

# Physician Frustrations and the ‘Economics’ of Growth Hormone Therapy Prior-Authorization Requests and Their Denial by Insurance Payers

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## Introduction

Growth hormone has been approved by the Food and Drug Administration (FDA) for treating short children with growth failure due to a variety of causes, including growth hormone deficiency (GHD), Turner Syndrome, Prader-Willi Syndrome, idiopathic short stature (ISS), chronic renal insufficiency and children born small for gestational age (SGA) with inadequate growth by their second birthday. Children with GHD tend to be the largest proportion of short children with growth failure. Growth hormone has a very short half-life in serum with a pulsatile pattern of release, like most pituitary hormones. A random blood draw for growth hormone is thus impractical as a means of diagnosing GHD. The diagnosis of GHD must be established usually by performing a growth hormone stimulation test. This is done by ‘provocation’ with pharmacological agents that cause the anterior pituitary to release stored growth hormone. The conventional cut off for diagnosing GHD under testing conditions is currently 5 micrograms/dL for adults and 10 micrograms/dL for children. Generally, growing children secrete higher levels of growth hormone than do adults, and thus would have higher serum levels under physiological conditions. Endocrinologists utilize various agents for the provocative tests; these include arginine, levodopa, clonidine, glucagon and insulin. Insulin is considered the ‘gold standard’ for growth hormone provocation tests though it is the least utilized, because of the associated danger of hypoglycemia and the need for the presence of qualified staff throughout the testing procedure to monitor and prevent such a complication.

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## Evaluating Short Children Prior to Recommending Growth Hormone Therapy

The initial approach is to screen the child for ‘indirect’ evidence of growth hormone secretion – usually by measuring serum levels of insulin-like growth factor-1 (IGF-1) and its major carrier protein, insulin-like growth factor binding protein – 3 (IGFBP-3); both considered to be largely dependent on levels of growth hormone secretion. IGF-1 is the main product and secondary messenger for growth hormone and its effects in the humans. About 80% of circulating serum IGF-1 is synthesized in the liver in response to growth hormone secretion, and serum levels are stable (longer half-life) and therefore a reliable measure of overall growth hormone secretion. Thus, in a short child with low levels of IGF-1, it is assumed that growth hormone secretion or action is inadequate. The next step then, is to perform a provocation test to ‘prove’ GHD.

To be considered eligible for insurance coverage of treatment, a child must ‘fail’ provocation tests with two separate pharmacological agents. Several criteria have to be met, including the child’s pattern of growth over several months at least; the size of the parents and siblings – to assess ‘genetic potential’ and the potential benefit to the child who would be subjected to possibly, several years of daily injections of growth hormone. Insurance companies require the performance of provocative testing on all children diagnosed with GHD, even when their growth chart recorded over several years clearly demonstrates growth failure, and serum IGF-1 levels are very low. “We do not treat ‘short stature,’ an insurance company official informed me, “You need to do provocative tests.”

The main thrust of the arguments in this paragraph have been eloquently summarized by Ron G. Rosenfeld and Pinchas Cohen in their chapter on disorders of growth hormone and IGF secretion and action.<sup>1</sup> Most endocrinologists think that these tests are un-physiological. They are largely not reproducible in many patients, and the establishment of cut-offs has little data to back it. The use of a common cut-off for all children, no matter their age, gender or pubertal status makes little physiological sense, but there is no data to stratify cut-offs. It is also possible to assess growth hormone

secretion by drawing samples every few minutes over a 12- or 24-hour period. This is expensive and not very convenient, and has been shown to pick-up a little more than half of children with GHD as identified by provocative tests. The recent addition of ISS to the indications for treatment with growth hormone has only made the situation murkier since, for all practical purposes, a short child with ISS is basically a short child with GHD who *does not* have growth hormone deficiency as defined by provocative testing. Testing does help differentiate between ISS and GHD but, if we are approved to treat ISS with growth hormone deficiency, and with all the problems associated with actually proving GHD in an otherwise healthy child, why do we continue to bother with testing? Besides, a child's performance on the provocation tests does not necessarily predict how such a child will respond to treatment with growth hormone. Endocrinologist like to make their evaluations and recommendations to treat with growth hormone as fast as possible.

