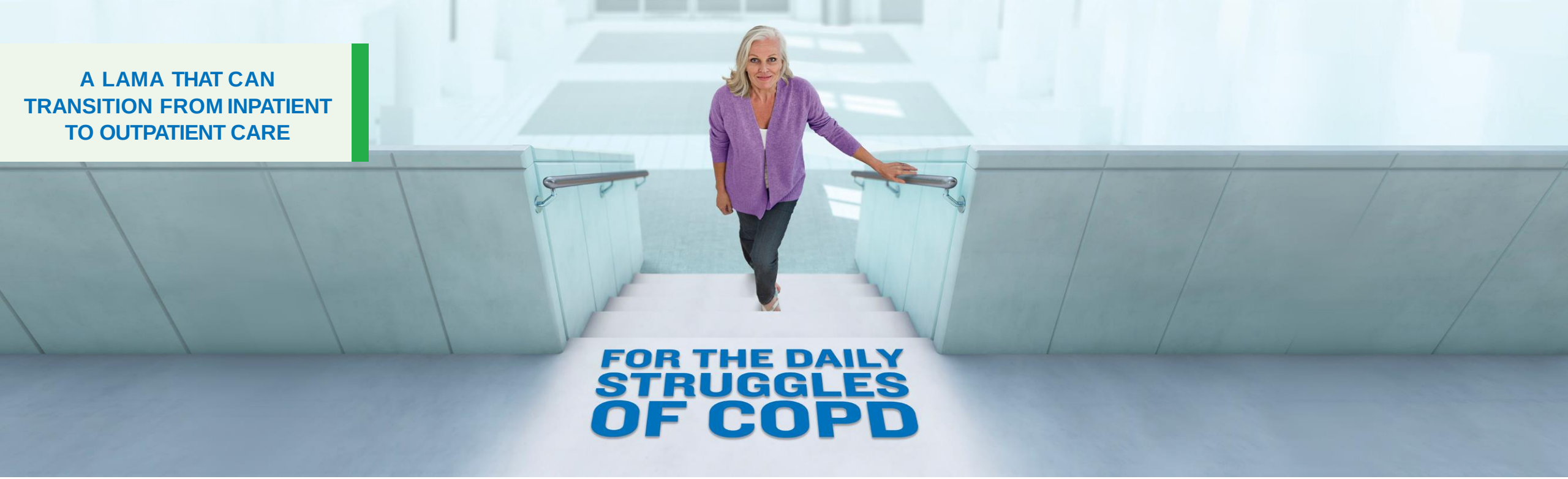
A LAMA THAT CAN TRANSITION FROM INPATIENT TO OUTPATIENT CARE



YUPELRI is the first and only once-daily nebulized LAMA, for a full 24 hours of lung function improvement[1]

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 full Important Safety Information.

YUPELRI® revefenacin inhalation solution

The burden of chronic obstructive pulmonary disease is substantial and growing

12.7M estimated number of US adults with COPD in 2013[2]

Up to 50% of cases of COPD are not diagnosed[2]

24M adjusted US prevalence, due to potential underdiagnoses[2]

155% projected increase of COPD in North America from 2010-2030[3]

It is important to discuss changes in symptoms and risk factors with your patients. Common symptoms of COPD include[4]:

Persistent airflow limitation

Chronic sputum production

Chronic cough

Dyspnea

Prompt, frequent, and routine assessment is essential in order to determine appropriate management and to identify complications or comorbidities.[4]

Incorrect inhaler technique can result in serious, long-term consequences[5]

Device technique and medication usage errors can negatively impact effective treatment and management of COPD*

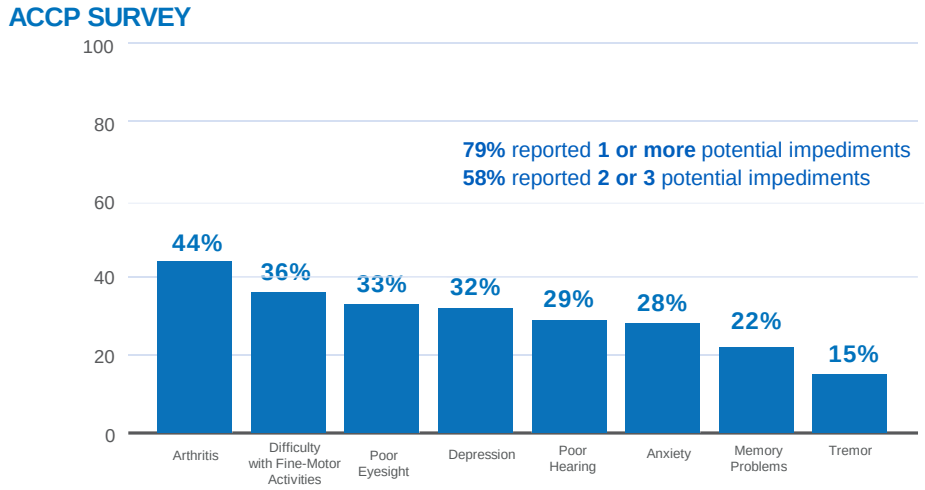
Inappropriate inhaler technique could lead to oropharyngeal rather than lung deposition, which may lead to[5]:

