

# INTRODUCTION OF BERINERT® SC (HUMAN C1-ESTERASE INHIBITOR) ADMINISTRATION IN THE HOME SETTING TO SUPPORT PROPHYLACTIC TREATMENT OF HEREDITARY ANGIOEDEMA PATIENTS

Kathryn Fenton<sup>1</sup>PhD, Sherif Youssef<sup>1</sup>PhD, and David Tognarini<sup>1</sup>PhD  
<sup>1</sup>Aesir Health PTY LTD, 85 Argus St Cheltenham VIC AUSTRALIA 3192

## INTRODUCTION

Hereditary Angioedema (HAE) is a rare (estimations are 1 / 50,000 Australians), potentially life-threatening genetic disorder, resulting from a deficiency (type 1 HAE) or dysfunction (type 2 HAE) of the C1-Inhibitor (C1-INH) protein. It is typically characterised by recurrent episodes of oedema (swelling) of the limbs, trunk, face and genitals, visceral swelling of the gastrointestinal tract, and in more serious manifestations, laryngeal swelling<sup>1</sup>.

In 2017, following NBA approval for funding of C1-INH concentrate, the Berinert NurseCare Patient Support Program (PSP) was established for HAE patients prescribed BERINERT® IV. In March 2020, the program was extended to patients prescribed BERINERT® SC (human C1 esterase inhibitor, subcutaneous) preparation, for prophylactic treatment. The focus of the PSP remained on education and training of preparation and self-administration, so that patients were empowered to be self-sufficient at home. Commissioned by CSL Behring, the PSP was developed and managed by an independent third-party, Aesir Health, with the aim being for enhancement of the quality use of medicines through patient support, education, through training by qualified registered nurses (RN).

## OBJECTIVE

The objective of this review was to assess the quality, effectiveness, and patient satisfaction of the Berinert NurseCare PSP, by reviewing the initial cohort of patients enrolled into the program for BERINERT® SC self-administration.

## METHODS

This review was conducted in patients enrolled into the Berinert NurseCare PSP by the patient's Prescriber for BERINERT® SC self-administration education. Patients were then contacted to ascertain of their willingness to participate in the program. Where nurse-led visits were conducted, the assessments focused on patient competencies with regards to:

- product storage & reconstitution,
- injection site selection,
- aseptic techniques,
- correct administration,
- post-procedure care and
- documentation (including a review of each patient's HAE management plan).

Where appropriate, the individual's support networks were invited to participate as part of the training. Total number of visits per patient, was then determined based on the above areas by the educating RN. Following completion of home-based training, patients were asked to provide feedback via a survey for their assessment of the quality of education and training they received.

