



Effective Health Care

Roflumilast versus Theophylline for COPD

Next Steps

The nominator is interested in a new systematic review on the comparison of roflumilast with theophylline in treatment of Chronic Obstructive Pulmonary Disease (COPD).

Due to limited program resources AHRQ will not further assess this topic at this time. However we identified 2 reviews that may be useful to the nominator. No further activity on this topic will be undertaken by the Effective Health Care (EHC) Program.

Topic Summary and Considerations

Topic Name and number: Roflumilast versus Theophylline for COPD, #674

Date: 7/31/2017

Key question from the nomination:

What is the comparative effectiveness of roflumilast compared to theophylline for the treatment of COPD?

- Chronic Obstructive Pulmonary Disease (COPD) is a chronic lung condition with progressive obstruction of airflow in or out of the lungs. Causes of COPD include cigarette smoking, exposure to cigarette smoke, air pollution, genetic conditions and certain infectious diseases.
- According to the Centers for Disease Control and Prevention, the prevalence of Chronic Obstructive Pulmonary Disease (COPD) varies from <4% in the Washington and Minnesota, to over 9% in Alabama and Kentucky [1].
- Death rates for COPD among men are 47.6 per 100,000; and in women are 46.4 per 100,000 [1].
- Treatment of COPD includes smoking cessation, medications, and physiotherapy. These are aimed at reducing risk factors, treating exacerbations or flare-ups, and maintaining function and avoiding exacerbations. Typically medications include a combination of medications including bronchodilators and inhaled corticosteroids. For more severe COPD, additional medications may be used, such as theophylline and roflumilast.
- Theophylline, a non-selective phosphodiesterase inhibitor, is an older medication that has significant side effects including headache, nausea and vomiting, restlessness and arrhythmias. Roflumilast, a phosphodiesterase-4 inhibitor, was approved by the FDA in 2011. Side effects include weight loss, nausea abdominal pain, and headache. Safety data submitted to the FDA have raised concerns about psychiatric adverse events related to suicidality [2].
- The nominator is interested in a review comparing roflumilast with theophylline citing concerns about its increased adoption despite side effects and cost.
- While we are unable to further assess this topic at this time due to program resources, these references may be useful to the nominator:
 - Chong J, Leung B, Poole P. Phosphodiesterase 4 inhibitors for chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2013, Issue 11. Art. No.: CD002309. DOI: 10.1002/14651858.CD002309.pub4.

- Oba Y, Lone NA. Efficacy and safety of roflumilast in patients with chronic obstructive pulmonary disease: a systematic review and meta-analysis. *Ther Adv Respir Dis* 2013;7:13–24.

References

1. *Chronic Obstructive Pulmonary Disease (COPD): Data and Statistics*. 2014, Centers for Disease Control and Prevention: Atlanta, GA.
2. *HIGHLIGHTS OF PRESCRIBING INFORMATION: DALIRESP® (roflumilast) tablets*. 2013, Food and Drug Administration: Rockville, MD.