Market Applicability													
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

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Opsumit (macitentan)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Opsumit (macitentan) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Opsumit (macitentan) may be approved if the following criteria are met:

I. Individual has pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1][2]; **AND**
II. Individual has the diagnosis of PAH confirmed by a right-heart catheterization showing all of the following (Hoeper, 2013; Ivy, 2013; Abman, 2015):
    A. Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest;
    B. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg;
    C. Pulmonary vascular resistance (PVR) greater than 3 Wood units; **AND**
III. Individual has WHO functional class II-IV[3] symptoms.

Opsumit (macitentan) may not be approved for the following:

I. Individual is initiating therapy and has a diagnosis of clinically significant anemia **OR**
II. In combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Letairis (ambrisentan) or Tracleer (bosentan).

Notes:

1. Opsumit (macitentan) has a black box warning for embryo-fetal toxicity. Pregnancy should be excluded prior to start of treatment, monthly during treatment, and 1 month after stopping treatment in females of reproductive potential. Opsumit should not be administered to pregnant females due to the potential of causing fetal harm. Pregnancy

Market Applicability													
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

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should be prevented using acceptable means of contraception during treatment and for one month after therapy discontinued. Opsumit will be available for all females, regardless of reproductive potential, through a restricted risk evaluation and mitigation strategy (REMS) program. As a component of the Opsumit REMS, prescribers, individuals, and pharmacies must enroll in the program.

2. WHO Pulmonary Hypertension (PH) Group Classification (ACCF/AHA 2009, Simonneau et al. 2013):
    A. Group 1: Pulmonary arterial hypertension (PAH)
    B. Group 2: PH due to left heart disease
    C. Group 3: PH due to lung diseases and/or hypoxia
    D. Group 4: Chronic thromboembolic PH (CTEPH)
    E. Group 5: Miscellaneous/PH with unclear multifactorial mechanisms

3. WHO functional classification of PH (CHEST 2014):
    A. Class l: No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
    B. Class ll: Slight limitation of physical activity. Comfortable at rest but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
    C. Class lll: Marked limitation of physical activity. Comfortable at rest but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.
    D. Class IV: Inability to carry out any physical activity without symptoms. Dyspnea and/or fatigue may be present at rest and discomfort is increased by any physical activity.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

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2. Badesch BD, Abman SH, Simonneau G, et al. Medical therapy for pulmonary arterial hypertension: updated ACCP evidence-based clinical practice guidelines. *Chest*. 2007; 131(6):1917-1928.

Market Applicability													
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

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6. Hoeper MM, Bogaard HJ, Condliffe R, et al. Definitions and Diagnosis of Pulmonary Hypertension. *J Am Coll Cardiol*. 2013; 62(suppl 25):D42- D50. Available at: http://www.onlinejacc.org/content/62/25_Supplement/D42. Accessed: January 11, 2019.
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