

BEFORE YOU BEGIN

- ALL wording in red should be edited to reflect your information; upon completion of this appeal letter there should no longer be any red areas.
- To write an appeal with the best chance of approval, you will need a copy of your insurance benefit coverage which lists the requirements for approval; this should be included in your denial letter and can be used for reference. Be sure to include the growth data points for your child that match as many of the insurance policy requirements/criteria as possible. If ISS is not a covered benefit in your plan, you must prove that your child's growth data meets the FDA's indication for GH treatment for a child with ISS as well as the current ISS consensus guidelines.
- If you are unsure of the growth data requested in this letter (height more than -2.25SDS below the mean which is 1.2% on the growth chart, poor growth velocity etc.) ask your pediatric endocrinologist's office for assistance as they will have this information on hand, or know where you can obtain it.

EXTERNAL APPEAL REQUEST this could also be an IMR
(Independent Medical Review Request - check your form

Today's Date

Name & Address of External Appeal
Organization

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

Fax/Email of External Appeal Organization

*any other information requested in your denial letter; may say address, phone number, etc.

My son/daughter, **First Name Last Name**, is currently at the external appeal stage 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 Idiopathic Short Stature (ISS). **Insurance Name** (this could also be your pharmacy benefit management company; check the denial letter to confirm who actually sent the denial)has denied coverage for Growth Hormone treatment based on **Denial Reason(s) Stated in Denial Letter** (Ex: Medical Necessity, diagnosis exclusion, etc.).

Growth hormone is used in the treatment of idiopathic short stature and is supported by randomized control trials and consensus guidelines. The FDA indication lists ISS as 'non-growth hormone deficient stature, defined by a height SDS less than or equal to -2.25, and associated with growth rates unlikely to attain an adult height in the normal range.'¹ However, **Insurance Company** does not consider GH treatment to be medically necessary for **First Name** who is clearly growth impaired.

First Name, had a pre-treatment height of ___ SDS below the mean (ask ped endo to provide this information). His/her growth velocity was only ___cm prior to GH treatment, which would not allow **him/her** to reach a normal adult height. **First name's** growth data meets the FDA ISS indication treatment requirements as well as the current standard of medical practice for GH use in the ISS patient in the United States.

** If the Insurance Company's policy excludes ISS from being covered, use the following paragraph; if GH is not excluded in your policy, skip/delete the paragraph below and go to the next section**

¹ Refer to references listed in citations

↳ **Insurance Company's** policy states that in order for a child to be treated with GH, they must have a diagnosis of (insert the accepted diagnoses listed in your Insurance company's policy, such as Pediatric Growth Hormone Deficiency, Turner Syndrome, etc.). This policy is not consistent with the current standard of care and the exclusion should not be in place. My child, **FULL NAME**, meets the FDA indication for ISS as well as the current standards of medical practice. The reference citations on using GH treatment in a child with a diagnosis of idiopathic short stature show that GH is appropriate for these children and should not be labeled as 'not medically necessary'. Idiopathic Short Stature is a Diagnosis by Exclusion, meaning the diagnosis is reached by process of elimination. Since the cause of the poor growth is unknown, the term idiopathic (unknown) is used.

Furthermore, recent cases with Anthem BCBS, United and Cigna who also carry policy exclusions for this diagnosis (ISS), have had their denials overturned by their independent review organizations. Their medical reviewers acknowledge that ISS is a condition for which GH use, when the designated criteria are met, should be approved. **Insurance Company** should not be allowed to arbitrarily decide to exclude treatment for these children.

*****Start here if your insurance policy does cover ISS but you were denied treatment**

The role of the pediatric endocrinologist is not only to identify a child's abnormal growth pattern, but also to advise the most appropriate treatment for the child's unique situation, which in this instance was growth hormone therapy. **Ped Endo's Name** has determined that my **son/daughter's** poor growth is not caused by any other medical or congenital condition; laboratory testing and their clinical knowledge supports this determination. **Child's Name's** significant poor growth IS a cause for concern and the specialist in this clinical area has recommended growth hormone treatment to help my child achieve a normal adult height.

