Tips for Drafting a Statement of Medical Necessity Letter

These tips are being provided as an educational resource to support healthcare professionals and the patients they serve. This is not intended to be a step-by-step guide or instructions. It is the healthcare professional's responsibility to ensure correct prior authorization policies are followed. Providers must ensure they accurately complete and submit necessary information to insurance companies.

It may be helpful to include a Statement of Medical Necessity (SMN) letter, explaining your rationale and clinical decision making behind the choice of a specific therapy, when submitting a prior authorization to a patient's health insurance.

Understand the Insurer's Prior Authorization Process. Review the patient's plan benefits thoroughly prior to drafting a Statement of Medical Necessity letter.

Ensure you have submitted all required information. Simple errors on insurance forms, including incorrect codes and failure to obtain or submit the necessary documentation, may lead to denials. If there was a documentation error, correct the form or contact the insurance plan.

Identify and meet specific insurer deadlines. Some plans have very short turnaround times, for example, 48 hours from the denial date.

Consider including the following information in the SMN Letter (See example on next page):

1. **Patient Information:**
   - Full name
   - Date of birth
   - Insurance ID number
   - Insurance Case ID number or Denial number
2. **Physician Information:**
   - Full name
   - National Provider Identification (NPI) number
   - Specialty
3. An introduction explaining the purpose of the SMN Letter, or the reason for the medical necessity of the prescribed medication.
4. A summary of the patient's diagnosis and the indication for the United Therapeutics therapy being prescribed. The summary should include diagnosis codes (ICD-10), prior treatments with their duration and response to treatment, and the severity of the patient's condition.
5. A clinical rationale for the prescribed treatment. The clinical rationale should include the FDA approved indication and any supporting clinical trial data.
6. If the plan is indicating a preferred formulary treatment, please provide an explanation of why it may not be applicable to your patient.
7. **Additional Documents**, including but not limited to:
   - Full Prescribing Information
   - Diagnostic test results, such as 6-minute walk test
   - Letter of Medical Necessity
   - Clinical notes and medical records

Be sure to maintain accurate records. Make a copy of anything you send. Record the time, date, and name of any representatives at the insurance company.

Sample Statement of Medical Necessity for Adcirca® (tadalafil)

[Date]

Attn: [Contact/Medical Director First & Last Name]

[Insurance Company]

[Address]

[City, State, ZIP code]

[Patient First & Last Name] [Date of Birth]

[Patient ID Number] [Claim/Case Number]

RE: LMN for Adcirca

Dear [Contact/Medical Director First & Last Name]

I am writing to document the medical necessity and to obtain authorization for Adcirca (tadalafil) on behalf of my patient, [Patient First & Last Name] . Adcirca is a phosphodiesterase 5 inhibitor (PDE-5i) indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. I believe that Adcirca is appropriate for my patient based on their relevant clinical history (provided below).

Studies establishing effectiveness of Adcirca included predominately patients with NYHA Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).

Brief summary of Patient's Medical History:

[Patient First & Last Name] is a [female/male] patient,[age] , who has been diagnosed with PAH as of [MM/DD/YYYY] . [He/She] has been in my care since[MM/DD/YYYY] .

{Include medical history, including, but not limited to: [Patient's diagnosis, date of diagnosis and any applicable diagnosis codes], [Laboratory results and date], [Brief description of patient's current medical condition], [Patient's previous and current treatments/therapies], [Patient's response to those treatments/therapies], [If the patient has discontinued, include information on lack of response or tolerability]}

Rationale for Treatment

Considering the patient's medical history, current medical condition, and the approval of Adcirca for PAH, I believe treatment with Adcirca at this time is warranted, appropriate, and medically necessary for this patient.

Thank you for your prompt attention to this matter and for your consideration and anticipated approval for Adcirca. Please call my office at (XXX) XXX-XXXX if you require any additional information or documentation. I look forward to your timely response.

Sincerely,

[Prescriber First & Last Name]

Enclosures:

[List enclosures, such as Prescribing Information, Important Safety Information, clinical evidence, or lab reports.]

Download and include the full prescribing information.

