BEFORE YOU BEGIN

- **All wording in red should be edited to reflect your child's information; upon completion of this appeal letter there should no longer be *any* red areas.**

- **Please review the external appeal process in your denial letter carefully as it will list the required process & the required information you will need to submit your appeal.**

- **You should have a copy of your insurance policy's benefit coverage on hand for reference. Be sure to include the growth data points for your child that match as many of the insurance policy's criteria for approval as possible.**

- **If you are unsure of the growth data requested in this letter (e.g. growth velocity, SDS, etc.), ask your pediatric endocrinologist/office for assistance as they will have this information on hand, or know where you can obtain it.**

EXTERNAL APPEAL REQUEST

Today's Date

Address of External Appeal Organization
Fax/Email of External Appeal Organization

NAME:Child's Full Name
DOB: 99/99/9999
INS ID#: 999999999

Note- include any sr/case# or other required information such as your daytime phone number and/or address. this will be listed in your denial letter under external appeal process, or on the external appeal form included with your final denial letter

My son/daughter, First Name Last Name, is currently at the external appeal level for coverage of brand name Growth Hormone Therapy. We strongly disagree with Insurance Company's decision to deny our child growth hormone treatment. Our reasoning is outlined within this letter.

First Name is a __yr old boy/girl followed for poor growth by ped endo's name, a Board Certified Pediatric Endocrinologist who has diagnosed my child with pediatric growth hormone deficiency. Insurance Company has denied coverage for Growth Hormone treatment based on Denial Reason(s) Stated in Denial Letter (EX: MEDICAL NECESSITY; NOT BELOW THE 3RD%,ETC). Insurance Company does not consider treatment to be medically necessary/a covered benefit/list any other reasons if noted in the denial letter for First Name who is growth impaired.

Insurance Company should not deny treatment for an individual who does not meet ALL of their mandated criteria, as EACH case of pediatric growth hormone deficiency is highly individualized and should be reviewed on the child's specific situation as well as on the child's pediatric endocrinologist's recommendation. My pediatric endocrinologist has the best understanding of my child's health. Insurance Company has the moral & ethical obligation to review every request for coverage on a case-by-case basis; this ensures that all medical and clinical information for the child is considered. It should be understood that failing to meet one criteria point is not grounds for denial of treatment when *all other* criteria points have been met.

Insurers must also adopt approval policies and criteria that are based on *current* consensus guidelines and established standards of care. Consensus Guidelines are developed by the physician leaders in the field of Pediatric Endocrinology. In the *2016 Pediatric Endocrine Society Consensus Guidelines' Primary Objectives of Growth Hormone Treatment,* it lists *"the acceleration of growth velocity to promote the normalization of growth and stature, and the attainment of normal adult height appropriate*

for the child's genetic potential"[1]. These guidelines support that a child diagnosed with growth failure due to an approved FDA indication for growth hormone treatment, should receive growth hormone therapy. By denying child's name growth hormone therapy, Insurance Company prevents the achievement of these two goals.

The role of the pediatric endocrinologist is to not only identify a child's abnormal growth pattern, but to also advise the most appropriate treatment for the child's unique situation. In this instance the treatment is growth hormone therapy; there are no other treatment alternatives. Child's Name meets the clinical definition of Growth Hormone Deficiency (GHD) for the following reasons:

USE/DISCARD THE FOLLOWING BULLETED POINTS AS THEY APPLY TO YOUR CHILD'S CASE & YOUR INSURANCE PAYOR'S GH POLICY CRITERIA. [PLEASE NOTE NOT ALL BULLETED POINTS NEED TO BE INCLUDED]

- He/She failed Growth Hormone Stimulation testing that was conducted in month,year. The agent #1 *(e.g. Arginine, Insulin or Glucagon)* test showed a peak level of peak level ng/mL, and the agent #2 *(e.g. Clonidine or L-Dopa)* test showed a peak level of only peak level ng/mL. This is below the accepted standard of 10 ng/mL and is considered an indication of GHD.

