

ADDRESS TO INSURANCE COMPANY OR APPEAL SOURCE
DATE

Appeal Regarding-

Name of denied pump

Add your plan information such as:

Formulary ID

Plan Type

Enrollee ID number

Contract ID

Plan ID

Group Number

Your Name and DOB

Policy Holder and DOB (omit if you are the policy holder)

Appeal for coverage of denied RX for pump

Name

Diagnosis

DOB

Applicable ICD-10 Diagnosis Codes

(Suggestions-

Adrenal Insufficiency (Addison's Disease) E27.1

Management of infusion pump Z45.1)

NAME OF PUMP is FDA approved for chronic drug administration. The **NAME OF PUMP** meets the recommendations for chronic glucocorticoid administration to treat Adrenal Insufficiency. Adrenal insufficiency is the failure of the body to produce cortisol, which is a life sustaining hormone. For comparison, it is similar to the disease of Type 1 diabetes, which renders a person insulin deficient. Adrenal insufficiency renders a person cortisol deficient, and cortisol replacement is necessary to sustain life. Administration of corticosteroids is the only treatment for adrenal insufficiency. **YOUR NAME** requires this treatment and as their physician, I have prescribed **NAME OF PUMP** as the recommended clinical treatment that is necessary to sustain their life.

According to the **Department of Health and Human Services Centers for Medicare and Medicaid Services Medicare Coverage Issues Manual Section 60-14 A:**

“6. Other uses of external infusion pumps are covered if the contractor’s medical staff verifies the appropriateness of the therapy and of the prescribed pump for the individual patient.”

According to above stated criteria, patient meets criteria for coverage.

According to Khalil A, Ahmed F, Alzohaili O. **Continuous glucocorticoid infusion for adrenal insufficiency is a novel approach to deliver corticosteroids in patients with poor cortisol absorption.** Presented at: American Association of Clinical Endocrinologists 28th Annual Scientific & Clinical Congress; April 24-28, 2019; Los Angeles, CA. “The results

indicated that the use of cortisol pumps was associated with a 78.5% risk reduction for adrenal crisis compared with oral corticosteroids, in addition to reducing the number of adrenal crises, this method was found to be associated with better symptom control and quality of life. Continuous pulsatile cortisol replacement via pump is an option for management of severe adrenal insufficiency in patients unresponsive to oral therapy.”

According to the recently passed **Right to Try Act**, this patient should have access to this treatment. (a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561A (21 U.S.C. 360bbb-0) the following: “SEC. 561B. INVESTIGATION “SEC. 561B. INVESTIGATIONAL DRUGS FOR USE BY ELIGIBLE PATIENTS. “(a) DEFINITIONS.—For purposes of this section— “(1) the term ‘eligible patient’ means a patient— “(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations)); “(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who— “(i) is in good standing with the physician’s licensing organization or board; and “(ii) will not be compensated directly by the manufacturer for so certifying; and “(C) who has provided to the treating physician written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent.

YOUR NAME has been diagnosed with adrenal insufficiency and cannot sustain life without administration of glucocorticoid medication. Patient has not responded to oral corticosteroid and therefore the denied **treatment NAME OF PUMP** is vital and life sustaining for this patient, as there is no alternative treatment for glucocorticoid administration in the management of adrenal insufficiency.

According to medically indicated criteria, patient meets criteria for coverage and denying this prescription would not only be inhumane but also lead to imminent death for this patient.

Physician Signature