

# DTB CME/CPD Answers



Drug and Therapeutics Bulletin

## ▼ Umeclidinium: another LAMA for COPD

### Question 1

For patients with stable chronic obstructive pulmonary disease (COPD) who remain breathless, or have exacerbations despite the use of short-acting bronchodilators as required and have forced expired volume in 1 second (FEV<sub>1</sub>) <50% predicted, which one of the following is recommended by the National Institute for Health and Care Excellence (NICE) as maintenance drug therapy?

- Monotherapy with a long-acting muscarinic antagonist (LAMA)
- Monotherapy with a long-acting beta<sub>2</sub> agonist (LABA)
- Monotherapy with an inhaled corticosteroid (ICS)
- LAMA and short-acting muscarinic antagonist
- LAMA and ICS

Answer: a. In people with stable COPD who remain breathless, or have exacerbations despite use of short-acting bronchodilators as required, NICE advises offering the following as maintenance treatment:

- if FEV<sub>1</sub> <50% predicted: a LABA with an ICS in a combination inhaler (or LABA and LAMA if ICS not tolerated or declined), or a LAMA.
- offer LAMA in addition to LABA+ICS to people who remain breathless or have exacerbations despite taking LABA+ICS, irrespective of their FEV<sub>1</sub>.
- consider LABA+ICS in addition to LAMA for people who remain breathless or have exacerbations despite taking LAMA, irrespective of their FEV<sub>1</sub>.

### Question 2

What is the 'delivered' dose of umeclidinium licensed for use in the UK?

- 55µg
- 62.5µg
- 110µg
- 125µg
- 150µg

Answer: a. The recommended dose for adults is one inhalation of umeclidinium once daily. Each single inhalation provides a delivered dose (the dose leaving the mouthpiece of the inhaler) of 55µg of umeclidinium (equivalent to 65µg of umeclidinium bromide), which corresponds to a pre-dispensed dose of 62.5µg.

### Question 3

Two key studies provide evidence of umeclidinium's efficacy. Approximately what proportion of patients in the studies had airflow obstruction <50% FEV<sub>1</sub> predicted?

- 15%
- 25%
- 35%
- 55%
- 75%

Answer: d. Over half the participants (55%) had airflow obstruction <50% FEV<sub>1</sub> predicted.

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### Question 4

In the two key studies what were the respective mean changes from baseline in trough FEV<sub>1</sub> for the dose of umeclidinium licensed in the UK compared with placebo?

- a. 76mL and 155mL
- b. 127mL and 115mL
- c. 52mL and 202mL
- d. 180mL and 143mL
- e. 202mL and 155mL

Answer: b. A double-blind placebo-controlled parallel-group study randomised 206 patients with a clinical history of COPD to umeclidinium 62.5µg once daily, umeclidinium 125µg once daily or placebo for a total of 12 weeks. There was a statistically and clinically significant improvement in the least squares mean change from baseline in trough FEV<sub>1</sub> for umeclidinium 62.5µg compared with placebo (127mL, 95% CI 52 to 202, p<0.001). In a second double-blind parallel group placebo controlled trial, 1,532 patients with COPD were randomised to receive either umeclidinium 62.5µg, umeclidinium 62.5µg and vilanterol 25µg combined in the same inhaler, vilanterol 25µg alone or placebo for a total of 24 weeks. All active treatments were found to have statistically significant improvements from baseline in trough FEV<sub>1</sub> when compared with placebo, including a clinically significant least-squares mean difference of 115mL for umeclidinium 62.5µg (95% CI 76 to 155, p<0.001).

### Question 5

Which one of the following statements regarding umeclidinium is correct?

- a. The inhaler device does not include a dose counter
- b. The inhaler device is dark green with a yellow mouthpiece cover
- c. Umeclidinium should be used with caution in patients with severe cardiovascular disorders
- d. Dose adjustment is required in patients over 65 years, those with renal impairment and those with hepatic impairment.
- e. If a dose is missed patients should be advised to take an additional dose the following day

Answer: c. The Summary of Product Characteristics advises that umeclidinium bromide should be used with caution in patients with severe cardiovascular disorders, particularly cardiac arrhythmias.