### How Insurance Companies Slow Down the Process

Growth hormone therapy is very expensive. Growth hormone dosing is indication specific. An SGA indication requires dosing of 0.48mg/kg/week, while an indication of GHD requires dosing of 0.35mg/kg/week, all divided into seven daily doses. A rough calculation using our hospital's drug price list showed that a 3-year old boy (weight 11kg) with SGA would require about \$14,000 worth of growth hormone a year, whereas a 12-year old (weight 33kg) with GHD will need \$30,000 to cover therapy annually. This does not include the cost of syringes and/or needles, disposal units, alcohol swabs, and other related costs. If treatment for the 12-year old with GHD is delayed for about six months (no matter the reasons for such a delay), then the insurance company would have 'saved' about 15 thousand dollars for that year, on a that patient's treatment. To achieve such 'savings' all manner of impediments are put in the way of the endocrinologists who requests treatment for a patient. The 'prior approval' process is the start of the delay tactics.

A few years back, physicians could secure initial prior approval for two years to treat a patient with GHD; and like most rationale citizens, we pediatric endocrinologist are also concerned about the cost of treatment we usually insist on monitoring our patients every quarter – not only to ensure that they are being compliant, but also to satisfy ourselves that response to therapy as robust as possible, even though no additional prior approval requests will be needed for two years. To achieve this level of supervision we would only issue prescriptions for three months at a time, and will not renew these until we have seen the family concerned, examined and reviewed the patient in question.

Prior approval requests require providing complete medical records of the patient (including information about parents, siblings etc); all the laboratory investigations and tests that have been done, bone age x-rays, a growth chart going back

over several months or years and, of course, the all important response to pharmacological provocative testing. It is a lot of work which requires several hours of office time by the endocrinologists and their office staff.

Recently however, health insurance companies have changed the rules on the physicians and their patients. As one example, prior approval is now limited to six months. After struggling to get approval to treat a patient, the endocrinologists and their staffs are expected to repeat the whole process in six short months. Some insurance companies have continuing therapy applications forms which are shorter than the initial application ones and simplify the process, but others still require the completion of the same application forms as were submitted for the initial request, providing the same answers to questions previously posed. This has resulted in delays and interruptions of therapy for several patients but 'saved' insurance companies thousands of dollars. I know of no other credible reason for such a requirement beyond discouraging the use of the expensive medication.

Efforts are made to get the patient to change from one form of health insurance to another, usually a 'managed care' form of the same general health insurance, especially for state sponsored health insurance outfits. These are usually what is available or affordable for poor families. After six months of therapy, it is not unusual for a new request for prior approval to continue treatment, submitted in the same manner as the original successful one is returned, with a checked mark against a box that says 'patient has managed care' and the request should be submitted to their managed care company. Some of our patients are usually unaware of this switch, and it comes as a shock to them sometimes to find that they do not have the same coverage they thought they had. This has happened with such frequency and such regularity that one is forced to conclude that it is a deliberate ploy to avoid/delay continued payment for growth hormone therapy.

And even when the patient has not succumbed to the inducement to 'opt for managed care' a new request for prior approval is not necessarily a done deal. We frequently encounter a wait of several weeks for a response to a prior approval request only to find out, *after* we call the insurance company, that not all documents requested have been submitted! Since we usually fax these documents and keep the original packet in the patient's chart, we are able to go through these documents, page by page, only for the official on the other end of the line to admit that, in fact, all the requested information is available to them. The usual excuse is that 'somebody else' has been handling that file and they are not available to answer why they made a note that needed documentation was still missing. In the meantime a few weeks have gone by without a decision to approve therapy and, thousands of dollars have been 'saved.'

When state controlled payers like Mass Health ask for additional documentation after issuing a denial notice they require also, that we re-submit every piece of documentation,

even though is presumably available to them, and had formed the basis for the decision to deny approval in the first place. It is common too, to receive a “denial of approval” notice without a specific reason beyond a checked ‘insufficient information’ box. The endocrinologists or his staff will then have to call the drug utilization review committee to find out the particular reason for such a denial. Considering all the effort and time put into such requests by physicians and their staff, one would think that it would be a simple courtesy to actually tell them what the missing piece of documentation is, to facilitate a rapid response, but we are forced to spend additional time on the phone talking to officials at insurance ‘headquarters’ in order to discover precisely what the missing piece of information is, so as to be able to provide it. And once we have gathered this additional piece of information we have to resubmit the whole packet, again.

