

Initial Prior Authorization

Daliresp

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
Daliresp	roflumilast

Indications

FDA-approved Indications

Daliresp is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

Limitations of Use

Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

Coverage Criteria

Chronic Obstructive Pulmonary Disease (COPD)

Authorization may be granted when the requested drug is being prescribed to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in a patient with severe COPD associated with

Reference number(s)
646-A

chronic bronchitis and a history of exacerbations.

Duration of Approval (DOA)

- 646-A: DOA: 12 months

References

1. Daliresp [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed July 31, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 07/31/2024).