



## Spiriva<sup>®</sup> Respimat<sup>®</sup> (tiotropium bromide) – Expanded Indication

- On February 16, 2017, [Boehringer Ingelheim announced](#) the FDA approval of [Spiriva Respimat \(tiotropium bromide\)](#) for the long-term, once-daily, maintenance treatment of asthma in patients 6 years of age and older.
  - Previously, Spiriva Respimat was approved for this use in patients 12 years of age and older.
  - Spiriva Respimat is not indicated for relief of acute bronchospasm.
- Spiriva Respimat is also approved for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations.
- Efficacy for the expanded indication of Spiriva Respimat was established based on the partial extrapolation of efficacy in adults and two trials (12 and 48 weeks duration) of 801 asthma patients 6 - 11 years of age. The primary efficacy endpoint in both trials was change from pre-treatment baseline in peak forced expiratory volume in 1 second (FEV<sub>1, 0-3hr</sub>).
  - There was a statistically significant increase from baseline in FEV<sub>1, 0-3hr</sub> in patients taking Spiriva Respimat vs. placebo in the 48-week study (mean difference = 0.17 L; [95% CI: 0.11, 0.23]).
  - The 12-week trial did not show a significant increase from baseline in FEV<sub>1, 0-3hr</sub> in patients taking Spiriva Respimat vs. placebo (mean difference = 0.04 L; [95% CI: -0.03, 0.10]).
- The most common adverse events (> 2%) with Spiriva Respimat use in adult asthma patients were pharyngitis, headache, bronchitis, and sinusitis.
- The most common adverse events (> 3%) with Spiriva Respimat use in COPD patients were pharyngitis, cough, dry mouth, and sinusitis.
- The recommended dose of Spiriva Respimat for the treatment of asthma in patients aged 6 years and older is 2 inhalations of Spiriva Respimat 1.25 mcg once daily.
- The recommended dose of Spiriva Respimat for the treatment of COPD is 2 inhalations of Spiriva Respimat 2.5 mcg once daily.



OptumRx<sup>®</sup> specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum<sup>®</sup> company — a leading provider of integrated health services. Learn more at [optum.com](http://optum.com).

All Optum<sup>®</sup> trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews<sup>®</sup> is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.