The endocrinologist making the request for prior approval is not always informed immediately about a decision to deny his request for approval of therapy. While the requests for approval of growth hormone therapy on behalf of the patient come from the physicians office, the denial notice is sometimes mailed to the patients’ home, and copied to the physician via snail mail, with a time limited demand to ‘appeal the denial’ within a very limited time window before it becomes permanent. Needless to say, several working class or inner city parents do not have the capability to deal promptly with such information/correspondence. By the time the physician has heard about this and requested clarification from the health insurance office, the window for appeal has closed, and the whole application for prior approval has to be redone and submitted anew. The hours that physicians and their staffs spend on these submissions, resubmissions, and appeals of denials are hours that are not reimbursed. Physicians may be reimbursed for the 20 or 30 minutes we spend with families and patients in clinic, but this is very little, compared to the hours of telephone calls, faxes and office time we spend dealing with the prior approval and denial of treatment processes; and the angst of our disappointed patients who require lots of hand holding and reassurance. None of these generates any revenue. In the current fiscal climate faced by most hospitals, even academic affiliated physicians are required to by their institutions to demonstrate sufficient relative value units (RVUs), and we would rather spend time in clinic seeing patients than hours on the phone with insurance companies that is not reflected in our value to our institutions. Our patients are the losers, and insurance company bottom lines are the winners.

### **Uninformed Clerks Deny Prior-Approval Requests**

Another trick is to use minimally educated (non-medical) staff to go through a check list of requirements but give them the power to issue denial notices to requesting physicians. A specific example will illustrate this point. An infant with

septo-optic dysplasia (SOD) who had several episodes of hypoglycemia in the nursery and needed growth hormone treatment to stabilize his blood sugar prior to discharge from hospital, is denied approval because there were no results from “stimulation testing!” in the packet submitted for prior approval. The request had all the necessary medical information and clearly, a physician reviewer would not have made a determination to reject such a request. Whoever made that determination was just checking boxes and did not find any stimulation test results and thus felt justified (according to his or her job description) in issuing a denial. A physician reviewer would have noted the diagnosis, the fact that this child was on several pituitary hormones - growth hormone, thyroid hormone, and cortisol (ACTH), and made the correct conclusion that the patient has multiple pituitary hormone deficiencies and required continued growth hormone therapy. Clearly, a clerk with no medical background should not be asked to make such a decision.

It should be safe to assume that an insurance company has enough records on their subscribers to make continuation of therapy feasible without much hassle. Which is why it is difficult to understand why an insurance company that has paid for the surgical removal of a craniopharyngioma from a child’s brain; paid for subsequent treatment of that child with thyroid hormone, cortisol, estrogen and anti-diuretic hormone, will then turn around and ask for the results of provocative test of the same child when presented with a request for growth hormone therapy because the growth chart and IGF-1 levels indicate just one thing – growth hormone deficiency? If the information is available, a physician reviewer would not make such a request, so health insurance companies should pass requests through physician reviewers in the first instance before making the determination to issue a denial. The only reason to do it the way it is done at present is to introduce more delays and extend the time to eventual approval, thus ‘saving’ 000s of dollars for their bottom line.

### **Conclusion**

What we are arguing is that health insurance companies should streamline their practices to be fair to subscribers and their physicians, so we have a clear idea of what to expect when we apply for prior approval for growth hormone therapy. They should recognize the time and effort physicians put into preparing applications for prior approval requests by treating these requests promptly and appropriately. In this regard, some are better than others, but we can wish that they all treat our efforts with respect.

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### **Reference**

1. Rosenfeld RG, Cohen P. Disorders of Growth Hormone/Insulin-like Growth Factor Secretion and Action. In: Sperlman M, eds. *Pediatric Endocrinology*. Saunders Elsevier, 2008, Chapter 8.