



Rannán na nOspidéal Ghéarmhíochaine
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Deputy Darragh O'Brien
Dáil Éireann
Leinster House
Dublin 2

24th April 2019

PQ 54090/18* *To ask the Minister for Health the status of the reimbursement of the drug Cinryze; and if he will make a statement on the matter.*

Dear Deputy O'Brien,

I have previously written to you in relation to this matter. However, some additional information has now been brought to my attention, outside the timeframe available for my initial response. I am sure that you appreciate that your question relates to a highly specialised aspect of management of a rare disease, affecting only approximately 50 patients in the country. I now am writing to you to update my original response. Additional information is underlined below.

Response:

Cinryze[®] is a C1 esterase inhibitor licensed for the management of hereditary angioedema.

The licensed indications are as follows:

- Treatment and pre-procedure prevention of angioedema attacks in adults, adolescents and children (2 years old and above) with hereditary angioedema (HAE).
- Routine prevention of angioedema attacks in adults, adolescents and children (6 years old and above) with severe and recurrent attacks of hereditary angioedema (HAE), who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment.

The SPC for Cinryze[®] includes the following information:

Home-treatment and self-administration

- There are limited data on the use of this medicinal product in home- or self administration. Potential risks associated with home-treatment are related to the administration itself as well as the handling of adverse reactions, particularly hypersensitivity. The decision on the use of home- treatment for an individual patient should be made by the treating physician, who should ensure that appropriate training is provided and the use reviewed at intervals

Cinryze[®] should only be prescribed by the specialist immunology unit managing the patient's hereditary angioedema (HAE). It is administered as an intravenous formulation and there are risks associated with its administration. Training for self-administration is provided for suitable patients in the three immunology centres (Beaumont Hospital, St James Hospital and Galway University Hospital) for on demand administration, targeted prophylaxis (usually during pregnancy) and long-term prophylaxis for severely affected patients. Training includes all aspects of administration, including

recognition of hypersensitivity reactions, and management of reactions should they occur. Typically the patient and a family member or other infusion partner undergo training. Self possession and self administration of emergency treatment is in line with the World Allergy Organisation/European Academy of Allergy and Clinical Immunology Guidelines for the management of this condition.

There are no central reimbursement pathways within the HSE for this treatment. To date consultant immunologists have applied to the local community health organisation for confirmation of funding when such treatment is required. There is work ongoing in an attempt to streamline this process, as home therapy of appropriate patients offers optimal treatment to patients, allowing full engagement in education and/or employment. Self-management of chronic disease in the home is in line with the Slaintecare programme, and it is anticipated that this will release some hospital capacity with beneficial effects on waiting lists.

I hope that you will understand the difficulty of accessing such highly specialised information in the timeframe allowed to respond to a PQ, but trust that this updated information will be of value to you.

Yours sincerely,



Helen Byrne
Assistant National Director
Acute Operations