Clinical Policy: Antifibrotic Respiratory Agents

Reference Number: PHW.PDL.557
Effective Date: 01/01/2020
Last Review Date: 11/2023

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Antifibrotic Respiratory Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Antifibrotic Respiratory Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Antifibrotic Respiratory Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antifibrotic Respiratory Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antifibrotic Respiratory Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**

6. If a current smoker, has documentation of being advised by the prescriber to stop smoking; **AND**

7. For a non-preferred Antifibrotic Respiratory Agent, **one** of the following:

a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Antifibrotic Respiratory Agents approved or medically accepted for the beneficiary's indication,
b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antifibrotic Respiratory Agent,

See the Preferred Drug List (PDL) for the list of preferred Antifibrotic Respiratory Agents at: https://papdl.com/preferred-drug-list;

AND

8. If a prescription for an Antifibrotic Respiratory Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN ANTIFIBROTIC RESPIRATORY AGENT: The determination of medical necessity of a request for renewal of a prior authorization for an Antifibrotic Respiratory Agent will take into account whether the beneficiary:

1. Based on the prescriber's assessment, is benefitting from the requested medication; **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Does not have a contraindication to the prescribed medication; **AND**

4. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**

5. If a prescription for an Antifibrotic Respiratory Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-

Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antifibrotic Respiratory Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of IPF Agents will be approved for up to 6 months.

E. References

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2. Distler O, Brown KK, Distler JHW, et al. Design of a randomised, placebo-controlled clinical trial of nintedanib in patients with systemic sclerosis-associated interstitial lung disease (SENSCIS™). Clinical and Experimental Rheumatology. 2017 Sep-Oct;35 Suppl 106(4):75-81.
3. Distler O., Highland, KB, Gahlemann M, et.al. (2019). Nintedanib for Systemic Sclerosis–Associated Interstitial Lung Disease. New England Journal of Medicine, *380(26), 2518–2528.* DOI:10.1056/nejmoa1903076
4. Esbriet Package Insert. South San Francisco, CA: Genentech, Inc.; July 2019.
5. Fernández-Codina A, Walker KM, Pope JE. and (2018), Treatment Algorithms for Systemic Sclerosis According to Experts. Arthritis Rheumatol, 70: 1820-1828. doi:10.1002/art.40560
6. Flaherty KR, Wells AU, Cottin V, et al. Nintedanib in Progressive Fibrosing Interstitial Lung Diseases. New England Journal of Medicine, 381:1718-27. DOI: 10.1056/NEJMoa1908681
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10. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guideline for diagnosis and management. American Journal of Respiratory Critical Care Medicine 2011; 183:788.
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12. Varga J. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Waltham, MA: UpToDate Inc. Updated February 7, 2019. Accessed July 23, 2020.
13. Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma). Waltham, MA: UpToDate Inc. Updated October 8, 2019. Accessed July 23, 2020.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021	11/2020
Q1 2023: policy revised according to DHS revisions effective 01/09/2023	10/2022
Q1 2024: policy revised according to DHS revisions effective 01/08/2024	11/2023