PHARMACY POLICY STATEMENT

Original Effective Date	Next Annual Review	Last Revision
12/31/2014	11/1/2017	11/29/2016
Policy Name		**Policy Number**
Idiopathic Pulmonary Fibrosis		SRX-0072
Policy Type		
Medical	Administrative	**PHARMACY** Reimbursement

Pharmacy 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, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy 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 Pharmacy Policy Statement. If there is a conflict between the Pharmacy 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

Contents of Policy

A. INTRODUCTION

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

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

NOTE: The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.

B. DEFINITIONS

1. None applicable.

C. POLICY COVERAGE CRITERIA

1. Site of Service

Site of Service Administration	Coverage Criteria
Office, Outpatient, Home	**Preferred place of service is in the home** **These medications can be self-administered and can be billed through the pharmacy benefit.** CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective settings that are supportive of the patient's medical condition(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member's current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication

2. Coverage Criteria

CareSource will approve the use of Esbriet (pirfenidone) and OFEV (nintedanib), an oral antifibrotic agent that reduces disease progression in IPF, and consider their use medically necessary when the criteria have been met for each condition listed below. Prior authorization request should be submitted with chart notes and documentation supporting medical necessity.

Condition	Esbriet Coverage criteria:
Idiopathic Pulmonary fibrosis	1) Prescribed by or in consultation with a pulmonologist 2) Aged 18 years or older 3) A diagnosis of mild to moderate idiopathic pulmonary fibrosis using high resolution computed tomography or lung biopsy 4) Not a current smoker 5) Forced vital capacity greater than 50% of expected value for member 6) Not used in combination of OFEV (nintedanib).

Condition	OFEV Coverage criteria:
Idiopathic Pulmonary fibrosis	A diagnosis of mild to moderate idiopathic pulmonary fibrosis using high resolution computed tomography or lung biopsy 1) Prescribed by or in consultation with a pulmonologist 2) Aged 18 years or older 3) Not a current smoker 4) Not used in combination with Esbriet (pirfenidone)

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

Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.

Notes:

- Documented diagnosis must be confirmed by portions of the individual's medical record which 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.

3. Dosage and Quantity Limits (listed if applicable)

Information for patients with renal or hepatic impairment is not included. See package insert for individual agents.

Condition	Dosage and Quantity Limit of Esbriet
Idiopathic Pulmonary Fibrosis	Maximum dose of 2403 mg daily Maximum of 270 capsules per 30 days

Condition	Dosage and Quantity Limit of OFEV
Idiopathic Pulmonary Fibrosis	Maximum of 60 capsules per 30 days

4. Authorization Period

Condition	Approval Period
Idiopathic Pulmonary Fibrosis	The initial authorization of Esbriet is valid for 1 year Continued treatment may be considered when patient shows a biological response. A reauthorization after successful initiation period will be placed for 1 year. **ALL** authorizations are subject to continued eligibility.
Idiopathic Pulmonary Fibrosis	The initial authorization OFEV valid for 1 year Continued treatment may be considered when patient shows a biological response. A reauthorization after successful initiation period will be placed for 1 year. **ALL** authorizations are subject to continued eligibility.

5. Coding

Not applicable – covered on pharmacy benefit

D. RELATED POLICIES

AD-0004: Medical Necessity - Off-Label, Approved Orphan and Compassionate Use Drugs

E. REVIEW/REVISION HISTORY

DATE	ACTION/DESCRIPTION
5/4/2015	Placed into new template
11/17/2015	Revisions include adding age for adults only
11/21/2016	Added forced vital capacity needs to be greater than 50% to both drugs Added quantity limits Removed safety criteria

F. REFERENCES

1. Pirfenidone for Treating Idiopathic Pulmonary Fibrosis." Pirfenidone for Treating Idiopathic Pulmonary Fibrosis | Guidance and Guidelines | NICE. National Institute for Health and Care Excellence, 24 Apr. 2013. Web. 16 Nov. 2016.
2. Esbriet [package insert] Brisbane, CA: Intermune Inc.; February 2016.
3. OFEV [package insert] Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. August 2016.
4. King E. Talmadge, et al. UpToDate; Treatment of idiopathic pulmonary fibrosis; Topic 4328 Version 49.0 7
5. Hayes, Inc. 2015 6.
6. What is Idiopathic Pulmonary Fibrosis? (2011, January 1). Retrieved January 1, 2014, from http://www.nhlbi.nih.gov/health/health-topics/topics/ipf/
7. 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.
8. King E. Talmadge, et al. UpToDate; Treatment of idiopathic pulmonary fibrosis; Topic 4328 Version 49.0 7.
9. Hayes, Inc. 2016

The Pharmacy Policy detailed above has received due consideration and is approved.