface for 2013 and Beyond. 77 Fed. Reg. 44722, at 44855 (July 30, 2012).