- Swallowed dose, resulting in systemic side effects
- Decreased efficacy

*A number of device types are available for the treatment of COPD, all of which have advantages and limitations that determine their suitability for any given patient. Considering patient preference and ability, along with proper instruction and routine assessment, is crucial to ensure optimal outcomes.[5]

Many patients experience issues that can potentially impede optimal device technique[6]

Percentage of patients reporting potential impediments to optimal device technique (N=499)[6]



Selected responses from a 127-question, quantitative, web-based, descriptive, cross-sectional survey of 499 patients with COPD in the United States. Survey participants were aged 55 to 74 years, predominantly former smokers, and were randomly chosen from a panel of individuals with self-identified COPD.[6]

The frequency of correct inhaler technique has not changed over a 40-year period.[7†]

†Data were extracted from 144 articles reporting on a total of 54,354 subjects performing 59,584 observed tests of technique. Fifty-four studies reported data on patients with asthma, 14 on patients with COPD, and the remaining 76 on both types of patients together or on patients with unspecified airway disease.

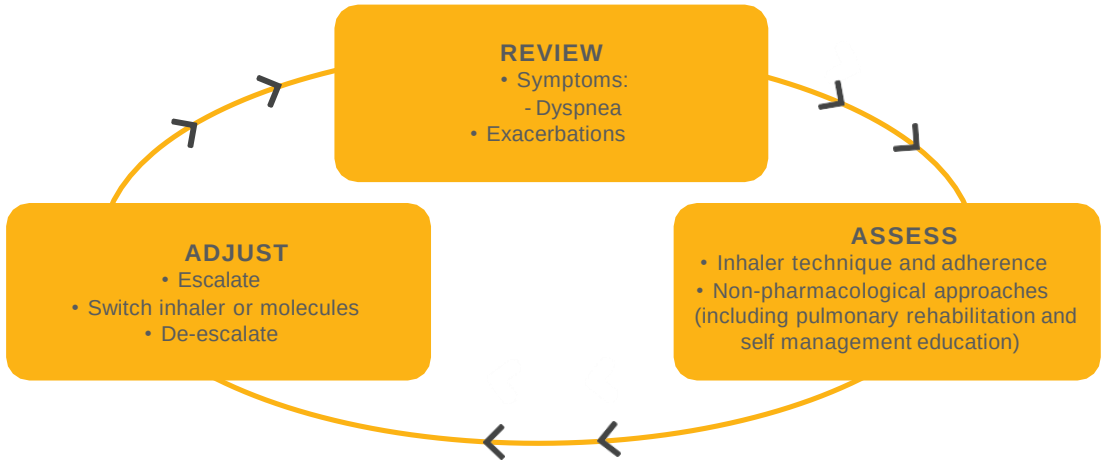
The GOLD report recommends that patients should be reassessed at each interaction[4*]

THE REFINED ABCD ASSESSMENT TOOL

≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization	**Group C**	**Group D**
0 or 1 moderate exacerbations (not leading to hospital admission)	**Group A**	**Group B**
	mMRC 0-1, CAT < 10	mMRC ≥ 2, CAT ≥ 10

Following implementation of therapy, patients should be reassessed for attainment of treatment goals and identification of any barriers for successful treatment.

MANAGEMENT CYCLE



Patients should be assessed at every opportunity, especially when experiencing worsening of symptoms.[4,8]

*GOLD does not endorse any specific treatments.

