YUPELRI CLINICAL EXPERIENCE CASE STUDY

Harry

66-year-old male

Admitted to hospital for increased dyspnea and worsening of COPD

Case based on real patient. Patient's name has been changed. Image is actor portrayal.
Case presented by Reynold A. Panettieri, Jr, MD.

Indication

YUPELRI® inhalation solution is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Important Safety Information

YUPELRI is contraindicated in patients with hypersensitivity to revefenacin or any component of this product.

YUPELRI should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD, or for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta$_2$-agonist.

Please see page 5 for full Important Safety Information.

ONCE-DAILY YUPELRI® revefenacin inhalation solution

"Harry's uncontrolled and advanced COPD motivated me to adjust his therapy. I felt there was a need to simplify his management by using one type of delivery system."

Reynold A. Panettieri, Jr, MD

Professor of Medicine, Robert Wood Johnson Medical School

Vice Chancellor, Clinical & Translational Science

Director, Rutgers Institute for Translational Medicine & Science

Emeritus Professor of Medicine, University of Pennsylvania

PATIENT PROFILE: HARRY

Case History

66-year-old male who had COPD for approximately 10 years before he was referred to a specialist for evaluation.

Retired plumber who lives with his wife. Smoked 60 pack-years while in the workforce and decreased his tobacco use since retiring to approximately half a pack per day. Maintains a busy social life and meets biweekly with a bowling league. Serves as a handyman on occasion and has insurance coverage through Medicare Part B with supplemental.

COPD history	Reported 3 exacerbations since diagnosis approximately 10 years ago, which indicates worsening of COPD. Recently admitted to the hospital due to increased dyspnea (difficulty breathing), for a total of 5 days.
Comorbidities	Mild hypertension (treated) and diabetes (non-insulin dependent; managed by lifestyle and oral diabetes agents).
COPD treatment regimen prior to hospitalization	Handheld SMI short-acting bronchodilator administered 4 times daily and also a rescue inhaler PRN.
Medications prescribed during hospitalization	Received a course of intravenous antibiotics, oxygen, and oral corticosteroid during 5-day hospital stay, and began using nebulized maintenance treatment for COPD symptoms on day 2. Continued on the same nebulized maintenance treatment upon discharge.

Physical exam and evaluation after hospital admission

Symptoms were consistent with uncontrolled COPD and bronchitis. Demonstrated poor handheld inhaler technique.

"Harry's poor hand coordination skills became apparent to me after I saw him struggling to pick up his cell phone. I knew he would be a good candidate for nebulized therapy."

HARRY MAY BENEFIT FROM NEBULIZED THERAPY

Nebulized therapy helped Harry's COPD

Harry reported having fewer COPD symptoms and had noticeable improvement in his ability to hold conversations again after using nebulized therapy while in the hospital.

Prior to Harry's hospital stay, his poor hand coordination skills made it difficult for him to take his medication. His persistent and often unpredictable episodes of significant breathlessness prevented him from working, and ultimately influenced his decision to retire early.

YUPELRI may help patients like Harry

"Harry has an active social life, so the once-daily dosing of YUPELRI could fit into his schedule. This, along with his poor hand coordination, made him a good candidate for YUPELRI."

YUPELRI is a nebulized LAMA* that is administered in approximately 8 minutes once daily.[1†]

YUPELRI is administered with any standard jet nebulizer with a mouthpiece. Harry can administer his daily dose of YUPELRI with normal, tidal breathing.[1]

Rx Treatment Plan

"Harry was initiated on YUPELRI on day 2 of his hospital stay. Upon discharge, Harry will continue to take YUPELRI (175 mcg once daily). His coordination issues, concerns he expressed about coverage, no history of glaucoma or visual impairment, and positive response to YUPELRI in the hospital confirmed my decision to keep him on nebulized therapy. I have arranged for a follow-up visit in 2 weeks to reassess his COPD, pulmonary function, and resting and exercise oxygen saturation. I will continue to monitor his response to YUPELRI and see how he is doing with a nebulized treatment approach for his COPD."

Important Safety Information

As with other inhaled medicines, YUPELRI can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with YUPELRI, it should be treated immediately with an inhaled, short-acting bronchodilator. YUPELRI should be discontinued immediately and alternative therapy should be instituted.

YUPELRI should be used with caution in patients with narrow-angle glaucoma. Patients should be instructed to immediately consult their healthcare provider if they develop any signs and symptoms of acute narrow-angle glaucoma, including eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema.

Please see page 5 for full Important Safety Information.

*LAMA=long-acting muscarinic antagonist.

†Using the PARI LC® Sprint nebulizer connected to a PARI Trek® S compressor under *in vitro* conditions.

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Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

Immediate hypersensitivity reactions may occur after administration of YUPELRI. If a reaction occurs, YUPELRI should be stopped at once and alternative treatments considered.

The most common adverse reactions occurring in clinical trials at an incidence greater than or equal to 2% in the YUPELRI group, and higher than placebo, included cough, nasopharyngitis, upper respiratory infection, headache and back pain.

Coadministration of anticholinergic medicines or OATP1B1 and OATP1B3 inhibitors with YUPELRI is not recommended.

YUPELRI is not recommended in patients with any degree of hepatic impairment.

Please see accompanying Full Prescribing Information.

ONCE-DAILY YUPELRI® revefenacin inhalation solution

YUPELRI is the first and only once-daily nebulized LAMA, for a full 24 hours of lung function improvement*

Proven 24-hour control[1]

Responses as early as 30 minutes[1,2]

Once-daily dosing[1]

Administered with any standard jet nebulizer with a mouthpiece

Demonstrated safety profile[1]

Up to 100% of patients with Medicare Part B are covered†

Permanent J-CODE J7677

YUPELRI was studied in two 12-week, randomized, double-blind, placebo-controlled, parallel-group confirmatory studies (studies 1 and 2) to evaluate the efficacy of once-daily YUPELRI vs placebo in patients with moderate to very severe COPD.[1]

The primary endpoint was change from baseline in trough (predose) FEV_1 at day 85 vs placebo: YUPELRI demonstrated a statistically significant difference vs placebo in Study 1 (146 mL, *P*<.0001 [YUPELRI, n=189; placebo, n=191]) and Study 2 (147 mL, *P*<.0001 [YUPELRI, n=181; placebo, n=187]).[1,2]

*In studies 1 and 2, a prespecified exploratory analysis was performed using serial spirometry on a substudy population over 24 hours on days 84/85. In study 1, LS mean changes from baseline in FEV_1 ranged from 55.8 mL to 240.4 mL in the YUPELRI group (n=45), and from -113.6 mL to 59.6 mL in the placebo group (n=44). In study 2, LS mean changes from baseline in FEV_1 ranged from 19.8 mL to 148.5 mL in the YUPELRI group (n=44), and from -176.4 mL to -13.0 mL in the placebo group (n=39).[1,2]

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†This is not a guarantee of coverage. Site of care will determine coverage. Check with your patient's insurance provider for coverage rules and restrictions. In certain limited instances, YUPELRI may be covered through a patient's Medicare Part D pharmacy benefit.

Please see page 5 for full Important Safety Information.

References: 1. YUPELRI (package insert). Morgantown, WV: Mylan Specialty LP; May 2019. **2.** Data on file, Mylan Specialty L.P.

Please see more information at YUPELRIHCP.com

Mylan® Theravance Biopharma

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