INDICATION

ADCIRCA® (tadalafil) is a phosphodiesterase 5 inhibitor (PDE-5i) indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).

IMPORTANT SAFETY INFORMATION FOR ADCIRCA® (TADALAFIL) TABLETS

CONTRAINDICATIONS

- **Nitrates and Guanylate Cyclase (GC) Stimulators:** Do not use ADCIRCA in patients taking medicines that contain nitrates or guanylate cyclase stimulators (such as riociguat), as the combination could cause a sudden, unsafe drop in blood pressure. Do not use nitrates within 48 hours of the last dose of ADCIRCA.
- Hypersensitivity Reactions: Patients with a known serious hypersensitivity to tadalafil should not take ADCIRCA

WARNINGS AND PRECAUTIONS

- **Cardiovascular:** Patients who experience anginal chest pain after taking ADCIRCA should seek immediate medical attention
- **Hypotension:** Phosphodiesterase 5 inhibitors (PDE-5is), including tadalafil, have mild systemic vasodilatory properties that may result in transient decreases in blood pressure. Before prescribing ADCIRCA, carefully consider whether patients with underlying cardiovascular disease could be adversely affected by such actions.
- **Worsening Pulmonary Vascular Occlusive Disease:** Pulmonary vasodilators may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD) and administration of ADCIRCA to these patients is not recommended
- **Vision/Hearing:** Patients who experience a sudden loss of vision in one or both eyes, which could be a sign of non-arteritic anterior ischemic optic neuropathy (NAION), or sudden decrease or loss of hearing after taking ADCIRCA should seek immediate medical attention
- **Prolonged Erection:** In rare instances, men taking PDE-5is (including tadalafil) for ED reported an erection lasting more than four hours. Male patients who experience a prolonged erection should seek immediate medical attention

SPECIAL POPULATIONS AND POTENTIAL DRUG INTERACTIONS:

- **Special Populations (Pregnant or Expecting Pregnancy):** Limited data from case series with tadalafil use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Pregnant women with untreated pulmonary arterial hypertension are at risk for heart failure, stroke, preterm delivery, and maternal and fetal death.
- **Special Populations (Renal or Hepatic Impairment):** The use of ADCIRCA is not recommended for patients with severe renal or hepatic impairment. Please see Full Prescribing Information for dosing recommendations for patients with mild to moderate renal or hepatic impairment
- **Potential Drug Interactions:** The use of ADCIRCA with alpha blockers, blood pressure medications, or alcohol may lower blood pressure significantly and may lead to symptomatic hypotension (light-headedness or fainting)
- **Potential Drug Interactions:** Tadalafil is metabolized predominately by CYP3A in the liver. Use of ADCIRCA with potent CYP3A inhibitors, such as ketoconazole and itraconazole, should be avoided. For patients on ADCIRCA therapy that require treatment with ritonavir, ADCIRCA should be discontinued at least 24 hours prior to starting ritonavir. For patients on ritonavir therapy that require treatment with ADCIRCA, start ADCIRCA at 20 mg once a day. Use of ADCIRCA with potent inducers of CYP3A, such as rifampin, should be avoided
- **Potential Drug Interactions:** ADCIRCA contains the same ingredient (tadalafil) as Cialis®, which is used to treat erectile dysfunction (ED) and the signs and symptoms of benign prostatic hyperplasia (BPH). The safety and efficacy of combinations of ADCIRCA with Cialis or other PDE-5is have not been studied. Therefore, the use of such combinations is not recommended

ADVERSE REACTIONS

- **Adverse Reactions:** The most common adverse event with ADCIRCA is headache (42% ADCIRCA vs 15% placebo). Other common adverse events (reported by ≥9% of patients on ADCIRCA and more frequent than placebo by 2%) include myalgia (14% vs 4%), nasopharyngitis (13% vs 7%), flushing (13% vs 2%), respiratory tract infection (13% vs 6%), extremity pain (11% vs 2%), nausea (11% vs 6%), back pain (10% vs 6%), dyspepsia (10% vs 2%), and nasal congestion (9% vs 1%)

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For more information about ADCIRCA, please see the accompanying Full Prescribing Information and Patient Information or call 1-800-545-5979.

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