YUPELRI® revefenacin inhalation solution

Consider a range of patient characteristics and preferences for nebulized therapy

Individual patient characteristics and clinical presentation play an important role in shaping your patients' treatment.[9]

Lifestyle preferences, changes, and constraints (finances, mobility, etc)

Comorbidities

Physical limitations and cognitive issues

Disease progression

When evaluating a treatment option for patients with COPD, important considerations include[10,11]:

- Ability to use the selected device correctly
- Need for multiple therapies
- Patients' Preference and satisfaction
- Patients' individual insurance coverage and out-of-pocket costs for drug and/or nebulizer
- Availability of specific drug and device pairings

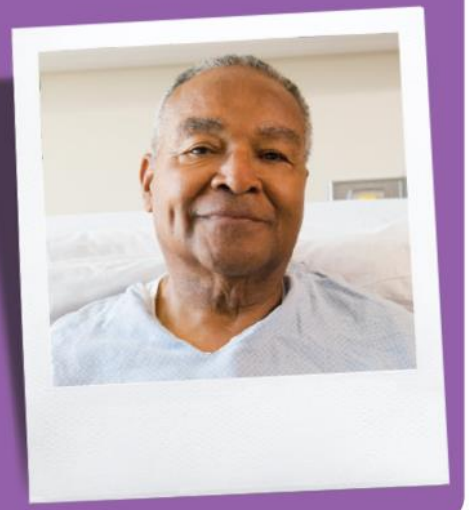
Shared decisions among healthcare providers and patients may help achieve better treatment outcomes[9]

Some patients may not know about all available options; ask them what they prefer and assess what delivery device may be appropriate.[12]

YUPELRI® revefenacin inhalation solution

Many of your uncontrolled COPD patients may be candidates for nebulized therapy

Ken is transitioning from hospital to home care*



- Age 68, FEV_1 ≈46% predicted, third exacerbation in past 12 months
- Using handheld maintenance and rescue inhalers preadmission; transitioned to nebulized maintenance and rescue therapies while hospitalized
- Chronic nonproductive cough, shortness of breath, and wheezing at admission
- Desires one type of delivery system while maintaining symptom control

- **Only 6%** of patients with severe COPD used their inhaler therapy regularly and with correct technique a majority of the time in the month following hospital discharge[13]
- It is critical for patients to be assessed for medication and device technique before leaving the hospital[4,9]

Maria has insufficient inspiratory force*

- Age 61, FEV_1 ≈59% predicted
- Currently using handheld maintenance inhaler and nebulized rescue therapy
- Symptomatic, experiencing exertional dyspnea
- Desires reliable symptom control

- **Approximately 19%** of patients with advanced COPD and ≥60 years of age have impaired inspiratory effort[14]
- Patients with impaired inspiratory effort may not be able to inhale medications using a handheld inhaler effectively[15]

*Not an actual patient.

YUPELRI® revefenacin inhalation solution

Poor inhaler technique may lead to inadequate drug delivery[6]

Consider nebulized therapy for patients with challenges using handheld inhalers

Robert struggles with his inhalers*

- Age 65, FEV_1 ≈50% predicted, osteoarthritis with poor hand-grip strength
- Currently using handheld maintenance and rescue inhalers
- Symptomatic, with worsening morning cough and shortness of breath
- Patient expresses concern with ability to use inhalers

- **Over half** of COPD patients 45+ years are likely to have coexisting arthritis[16]
- 44% of COPD patients self-reported having arthritis. Arthritis or other manual dexterity issues may prevent patients from using handheld inhalers properly[6]

Susan is experiencing cognitive decline*

- Age 75, FEV_1 ≈45% predicted, mild dementia
- Currently using handheld maintenance inhaler and nebulized rescue therapy
- Symptomatic, with shortness of breath, fatigue, and disrupted sleep
- Caregiver expresses need for simplified delivery, requiring less hand-breath coordination

- **As many as one-third** of COPD patients were classified as having either borderline or impaired cognitive functioning[13,17,18†]
- Cognitive impairments in COPD patients are a common barrier to correct inhaler administration[6,13]

*Not an actual patient.

†On tests measuring psychomotor speed and executive control functioning.

