**Sample Format: Letter of Medical Necessity**

[Insert onto physician letterhead]

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

**REQUEST:** Authorization for treatment with OPSYNVI® (macitentan/tadalafil)

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

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

**REQUEST TYPE:** ☐ Standard ☐ Expedited ☐ Peer-to-peer review [confirm the peer-to-peer review process with insurer before requesting it in this letter]

Dear [Insert Name of Medical Director]:

I am writing to support my request for an **authorization** for the above-mentioned patient to receive OPSYNVI® (macitentan/tadalafil). OPSYNVI® is the combination of macitentan and tadalafil indicated for the chronic treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I and WHO Functional Class (FC) II-III). Individually, macitentan reduces the risk of clinical worsening events and hospitalization, and tadalafil improves exercise ability.1 PAH is defined as the mean pulmonary arterial pressure >20 mmHg at rest, pulmonary arterial wedge pressure ≤15 mmHg, and pulmonary vascular resistance >2 Wood units.2

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**

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

[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 OPSYNVI®, 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 emergency department (ED) if applicable
* Summary of your professional opinion of the patient’s likely prognosis without treatment with OPSYNVI®
* Summary of your professional opinion of the need for the patient to take a single-tablet combination
* Summary of your credentials in treating PAH

**Rationale for Treatment**

[Insert summary statement for treatment rationale such as: Considering the patient’s history, condition, challenges with treatment compliance, and the full Prescribing Information supporting uses of OPSYNVI®, I believe treatment with OPSYNVI® 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 OPSYNVI® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines, (such as the 2022 ESC/ERS Clinical Practice 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]

**Please read full** [**Prescribing Information**](https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/OPSYNVI-pi.pdf)**, including BOXED WARNING, for OPSYNVI®.**

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

**References:** **1.** OPSYNVI® [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc. **2.** Humbert M et al. *Eur Heart J.* 2022;43:3618-3731.

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