



## **CHANGES TO CRITERIA TO ACCESS IVIg FOR PATIENTS WITH ACQUIRED HYPOGAMMAGLOBULINAEMIA ASSOCIATED WITH A HAEMATOLOGICAL CONDITION**

### **What are the Criteria?**

Within Australia, access to intravenous immunoglobulin (IVIg) therapy is funded by governments for a range of medical conditions defined within the *Criteria for the Clinical Use of IVIg in Australia* (the Criteria).

### **What has changed and who will it affect?**

The Criteria has recently been reviewed to ensure that access to funded IVIg remains consistent with evidence of demonstrable patient benefits.

As a result of this review, a number of changes have been made and the revised *Criteria for the Clinical Use of IVIg in Australia* Second Edition (IVIg Criteria Second Edition) has now been implemented.

One of the changes relates to access to IVIg for patients with acquired hypogammaglobulinaemia (lack of antibodies) associated with a haematological condition.<sup>1</sup>

### **What will this change mean for me?**

The key change to the IVIg Criteria Second Edition for acquired hypogammaglobulinaemia is to the requirements for review, by your doctor every six months, to determine if you can continue to receive IVIg.

At your review, your doctor will assess if your condition has improved as a result of the IVIg treatment. Part of this assessment requires that, every 12 months, your doctor should consider stopping your IVIg therapy to allow them to re-evaluate your immune system.

You will only continue to receive IVIg if it is shown to be effective in treating your condition. If IVIg is not effective for you, then you will stop receiving it and your doctor may recommend an alternative which may be more beneficial.

### **What if my doctor is considering stopping my IVIg therapy?**

---

<sup>1</sup> haematological condition – disorder of blood and blood-forming tissues, such as chronic lymphocytic leukaemia, multiple myeloma, non-Hodgkin lymphoma and following haemopoietic stem cell transplantation

If your doctor is considering stopping your IVIg therapy, they may decide to continue your treatment until the end of the winter so that you can stop in September/October. This will help avoid exposure to winter colds and flu during the months immediately after you stop treatment.

Your doctor may also wish to prescribe antibiotics during this period to help to reduce your risk of infection.

It can take up to six months after ceasing IVIg therapy before your immune system can be properly re-evaluated.

### **What if my doctor does not believe that it would be safe to stop my IVIg therapy?**

If your doctor believes that it is not safe to stop your IVIg therapy, they must confirm in writing that they have seen you, and that you have benefited from IVIg therapy, but that it would not be safe to stop your treatment.

### **Why has this change been made?**

IVIg is a scarce product with limited supply because it is made from human plasma. As a matter of principle, IVIg should only continue to be prescribed for medical conditions where there is a demonstrated clinical benefit.

It is, therefore, important for your doctor to consider periodically whether it is safe to stop IVIg treatment and reassess your immune system.

### **When will the changes take effect?**

A six-month transition period has been allowed for doctors to review those patients who were receiving IVIg for acquired hypogammaglobulinaemia prior to the introduction of the IVIg Criteria Second Edition. The transition period runs from 10 August 2012 to 10 February 2013.

The IVIg Criteria Second Edition will apply to all new patients from 10 August 2012