Growth Hormone Overproduction

KNOW YOUR RIGHTS

A resource for people with growth hormone overproduction and their loved ones.

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OVERVIEW

Growth hormone (GH) is essential for muscle and bone growth, strength, and distribution of body fat.[1] GH is produced by the brain's pituitary gland.[2] While many individuals will not have problems with their body's production of GH, some individuals can develop either an underproduction of GH or an overproduction of GH. When an individual's body is unable to produce the appropriate about of GH, they may have a condition known as "growth hormone deficiency."[3] Alternatively, when an individual's body overproduces GH they may have a condition known as "acromegaly" or "gigantism."[4]

While these conditions are caused by separate problems with the body's production of growth hormone, the barriers to their treatment can often be similar. Barriers may include overly burdensome benefit utilization policies, challenges receiving coverage for more convenient long-acting injections, and difficulties in receiving medical necessity coverage for non-formulary treatments.

This resource specifically focuses on growth hormone overproduction. If you are interested in learning more about growth hormone deficiency, please read our Know Your Rights resource, available here.

OVER PRODUCTION

Acromegaly & Gigantism

An overproduction of GH can be attributable to acromegaly or gigantism. Acromegaly and gigantism are both caused by an overproduction of GH by the pituitary gland.[5] In some cases, overproduction of GH can be caused by a tumor on the pituitary gland.[6] Some experts consider an overproduction of GH in children as gigantism, and adult overproduction of GH as acromegaly.[7]

Symptoms

Symptoms of GH overproduction vary depending on how long an individual has had the condition but can include swelling of hands and feet; coarse facial features with bone growth; increased perspiration and body odor; protruding jaw; voice deepening; joint pain; thickened ribs; and enlarged heart or other organs.[8]

Diagnosis

Testing for gigantism can be completed through a variety of tests, such as GH and IGF-1 blood tests, glucose tolerance tests, and magnetic resonance imaging (MRI) or computed tomography (CT) scans.[9] Similarly, acromegaly is diagnosed through serial photos taken over the years, blood tests checking growth hormone levels, and x-rays.[10]

Treatment

GH overproduction can be treated by radiation therapy; surgery; and/or with medications that block, regulate, reduce, or lower GH production.[11] Like GHD, treating overproduction of GH is important to prevent excessive height growth and associated complications.[12] Medications for GH overproduction can also include daily and long-acting injections.[13] Daily injections require individuals to self-administer the treatment three times per day.[14] This regimen may be difficult to maintain for some individuals, resulting in lack of treatment adherence. For instance, one study found that adherence to treatments was significantly higher with once-daily dosing compared to three or more daily doses.[15] Thus, long-acting treatments may be better alternatives for those who are unable to consistently administer their treatment multiple times per day.

Meeting Your Cost Sharing Requirements

Health plans may have high cost sharing requirements for some treatments. If you are concerned about the cost of your medication, you may be eligible for third-party assistance. Third-party assistance comes in multiple forms including manufacturer copay-assistance programs, patient assistance programs for uninsured or underinsured patients, and charitable assistance programs. However, some of these programs have income and condition requirements and, therefore, you will need to determine whether you meet the program eligibility criteria. In addition, if your health plan has adopted a copay accumulator policy, this third-party assistance will not count towards meeting your cost-sharing requirements.

Health insurers use a variety of practices that may delay or deny access to your treatment for a GH disorder. To find out whether your insurer may have improperly delayed or denied access to your treatment, ask yourself the following questions:

STEP THERAPY

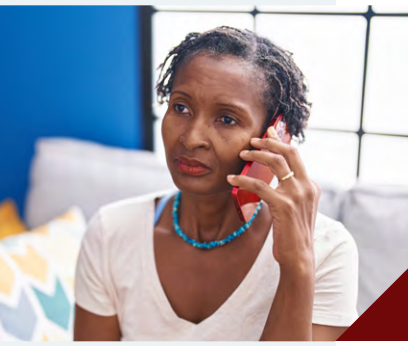
Did my insurer make me try a different treatment before covering the GH disorder medication or therapy that my care team originally prescribed?

