

Updated Criteria for Long-Acting Bronchodilators & Combination Inhalation Therapy in Chronic Obstructive Pulmonary Disease (COPD)

The Atlantic Common Drug Review (ACDR) has recently completed a review of the evidence for long-acting bronchodilators (tiotropium, long-acting beta₂ agonists) in the treatment of chronic obstructive disease (COPD). Special Authorization criteria are being updated based on evidence published in the past year.

Changes to the Special Authorization criteria are relevant for patients with moderate to very severe COPD, reflecting to the populations studied in recent trials.

Updated Criteria for Long-Acting Bronchodilators in COPD Effective November 1, 2008

Tiotropium Bromide (Spiriva)

Long-Acting Beta2 Agonists (Foradil, Oxeze, Serevent)

Long-Acting Beta2 Agonists/Inhaled Corticosteroid (Advair, Symbicort)

- For the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persists after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at maximum dose of 8 puffs/day or ipatropium at maximum dose of 12 puffs/day).
- Coverage can be approved without a trial of a short-acting agent if:
 - There is spirometric evidence of at least moderate to severe airflow obstruction, i.e. $FEV_1 < 60\%$ AND FEV_1/FVC ratio < 0.7 , and significant symptoms i.e. MRC score 3-5.*
- Combination therapy with tiotropium and a long-acting beta₂ agonist/corticosteroid (i.e. Spiriva plus Advair or Symbicort) will only be considered if:
 - There is spirometric evidence of a least moderate to severe airflow obstruction ($FEV_1 < 60\%$ AND FEV_1/FVC ratio < 0.7), and significant symptoms i.e., MRC score of 3-5. *

AND

- There is evidence of one or more moderate to severe exacerbations per year on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

NOTE:

- Coverage of combination therapy with tiotropium and a long-acting beta₂ agonist (without an inhaled corticosteroid) will not be considered due to insufficient evidence to support substantial benefit.
- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale).

*See Canadian Thoracic Society COPD Classification by symptom/disability for full details

*Canadian Thoracic Society COPD Classification by symptom/disability:

Moderate - (MRC 3-4) shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after walking a few minutes) on the level.

Severe - (MRC 5) shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

MRC = Medical Research Council Dyspnea Scale.

Below is a summary of the changes:

- Patients with spirometric evidence of moderate to severe airflow obstruction will be eligible for coverage of **one** long-acting bronchodilator (e.g. tiotropium, salmeterol, or formoterol) **without** a trial of maximum doses of a short-acting bronchodilator.
- Patients with spirometric evidence of moderate to severe airflow obstruction and with more frequent exacerbations* will be eligible for coverage of **both** tiotropium and a long-acting beta₂ agonist (LABA)/inhaled corticosteroid combination.

Below is a summary of what will remain the same:

- Coverage for long-acting bronchodilators (e.g. tiotropium, salmeterol, formoterol) using a step-wise approach following initial therapy with maximum doses of short-acting bronchodilators remains the same.
- Short-acting bronchodilators (beta₂ agonists and anticholinergics) alone or in combination remain open benefit. Please note that in accordance with the tiotropium (Spiriva) monograph, combination therapy of tiotropium with other anticholinergic containing drugs (e.g. ipatropium) has not been studied and therefore not recommended.

Comparison of Costs for Selected Inhaled Drugs for COPD (cost/month)