YUPELRI® revefenacin inhalation solution

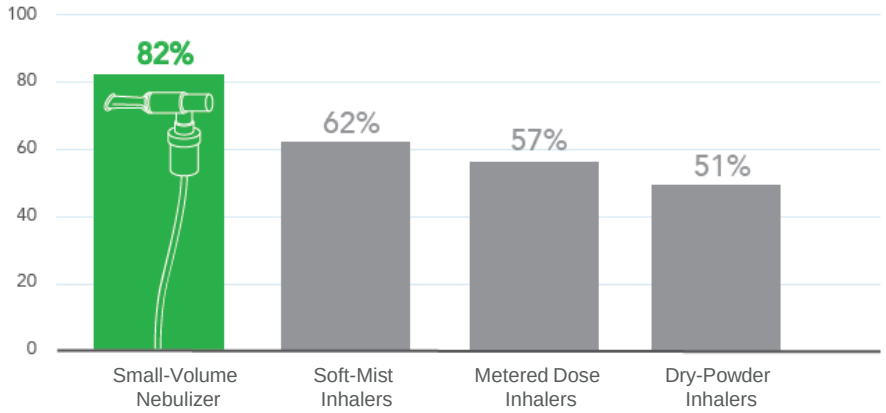
Have you considered the role of nebulization in COPD maintenance therapy?

The GOLD 2020 report recommends: *"Maintenance therapy with long-acting bronchodilators should be initiated as soon as possible before hospital discharge."* [4]*

Nebulizers: A user-friendly option for COPD patients[19]

- Nebulizers require only **normal tidal breathing** and do not require extra effort generating adequate inspiratory force[6,20,21]
- No hand-breath coordination is needed[6,22]
- Today's nebulizers include compact, portable, and low cost options for most patients[23,24]

Percent of patients reporting they were very confident about medication delivery by device type[6]



Selected responses from a 127-question, quantitative, web-based, descriptive, cross-sectional survey of 499 patients with COPD in the United States. Survey participants were aged 55 to 74 years, predominantly former smokers, and were randomly chosen from a panel of individuals with self-identified COPD.

- 61% to 69% of patients believed that they used their device correctly all the time; patients using small-volume nebulizers were the most confident[6]

*GOLD does not endorse any specific treatments.

YUPELRI® revefenacin inhalation solution

Availability of jet nebulizers

Jet nebulizers are commonly available[19]

- Jet nebulizers are considered standard among all nebulizer types[19]
- Most nebulizers are 100% covered as durable medical equipment (DME) through Medicare Part B[25]

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.

These data are referenced from a 2008 survey.

Based on the estimated prevalence of COPD in the US, several million patients use nebulizers on a regular basis.[20]

YUPELRI® revefenacin inhalation solution

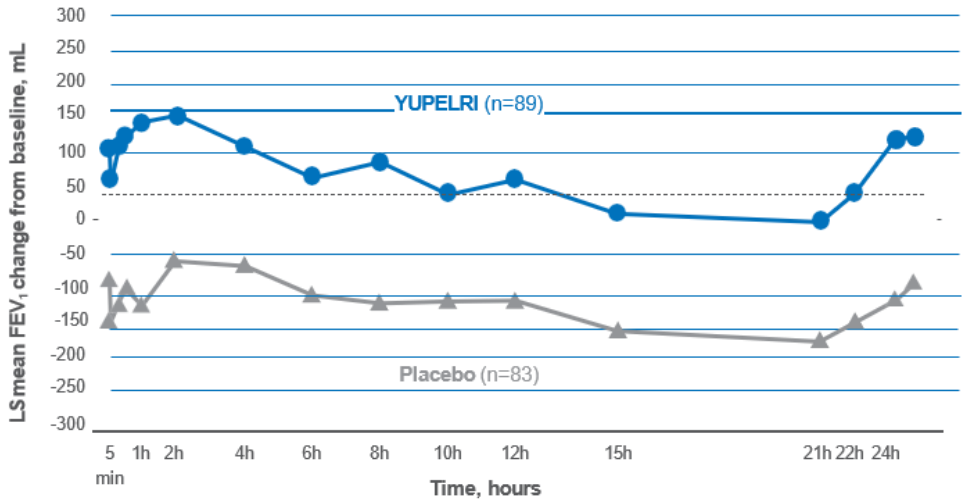
YUPELRI delivers a full 24 hours of efficacy in a single daily dose

- 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 YUPELRI vs placebo in patients with moderate to very severe COPD[1]

Consistent improvement in FEV_1 vs placebo over 24 hours on days 84/85[1,26]

In Studies 1 and 2, serial spirometry was performed on a substudy population. Pooled results are shown.

Primary efficacy endpoint was change from baseline in trough (predose) FEV_1 at day 85 vs placebo.



