Reference number(s)
646-A

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

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).

Document History

Written by: UM Development (RP)

Date Written: 04/2011

Revised: (RP) 06/2011 (revised question #2, added question #3), 02/2012; 10/2012 (extended duration); (RP) 02/2013, (TM) 11/2013; (RP) 11/2014, 11/2015 (no clinical changes), 11/2016, 11/2017 (no clinical changes); (KC) 11/2018 (no clinical changes), 04/2019 (changed DOA to 12 months); (RP) 03/2020 (no clinical changes); (TM) 11/2020 (no clinical changes); (PM) 10/2021 (no clinical changes); (KMB) 10/2022 (no clinical changes); (MRS) 09/2023 (no clinical changes); (NSS) 08/2024 (no clinical changes)

Reviewed: Medical Affairs (KP) 04/2011, 06/2011, 02/2012, 10/2012; (LS) 02/2013, (DC) 11/2013; (LMS) 11/2014; (ME) 11/2016; (GAD) 04/2019; (CHART) 03/26/2020, 12/03/2020, 10/14/2021, 09/22/2022, 9/28/2023, 08/29/2024

External Review: 06/2011, 06/2012, 06/2013, 04/2014, 02/2015, 02/2016, 02/2017, 02/2018, 02/2019, 06/2019, 06/2020, 02/2021, 02/2022, 02/2024, 12/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in a patient with severe COPD associated with chronic bronchitis and a history of exacerbations? [No further questions]	Yes	No

Reference number(s)
646-A

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Approve, 12 Months	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for severe Chronic Obstructive Pulmonary Disease (COPD). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]