



IVIG Treatment for Alzheimer's Disease

Last Updated 2/20/09

Frequently Asked Questions

In recent months there has been a growing interest in early and ongoing research into the use of a class of drugs called IVIG (intravenous immune globulin) and its effects on Alzheimer's disease. Although it is too early to form an opinion about its efficacy several small studies have shown promise which has excited researchers. Particularly of interest is that in some of these studies patients showed actual cognitive improvement not just a slowing or halting of deterioration. This overview of IVIG is intended as an educational piece for patients and clinicians who are interested in these drugs. Because IVIG is currently available and physicians are already prescribing it for Alzheimer's disease there has been an increased level of interest in it. This document is in no way intended to replace medical advice. If you are a patient or family member contact your physician and discuss any drug therapy with him or her. We will be happy to provide you or your doctor's office any information available to us regarding IVIG. To speak with a nurse or pharmacist about IVIG call us toll free at 866.44.BIORX (866.442.4679) or email us at iviginfo@biorx.net.

- **What is Alzheimer's disease?**

Alzheimer's disease is a degenerative brain process that produces, usually slowly over time, dementia or senility. It is also known as senile dementia. The brain is disrupted from the way it normally works. Mental function becomes impaired, and the patient's memory, ability to think clearly, and sometimes language are impaired. The causes of Alzheimer's are still unknown, but we do know that the disease produces physical changes in the brain. There is shrinking and widening in areas of the brain that cause connections to break and disrupts the electrical signals.

- **What is IVIG?**

IVIG or IntraVenous Immune Globulin therapy is the infusion of immune globulin into a vein. Immune globulins are antibodies found in human blood plasma. In the simplest terms, "immune globulin" and "antibody" are the same things. Antibodies are important in the body's defense against foreign substances such as viruses and other disease causing pathogens. The antibodies are collected from the pooled plasma of thousands of donors that have been carefully screened and tested for safety. IVIG manufacturers take plasma from large numbers of donors and extract the antibodies from the "pool" then concentrate, clean, and preserve the antibodies into a medically useful pharmaceutical product. IVIG is typically used for patients with autoimmune neuromuscular disorders, primary immune disorders, certain types of leukemia, and bone marrow transplants. The number of diseases treated by this group of drugs is continually growing.

There are currently several brands of IVIG. For a complete listing and their chemical characteristics go to http://www.biorx.net/IVIG_chart.pdf



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- **How is IVIG treatment given, and how often?**

IVIG treatment must be prescribed by a physician. IVIG is administered, typically by a registered nurse, as an infusion into a vein (intravenous), a process that typically takes several hours. IVIG is administered in a variety of dosages for Alzheimer's treatment. Current dosing is based on body weight and is typically given as an infusion every 2 weeks, every 4 weeks, or every month depending on physician's orders. Keep in mind that research into the dosing and frequency is in its early stages. Physician's prescribing IVIG for Alzheimer's disease have used a variety of doses generally falling between 1-2 grams of IVIG per kilogram of body weight.

- **How does IVIG help Alzheimer's?**

Despite very promising results in several small early-stage studies, it is not fully understood to what degree IVIG is effective in treating Alzheimer's or exactly how or why it may work in this disease. The most widely accepted theory is that IVIG contains antibodies that may bind to beta amyloid (A β), a central component of the plaque in the brains of Alzheimer's patients. It is believed that IVIG may help promote the clearance of A β from the brain and block A β 's toxic effects on brain cells.

- **Is IVIG a new treatment?**

IVIG has been available for many years and is approved by the FDA for treating several immune disorders. It has been safely used in hundreds of thousands of patients. According to the Plasma Protein Therapeutics Association about 37,000,000 grams of IVIG have been distributed for use in the past year in the US. This means that approximately 50,000 people in the US receive IVIG monthly. This number has been steadily growing as researchers continue to find beneficial uses for these drugs.

- **How effective is IVIG in treating Alzheimer's?**

It should be noted that IVIG use in Alzheimer's is in the early stages of investigation. However, as of 1/1/09 a few small clinical studies have shown very promising results. Two clinical studies have been carried out examining the effects of IVIG in Alzheimer's disease at a mild to moderate stage of the illness. A total of 13 patients were treated in each of these two studies. While the study group was too small a number to establish conclusively whether or not the treatment works, IVIG was well-tolerated by the patients over six months of treatment. The majority showed improved cognitive ability. This has been exciting to investigators as other drugs on the market currently only work to temporarily halt or slow deterioration.

In 2005, researchers at the New York-Presbyterian Hospital/Weill Cornell Medical Center concluded the first clinical study that suggests that IVIG may stabilize or improve cognitive function in Alzheimer patients, when administered over a period of a year or more. To learn more about this study, please go to: http://news.med.cornell.edu/wcmc/wcmc_2005/04_11_05.shtml

A larger and more thorough Phase III Clinical Study is currently being developed. This study will involve a higher number of patients and blind studies (control groups) that incorporate placebo controls, to determine the usefulness of IVIG in the treatment of Alzheimer's disease.

