JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS072
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		Review Date	03/01/2014
	Subject **Daliresp, generic roflumilast**	*Revision Date*	01/25/2023
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: daliresp

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I. POLICY

A. Daliresp and generic roflumilast will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Roflumilast may be approved for patients meeting ALL of the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing the patient has been diagnosed with severe COPD with chronic bronchitis
   3. Patient has had at least 2 exacerbations in the last 6 months
      a. exacerbations have been reflected through paid claims for oral corticosteroids or progress notes
   4. Documentation has been submitted supporting that the patient is using a concurrent regimen consisting of a long-acting bronchodilator (either anticholinergic or beta agonist)
      a. current long-acting bronchodilator use is evidenced by a minimum of five paid claims for a bronchodilator within the last 6 months

B. Requirements for Brand **Daliresp**:
   1. Patient has met the criteria for coverage of the generic roflumilast (noted above)
   2. Documentation has been submitted showing trial and inadequate response to generic roflumilast

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 12 months of therapy.

B. Approval for continuation of therapy can be extended in 12-month intervals with clinical documentation supporting the patient's symptom improvement with treatment.

C. Limitation: Dosage is limited to a maximum of 500mcg daily

IV. EXCLUSIONS

A. Daliresp will NOT be approved for patients with the following:
   1. Moderate to severe liver impairment
   2. Relief acute bronchospasm
   3. Any indications or uses that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Daliresp [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2020.
2. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: 2022 Report. Global Initiative for Chronic Obstructive Lung Disease, Inc. Available at http://www.goldcopd.com (Accessed on 12/02/2021).

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
03/30/2016	Updated clinical references and related policy phrasing, removed background information
07/27/2017	Updated Exclusions section regarding physician samples
07/01/2018	Removed EHP Line of Business
12/02/2021	Updated references
01/25/2023	Clarified criteria for generic and brand formulations

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