australasian society of clinical immunology and allergy

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Kerry Atkins
DUSC Secretary
Director – Drug Utilisation Section
Technology Assessment and Access Division | Health Financing Group
Office of Health Technology Assessment Policy Branch
Australian Government Department of Health
T: 02 6289 1451 | E: kerry.atkins@health.gov.au

Dear Kerry,

Thank you for your email of 4 May 2020, sent on behalf of the Drug Utilisation Sub Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC).

We have reviewed the confidential report on the use of omalizumab for the treatment of chronic spontaneous urticaria (CSU)and provide the following answers to your questions.

1. Whether relevant commonly used drugs to treat urticaria have been captured in Table 1 on page.

The ability to prescribe omalizumab in patients with CSU has been one of the most effective and satisfying treatments for clinical immunology/allergy specialists to prescribe.

Regarding Table 1 on page 2:

- H2 antagonists have largely become unavailable and should now be removed from this table.
- It is reasonable to assume patients have tried high dose antihistamines in combination with montelukast for a short period of time, but it is not reasonable to expect all patients to try doxepin because many are so intolerant of it.
- It is incorrect to list omalizumab under "Immunosuppressants" because it is not. It should have its own category (e.g. monoclonal antibodies or biological therapies).

2. If the proportion of patients continuing on omalizumab is consistent with clinical experience on patient response to omalizumab (see pages 13 and 14 of the report), and whether this may relate to patient willingness to receive an injection to control their symptoms over alternative oral therapy.

- There is no good epidemiological data on CSU in Australia, so it is not surprising that more patients than predicted have accessed omalizumab treatment. Given that it is so effective, patients with CSU now come forward for treatment.
- Clinical experience continues to support the excellent safety profile of omalizumab, so it is reasonable for home use, and this is particularly relevant during the COVID-19 pandemic.

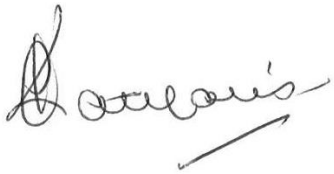
3. Usual dosing practices for omalizumab that are used in Australia. Most patients on PBS therapy appeared to use a 300 mg dose for initial and continuing treatment, few patients were down-titrated and up-dosing was only identified in a small proportion of patients.

Regarding dosing:

- The experience in Australia and overseas strongly suggests that approximately 20% of patients require longer than 3 months to gain good response, so initial prescription time could be lengthened.
- Some patients require up-dosing to 450mg so the ability to access this is important.
- Approximately 20-30% patients can space the dose to 6-8 weeks successfully. There is published data on this as there is for the fact that 150mg q4h is effective in less than a third of patients.
- Practically patients prefer spacing doses and injections than having monthly injections at lower doses. (see Bernstein et al Expert opinion on biological therapy 2018;18:4:425 https://www.tandfonline.com/doi/full/10.1080/14712598.2018.1438406)

We hope that this letter provides sufficient information for the June 2020 meeting.

Yours sincerely,



Dr Brynn Wainstein
ASCIA President

Prof Connie Katelaris AM
Chair, ASCIA CSU Working Party
Past ASCIA President

Copy:
Dr William Smith
Deputy Chair, ASCIA CSU Working Party
Past ASCIA President