- In Studies 1 and 2, a prespecified exploratory analysis was performed.
- In Study 1, LS mean changes from baseline in FEV_1 ranged from 55.8 mL to 240.4 mL in the YUPELRI group, and from -113.6 mL to 59.6 mL in the placebo group.
- In Study 2, LS mean changes from baseline in FEV_1 ranged from 19.8 mL to 148.5 mL in the YUPELRI group, and from -176.4 mL to -13.0 mL in the placebo group[26]

Once-daily dosing[1]

24-hour duration[1]

Patients responded in as early as 30 minutes[26]*

*An exploratory analysis of the time to achieve a 100 mL increase in FEV_1 on day 1 showed that the median time to achieve an increase in FEV_1 of 100 mL was 30 minutes in Study 1 (30 to 60 minutes) and Study 2 (30 to 90 minutes).

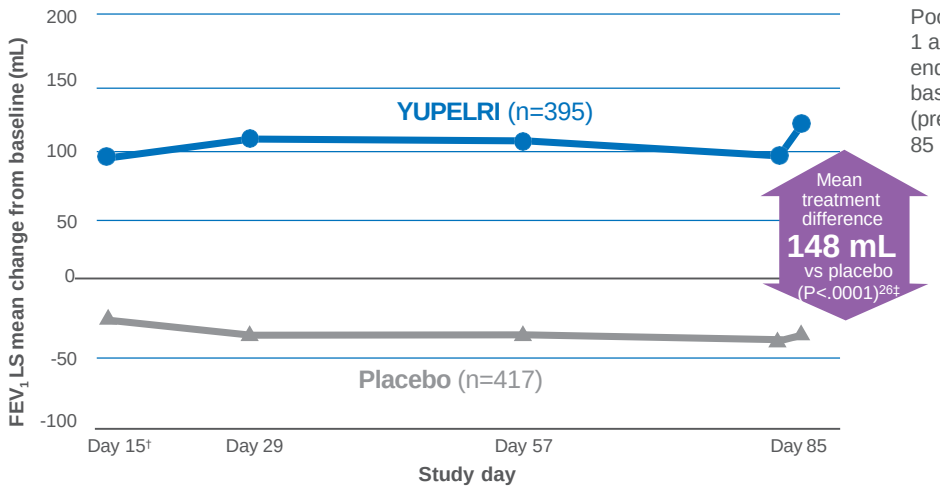
Important Safety Information

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.

Please see full Important Safety Information.

YUPELRI delivers consistent control* over 12 weeks

Consistent improvements† in trough FEV_1 over the 12-week study period[1,26]



Pooled data from Studies 1 and 2. Primary efficacy endpoint: change from baseline in trough (predose) FEV_1 at day 85 vs placebo.

*In Study 1, LS mean change from baseline in trough FEV_1 on day 85 was 127 mL (YUPELRI, n=189) and -19 mL (placebo, n=191), with a statistically significant difference vs placebo of 146 mL (P<.0001). In Study 2, LS mean change from baseline in trough FEV_1 on day 85 was 102 mL (YUPELRI, n=181) and -45 mL (placebo, n=187), with a statistically significant difference of 147 mL (P<.0001).[26]

†The first measurement was taken at 2 weeks.

‡LS mean difference from placebo (SE) is 148.13 (16.782), pooled estimate adjusts the LS mean for placebo as well.[26]

Studies 1 and 2 patient characteristics[1]

- Mean age 64 years (range, 41-88 years)
- Mean smoking history of 53 pack-years; 48% current smokers
- Moderate to very severe COPD (mean post-bronchodilator % predicted FEV_1 of 55%)
- 37% were on concomitant LABA or ICS/LABA therapy
  - The clinical relevance of combining YUPELRI with a LABA or ICS/LABA is unknown

Important Safety Information

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 full Important Safety Information.

Health-related quality of life (HRQoL) with once-daily YUPELRI

- The St. George's Respiratory Questionnaire (SGRQ) is a validated, patient-reported, disease-specific instrument designed to measure impact on 3 main components, which comprise a total score[1,27]
- A change of 4 units' improvement in the SGRQ is considered a minimum clinically important difference[27]

- In Study 1, the SGRQ responder rate for the YUPELRI treatment arm on day 85 was 49% compared to 34% for placebo (odds ratio=2.11; 95% CI, 1.14-3.92)[1]*
- In Study 2, the SGRQ responder rate for the YUPELRI treatment arm was 45% compared to 39% for placebo (odds ratio=1.31; 95% CI, 0.72-2.38)[1]
- The clinical relevance of this data is unknown

*The SGRQ responder rate was defined as an improvement in score of 4 or more as threshold.

