ascia
australasian society of clinical immunology and allergy

27 May 2019

Michael Stone
Deputy Chief Executive
Commercial Blood Products and Business Services
National Blood Authority (NBA), Australia
Email: Michael.Stone@blood.gov.au

Dear Michael,

ASCIA feedback regarding NBA BloodSTAR

On behalf of ASCIA, we write to you regarding concerns expressed in recent months by some members of ASCIA, the Australasian Society of Clinical Immunology and Allergy, regarding the National Blood Authority (NBA) BloodSTAR program for authorisation of immunoglobulin replacement therapy (IRT).

After discussions with you and Jo Cameron on 8 March 2019, we understand that some issues with BloodSTAR that have been raised as concerns by ASCIA members are being addressed by the NBA. This letter includes those issues as well as others of which you may not be aware of.

Clinical immunology specialists conduct regular reviews of patients on IRT for treatment of immunodeficiencies, in specialist clinics. Whilst the NBA BloodSTAR process has applied some stringency in approval of supply, and has brought many patients into specialist clinics, who had not previously been under specialist review, the current authorisation process is time consuming and inefficient, which can adversely affect clinical practice.

Specific issues raised by some ASCIA members include:

1. The increase in time spent entering data significantly extends clinic time, therefore reducing the time that a specialist can spend talking with, and clinically reviewing the patient. Whilst this may be performed by registrars or other junior staff in a hospital clinic, this is not possible if the patient is seen in a private specialist clinic.

2. Some entries are repetitive and unnecessary, including age and date of birth in a patient who is already registered (with date of birth already on the system), and then having to tick a box to say that the patient is greater than four years of age.

3. Having to enter some data is meaningless. For example, IgA and IgM levels in patients who have absent IgA and IgM, and in whom these parameters have not been measured in recent years; infection history prior to commencement of IRT in patients who started in childhood, who have no memory of this (and records may be held elsewhere); The date of a non-existent infection, in patients who have had no infections over the past review period.

4. If patients miss their appointment, they may not be able to rescheduled within a month or two, and then authorisations often run out.

5. Having to go through this lengthy process every 10-12 months for long-term IRT patients, who have a known condition with a definite lifelong requirement for IRT.

We have also received examples from individual ASCIA members of situations in which BloodSTAR has contributed to problems, frustration and unnecessarily increased workload. These are listed on the attached pages.

We hope that the NBA will consider the issues listed above, and make changes to the NBA BloodSTAR program to help address the concerns of ASCIA members.

We look forward to your response.

Yours sincerely,



Dr Brynn Wainstein
ASCIA President

Dr Theresa Cole
Chair, ASCIA Immunodeficiency committee

Jill Smith
ASCIA CEO

Copy: Jo Cameron, NBA Director Ig Governance
Email: Jo.Cameron@blood.gov.au

Attachment: Examples of feedback from individual ASCIA members of situations in which BloodSTAR has contributed to problems, frustration and unnecessarily increased workload

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Example A

A patient who has learnt to administer SCIg was due to collect their first dose at hospital close to home I ordered it on BloodSTAR with XX as treating hospital and X as dispensing hospital, provided the script and sent the family to collect. Hospital X refused to accept dispensing responsibility and so I spent much time doing the following: Speaking with family, on phone to BloodSTAR, failing to get help with BloodSTAR, speaking with contact at NSW MoH. MoH replied saying that hospital X has a local policy in place which overrides their responsibility as a dispensing hospital. I had to cancel that order/request and reorder to be delivered at hospital XX and the family then had a considerable drive to collect their SCIg. There were further logistical issues locally as they were not expecting the patient. Why is there a drop down box offering hospital X if they are not willing to undertake this role?

Example B

Patient prescribed 16g per month, unable to specify vial size, so patient given a 10 g vial a 4 g vial and a 2 g vial, resulting in plenty of work for staff and wastage of Ig.

Example C

Requested 8 weeks supply of SCIg, patient given 6 weeks only. This was brought to my attention after the event as the patient was unsuccessful in getting further 2 weeks supply. This resulted in a lot more work for staff.

Example D

The biggest problem that has arisen in my experience (mostly in the private setting) has been delays in treatment for patients who are awaiting immunologist review, that I discover when I see them for the first time at their appointment. I generally try to see PID patients sooner rather than later, but in these cases no information as to the timing of the required review is provided with the referral and nor is the patient informed, except by a call from Blood Bank saying that their infusion has been delayed.

From the governance document you can piece together responsibilities that would avert this. The dispensing Blood Bank and treatment centre should keep track of the expiry and inform the treating specialist, the treating specialist should seek interim arrangements in consultation with the Blood Service, the Blood Service staff should- and do- facilitate interim authorisation while the immunology review is pending, and the patient can always take some ownership and press for these. However. in reality the responsibility is too diffuse and patients fall through the cracks. Part of this relates to lack of awareness and education with regard to the complexities of the new system, but then all of the other difficulties in the system, and the fact that everyone is very busy, conspire to make the outcome of an inadvertent trial off immunoglobulin product more likely.

Example E

Having used BloodSTAR since it began, the product on this latest update is not user focused. Asking people to enter dates of birth and age (and asking if they are older than 4) when this information is known but no one bothered to write the line of code speaks volumes for clinical consideration.
There is also a clear breach of fairness in that one generally doesn't need to re-apply or consider ceasing therapy just because requirements have changed. Whilst I agree many patients in the past will have received IgG inappropriately, when you are asked to see them 20 years after they started IVIG, it is fairly hard to stop it when the patient says it has been on clinical benefit. In addition, asking the qualifying information for people, the sending of reminders way to early when you can't actually do the form, and repeatedly being asked why a trial off isn't being done, when it has been is frustrating.

Example F

My bugbears with BloodSTAR include :

- Asking the doctor to enter the date of the patient's planned next infusion during the re-approval process. Scheduling of infusions is well out of the doctors' hand (public and private), and not readily available. The medical re-approval should be limited to medical criteria, and scheduling questions need to go elsewhere to other categories of BloodSTAR users (nurses/secretaries etc).
- Once an approval expires, it is not possible to transfer the patient's pending authorisation to another specialist ... but it is possible before it expires. Should be possible either way (I've emailed and called BloodSTAR about this ... they are "working on it"). Matters when a) you are about to go on maternity leave and b) when you share a lot of patients with other specialties e.g. neurology and they are away etc.
- What is the process for accessing urgent IVIg after hours / over weekend in a public hospital? Our institution has sent out an email saying consultants need to be doing all their own applications/approvals ... this is very hard on a weekend when on call and if an SJS comes in or something ... there should be standard procedures allowing for delegation to appropriate registrars/residents.