- His/Her bone age as of mm/dd/yyyy indicated that their skeletal age was behind their chronological age by more than # standard deviations, the BA report reflects this.

**** If child's BA reading does not meet their requirement include the following bullet point,*** **Omit this bullet if not applicable**

- Insurance co name stated that the BA reading does not meet their listed parameter. This parameter should not be considered as a reason for denying therapy as bone age readings can vary and are dependent on the expertise of the individual who reads it. It is considered an art and not a science and should not be used to determine whether a child does or does not have GHD.

- First Name's IGF-1 levels of ###ng/mL are below the normal range of ###-####.***ONLY USE THIS BULLET IF IGF-1 LEVELS ARE BELOW NORMAL; OTHERWISE DELETE; LOOK AT THE LAB REPORT AND UNDER THE RESULT WILL BE LISTED SDS VALUE; INCLUDE THE VALUE IF IT HAS A MINUS SDS SCORE SUCH AS -1SDS AS THIS IS PROOF OF UNDERPRODUCTION EVEN IF THE VALUE LOOKS LIKE IT IS IN THE NORMAL RANGE**

- First Name's stature is ### standard deviations below the mean for age & sex.

- First Name's growth velocity # centimeters over a # month period; giving him a growth velocity of # per year which is # standard deviations below the mean for age and gender. ***YOU MAY WISH TO ASK YOUR PHYSICIAN FOR HELP WITH THIS PART AND ALSO ASK IF YOUR CHILD HAS HAD THEIR GROWTH VELOCITIES PLOTTED ON A GROWTH VELOCITY CHART AS THESE CHARTS SHOW POOR GROWTH MUCH BETTER THAN THE STANDARD GROWTH CHARTS. ASK THEM TO DO THIS IF THEY HAVE NOT DONE THIS ALREADY. APPLY THIS AGAINST**

[1] See Reference Citations

THEIR GROWTH VELOCITY REQUIREMENT IF THE GROWTH VELOCITY IS BELOW NORMAL FOR AGE AND SEX

- First Name currently is # Standard Deviations below his mid-parental target height. ***ASK YOUR PED ENDO FOR THIS INFORMATION AS WELL. DELETE THIS BULLET IF THIS STATEMENT DOES NOT APPLY***

According to the Pediatric Endocrine Society "*GHD should be suspected in a child with persistently subnormal growth rate with no other identifiable cause, in whom hypothyroidism, chronic illness, undernutrition, and genetic syndromes have been excluded.*"[2] Prior to beginning treatment, First Name's growth chart indicates that he/she was in the # percentile which is # standard deviations below the average. Expectations of height for a child that are based on the *mid-parental height* provide for a far more accurate calculation versus the results of height expectation based on the population at large. First Name is currently more than # standard deviations below his mid-parental target height of ## inches.

****Skip the following paragraph if adult predicted height has not been calculated or if child is within the normal range**

In order for First Name to meet his/her mid-parental height (MPH) target of # feet # inches, he/she would need to follow the growth curve at the ## percentile. If First Name continues to grow at his/her current rate of approximately # inch per year, the predicted adult height is only # feet # inches.The predicted adult height (PAH) that has been projected by First Name's pediatric endocrinologist assumes a "*normal*" growth velocity, however First Name's current rate of growth is below what is clinically accepted as the standard or norm for growth velocity and therefore First Name would not meet this height.******

Currently First Name has been on GH brand name for over # months, and during this time has grown # inches. With this current rate of growth, the potential exists for Name to grow # inches per year. It should be noted that prior to treatment, his/her growth rate was approximately ## inches per year. The medication trial clearly demonstrates that First Name is benefitting from continued use of growth hormone therapy.

INSURANCE COMPANY states that they approve GH treatment, but only if a list of specific criteria are met. These guidelines and restrictions do not take into consideration a child's unique clinical situation where one or more parameters outweigh another. An example of this would be a child falling down across percentiles, this should take precedence over the requirements of being 2 SDS below the mean because it highlights the fact that the child has undergone significant growth failure. The INSURANCE COMPANY's requirements for approval are meant to facilitate

[2] See Reference Citations

denial of treatment, not approval, and they are ignoring my child's specific clinical information which support the diagnosis of GHD.