Important Safety Information

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.

Please see full Important Safety Information.

The safety profile of YUPELRI has been demonstrated in 3 clinical studies

- Safety database included 2,285 patients with COPD in two 12-week efficacy studies and one 52-week long-term safety study[1]*
- A total of 730 patients received YUPELRI 175 mcg once daily[1]

Adverse events from two 12-week placebo-controlled efficacy trials (N=813)

Adverse events ≥2% incidence and higher than placebo[1]

ADVERSE EVENT	YUPELRI (n=395)	Placebo (n=418)
Cough	17 (4%)	17 (4%)
Nasopharyngitis	15 (4%)	9 (2%)
Upper respiratory tract infection	11 (3%)	9 (2%)
Headache	16 (4%)	11 (3%)
Back pain	9 (2%)	3 (1%)

Fewer patients discontinued treatment with YUPELRI (13%) than with placebo (19%)[1]

Safety results from a 52-week, long-term trial vs tiotropium (N=1,055)[1]

- YUPELRI was studied in a 52-week open-label active control safety study in patients with COPD (YUPELRI 175 mcg QD, n=335; tiotropium 18 mcg QD, n=356)
- The adverse reactions reported in the long-term safety trial were consistent with those observed in the 12-week placebo-controlled studies

*Included patients who received an investigational 88 mcg/day dose of YUPELRI.

Important Safety Information

Indication

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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: The only LAMA you can use with any standard jet nebulizer

Administered in approximately 8 minutes once daily,* to conveniently fit in your patients' day[1]

- Recommended dose of YUPELRI is one 175 mcg unit-dose vial **once daily**
  - Administered by a standard jet nebulizer using a mouthpiece
  - Connected to an air compressor
- No dosage adjustment is required for geriatric patients, or patients with renal impairment
- YUPELRI is not recommended in patients with any degree of hepatic impairment
- Drug compatibility (physical and chemical), efficacy, and safety of YUPELRI when mixed with other drugs in a nebulizer have not been established
- No refrigeration needed
  - Store at room temperature from 68°F to 77°F (20°C to 25°C); excursions permitted from 59°F to 86°F (15°C to 30°C)

Single-use vials
- Unlike MDIs, SMIs, or DPIs, avoids wasted medication: 1 vial per day of stay[28]

Not actual size.

*Using the PARI LC® Sprint nebulizer connected to a PARI Trek® S.

Important Safety Information

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Please see full Important Safety Information.

YUPELRI® revefenacin inhalation solution

Comprehensive coverage for your YUPELRI patients

For Your Patients With Medicare*

YUPELRI is covered for up to 100% of patients with Medicare Part B.

- For patients with supplemental insurance (over 80% of beneficiaries), coinsurance costs can be as low as $0
- Medicare Part B covers most nebulizers as durable medical equipment (DME) for patient use at home[25]*

J-CODE J7677

For Your Patients With Commercial Coverage

YUPELRI may be covered under individual insurance plans.

- Commercially insured patients may be eligible to save on their out-of-pocket costs with the YUPELRI Patient Savings Card†

Not an actual card.

- Eligible, commercially insured patients can save up to $550 per 30-day prescription up to 12 times per calendar year, with a max yearly savings of $6,600

For Your Patients Who Are Uninsured

They may qualify for the Mylan Patient Assistance Program.‡

- For more information, please direct patients to email or call:

customer.service@mylan.com

1-800-796-9526

Learn more at YUPELRIHCP.com

*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 full terms and conditions at YUPELRIHCP.com. This offer is not valid for patients covered through Medicare, Medicaid, or any other federal or state-funded healthcare program or where prohibited by law. Mylan Specialty L.P. reserves the right to amend or end this program at any time without notice.

‡Patients must meet financial and other program-specific criteria to be eligible for assistance.

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

A LAMA THAT CAN TRANSITION FROM INPATIENT TO OUTPATIENT CARE

Proven 24-hour control[1]

Responses as early as 30 minutes[26]

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

J-CODE J7677

Demonstrated safety profile[1]

Fewer discontinuations with YUPELRI (13%) vs placebo (19%)

Once-daily dosing[1]

Administered with any standard jet nebulizer with a mouthpiece

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Please see full Important Safety Information.

YUPELRI® revefenacin inhalation solution

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