Reference number(s)
139-H

Quantity Limit Criteria Anticholinergic, Combination, and Mast Cell Stabilizer Oral Inhalation

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Atrovent HFA	ipratropium
Combivent Respimat	ipratropium/albuterol
cromolyn sodium (brand unavailable)	cromolyn sodium inhalation solution
Incruse Ellipta	umeclidinium
ipratropium bromide (brand unavailable)	ipratropium bromide inhalation solution
ipratropium bromide/albuterol sulfate (brand unavailable)	ipratropium bromide/albuterol sulfate inhalation solution
Lonhala Magnair	glycopyrrolate inhalation solution
Spiriva Handihaler	tiotropium
Spiriva Respimat	tiotropium
Tudorza Pressair	aclidinium
Yupelri	revefenacin inhalation solution

Indications

FDA-approved Indications

Atrovent HFA

Atrovent HFA Inhalation Aerosol is indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Combivent Respimat

Combivent Respimat is a combination of ipratropium bromide (an anticholinergic agent) and albuterol sulfate (a beta2-adrenergic agonist) indicated for use in patients with chronic obstructive pulmonary disease (COPD) on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator.

Cromolyn Sodium Inhalation Solution

Cromolyn sodium inhalation solution USP is a prophylactic agent indicated in the management of patients with bronchial asthma. In patients whose symptoms are sufficiently frequent to require a continuous program of medication, cromolyn sodium inhalation solution USP is given by inhalation on a regular daily basis. The effect of cromolyn sodium is usually evident after several weeks of treatment, although some patients show an almost immediate response. In patients who develop acute bronchoconstriction in response to exposure to exercise, toluene diisocyanate, environmental pollutants, etc., cromolyn sodium should be given shortly before exposure to the precipitating factor.

Incruse Ellipta

Incruse Ellipta is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Ipratropium Bromide Inhalation Solution

Ipratropium Bromide Inhalation Solution administered either alone or with other bronchodilators, especially beta adrenergics, is indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

Ipratropium Bromide / Albuterol Sulfate Inhalation Solution

Ipratropium bromide and albuterol sulfate inhalation solution is indicated for the treatment of bronchospasm associated with COPD in patients requiring more than one bronchodilator.

Lonhala Magnair

Lonhala Magnair is indicated for the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Spiriva HandiHaler

Spiriva HandiHaler (tiotropium bromide inhalation powder) is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Spiriva HandiHaler is indicated to reduce exacerbations in COPD patients.

Spiriva Respimat

Maintenance Treatment of Chronic Obstructive Pulmonary Disease

Spiriva Respimat (tiotropium bromide) is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Spiriva Respimat is indicated to reduce exacerbations in COPD patients.

Important Limitation of Use

Spiriva Respimat is NOT indicated for the relief of acute bronchospasm.

Maintenance Treatment of Asthma

Spiriva Respimat is a bronchodilator indicated for the long-term, once-daily, maintenance treatment of asthma in patients 6 years of age and older.

Important Limitation of Use

Spiriva Respimat is NOT indicated for the relief of acute bronchospasm.

Tudorza Pressair

Tudorza Pressair (aclidinium bromide inhalation powder) is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Yupelri

Yupelri is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Inital Limit Quantity

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Medication	Maintenance Dose	Maximum Daily Dose	Package Size	1 Month Limit 3 Month Limit
Atrovent HFA (ipratropium)	2 inhalations four times daily	12 inhalations	200 inhalations per 12.9 gm canister	2 packages (12.9 gm each) / 25 days 6 packages (12.9 gm each) / 75 days
Combivent Respimat (ipratropium / albuterol)	1 inhalation four times daily	6 inhalations	120 inhalations per 4 gm cartridge	2 packages (4 gm each) / 25 days 6 packages (4 gm each) / 75 days

