**Sample Format: Letter of Medical Necessity**

[Insert onto physician letterhead]

|  |  |
| --- | --- |
| [Medical Director]  [Insurance Company]  [Address]  [City, State, ZIP] | **RE: Member Name** [Insert Member Name]  **Member Number** [Insert Member Number]  **Group Number** [Insert Group Number] |

**REQUEST:** Authorization for treatment with OPSUMIT® (macitentan)

**DIAGNOSIS:** [Insert Diagnosis] [Insert ICD]

**DOSE AND FREQUENCY:** [Insert Dose & Frequency]

**REQUEST TYPE:** ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to support my request for an **authorization** for the above-mentioned patient to receive treatment with OPSUMIT® (macitentan) for the treatment of pulmonary arterial hypertension (PAH, WHO Group I), defined as mean pulmonary arterial pressure ≥25 mmHg, pulmonary arterial wedge pressure ≤15 mmHg, and pulmonary vascular resistance >3 Wood units.

OPSUMIT is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

My request is supported by the following:

**Summary of Patient’s Diagnosis**

[insert patient’s diagnosis, date of diagnosis, lab results and date, current condition]

**Summary of Patient’s History**

[Insert summary of patient history per your medical judgment. You may want to include:

* Previous therapies/procedures and response to those interventions
* Previous treatment of PAH including OPSUMIT, if applicable, and patient’s response
* Brief description of the patient’s recent condition and test results (eg, right heart catheterization, acute vasoreactivity, echocardiography, functional class, oxygen use, or 6-minute walk distance)
* History of patient’s routine and non-routine visits, including ED if applicable
* Summary of your professional opinion of the patient’s likely prognosis without treatment with OPSUMIT
* Summary of your credentials in treating PAH

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient’s medical condition.]

**Rationale for Treatment**

[Insert summary statement for treatment rationale such as: Considering the patient’s history, condition, and the full Prescribing Information supporting uses of OPSUMIT, I believe treatment with OPSUMIT at this time is medically necessary and should be a covered treatment for my patient. You may consider including documents that provide additional clinical information to support the recommendation for OPSUMIT for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [insert phone number] if I can provide you with any additional information.

Sincerely,

[Insert Physician Name and Participating Provider Number]

Enclosures: [include full Prescribing Information and the additional support noted above].

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