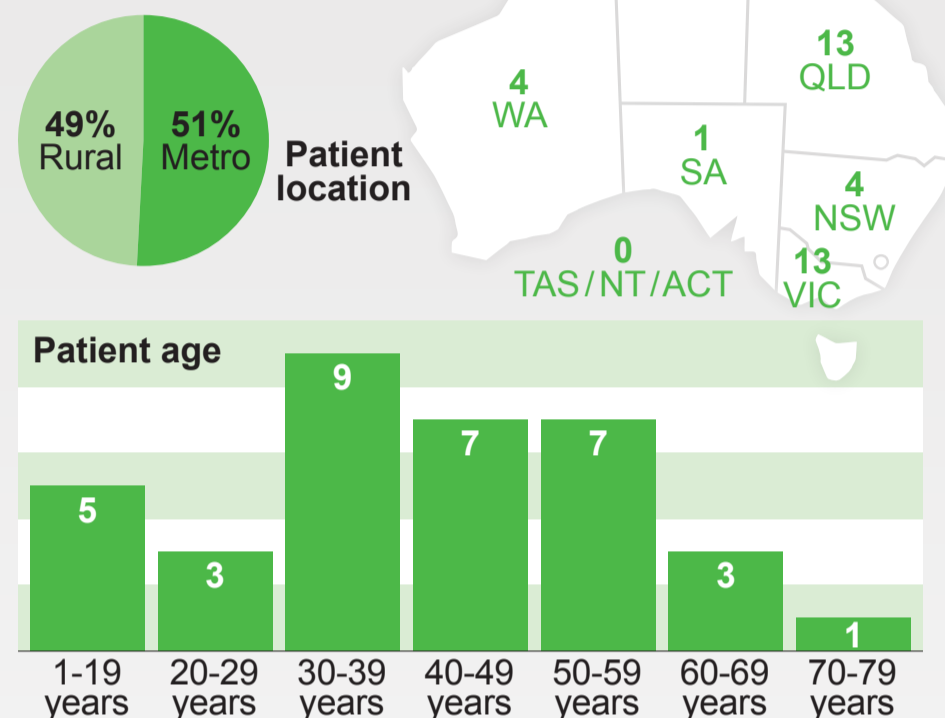
## RESULTS

### Demographics and Previous Treatment

Enrolment of the initial 35 patients included in this cohort commenced in March 2020 from all areas across Australia for those patients eligible for prophylactic treatment using BERINERT® SC. The enrolments by State and split of

Metropolitan-based vs Regionally-based patients (defined as outside State capital cities) can be seen in Figure 1. Patients' ages for this cohort ranged between 9 to 72 years with a mean age of 40.2 years (Figure 1). Based on gender, 26 females and 9 males were enrolled across the cohort.

**Figure 1: Demographics of initial 35 patients enrolled into the Berinert NurseCare PSP**



Within this particular cohort, patients were switched to BERINERT® SC self-administration from the following treatment regimens:

- 26 from prophylaxis BERINERT® IV,
- 3 from oral therapy (Danazol), and,
- 6 from on demand therapy.

### Education and Training

Of the 35 patients enrolled for BERINERT® SC self-administration, 4 patients declined training citing they were confident due to previous IV or SC administration experience. 31 were trained in home via nurse-led visits: 88% of these were face-to-face and 12% via Telehealth. Interestingly, 93% of nurse-led visits were conducted between during the peak of the first wave of the COVID-19 pandemic. The total number of nurse visits required among the cohort was 43, with an average of 1.4 visits per patient required (range 1 – 4).

The majority of the cohort were educated and trained following 1 – 2 nurse visits, with only 1 patient requiring 4 visits to achieve both confidence and competency in the SC self-administration process. A summary is provided in Table 1.

Perhaps most importantly, as at July 2021 (14–16 months post commencement on BERINERT® SC and enrolment into the PSP), 33 of the reviewed cohort have continued to administer BERINERT® SC for management of their HAE. Figure 2 outlines the key or critical elements in the design, development, and implementation of the Berinert NurseCare PSP which can be attributed to the success of the program, and the continued compliance of patients.

**References:** 1. ASCIA HP HAE Position Statement. 2020 [https://www.allergy.org.au/images/docs/ASCIA\\_HP\\_Position\\_Paper\\_HAE\\_2020\\_Aug\\_Update.pdf](https://www.allergy.org.au/images/docs/ASCIA_HP_Position_Paper_HAE_2020_Aug_Update.pdf) 2. ASCIA 2018 Poster; Tognarini, D et al. Self-Infusion of Berinert® (Human C1-Esterase Inhibitor) in the Home. Early Learnings from Berinert NurseCare, a Home-based Education Program to teach patients how to self-infuse.

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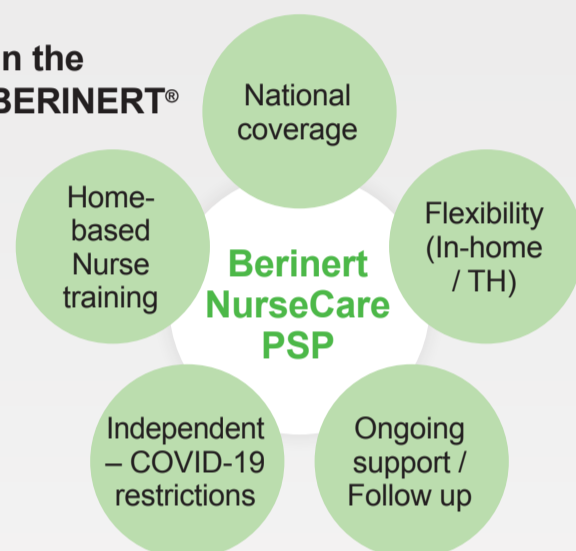
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## RESULTS contd.

