WELL SENSE HEALTH PLAN

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Pharmacy Policy

Ofev

Policy Number: 9.133
Revision Number: R0
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☒ New Hampshire Medicaid ☐ _____	**Boston Medical Center HealthNet Plan** ☐ MassHealth ACO ☐ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options ☐ _____

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Ofev (nintedanib)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All approved FDA indication unless otherwise excluded
Exclusion Criteria	Concurrent use of Esbriet®
Required Medical Information	Documentation of the following: 1. A diagnosis of idiopathic pulmonary fibrosis; ***OR*** 2. A diagnosis of a chronic fibrosing interstitial lung disease (ILD)* with a progressive phenotype; ***OR*** 3. A diagnosis of systemic sclerosis-associated interstitial lung disease; ***AND***

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	i) Disease progression despite treatment with mycophenolate or cyclophosphamide; ***OR*** ii) Unable to tolerate or has a contraindication to both mycophenolate AND cyclophosphamide. *****There are over 200 diseases that fall into this category, including unclassifiable ILDs, autoimmune ILDs, chronic hypersensitivity pneumonitis, sarcoidosis, myositis, Sjorgen's syndrome, etc.
Age Restrictions	18 years or older
Prescriber Restriction	Prescribed by or in collaboration with a pulmonologist
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Initial criteria were previously met; **AND** 2. There is a decrease in pulmonary function deterioration and no significant adverse events.

Clinical Background Information and 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. Mar 15 2011;183(6):788-824.
2. Godfrey, A. Idiopathic Pulmonary Fibrosis. Available at http://emedicine.medscape.com/article/301226-overview
3. Non-pharmacological treatments for idiopathic pulmonary fibrosis. Available at: http://formularyjournal.modernmedicine.com/formulary-journal/RC/top-non-pharmacological-treatments-ipf
4. Ofev® [package insert]. Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT. March 2020
5. King TE. Treament of idiopathic pulmonary fibrosis. UpToDate. Last updated Jun 07, 2018. Accessed: June 14, 2018. Available: www.uptodate.com
6. Raghu, Ganesh, et al. "An official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis. An update of the 2011 clinical practice guideline." American journal of respiratory and critical care medicine 192.2 (2015): e3-e19.
7. Arita, M., T. Ishida, and S. Konishi. "Pirfenidone in Patients With Idiopathic Pulmonary Fibrosis." Am J Respir Crit Care Med 185 (2012): A4503.
8. King Jr, Talmadge E., et al. "A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis." New England Journal of Medicine 370.22 (2014): 2083-2092.
9. King TE. Treatment of idiopathic pulmonary fibrosis. Last updated Jun 07, 2018. UpToDate®. Available at www.uptodate.com. Accessed June 14, 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by

12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.197 Ofev Policy retired, new policy created	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.