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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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Definition, aims, and implementation of GA²LEN/HAEi Angioedema Centers of Reference and Excellence

To the Editor,

GA²LEN, the Global Allergy and Asthma European Network, and HAE international (HAEi), the global umbrella organization for the world's hereditary angioedema (HAE) patient groups, have launched their joint ACARE (Angioedema Center of Reference and Excellence) program, within GA²LEN's center of reference and excellence (CORE) initiative. Angioedema is a common, heterogeneous, often debilitating and chronic condition and is frequently a challenge for physicians and affected patients, especially patients suffering from recurrent attacks. Additionally, it can be a challenge for some patients to understand the underlying etiology of their angioedema (Table 1). GA²LEN's CORE networks, such as UCARE for urticaria and ADCARE for atopic dermatitis, help to improve the management of difficult-to-treat conditions. Here, we describe the aims, requirements, provisions, application process, audit, and accreditation

protocol for GA²LEN/HAEi ACAREs. ACAREs aim to provide excellence in angioedema management, increase the knowledge of angioedema through research and education, and promote advocacy activities that raise angioedema awareness. To become a certified ACARE, angioedema centers must fulfill 32 requirements, defined by specific provisions that will be assessed during an audit visit. The ACARE program will result in a strong network of angioedema specialists, promote angioedema research and awareness, and harmonize and improve angioedema management globally. ACAREs will expand access to modern angioedema medicines in countries where they are available and help to bring them to countries where they are not.¹

This document summarizes the aims of GA²LEN/HAEi Angioedema Centers of Reference and Excellence (ACAREs) and elaborates the requirements that ACAREs must fulfill to become

TABLE 1 Classification of angioedema

Bradykinin-mediated angioedema				Mast cell mediator-mediated angioedema		Unknown mediator
C1-INH deficiency/defect		C1-INH normal		IgE mediated	Non-IgE mediated	
Inherited	Acquired	Inherited	Acquired			
HAE-1	AAE-C1-INH	HAE nC1-INH (HAE-FXII, HAE-ANGPTI, HAE-PLG, HAE-KNG1, HAE-UNK)	AE due to medication that interferes with BK degradation, eg ACEi	Angioedema with or without wheals in patients with urticaria Anaphylaxis	Angioedema with or without wheals in patients with urticaria	Idiopathic AE

Abbreviations: AAE-C1-INH, acquired angioedema due to C1-inhibitor deficiency; ACEI-AE, angiotensin-converting enzyme inhibitor-induced angioedema; BK, bradykinin; HAE nC1-INH, hereditary angioedema with normal C1-inhibitor levels, either due to a mutation in factor XII (F12), angiotensin-converting enzyme 1 (ACE1), plasminogen (PLG), kininogen-1 (KNG1), or unknown (UNK) (HAE-FXII, HAE-ANGPTI, HAE-PLG, HAE-KNG1, HAE-UNK); HAE-1, hereditary angioedema due to C1-inhibitor deficiency; HAE-2, hereditary angioedema due to C1-inhibitor dysfunction.

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(A)

Head of the Center:		Auditor:		Last audit:	
<p>GALEN Network of Excellence HAEi</p>					
Introduction / Not up					
Requirement	Description	Subscribed	Yes/No	Yes	Yes
1. Mission statement or objective	Center needs to be a leader or affiliated with a center with a clear mission statement and a clear vision for the future.	Existence of a clear mission statement or objective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Clear financial data with clear costs and a budget	Center needs to have clear financial data with clear costs and a budget for the next year.	Existence of a clear financial statement or budget.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Clear information on the center's activities and its impact on the community	Center needs to have clear information on its activities and its impact on the community.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Management					
Requirement	Description	Subscribed	Yes/No	Yes	Yes
21. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Research					
Requirement	Description	Subscribed	Yes/No	Yes	Yes
33. Research activities	Center needs to have research activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Research activities	Center needs to have research activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. Research activities	Center needs to have research activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. Research activities	Center needs to have research activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Research activities	Center needs to have research activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. Research activities	Center needs to have research activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. Research activities	Center needs to have research activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. Research activities	Center needs to have research activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education					
Requirement	Description	Subscribed	Yes/No	Yes	Yes
41. Educational activities	Center needs to have educational activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Educational activities	Center needs to have educational activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. Educational activities	Center needs to have educational activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44. Educational activities	Center needs to have educational activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45. Educational activities	Center needs to have educational activities in the field of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Activity					
Requirement	Description	Subscribed	Yes/No	Yes	Yes
46. Increase awareness of angioedema	Center needs to have activities to increase awareness of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
47. Increase awareness of angioedema	Center needs to have activities to increase awareness of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
48. Increase awareness of angioedema	Center needs to have activities to increase awareness of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
49. Increase awareness of angioedema	Center needs to have activities to increase awareness of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
50. Increase awareness of angioedema	Center needs to have activities to increase awareness of angioedema.	Existence of a clear information statement or brochure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Audit result:
 All requirements fulfilled, no areas with a need for further improvement, center should be certified
 All requirements fulfilled, some areas require further improvement, center should be certified Area with a need for further improvement: _____
 Most requirements fulfilled, center should be certified after _____ providing documentation that the following requirements are fulfilled: _____
 no audit in _____ months

Comments:

GALEN Requirements of the Angioedema Center of Reference and Excellence (ACARE) are hereby certified that the Department and Center Name and for Name of Head of Center, City, Country has been externally audited and fulfills the GALEN HAEi quality criteria as a GALEN HAEi Angioedema Center of Reference and Excellence (GALEN HAEi ACARE).

