



Where Does My IVIG Come From?

IVIG Supply Consistency

By Chris Ground

Patients and healthcare providers often wonder why we do not have a consistent supply of intravenous immune globulin products (IVIG), and, like most issues surrounding plasma products, the answer is not simple. In fact, IVIG supply consistency is a very complex issue. One easy way to think about this is to break it down into the four basic elements of the IVIG supply channel.

- ① Human plasma supply
- ② Manufacturer supply
- ③ Distribution supply
- ④ Demand for IVIG

Human Plasma Supply

Human plasma is the raw material for IVIG production, and its availability determines how much overall output of IVIG can be manufactured to supply the market. The supply of human plasma is not consistent; it varies, based on the number of plasma collection centers that are operational at any given time and on the success of each center to recruit donors.

Manufacturer Supply

The supply of IVIG at the manufacturer level also varies. As each lot of IVIG is filled and finished, it is subject to an FDA release process. At any given time, a lot can be held or denied release by the FDA for myriad reasons, most often to protect patients from potential contaminants or other concerns that may put a patient at risk. This can then create a “dip” or “hole” in the supply chain for that particular brand of IVIG. In addition, sometimes shipping challenges hamper getting product into the distribution chain by a week or more, creating a short-term disruption in supply. However, patient needs cannot be postponed for a week or more. This leads to the third link of the supply process.

Distribution Supply

Manufacturers typically use a network of specialty distributors to move IVIG to healthcare providers throughout the United States. During periods of short supply of IVIG, when demand outpaces manufacturers’ ability to supply enough IVIG, distributors will employ various methods of allocating product to each provider in an effort to maintain as consistent a supply to patients as possible. However, when a certain brand of IVIG is not available from a manufacturer at the time the provider needs it, due to one or more of the various reasons mentioned above, the distributor may offer another brand of IVIG to ensure that the patient is infused within the time frame necessary to maintain efficacy of the treatment.

Demand for IVIG

Demand for IVIG continues to grow. New areas of use for IVIG outside the currently approved FDA indications continue to be explored and identified by the clinical community. And, although these new indications appear to translate into a beneficial clinical response for patients, they also result in increasing demand, exacerbating an already thin supply of IVIG.

So, all four of these factors work together to define the “consistency factor” for IVIG. When the four elements are balanced consistently, the supply is consistent, but this is rarely the case. More often, one element is out of balance, inevitably resulting in an inconsistent supply of IVIG.

One of the most helpful things *IG Living* readers can do to improve IVIG supply consistency is encourage every healthy person you know to become a regular plasma donor. As so many of you are aware, each donation contributes to the making of a miraculous lifesaver! ■