****THE FOLLOWING PARAGRAPH ONLY WORKS IF CHILD WAS PREVIOUSLY COVERED FOR GH MED BY INS AND NOW IS BEING DENIED, DELETE IF NOT APPLICABLE TO YOUR SITUATION.**
Bear in mind, the Affordable Care Act prohibits insurance companies from refusing to cover a pre-existing condition. First Name's pre-existing condition of GHD has been well documented. First Name has been diagnosed and received GH treatment for several years now.*******

The Social Security Administration states in SSI Code 109.0 *"pituitary growth hormone deficiency in growing children limits bone maturation and results in PATHOLOGICAL short stature, and is evaluated by Social Security under code 100.00."*[3] The Social Security Administration Act states that growth impairment is a disability; INSURANCE COMPANY is ignoring the federal policy by denying treatment coverage.

Should coverage for the therapy not be provided and First Name's condition is left untreated, it could cause long-lasting irreparable harm. Consequences can include but are not limited to:

- ➔ lack of sufficient bone density
- ➔ weak muscle tone/hypotonia
- ➔ osteoporosis
- ➔ psychological/psychosocial damage
- ➔ permanent short stature/dwarfism

Pediatric Endocrinologist Dr. Name states that growth hormone therapy is crucial for First Name's development. She/He has *<u>also</u>* requested that if the denial is upheld, that she/he be contacted for a peer to peer review with Insurance Name's Medical Director. We request that this external appeal be reviewed by a Board Certified Pediatric Endocrinologist.

It is for the aforementioned reasons we request you exercise your authority to overturn INSURANCE COMPANY's decision to deny GH treatment coverage for First Name Last Name. Our ultimate goal is to ensure First Name has the opportunity to live a healthy life. We sincerely hope that you share the same vision. If further action is needed, we will go to our State Insurance Commissioner and file a formal complaint against Insurance Company Name.

[3] See Reference Citations

PLEASE NOTE- THE FOLLOWING LIST IS AN EXAMPLE OF THE INFORMATION COMMONLY REQUESTED AS PART OF AN EXTERNAL APPEAL- CRITERIA/DOCUMENTATION REQUIRED CHANGES FROM COMPANY TO COMPANY. REFER TO YOUR FINAL ADVERSE DETERMINATION LETTER AND/OR FILING AN EXTERNAL APPEAL NEXT-STEPS TO ENSURE YOU ARE INCLUDING THE NECESSARY DOCUMENTATION TO FILE THIS EXTERNAL APPEAL

Enclosed with this letter, please find the following supporting documentation for your reference, full reference articles can be made available upon request:

- External Review Request form IF FORM REQUIRED, IT MUST BE COMPLETED AND SENT IN WITH THIS APPEAL LETTER
- Insurance card (FRONT & BACK)
- Level I Physician's Appeal Letter & Insurance Denial Letter
- Level II Physician's Appeal Letter & Insurance Denial Letter
- Complete Medical File of FULL NAME OF CHILD
- Supporting Reference Citations:
    - *Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency*
    - *Adda Grimberg et al on behalf of the Drug and Therapeutics Committee and Ethics Committee of the Pediatric Endocrine Society Horm Res Paediatr 2016;86:361–397 DOI: 10.1159/000452150*
    - *USE THE 2016 PES CONSENSUS GUIDELINES AS IT IS QUOTED IN THE LETTER AND AVAILABLE FROM OUR WEBSITE; OTHER REFERENCES THAT SUPPORT YOUR CHILD'S MEDICAL DIAGNOSIS CAN OFTEN BE OBTAINED VIA GOOGLE AND A LINK TO THE ARTICLE IS ENOUGH ADDRESSES GROWTH HORMONE TREATMENT, LOOK FOR ONES THAT MATCH YOUR CHILD'S SITUATION
- Contact information for Dr.NAME, M.D., *Pediatric Endocrinologist*
  Address, Ph/Fx, Email

Regards,

Your Signature

Printed Name(s)