Medication	Maintenance Dose	Maximum Daily Dose	Package Size	1 Month Limit 3 Month Limit
Cromolyn sodium inhalation solution	nebulization of 1 vial (2 mL) four times daily	4 vials (2 mL each)	60 vials (2 mL each) per carton	2 packages (120 vials x 2 mL) / 25 days 6 packages (360 vials x 2 mL) / 75 days
Incruse Ellipta (umeclidinium)	1 inhalation once daily	1 inhalation	30 blisters per inhaler	1 package (30 blisters) / 25 days 3 packages (90 blisters) / 75 days
Ipratropium bromide inhalation solution, 0.02%	nebulization of 1 vial (2.5 mL) three to four times daily	4 vials (2.5 mL each)	25 vials (2.5 mL each) per carton	5 packages (125 vials x 2.5 mL) / 25 days 15 packages (375 vials x 2.5 mL) / 75 days
Ipratropium bromide inhalation solution, 0.02%	nebulization of 1 vial (2.5 mL) three to four times daily	4 vials (2.5 mL each)	30 vials (2.5 mL each) per carton	4 packages (120 vials x 2.5 mL) / 25 days 12 packages (360 vials x 2.5 mL) / 75 days
Ipratropium bromide inhalation solution, 0.02%	nebulization of 1 vial (2.5 mL) three to four times daily	4 vials (2.5 mL each)	60 vials (2.5 mL each) per carton	2 packages (120 vials x 2.5 mL) / 25 days 6 packages (360 vials x 2.5 mL) / 75 days
Ipratropium bromide / albuterol sulfate inhalation solution	nebulization of 1 vial (3 mL) four times daily	6 vials (3 mL each)	30 vials (3 mL each) per carton	6 packages (180 vials x 3 mL) / 25 days 18 packages (540 vials x 3 mL) / 75 days
Ipratropium bromide / albuterol sulfate inhalation solution	nebulization of 1 vial (3 mL) four times daily	6 vials (3 mL each)	60 vials (3mL each) per carton	3 packages (180 vials x 3mL) / 25 days 9 packages (540 vials x 3mL) / 75 days
Lonhala Magnair Starter Kit and Refill Kit (glycopyrrolate)	1 inhalation twice daily	2 inhalations	60 vials (1 mL each) (2 vials in each pouch, 30 pouches) per kit	1 package (60 vials x 1 mL) / 25 days 3 packages (180 vials x 1 mL) / 75 days
Spiriva HandiHaler (tiotropium)	2 inhalations of the powder contents of 1 capsule once daily	1 capsule	30 capsules per carton	1 package (30 capsules) / 25 days 3 packages (90 capsules) / 75 days

Medication	Maintenance Dose	Maximum Daily Dose	Package Size	1 Month Limit 3 Month Limit
Spiriva HandiHaler (tiotropium)	2 inhalations of the powder contents of 1 capsule once daily	1 capsule	90 capsules per carton	1 package (90 capsules) / 75 days
Spiriva Respimat (tiotropium)	2 inhalations once daily	2 inhalations	60 inhalations per 4 gm cartridge	1 package (4 gm) / 25 days 3 packages (4 gm each) / 75 days
Tudorza Pressair (aclidinium)	1 inhalation twice daily	2 inhalations	30 inhalations per inhaler	2 packages / 25 days 6 packages / 75 days
Tudorza Pressair (aclidinium)	1 inhalation twice daily	2 inhalations	60 inhalations per inhaler	1 package / 25 days 3 packages / 75 days
Yupelri (revefenacin)	nebulization of 1 vial (3 mL) once daily	1 vial (3 mL each)	30 vials (3 mL each) per carton	1 package (30 vials x 3 mL) / 25 days 3 packages (90 vials x 3 mL) / 75 days

References

1. Atrovent HFA [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2023.
2. Combivent Respimat [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; December 2021.
3. Cromolyn Sodium Inhalation Solution [package insert]. Columbia, SC: Ritedose Pharmaceuticals, LLC; June 2024.
4. Incruse Ellipta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2023.
5. Ipratropium Bromide [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; September 2022.
6. Ipratropium Bromide and Albuterol Sulfate [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; August 2022.
7. Lonhala Magnair [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; August 2020.
8. Spiriva Handihaler [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; November 2021.
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10. Tudorza Pressair [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
11. Yupelri [package insert]. Morgantown, WV: Mylan Specialty L.P.; May 2022.

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