[Provider Letterhead]

[Date]

Attn: Medical or Pharmacy Director
[Payer Name]
[Payer Address]
[Payer City, State ZIP Code]
[Payer Phone Number]
[Payer Fax Number]

RE: Corlanor® (ivabradine) Letter of Medical Necessity
Patient: **[Patient's First and Last Name]**
Policy # / Patient ID #: **[Policy # / Patient's ID #]**
Group #: **[Group #]**
Patient Date of Birth: **[Patient Date of Birth]**

Dear Medical or Pharmacy Director:

I am writing on behalf of my patient, **[Patient Name]**, to document the medical necessity of Corlanor® for the treatment of **[patient's diagnosis]**. This letter provides information about the patient's medical history, diagnosis, and treatment plan with Corlanor®.

Corlanor® is an oral medication approved by the Food and Drug Administration (FDA) on April 15, 2015 and is indicated to reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

[Mr/Mrs/Ms Patient Last Name] has been diagnosed with **[patient's diagnosis]** and prescribed Corlanor® **[dosage and frequency]** as the recommended course of treatment. Below is a brief summary of the attached medical records documenting **[Mr/Mrs/Ms Patient Last Name's]** clinical condition and medical history supporting medical necessity for treatment with Corlanor®.

- Medical history and diagnosis: **[Provide a brief statement about the patient's diagnosis and medical history including any underlying health issues that affect your treatment selection.]**

- Prior treatments and response to those treatments: **[Provide a list of current and past medications, as well as reasons for not prescribing a medication (e.g., contraindications, drug interactions, etc.) and a summary of patient experience for each medication, including clinical outcome, any adverse drug reactions, and length of therapy.]**

In summary, based on my clinical opinion, Corlanor® is medically necessary and reasonable for **[Mr/Mrs/Ms Patient Last Name's]** medical condition. Please contact me at **[provider phone number]** if any additional information is required to ensure prompt approval for this course of treatment.

Sincerely,

[Provider's Name]

Enclosures: **[Corlanor® (ivabradine) Prescribing Information, prior authorization forms, patient medical records, or other supportive medical literature.]**

IMPORTANT SAFETY INFORMATION

Contraindications: Corlanor® is contraindicated in patients with acute decompensated heart failure, clinically significant hypotension, sick sinus syndrome, sinoatrial block, 3rd degree atrioventricular block (unless a functioning demand pacemaker is present), clinically significant bradycardia, severe hepatic impairment, pacemaker dependence (heart rate maintained exclusively by the pacemaker), and concomitant use of strong cytochrome P450 3A4 (CYP3A4) inhibitors.

Fetal Toxicity: Corlanor® may cause fetal toxicity when administered to a pregnant woman based on embryo-fetal toxicity and cardiac teratogenic effects observed in animal studies. Advise females of reproductive potential to use effective contraception when taking Corlanor®.

Atrial Fibrillation: Corlanor® increases the risk of atrial fibrillation. The rate of atrial fibrillation in patients treated with Corlanor® compared to placebo was 5% vs. 3.9% per patient-year, respectively. Regularly monitor cardiac rhythm. Discontinue Corlanor® if atrial fibrillation develops.

Bradycardia and Conduction Disturbances: Bradycardia, sinus arrest and heart block have occurred with Corlanor®. The rate of bradycardia in patients treated with Corlanor® compared to placebo was 6% (2.7% symptomatic; 3.4% asymptomatic) vs. 1.3% per patient-year, respectively. Risk factors for bradycardia include sinus node dysfunction, conduction defects, ventricular dyssynchrony, and use of other negative chronotropes. Bradycardia may increase the risk of QT prolongation which may lead to severe ventricular arrhythmias, including torsades de pointes, especially in patients with risk factors such as use of QTc prolonging drugs.

Concurrent use of verapamil or diltiazem also increases Corlanor® exposure, contributes to heart rate lowering, and should be avoided. Avoid use of Corlanor® in patients with 2nd degree atrioventricular block unless a functioning demand pacemaker is present.

Adverse Reactions: The most common adverse drug reactions reported at least 1% more frequently with Corlanor® than placebo and that occurred in more than 1% of patients treated with Corlanor® were bradycardia (10% vs. 2.2%), hypertension or increased blood pressure (8.9% vs. 7.8%), atrial fibrillation (8.3% vs. 6.6%), and luminous phenomena (phosphenes) or visual brightness (2.8% vs. 0.5%).

In postmarketing experience, torsades de pointes has been observed.

Please click here for full Prescribing Information and Medication Guide.