PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Pulmonary – Antifibrotics PSM Policy
- Esbriet® (pirfenidone capsules and film-coated tablets – Genentech, generic)
- Jascayd® (nerandomilast tablets – Boehringer Ingelheim)
- Ofev® (nintedanib capsules – Boehringer Ingelheim)

REVIEW DATE: 01/28/2026; effective 02/13/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Jascayd, Ofev, and pirfenidone are all indicated for the treatment of idiopathic pulmonary fibrosis (IPF) in adults.[1-3] Jascayd has an additional indication for progressive pulmonary fibrosis (PPF) in adults.[1] Ofev has two additional indications: slowing the rate of decline in pulmonary function in adults with systemic sclerosis-associated interstitial lung disease (ILD) and treatment of chronic fibrosing ILDs with a progressive phenotype in adults.[2] Of note, the terms PPF and chronic fibrosing ILDs with a progressive phenotype are used interchangeably.[4]

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try one Preferred Product(s) prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year. If the patient meets the standard *Pulmonary – Antifibrotics – Jascayd Prior Authorization Policy* criteria, but has not tried a Preferred Product, a review will be offered for the Preferred Product using the respective standard *Prior Authorization Policy* criteria.

Preferred Products: Generic pirfenidone, Ofev
Non-Preferred Products: Jascayd

***Pulmonary – Antifibrotics Preferred Specialty Management Policy* non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.**

Non-Preferred Product	Exception Criteria
Jascayd	**1. Idiopathic Pulmonary Fibrosis**. Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Pulmonary – Antifibrotics – Jascayd Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i, ii, iii, or iv): **i.** Patient has tried generic pirfenidone or Ofev for 90 days; OR **ii.** According to the prescriber, patient has tried but could not complete a 90-day trial of pirfenidone or Ofev due to an intolerance; OR **iii.** According to the prescriber, patient cannot use pirfenidone or Ofev due to a clinical contraindication; OR Note: Examples of clinical contraindications include hepatic impairment, estimated glomerular filtration rate (eGFR) < 30mL/min, pregnancy, or being at high risk of coronary artery disease, bleeding events or gastrointestinal perforation. **iv.** Patient cannot swallow whole tablets or capsules or has difficulty swallowing tablets or capsules. **2. Progressive Pulmonary Fibrosis**. Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Pulmonary – Antifibrotics – Jascayd Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i, ii, iii, or iv): **i.** Patient has tried Ofev for 90 days; OR **ii.** According to the prescriber, patient has tried but could not complete a 90-day trial of Ofev due to an intolerance; OR **iii.** According to the prescriber, patient cannot use Ofev due to a clinical contraindication; OR Note: Examples of clinical contraindications include hepatic impairment, estimated glomerular filtration rate (eGFR) < 30mL/min, pregnancy, or being at high risk of coronary artery disease, bleeding events or gastrointestinal perforation. **iv.** Patient cannot swallow whole tablets or capsules or has difficulty swallowing tablets or capsules. **3.** If the patient has met the standard *Pulmonary – Antifibrotics – Jascayd Prior Authorization Policy* criteria (1A or 2A), but has not met exception criteria (1B) or (2B) above for Jascayd: offer to review for generic pirfenidone or Ofev using the standard *Pulmonary – Antifibrotics – Pirfenidone Prior Authorization* criteria or *Pulmonary – Antifibrotics – Ofev Prior Authorization* criteria. **4.** If the patient is continuing therapy with Jascayd, approve for 1 year if the standard *Pulmonary – Antifibrotics – Jascayd Prior Authorization* criteria are met.

REFERENCES

1. Jascayd® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; October 2025.
2. Esbriet® capsules and film-coated tablets [prescribing information]. South San Francisco, CA: Genentech; February 2023.
3. Ofev® capsules [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; May 2025.
4. Raghu G, Remy-Jardin M, Richeldi L, et al, on behalf of the ATS, ERS, JRS, and ALAT. Idiopathic pulmonary fibrosis (an update) and progressive pulmonary fibrosis in adults. An official ATS/ERS/JRS/ALAT clinical practice guideline. *Am J Respir Crit Care Med*. 2022;205(9):e18-e47.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 02/13/2026	01/28/2026