



CHANGES TO CRITERIA TO ACCESS IVIg FOR PATIENTS WITH IgG SUBCLASS DEFICIENCY

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).

IVIg has not been funded for patients with IgG subclass deficiency since the introduction of the first edition of the Criteria in 2008. There were, however, a number of patients receiving funded IVIg for this condition prior to the introduction of the Criteria who have, for various reasons, continued to receive treatment.

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 these changes relates to access to IVIg for patients with IgG subclass deficiency.

What will this change mean for me?

The key change to the IVIg Criteria Second Edition for IgG subclass deficiency is to the requirements for review by your doctor to determine if you can continue to receive IVIg.

The change requires that your doctor consider stopping IVIg treatment, at least every 12 months, to allow re-evaluation of your immune system.

What if my doctor is considering stopping my IVIg therapy?

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.

On re-evaluation, your doctor may consider it appropriate for you to recommence IVIg therapy for a medical condition other than IgG subclass deficiency.

If you cease therapy, you will no longer be able to receive IVIg for IgG subclass deficiency as this condition is not funded under the Criteria.

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 will be required to 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.

In this case, your doctor will need to seek the opinion of a second specialist doctor who will also be required to write a letter confirming that it is not clinically appropriate to stop your IVIg therapy. You do not need to be seen by the other specialist doctor. Your treating doctor can seek their opinion over the phone.

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.

IgG subclass deficiency is not fully understood. Antibody production will improve for many patients over time. Many people with IgG subclass deficiency do not get sick and do not need IVIg.

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 IgG subclass deficiency 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.