

Highlights from the IG Living Teleconference, June 25, 2015

Topic: IG Therapy and Reimbursement

Guest Speaker: Leslie Vaughan, RPh, NuFACTOR Senior Vice President of Clinical Programs, has extensive experience in the clinical management of immune globulin infusions, as well as compliance on insurance and reimbursement issues.

This teleconference was an open question-and-answer session focusing on immune globulin therapy and reimbursement. Following is a summary of the questions and answers discussed.

IG Therapy

What Can a Patient Do Between Infusions to Stay Healthy?

There are two main things individuals can do to stay healthy between infusions:

- 1) The general things everyone does to try to stay healthy overall: good diet, hydration and exercise (depending upon how much mobility one has)
- 2) For those with an immune deficiency, avoiding exposure to germs

How Long Should a Patient Continue IG if There Is Not a Result After Six Infusions?

Everyone responds differently to immune globulin (IG). Some respond immediately; others take a bit longer. Sometimes it depends on how long it took to diagnose the illness. On average, some sort of improvement is seen after three or four courses of therapy.

A patient who isn't getting any results from IG therapy after a number of infusions should get in touch with their physician, explain what's happening and ask what to expect. It's possible that the patient isn't getting the right dose, or that a change in frequency might be in order. But those issues need to be discussed with the physician and pharmacist.

A patient's group of healthcare providers (nurse, physician, pharamacist) can see if there is something that can be done to improve the results or if there is a different type of therapy that might better help. Sometimes IG is not necessary for the

diagnosis, and instead, other therapies such as steroids or immune suppressive therapies might work better.

What Are Realistic Expectations for IG Treatment?

Realistic expectations often depend on the disease state being treated. With any disease, the goal is to see improvement.

For primary immunodeficiency patients, the goal of IG therapy should be to minimize the length, severity and number of infections. A patient should not expect infections to go away, but merely to get better. For those with autoimmune conditions, the expectation should be the same. For instance, if a patient has a hard time walking, that should improve. Or, a realistic expectation could be to go from a walker to a cane or from a cane to not having to use the cane all the time.

It's good to understand that IG is not without its own set of side effects. So, realistically, around infusion time, a patient might not feel good; they may be tired and have a headache and/or fever. This is because IG is a plasma protein, and it has a half-life. Over the course of 20 to 23 days, the antibodies in the IG medicine start to degrade, causing a drop in what is called the trough level, which is when weakness or fatigue returns.

IG Reimbursement

What Are Some General Suggestions for IG Reimbursement Challenges

In the last couple of years, insurance companies have been focusing on immune globulin reimbursement (IG) due to the drug's high cost. As a result, there are a couple of changes in the way many insurance companies are approaching IG reimbursement:

- 1) Neuropathies/Autoimmune Diseases: Depending on the diagnosis, most insurance companies are looking at these types of disorders as relapsingremitting, which means they are disorders that may go into remission after being treated with IG. The companies have looked at literature that supports this, and the only way they can determine if a person is in remission is to stop the IG or to lengthen the time between infusions to see how long the patient can stay symptom-free or if the patient relapses.
- 2) Immune Deficiencies: Especially when there is an insurance change, a new insurance company is looking to make sure the diagnosis is appropriately documented. This is a way for insurance companies to reduce costs. Depending on who is providing the IG, a patient needs to look at that company to be a resource for them and to fight the battle with them. Most companies are good at writing appeal letters and explaining to an insurance company why it's important not to stop IG treatments. If a patient has had to stop IG therapy and has relapsed, they should keep the documentation to show the insurance company.

When Changing Insurance, What Is the Best Way to Communicate with the Prescribing Physician's Nurses and Staff to Be Sure the Process Goes Smoothly?

If a patient knows their insurance is going to change, they need to be proactive. First, the patient needs to let their physician know. An insurance company won't consider whether it will approve therapy until a patient is insured with it, but a patient can still be prepared with diagnoses, copies of lab reports, records of how they've responded to IG, etc. Once the change takes effect, the provider can then submit that information to the insurance company.

If a patient is not changing insurance but authorization for IG is set to expire, that patient needs to be their own advocate by keeping a record of when that authorization is going to expire and then let their healthcare team know ahead of time. As soon as a patient knows the authorization is going to expire, they should make a follow-up appointment with their physician 30 days prior to expiration. Then, the request can be made at that time, and there will be plenty of time for new lab tests, appeals, etc.

How Is Payment Going to Be Made for Both Infusions and the IG Medication Once a Patient Transitions to Medicare?

This is a two part-answer:

- 1) A lot will depend on where a patient receives their infusions. If infusions are received at home and the diagnosis is a primary immunodeficiency, Medicare Part B only covers IG therapy for five specific diagnoses. Unfortunately, however, most home infusion companies will not continue to provide IG at home even for those five codes because, usually, reimbursement doesn't cover the entire cost of the therapy. Medicare only pays as much as what it costs for the medicine. If the patient is willing to change to a subcutaneous IG product, then the infusion company will continue to provide the drug and supplies and will answer any questions the patient has. That, then, would just require getting the prescription changed to the new product, and approximately three to five visits until the patient can self-administer the IG at home.
- 2) For a patient who doesn't have one of those five diagnosis codes, chances are reimbursement will shift to coverage under Medicare Part D, the prescription drug benefit. However, there is no coverage for nursing or supplies, so the home infusion company will give the patient a quote for a nurse to come to the home and to get the supplies for administration. In some instances, home infusions companies will help to offset co-pays.
- 3) For a patient treated in an infusion center or hospital/doctor's office. reimbursement doesn't normally change much. There are some diagnosis limitations, and not every diagnosis is going to be covered under those settings. So, if a patient knows they're in transition, they need to start working with the infusion company several months in advance. It also may

be time to consider getting a Medicare Part D plan or to move to a home setting.

How Is IG Reimbursed When Living Outside the U.S. for a Period of Time Each Year?

Most companies aren't able to supply IG outside of the U.S. So, a patient who knows they will be outside of the U.S. for an extended period could try to work with a commercial provider to see if they can receive a three-month supply to take with them. A lot of patients who go on extended vacations take their medication with them. But, going out of the country is trickier, especially when on Medicare.