The FDA label indication- as well as what is considered the current standard of care for GH use in Idiopathic Short Stature- has been met by **Child's Name** and can be seen in the following growth data.

1. **First Name's** stature has a height standard deviation score that is ≤ -2.25 or $\leq 1.2\%$, and associated with a growth rate that will unlikely permit (him or her) to reach an adult height within the normal range
2. **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 and will not allow him to attain an adult height in the normal range

The Social Security Administration's 'Policy for Poor Growth' is listed under SSI Code 109.0 and states:

A physical or mental disorder may have physical effects that vary in kind and intensity, and may make it difficult for a child to perform activities independently or effectively. A child may experience problems such as generalized weakness, dizziness, shortness of breath, reduced stamina, fatigue, psychomotor retardation, allergic reactions, recurrent infection, poor growth, bladder or bowel incontinence, or local or generalized pain. A child may have difficulty with senses, including reduced hearing or visual acuity.

The Social Security Administration states that growth impairment is a disability. As such, the payor is ignoring the federal policy by denying treatment coverage and the action may be construed as discrimination against a disabled person.

It is because of the above referenced evidence that we respectfully request you exercise your authority to overturn **INSURANCE COMPANY's or PBM** decision to deny GH treatment coverage for **First/Last Name**. As parents, our ultimate goal is to ensure that **First Name** has the opportunity to live a healthy life. We sincerely hope that you share the same vision. We are prepared to file a grievance with our State Insurance Commissioner if necessary. We would also like to request that this external appeal be reviewed by a Board Certified Pediatric Endocrinologist.

→ Please Note: the following list is an example of the information commonly submitted for an external appeal. Criteria/documentation to include with this letter changes from company to company. Refer to your Final Adverse Determination Letter and/or the External Appeal Request Form as these often list the documents needed for reconsideration.

→ If agency asks you to send full references after you have submitted your appeal letter, contact MAGIC at appeals@magicfoundation.org and we will provide them to you.

→ Missing information or incomplete appeal requests can result in the rejection of your appeal by the independent review organization (IRO).

Enclosed please find the following supporting documentation for your reference (full articles can be made available upon request):

- ❖ Request for External Review Form
 - each payor has a form you must complete and send in with this letter, blank form is usually included with Final Insurance Denial 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 **CHILD'S FULL NAME**
- ❖ Supporting Articles:
 - I. "ISS:Definition,Epidemiology, and Diagnostic Evaluation Article in Growth Hormone & IGF Research"-May 2008 DOI:10.1016/j.ghir.2007.11.004

- II. "Growth Hormone for Treatment of Idiopathic Short Stature in Children" by S Zayed et al in Am Fam Physician. 2015 Jul 1;92(1):64.
- III. "Efficacy and Safety of Human Growth Hormone in Idiopathic Short Stature" by Songxue Tao 1, Guimei Li, Qian Wang, Yanyan Hu in PMID: 25893526 DOI: 10.1007/s12098-015-1746-y
- IV. "The Effect of Recombinant Growth Hormone Treatment in Children with Idiopathic Short Stature and Low Insulin-Like Growth Factor-1 Levels" by Zeynep et al in J Clin Res Pediatr Endocrinol. 2015 Dec; 7(4): 301–306. Published online 2015 Dec3. doi: 10.4274/jcrpe.211PMCID: PMC4805225

VI. Met Healthcare Solutions IRO decision for United Healthcare denial of ISS2021 VII. CIMRO Quality Healthcare Solutions IRO decision for Cigna denial of ISS2021 VIII. 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 by A Grimberg et al in Horm Res Paediatr 2016;86:361-397
IX. <https://www.ssa.gov/disability/professionals/childhoodssi-pub049.htm>

❖ Contact Information for Dr. **NAME**, M.D. Pediatric Endocrinologist
Address, Ph/Fx, Email

Regards,

Signature

Parent(s) Name(s)