To obtain more information about this study and to enroll, go to

<http://www.clinicaltrials.gov/ct2/results?term=IVIG+and+Alzheimer%27s> where details are posted.



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Currently, IVIG is **not** FDA approved for the treatment of Alzheimer's disease but physicians are free to prescribe it if they believe it is warranted in a particular case. Some analysts estimate that as many as 2,000 Alzheimer's patients in the US have received IVIG. You should ask your physician whether this is right for you or your family member.

- **Is IVIG safe and what about side effects?**

IVIG has been administered safely to several hundred thousand people over the years. Normally, it is well-tolerated; but as with any medication, there are risks and side effects. You should discuss these with your physician. Side effects associated with IVIG therapy tend to be few and are often related to the rate of infusion or dosage. Headache is the most common adverse reaction associated with IVIG therapy. Other common side effects may include chills, fever, muscle aches, nausea, rash, and chest tightness. The manufacturer's package insert may be reviewed for a more detailed summary of adverse reactions and contraindications. Slowing the rate of infusion can often help decrease these side effects. Pre-medication with drugs such as Benadryl and acetaminophen can also help to decrease or eliminate the discomfort of possible side effects. Being well hydrated prior to your infusion may help as well. Your physician and infusion nurse will help to advise you if pre-medications are required and administer them prior to your next infusion.

Possible severe reactions include severe headache (aseptic meningitis), stroke, and anaphylaxis (severe allergic reactions). Your healthcare provider should explain these risks and take precautions to protect or treat you in the event they occur. While very rare, severe drug reactions can occur and should be discussed if you have concerns.

Because IVIG is derived from human plasma, IVIG carries with it a theoretical risk of transmission of some blood-borne pathogen, such as viruses. Advances in manufacturing processes in recent decades have included several viral-elimination technologies that have been effective at keeping the IVIG supply safe. The US blood and plasma supply is widely accepted as the safest in the world. There have been no documented cases of these diseases being transmitted by IVIG in the United States in almost 25 years. There may be additional unknown risks associated with its use in an elderly population with Alzheimer's, but many older persons have received IVIG without difficulty.

- **Is IVIG currently available and how do you qualify for IVIG treatment for Alzheimer's?**

A physician may prescribe IVIG for Alzheimer's if he/she feels it is warranted. A physician would evaluate the Alzheimer's patient and, based on his/her assessment, develop a plan of treatment, which may or may not include IVIG therapy. Treatment varies from physician to physician.



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- **How do you obtain IVIG treatment?**

BioRx is a specialty pharmacy and infusion therapy provider which specializes in the administration of IVIG. If your physician prescribes IVIG (or is interested in prescribing IVIG) you may contact BioRx at 866.44.BIORX (866.442.4679) in order to arrange care or to have BioRx give you information on cost and availability. If you are unsure or want more information, you can call us or email us at iviginfo@biorx.net and a clinician will respond to your request.

A physician must prescribe the IVIG treatment. IVIG treatments are typically administered at home, in a physician's office or at a hospital. Typically the pharmacy will determine whether the insurance carrier will cover the medication and inform the patient of his/her financial responsibility. Then the pharmacy will make arrangements for IVIG to be administered in an outpatient or home setting, based on the individual patient's needs. The pharmacy will coordinate medication, nursing and supplies for administration.

- **What is the cost of IVIG treatment?**

IVIG costs vary widely from patient to patient. Cost is dependent upon the dose ordered (weight of the patient), the IVIG brand used, and where the patient receives it. One month of treatment typically costs between \$5,000 - \$10,000, which includes the expense of the IVIG itself, the infusions and other related costs. This is only an example; each patient will be different.

- **Will your insurance cover IVIG treatment for Alzheimer's?**

At present, IVIG is considered an off-label use for the treatment of Alzheimer's disease and is not covered by most insurance companies and may be the patient's financial responsibility. Once the Phase III Clinical Study concludes, it is possible that Medicare and other third-party payers will re-evaluate their policies regarding payment for this treatment based on the outcome of the trial(s).

- **Are there any studies you can participate in to receive free treatment?**

A Phase III clinical trial for the treatment of Alzheimer's disease with IVIG is being sponsored by Baxter Healthcare Corporation. To obtain more information and to enroll, please go to <http://www.clinicaltrials.gov/ct2/results?term=IVIG+and+Alzheimer%27s> where details are posted.

- **Does BioRx recommend patients with Alzheimer's receive IVIG?**

Choosing to receive any medication, especially an intravenous medication such as IVIG is a decision that should only be made after careful and deliberate discussion with your physician. BioRx does not make any treatment recommendations but strongly advises you to speak with your physician about new drug research.