

Dear Clinician,

What follows is a templated Sample Letter of Medical Necessity for Sandoz® Treprostinil Injection. The template includes placeholders for the information your patient's insurance company will expect when evaluating treatment necessity.

The goal of this template is to streamline the treatment authorization process so that you can submit a comprehensive and impactful letter efficiently—and your patient can begin treatment as soon as possible. The brackets and checkboxes in red indicate the parts of the template for you to complete.

We hope you find this template to be a helpful tool that may expedite the authorization process for both you and your patient.

Please note that this letter is provided as an example and is not a guarantee of insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Sincerely,

Your Liquidia and Sandoz Treprostinil Injection Team

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Sample Letter of Medical Necessity for Sandoz® Treprostinil Injection

[Insert clinician letterhead]

[mm/dd/20xx]

[Full Name of Medical Director] [Insurance Company] [Street Address] [City, State, ZIP] RE: Member Name [Member Name]
Member Number [Member Number]
Group Number [Group Number]

REQUEST: Authorization for treatment with Sandoz® Treprostinil Injection

DIAGNOSIS: [Insert Diagnosis], [Insert ICD]

DOSE AND FREQUENCY: [Dose], [Frequency]

REQUEST TYPE:
Standard
EXPEDITED

Dear [Name of Medical Director],

I am writing to request an **authorization** for [Patient Name], DOB [Patient DOB: mm/dd/yyyy], to receive treatment with **Sandoz**® **Treprostinil Injection**.

Sandoz® Treprostinil injection is a prostacyclin mimetic indicated for:1

- Treatment of pulmonary arterial hypertension (PAH), World Health Organization (WHO) Group 1, to
 diminish symptoms associated with exercise. Studies establishing effectiveness included patients with
 NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated
 with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases
 (19%).
- Patients with PAH requiring transition from epoprostenol, to diminish the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition.

I offer the following in support of my request:

1. Summary of my patient's diagnosis

[Patient Name] was diagnosed with [diagnosis] on [mm/dd/20xx].

Study and lab results:

- [Insert result], mm/dd/20xx
- [Insert result], mm/dd/20xx
- [Insert result], mm/dd/20xx
- [Insert result], mm/dd/20xx

My patient's current condition is [condition].

2. Summary of my patient's history

[Insert a brief summary of patient's history per your medical judgment].

Potential elements to include

- [Previous therapies/procedures and patient's response]
- [Previous treatment of PAH, including Treprostinil (if applicable), and patient's response]

- [Brief description of patient's recent condition and applicable test results (eg, RHC, acute vasoreactivity testing, echocardiography, WHO Functional Class, oxygen use at rest and with activity, or 6MWT results)]
- [History of patient's routine and nonroutine visits, including ED, if applicable]

[Insert summary of your professional opinion of the patient's likely prognosis without treatment with Treprostinil.] [Insert summary of your credentials in treating PAH.]

3. Rationale for treatment

[Insert summary statement for treatment rationale.]

Example summary statement

I have taken great consideration regarding the patient's current condition and prognosis. I believe treatment with Sandoz® Treprostinil Injection is medically necessary at this time and should be a covered treatment option for [Patient Name].

If you decide to include the full Prescribing Information, include this line. Otherwise, delete

The full Prescribing Information of Sandoz® Treprostinil Injection provides clinical information that played a key part in making my determination that this is the appropriate treatment.

If you decide to include other support documents, include this line. Otherwise, delete

I have also included with my letter additional documentation to further support my recommendation to treat [Patient Name] with Sandoz® Treprostinil Injection.

Enclosures:

- [Document 1]
- [Document 2]
- [Document 3]

Given the urgent nature of this request, please provide a timely authorization. If I can provide you with additional information, please contact my office at [Insert phone number].

Sincerely,

[Clinician name and participating provider number]

References: 1. Treprostinil Injection [package insert]. Princeton, NJ: Sandoz Inc; 2023.