**Sample Format: Letter of Appeal**

[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] |

Dear [Insert Name of Medical Director]:

I am writing to ask for a reconsideration of my request for [insert patient name] 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

In brief, treatment with OPSYNVI® is medically appropriate and necessary and should be a covered treatment for my patient.

[Insert plan name] has denied coverage of OPSYNVI® for [insert patient’s name] because [insert reason for denial as indicated on the explanation of benefits]. The following rationale supports my decision to prescribe OPSYNVI® and outlines [insert patient name]’s medical history, prognosis, and my treatment decision.

In my judgment, [insert preferred product name] is not a medically appropriate treatment for [insert patient name] because [insert rationale, eg, personal medical history of/family history of X condition, contraindication, comorbid condition, prior inadequate response, or an adverse reaction to preferred product].

**Summary of Patient’s History and Treatment Rationale**

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

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

* Previous therapies/procedures and response to these 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
* Hospital admission information, 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**

Given the patient’s history, condition, and the published data supporting the use of OPSYNVI®, treatment of [insert patient name] with OPSYNVI® is warranted, appropriate, and medically necessary.

The attached copies of [clinical peer-reviewed literature, clinical guidelines, (such as 2022 ESC/ERS Clinical Practice Guidelines,) and full Prescribing Information, etc] document that OPSYNVI® is an appropriate treatment option for this patient. [Insert the following If an expert opinion is needed: This case needs to be reviewed by an expert in pulmonology or cardiology to understand the complex nuances of the case. I urge you to consult an expert before upholding your initial decision to deny.]

[I wish to formally request a peer-to-peer review with a medical director who has expertise in PAH.]

I look forward to receiving your timely response and approval of this request.

Sincerely,

[Insert doctor’s name, contact information, 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: [List enclosures such as explanation of benefits, denial letter, Prescribing Information, clinical evidence, or test results/lab reports.]

**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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