MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
12/31/2014	11/01/2016	11/17/2015

Policy Name	Policy Number
Idiopathic Pulmonary Fibrosis	**SRX-0026**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Idiopathic Pulmonary Fibrosis

- Esbriet (pirfenidone)
- OFEV (nintedanib)

B. BACKGROUND

Idiopathic pulmonary fibrosis is a condition resulting in progressive scarring of the lungs. This scarring causes irreversible tissue damage and is associated with a decline in oxygenation, cough, increasing shortness of breath, and a decline in physical functional capacity.

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the **Idiopathic Pulmonary Fibrosis (IPF)** (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A

D. POLICY

I. CareSource will approve the use of **Esbriet (pirfenidone), an oral antifibrotic agent** that reduces disease progression in IPF, and consider its use as medically necessary when **ALL** of the following criteria have been met:
   A. A diagnosis of mild to moderate idiopathic pulmonary fibrosis using high resolution computed tomography or lung biopsy
   B. Prescribed by or in consultation with a pulmonologist
   C. Aged 18 years or older
   D. Not a current smoker or are on smoking cessation treatment
   E. No signs of severe liver disease (Child Pugh Class C)
   F. Not in end-stage kidney disease or requiring hemodialysis
   G. Not used in combination with nintedanib

II. CareSource will approve the use of **OFEV (nintedanib), a mediator of fibrogenic growth factors** that slows the decline in lung function in IPF, and consider its use as medically necessary when **ALL** of the following criteria have been met:
   A. A diagnosis of mild to moderate idiopathic pulmonary fibrosis using high resolution computed tomography or lung biopsy
   B. Prescribed by or in consultation with a pulmonologist
   C. Aged 18 years or older
   D. Not a current smoker or are on smoking cessation treatment
   E. No signs of moderate to severe liver disease (Child Pugh Class B and C)
   F. Not pregnant, nor will become pregnant for at least 3 months after taking last dose
   G. Not used in combination with pirfenidone

All other uses of Esbriet and OFEV are considered experimental/investigational and therefore, will follow CareSource's Off-Label policy.

NOTE: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office or hospital admission notes.

Refer to the product package insert for dosing, administration and safety guidelines.

For Medicare Plan members, reference the Applicable National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Compliance with NCDs and LCDs is required where applicable.

CONDITIONS OF COVERAGE
Place of Service
Office, Outpatient, Home
****Preferred place of service is in the home.**
This medication can be self-administered and can be billed through the pharmacy benefit.
Note: CareSource supports administering inject able medications in various setting, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

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AUTHORIZATION PERIOD
Approved initial authorizations are valid for 3 (three) months. Continued treatment may be considered when the member has shown biological response to treatment. A reauthorization after successful initiation period will be placed for 1 (one) year. **ALL** authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

Date Issued:	12/31/2014
Date Reviewed:	12/31/2014
Date Revised:	05/04/2015 – Placed into new template.
	11/17/2015 – Revisions include adding age for adults only.

F. REFERENCES

1. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J Respir Crit Care Med*. 2011 Mar 15;183(6):788-824.
2. OFEV [package insert] Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc.; October 2014.
3. Esbriet [package insert] Brisbane, CA: Intermune Inc.; September 2015.
4. What is Idiopathic Pulmonary Fibrosis? (2011, January 1). Retrieved January 1, 2014, from http://www.nhlbi.nih.gov/health/health-topics/topics/ipf/
5. Hayes, Inc. 2015
6. King E. Talmadge, et al. UpToDate; Treatment of idiopathic pulmonary fibrosis; Topic 4328 Version 49.0
7. National Institute for Health and Care Excellence (NICE). Pirfenidone for treating idiopathic pulmonary fibrosis. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 66 p. (Technology appraisal guidance; no. 282). http://www.guideline.gov/content.aspx?id=45133&search=pulmonary+fibrosis

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.