JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS090
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Esbriet, Ofev

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I. POLICY

A. Ofev (nintedanib) & Esbriet (pirfenidone) require prior authorization to ensure this medication is used only when clinically appropriate. All other necessary procedures for initiation of prior authorization review 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. **Ofev** may be approved for the following
   1. Idiopathic pulmonary fibrosis (IPF)
      1. Patient is 18 years of age or older
      2. Documentation has been submitted showing ALL the following:
         1. IPF diagnosis has been confirmed by both of the following:
            1. Exclusion of other known causes of interstitial lung disease, such as domestic and occupational environmental exposures, connective tissue disease, drug toxicity, etc.
            2. High Resolution Computerized Tomography (HRCT) pattern, and surgical lung biopsy(if available) findings consistent with a diagnosis of IPF
      3. Documentation has been submitted showing ALL the following:
         1. Baseline liver function tests(LFT) within normal limits
         2. Baseline Forced Vital Capacity (FVC) greater than or equal to 50% of predicted
         3. Baseline carbon monoxide diffusing capacity (DLCO) 30% to 79% of predicted.
         4. Patient has a low risk of any cardiovascular events
         5. If patient is female and of childbearing age:
            1. Verification of non-pregnant status prior to treatment initiation
            2. Documentation that the patient will utilize two forms of birth control during treatment, and up to 3 months post-treatment

4. Prescriber is, or has consulted with, a pulmonologist

2. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
    1. Patient is 18 years of age or older
    2. Documentation has been submitted showing ALL the following:
        1. A clinical diagnosis of chronic fibrosing ILD with evidence of the following:
            1. HRCT confirmation of fibrosis (greater than 10% fibrotic features)
            2. Signs of disease progression since diagnosis, defined as at least one of the following:
                1. FVC decline greater than or equal to 10%
                2. FVC decline less than 10% but greater thant or equal to 5% with worsening symptoms or imaging
                3. Worsening symptoms and worsening imaging
    3. Documentation has been submitted showing ALL the following:
        1. Baseline liver function tests(LFT) within normal limits
        2. Baseline Forced Vital Capacity (FVC) greater than or equal to 45% of predicted
        3. Baseline carbon monoxide diffusing capacity (DLCO) 30% to 79% of predicted.
        4. Patient has a low risk of any cardiovascular events
        5. If patient is female and of childbearing age:
            1. Verification of non-pregnant status prior to treatment initiation
            2. Documentation that the patient will utilize two forms of birth control during treatment, and up to 3 months post-treatment
    4. Prescriber is, or has consulted with, a pulmonologist
3. Systemic sclerosis-associated interstitial lung disease(SSc-ILD)
    1. Patient is 18 years of age or older
    2. Documentation has been submitted showing ALL the following:
        1. SSc-ILD diagnosis has been confirmed by the following:
            1. HRCT confirmation of greater than or equal to 10% fibrosis
            2. Clinical manifestations of disease, such as skin thickening of the fingers of both hands, finger tip lesions, abnormal nail-fold capillaries, pulmonary arterial hypertension, Raynaud's phenomenon, or the presence of scleroderma-specific antibodies
    3. Documentation has been submitted showing ALL the following:
        1. Baseline liver function tests(LFT) within normal limits
        2. Baseline Forced Vital Capacity (FVC) greater than or equal to 40% of predicted
        3. Baseline carbon monoxide diffusing capacity (DLCO) 30% to 89% of predicted.
        4. Patient has a low risk of any cardiovascular events
        5. If patient is female and of childbearing age:
            1. Verification of non-pregnant status prior to treatment initiation
            2. Documentation that the patient will utilize two forms of birth control during treatment, and up to 3 months post-treatment
    4. Prescriber is, or has consulted with, a pulmonologist or rheumatologist

B. **Esbriet** may be approved for the following:
    1. Patient is 18 years of age or older
    2. Documentation showing a diagnosis of IPF, confirmed by the following:
        1. Exclusion of other known causes of interstitial lung disease, such as domestic and occupational environmental exposures, connective tissue disease, drug toxicity, etc.

2. High Resolution Computerized Tomography (HRCT) pattern, and surgical lung biopsy(if available) findings consistent with a diagnosis of IPF

3. Documentation has been submitted showing ALL the following:
    1. Baseline liver function tests(LFT) within normal limits
    2. Baseline Forced Vital Capacity (FVC) greater than or equal to 50% of predicted
    3. Baseline carbon monoxide diffusing capacity (DLCO) greater than or equal to 30% of predicted.
    4. Patient has a low risk of any cardiovascular events
    5. If patient is female and of childbearing age:
        1. Verification of non-pregnant status prior to treatment initiation
        2. Documentation that the patient will utilize two forms of birth control during treatment, and up to 3 months post-treatment
4. Prescriber is, or has consulted with, a pulmonologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months.

B. Continuation of therapy may be extended in 12-month intervals with documentation showing the following:
    1. Reduction in the annual rate of decline in Forced Vital Capacity (FVC)
    2. Improvement of, or no worsening in, clinical symptoms

IV. EXCLUSIONS

A. Ofev and Esbriet will be approved for the following:
    1. Pediatric patients has the safety and effectiveness has not been established in this population.
    2. Patients who are current smokers
    3. Any indication or usage that is not FDA-approved, or guideline-supported

B. Additionally, Ofev will not be approved for the following:
    1. Patients with moderate or severe hepatic impairment
    2. Patients with history of previous MI, stroke, intracranial bleeding
    3. Patients with history of abdominal surgery
    4. Patients with history of pathological bleeding disorders

C. Additionally, Esbriet will not be approved for the following:
    1. Patients with severe hepatic impairment
    2. Patients with end-stage renal disease on dialysis

D. 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. Johns Hopkins HealthCare Pharmacy Policy PHARM20, Step Therapy, Prior Authorization and Quantity Limits.
2. Ofev [prescribing information].Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; January 2022.
3. Esbriet [prescribing information].Brisbane, CA: Intermune, Inc; February 2023.
4. Raghu G, Remy-Jardin M, Myers JL, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: Diagnosis of idiopathic pulmonary fibrosis. Am J Respir Crit Care Med. 2018;198(5):e44-e68
5. van den Hoogen F, Khanna D, Fransen J, et al. 2013 Classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism
collaborative initiative. Ann Rheum Dis 2013;72:1747-1755.

6. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for Systemic Sclerosis-Associated Interstitial Lung Disease. N Engl J Med. 2019 Jun 27;380(26):2518-2528.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
07/27/2017	Updated Exclusions section regarding physician samples
07/01/2018	Removed EHP Line of Business
07/15/2020	Updated criteria based on FDA-approved prescribing information for Ofev and Esbriet

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