**Table 1. Summary of Berinert NurseCare PSP training experience for cohort**

Patients trained for SC self-administration	89% (31 of 35 pts)
Nurse-led visits (Total)	43
Ratio: In-home vs Telehealth education	7.6 : 1
Avg no. visits / pt to achieve competency; median	1.4 visits; 1 visit
Reason for switching:	
• Convenience / easier administration	74.3%
• Previous treatment withdrawn (Danazol)	8.6%
• Previously administering on demand	17.1%

**Figure 2: Key elements in the success of the PSP for BERINERT® SC self-administration**



### Patient Satisfaction

At the time of this analysis, 9 patients (29%) who undertook training as part of the program had completed a feedback questionnaire. Overall patient satisfaction with respect to the program and services provided was extremely high with an average rating of 9.7/10. Across all categories, the average rating scored by patients for the Berinert NurseCare PSP was 9.5/10. Figure 3 highlights the average ratings for all responses across these categories.

**Figure 3: Patient Satisfaction ratings for the Berinert NurseCare PSP (Rating Scale: 1-10; n = 9)**

Enrollment Process	9
Nurse Training Provided	9.6
Confidence / Competence	9.6
Coordinator support	9.7
Overall Satisfaction	9.7

## DISCUSSION

The Berinert NurseCare PSP has demonstrated the effectiveness of supporting enrolled patients prescribed BERINERT® SC for home-based therapy. Moreover, the program has provided not only positive outcomes whilst ensuring the quality use of medicines to this cohort of patients, but through quality home-based learning, has enabled patients to have a more convenient and easier approach for their HAE treatment. These, plus the resulting control of HAE swelling / symptoms must all contribute to the high concordance with therapy.

**Disclosure of interest:** This program was supported by CSL Behring Australia. The company was involved in the review of this poster. Aesir Health has been engaged by CSL Behring as an independent third-party provider of patient support services including Berinert NurseCare.

A wide range of patients were referred to the support service. Children as well as elderly, living in either major capital cities or in regional or remote Australia. The preference for the service was always to conduct visits face-to-face in order to provide the best possible training experience. Where patients were either too remotely located to attend in home, or, restricted from access due to the COVID-19 pandemic, telehealth was offered, but rarely required (only 12% of visits). Fortunately, despite heavy COVID-19 restrictions in place preventing patients attending appointments in clinic, the Berinert NurseCare PSP was still able to continue support and was highly effective in providing continuity of HAE treatment through the height of the pandemic. Clearly, transitioning from BERINERT® IV to SC was deemed straightforward by many patients and overall, we found an average of only 1.4 visits per patients were required. This is lower than a previous report from the BERINERT NurseCare which focused on IV administration and found 2.4 visits were required on average<sup>2</sup>. Of those patients who declined education and training with the RN as part of the PSP, in all 4 cases, these patients felt previous experience in other SC administration of products was sufficient.

Where patients completed a feedback survey following completion of training, the overall response to satisfaction with the program and various elements was very high, again, giving an indication that the Berinert NurseCare PSP was a highly effective program, and the patients' expectations for the quality of education and training provided also very highly met.

Perhaps most importantly, is the finding that over 1 year after initiation, the majority of this cohort remain on therapy. Clearly this is multifactorial, including therapeutic effective control of their HAE, but it does suggest the importance of quality patient education and ongoing support is effective in helping patients to achieve competency, and, empower them to manage their SC self-administration.

## CONCLUSIONS

In conclusion, this initial review has demonstrated the effectiveness, convenience and quality of the home-based program, Berinert NurseCare PSP, and has highlighted that the considerations taken into account for each individual's treatment, circumstances at home and supporting networks are all very important in undertaking both the design and execution of these support initiatives.

The program has achieved this by providing flexibility and patient-centric focus to helping facilitate home education. The PSP has provided clinics a support service that ensures their patients are well trained, confident, competent and supported with their ability to consistently administer their BERINERT® SC for HAE prophylaxis.

**BERINERT® SC**  
Human C1 Esterase Inhibitor Subcutaneous

**BERINERT® nursecare**  
program

**aesir health**

Aesir Health PTY LTD,  
85 Argus St Cheltenham  
VIC AUSTRALIA 3192  
Within Australia: 1800 668 669  
International: +613 8526 2500