This practice is called "step therapy" or "fail first" because it requires patients to try other treatments first and demonstrate that they do not work or are intolerable before the health plan will cover the originally prescribed treatment. Your insurer may require you to try and fail on multiple different treatments before covering the one prescribed by your care team.[16] This can lead to delays in access to medically necessary treatment, which in turn, can result in disease progression. Step therapy policies may violate federal or state laws if your insurer treats you and others with similar diagnoses differently because of your health condition. In addition, some states have passed legislation to limit the type of step therapy protocols that can be used. For instance, some state laws prohibit trying and failing on more than one treatment, failing on a treatment you have already tried and found ineffective, or failing on an off-label treatment. Additionally, you may also be entitled to an exception from the step therapy process.

NON-MEDICAL SWITCHING

Is my insurer forcing me to take a different medication, even though my current treatment is working, by refusing to cover it any longer or increasing my copay?

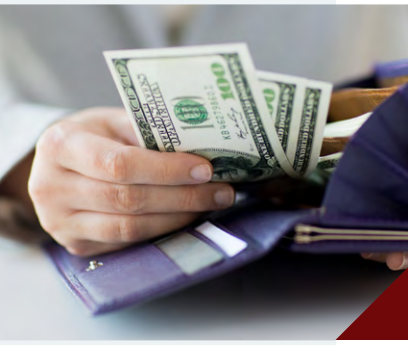
This practice is referred to as "nonmedical switching." It occurs when your insurer (not your health care professional or pharmacist) forces you to switch from your current treatment to a different (but not a generic equivalent) treatment by either refusing to cover your drug therapy any longer or increasing the out-of-pocket cost of your treatment.[17] Nonmedical switching can result in relapse and disease progression. One study found that when patients were nonmedically switched, over 75 percent of them experienced side effects as a result of the switch.[18] In addition, nonmedical switching may violate certain states' consumer protection laws.[19]



PRIOR AUTHORIZATION

Do I need to get my insurer's approval before I can begin or continue my prescribed GH disorder treatment or therapy?

This practice is called "prior authorization." It happens when your insurer requires you or your doctor to get your insurer's approval before the treatment or therapy is covered. Approval is based on the insurer's standards, which may be inconsistent with medical standards of care and harmful to patients. For those living with a GH disorder, the results can be devastating. These policies can also violate state and federal laws if applied in a certain manner.



ADVERSE TIERING

Do I have to pay a high copay for certain medications that treat my condition?

This practice is called "adverse tiering." It can be used by insurers to shift much of the cost for newer or innovative therapies to patients by placing expensive drugs on what are called "specialty tiers." Certain tiering policies may also violate certain federal and state laws if used in a discriminatory way.[20]

COPAYMENT ACCUMULATORS

If I receive coupons or discounts to help pay for my medication copays, does my insurer prohibit those coupons or discounts from counting toward my annual deductible?

This policy is known as a "copayment accumulator." Copayment accumulators force patients to pay more out of pocket when copayment assistance runs out and the insurance deductible has not been met. These policies are frequently buried in the fine print of insurance contracts and may violate state consumer protection laws.[21] In addition, 16 states have passed laws that prohibit health plans from implementing copayment accumulators.

"EXPERIMENTAL-TREATMENTS"

Has my treatment recently been approved by the FDA and my insurer has denied coverage because it considers the treatment "experimental"?

In general, an insurer may deem a treatment experimental if it determines that the treatment is not the standard of care for a particular condition.[22] Experimental treatments may include non-FDA-approved treatments, those that lack substantial evidence to support their medical effectiveness, and off-label treatments.[23]

My insurer refuses to cover a GH disorder treatment or therapy that my health care professional prescribed to me. **What can I do?**

If your insurer refuses to cover your treatment, here are three steps you can take to try to change your insurer's decision:

- Appeal the decision;
- Request an external review; or
- File a consumer complaint.

How do I appeal the decision?

If your insurer denies your claim, you have the legal right to an internal appeal.[24] This means you can ask your insurer to conduct a full and fair review of its decision. To appeal the denial, you should do the following:

Review the determination letter. Your insurer should have sent you a determination letter to tell you that it would not cover your claim. Review this document so you can understand why your insurer denied your claim and how you can appeal the denial.

Collect information. Collect the determination letter and all other documents the insurance company sent you. This includes your insurance policy and your insurer's medical necessity criteria. "Medical necessity criteria" refers to your insurer's policy for determining whether a treatment or service is necessary for your condition.[25]

Request documents. If you did not receive the determination letter or do not have your policy information, the medical necessity criteria, or the instructions and forms for filing an appeal, call the insurer's customer service representative and ask for these documents. The company website will list the toll-free telephone number to call.

