MGFA IVIG Shortage Statement

Dear MG Community:

We have heard concern from many of you regarding the current shortage of many of the brands of Immune Globulin therapy that you rely on. MGFA takes this issue very seriously and our Advocacy Committee is investigating the causes of this nationwide shortage, as well as developing a strategy on ways to ensure that our community receives priority access as needed to prevent disease worsening or crisis.

As you know, Immune Globulin Therapy (IVIG/SCIG) is made from human plasma and is a complex process that relies on three key components: raw materials (plasma), manufacturing capacity and demand. One transfusion of IVIG is made up from about 100 plasma donors. So, we must remember that it is not as easy to make this product as making pills. With that said, all manufacturers are manufacturing at full capacity and one manufacturer has invested in a new facility to manufacturer even more IVIG into the marketplace. There are also some new brands of IVIG and SCIG (subcutaneous immune globulin therapy) coming into the market. So, why are we not able to get the brand of IVIG or SCIG we need in the site of care we receive it in?

In 2018, one brand of IVIG left the marketplace and another brand is slowly being reduced from the marketplace in 2019. One manufacturer has plasma shortages, while the other manufacturers have more than enough plasma to meet production needs. We have seen production problems with multiple manufacturers throughout this year and some continue to have some problems. Finally, we are seeing a trend of new brands of IVIG and SCIG entering the market only available to a limited number and types of sites of cares.

Which patients in the community are being affected the most? It appears that the most significant impact has been on patients receiving their infusions in hospital infusion centers or physician infusion suites. These sites of care may have fewer brands available to them and/or may have contracts to buy only certain brands of IVIG. When there is a shortage, sites may also triage patients to determine the most acute needs, and MG patients may not be at the top of the list. MGFA’s position is that missing treatments can be life threatening for people who are
dependent on the treatment for maintenance, and that it is also critically important as a treatment for people with acute exacerbation/impending MG crisis.

What can you do if you are being affected by the shortage? If you are not receiving your infusion, speak to your doctor about being prioritized at your infusion center or transferred to home infusion if that is a safe alternative for you. Discuss both IVIG and SCIG with your physician. Please contact MGFA to let us know that you are having problems and we can help you get in touch with a Patient Advocate. Also, contact the FDA shortage hotline at CBERshortage@fda.hhs.gov or 240-402-8380.

We will continue to update you on the IVIG shortage and ways we can work together to get through this health care crisis.