

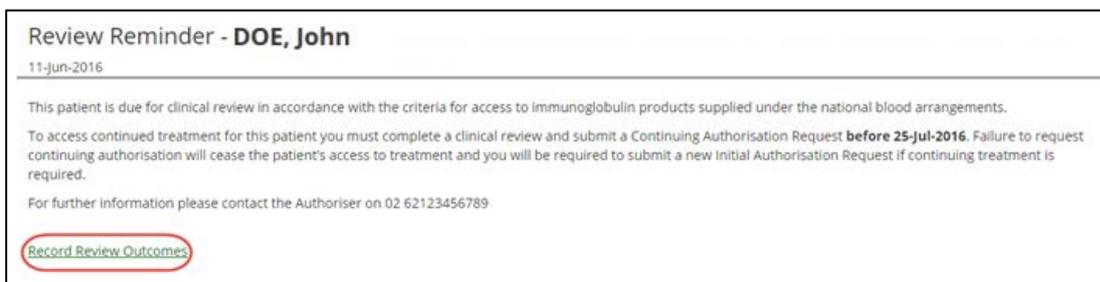
Submitting Review Outcomes and Creating a Continuing Authorisation Request

Once an approved Immunoglobulin (Ig) Authorisation is nearing or has just exceeded its expiry date, BloodSTAR will notify Medical Officers involved with the authorisation and prompt them to submit review outcomes and will provide the option to submit a Continuing Authorisation Request.

Recording Review Outcomes

There are two ways of recording patient review outcomes.

1. **Option one:** click on the link in your emailed notification and you will be automatically directed to the relevant BloodSTAR message in the *BloodSTAR Messages* tab. Within that relevant message, click the link *Record Review Outcomes* at the bottom.



Option two: once you are logged in as a Medical Officer select the *Pending Reviews* tab. This will display all authorisations that require review in the next 8 weeks or those that have expired in the last 8 weeks. Locate the patient you want to record a review for and click *Record Review*.

The screenshot shows the BloodSTAR web application interface. The top navigation bar includes "Home", "Patients", "Authorisation Requests", "Treatment", and "BloodSTAR Messages". Below this, there are tabs for "My Authorised Patients", "Pending Reviews", and "Authorisation Requests". The "Pending Reviews" tab is selected and highlighted with a red circle and a red arrow. Below the tabs is a table with the following columns: Patient, Date of Birth, Treating Facility, Patient ID, Medical Condition, Review Due Date, and an action column. The table contains one row for "CITIZEN, Simon" with a review due date of "29-Jun-2016". In the action column for this row, there is a red button labeled "Record Review" with a magnifying glass icon, which is circled in red and pointed to by a red arrow. At the bottom of the table, there are pagination controls showing "1" of 10 items per page and "1 - 1 of 1 items".

2. On the *Review Outcome Form*, confirm that all patient details are correct and, if necessary, change or update them by selecting *Edit Patient Details*.
3. Scroll down, enter the review date and nominate the Reviewing Medical Officer.

The screenshot shows the "Review Details" form. It has the following fields and options:

- Review Date ***: A date input field with the value "29-Mar-2017" and a calendar icon.
- Reviewing Medical Officer ***: A radio button selection with three options:
 - Treating Medical Specialist
 - A different medical officer
 - Not in the list
- Under "Treating Medical Specialist", there is a text input field with the value "Doctor - The Canberra Hospital".
- Under "A different medical officer", there is a dropdown menu with the placeholder text "Enter practitioner name or part of it".

4. Under *Review Criteria*, select all applicable options for the *Qualifying Criteria* according to your patient's condition and fill in all relevant *Supporting Evidence* details. These options are dependent on the original diagnosis and, if selected, will create fields for you to enter more information about the patient.

5. In *Review Outcome*, select the overall review outcome from the available options, which can be broadly separated into two categories:

Review Outcome

Review Outcome *

A **Request Continuing Treatment**
These review outcomes provide supporting information for assessment of an extension to the authorisation period.

Interim review only
Access to therapy will continue unchanged to the authorisation end date or until a later review and request for continuing authorisation has been assessed and approved. This option is not available within 2 weeks of the authorisation end date.

B **Trial Cessation**
A trial period of cessation will commence to assess clinical benefit of Ig therapy. The proposed cessation date must be within the current authorisation period. Recommending Ig therapy will require submission of a new initial authorisation request form.

Cease Treatment
End the current authorisation now because there has been either no demonstrated clinical benefit or Ig therapy has undesirable side effects.

A **Request Authorisation under a different indication**
End the current authorisation and submit a new initial authorisation request form under a different indication.

- A. Either of these options will prompt for the Ig Authorisation status to continue, either through putting in a request for a continuation of the patient's current authorisation or the creation of a new authorisation request under a different indication.
- B. Any of these three options will end the current Ig Authorisation, either immediately or at the expiry date, and will not provide a Continuing Authorisation Request or immediately prompt a New Initial Authorisation request.

If you elect to end the current authorisation you will be prompted to enter a Cessation Date if it is to end immediately. Enter the date if earlier than the current authorisation end date and click *Submit*.

If you have chosen to seek authorisation under a different indication, click *Submit* and then begin a New Initial Authorisation.

Creating a Continuing Authorisation Request

1. If you selected *Request Continuing Treatment* under *Review Outcomes*, a section labelled *Continuing Authorisation Request* will appear. Enter your patient's weight and the dosing regimen you would like to submit for authorisation.

Continuing Authorisation Request

Patient Weight * kg Use Ideal Body Weight Adjusted Dosing

Maintenance Dose

Subcutaneous administration of immunoglobulin can be considered as an alternative to IVIg. A suggested dose is 0.1 g/kg lean body mass every week, modified to achieve an IgG trough level of at least the lower limit of the age-specific serum IgG reference range.

The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.

Refer to the current product information sheet for further information.

2. Once these details are entered, click the checkbox next to the *Terms and Conditions* and click *Submit*.