Call your health care professional's office. The health care professional's office or clinic has people on staff to help with the appeal process. They will tell you how to fill out the forms to request an appeal, write an appeal letter on your behalf, or handle the appeal request for you.

Submit the appeal request. It is important for you or your health care professional's office to submit the appeal request as soon as possible along with the letter from the health care professional and all additional information the insurer requested.

Once you file an appeal request, expect to wait up to 30 days to hear back from the insurance company regarding a treatment you hope to receive. It can take up to 60 days for a response if you received the treatment and are waiting for reimbursement.

Follow up. Follow up with your insurer regularly until you hear back. Be sure to keep a record of the name of any representative you speak with about the appeal, the date and time you spoke with that person, a confirmation number for the call, and a summary of your discussion.

How do I tell my insurer the treatment my health care provider prescribed is not experimental?

You should ask your insurer for a written statement of the exact reasons for the denial (i.e., why the treatment is considered experimental), if that information has not already been provided. Review your plan documents carefully to see how the plan defines "experimental" (or "investigational" or "unproven") treatment. These terms can vary from plan to plan.

The FDA will only approve a treatment if there is evidence that the treatment is safe and effective. Therefore, if your treatment has recently been approved by the FDA and is indicated for your condition, then you may be able to appeal the denial on the basis that it is no longer "experimental." If you are being prescribed an FDA-approved treatment off label (i.e., it is not indicated for your condition), review your plan documents closely. Some plans have exceptions for coverage of FDA-approved off-label treatments for certain disorders if specific conditions are met.[26]

What if my insurer denies my appeal?

Under law, you are entitled to take your appeal to an independent third party for an "external review," which means the insurance company no longer gets the final say over whether to approve a treatment or pay a claim. The situation applies if the insurer denies your appeal or if your medical situation is urgent and waiting would jeopardize your life or ability to function.

How do I request an external review?

To trigger an external review, file a written request with the independent organization within 60 days of the date your insurer sent you a final decision. The process should take no more than 60 days. However, in urgent situations requiring an expedited review, the process should take no longer than four business days. To find out whom to contact in your state to request an external review, please go to www.CoverageRights.org.

How do I file a complaint?

If your insurer denies your coverage after the external review process, you can file a complaint with the insurance commissioner or attorney general in your state. To determine whom to contact and how to submit the complaint, please go to www.CoverageRights.org

Your complaint should include the following information:

- The name, address, email address, and telephone number of the person filing the complaint ("Complainant");
- The name of the insured individual, if different from the Complainant;
- The names of any other parties involved in the claim (for example, the plan administrator or pharmacy benefit manager);
- The name of the insurance company and the type of insurance;
- The state where the insurance plan was purchased;
- Claim information, including the policy number, certificate number, claim number, dates of denial, and amount in dispute;
- The reason for and details of the complaint; and
- What you consider to be a fair resolution.

You should also submit the following supporting documents with your complaint:

- A copy of your insurance card;
- Copies of coverage denials or adverse benefit determinations from your insurer;
- Copies of any determinations made by internal and external reviewers;
- Any materials submitted with prior appeals and complaints;
- Supporting documentation from your health care professional;
- A copy of your insurance policy; and
- All responses from your insurer.

What happens after the state insurance commissioner or attorney general receives my complaint?

The insurance commissioner or attorney general will assign someone to research, investigate, and resolve your complaint. That person will examine your account, records, documents, and transactions. He or she may question witnesses, request additional documents from other parties, and hold a hearing. If the insurance commissioner or attorney general determines that the insurer violated laws or regulations, he or she may order the insurer to give you the requested coverage or compensate you.

Whom should I call if I have any questions about filing a complaint?

To determine whom to call in your state, please visit CoverageRights.org.

Other helpful resources:

The Magic Foundation – The Magic Foundation is a charitable non-profit organization created to provide support services for the families of children afflicted with a wide variety of chronic and/or critical disorders, syndromes and diseases that affect a child's growth. The Magic Foundation has developed resources specific for individuals navigating a claim denial for GH therapy and injections. View their resources here.

The Acromegaly Community – The Acromegaly Community is a non-profit organization whose mission is to provide an emotional and communal support network for people touched by Acromegaly. They offer a central location for medical information on issues including: surgery, medication, radiation, and post diagnosis support. View their resources here.

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