Date: 04/20/2019 Valid until: 04/20/2021

GALEN HAEi ACARE

ACARE A GALEN HAEi ACARE

HAEi

FIGURE 1 A and B, Audit checklist for GA²LEN/HAEi Angioedema Center of Reference and Excellence (ACARE) certification (A) and certificate awarded to GA²LEN/HAEi ACAREs upon a successful audit (B). A, The list shows and explains the requirements for becoming a GA²LEN/HAEi ACARE and the deliverables that are reviewed during the audit process. B, The certificate is awarded for 2 y and requires successful re-audit to be extended

certified. It also provides (see Appendix S1) background information on GA²LEN and HAEi, including HAEi member organizations and regional patient advocates, on why we need an Angioedema Center of Reference and Excellence (ACARE) program and network, and on the accreditation and certification process, governance and funding, and on the interaction with other GA²LEN networks of centers of reference and excellence. The protocols, aims, requirements, and provisions related to becoming a certified ACARE are based on (a) the experience of the GA²LEN UCARE network and (b) input from angioedema patients, general practitioners, and angioedema specialists.

What are the aims of GA²LEN/HAEi ACAREs? The aims of ACAREs are to set the global standard for excellence in comprehensive angioedema care through research, education, advocacy, and interaction among ACAREs. By serving as referral centers for the diagnosis and management of patients with angioedema, ACAREs will complement the local healthcare system. ACAREs aim to increase knowledge and awareness of angioedema.

What are the requirements for GA²LEN/HAEi ACAREs? ACAREs are required to demonstrate excellence in the management of angioedema, research activities, efforts in education, and advocacy activity. ACAREs need to fulfill 32 requirements, which are explained in the audit checklist (Figure 1A). This checklist includes specific deliverables for each requirement. For example, the requirement to know and follow international guidelines and consensus documents for angioedema (Requirement #16) entails that physicians and other ACARE healthcare professionals have read and understood the current versions of these guidelines and consensus documents and that their recommendations are implemented in their center.

These guidelines and consensus documents include, for example, the international WAO/EAACI guideline for HAE, the EAACI/GA²LEN/EDF/WAO guideline for urticaria, the International/Canadian hereditary angioedema guideline,^{2,5} the international consensus on the diagnosis and management of pediatric patients with hereditary angioedema with C1 inhibitor deficiency, the international consensus on the use of genetics in the management of HAE,⁶ and the international consensus and practical guidelines on the gynecologic and obstetric management of female patients with hereditary angioedema caused by C1 inhibitor deficiency.⁷ The deliverables for this requirement are that (a) current guideline and consensus document versions are present (paper or electronic version) at the center, (b) ACARE staff can answer questions on the recommendations these documents provide, and (c) ACARE physicians can show, upon request, by use of a patient file, that patient

management decisions are based on guideline recommendations (Figure 1B).

This publication marks our intent to start the implementation of the GA²LEN/HAEi ACARE initiative. Specialty centers for angioedema have started to apply to become ACAREs, and audits and certifications are ongoing (Figure 1B). We expect that most GA²LEN UCARE centers and many angioedema specialty centers will become ACAREs in the near future. We predict and hope that by 2022, GA²LEN/HAEi ACAREs will be established in every continent. This will result in a strong global network of angioedema specialists, promote angioedema research, and harmonize and improve angioedema management worldwide. GA²LEN and HAEi will measure the impact of ACAREs over time and document and report the benefits of this initiative. ACARE network activities and a current list of ACAREs are posted on the network's website (www.acare-network.com).

ACKNOWLEDGMENTS

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CONFLICT OF INTEREST











Dr Maurer reports grants and personal fees from Allakos, personal fees from Aralaz, grants and personal fees from AstraZeneca, grants and personal fees from BioCryst, grants from Blueprint, grants and personal fees from CSL Behring, grants and personal fees from FAES, grants and personal fees from Genentech, grants from Kalvista, grants from Lilly, grants from Menarini, grants and personal fees from Novartis, grants from Leo Pharma, grants from Moxie, grants from Pharming, personal fees from Pharvaris, grants and personal fees from Roche, from Sanofi, grants and personal fees from Shire/Takeda, grants and personal fees from UCB, grants and personal fees from Uriach, outside the submitted work. Dr Aberer reports other from Takeda, other from CSL Behring, outside the submitted work. Dr Ansotegui reports personal fees from Mundipharma, personal fees from Roxall, personal fees from Sanofi, personal fees from MSD, personal fees from Faes Farma, personal fees from Hikma, personal fees from Astra Zeneca, personal fees from Stallergens, outside the submitted work. Dr Aygören-Pürsün reports personal fees from Adverum, grants and personal fees from BioCryst, grants and personal fees from CSL Behring, grants and personal fees from Kalvista, personal fees from Pharming, grants and personal fees from Shire/Takeda, during the conduct of the study. Dr Banerji reports grants from Takeda, BioCryst, personal fees from Takeda, BioCryst, CSL, Pharming, Pharvaris, Kalvista, outside the submitted work. Dr Aberer reports other from Takeda, other from CSL Behring, outside the submitted work. Dr Bernstein reports grants and personal fees from Shire/Takeda, grants and personal fees from CSL Behring, grants and personal fees from BioCryst, grants and personal fees from Kalvista, grants from IONIS, grants and personal fees from Novartis/Genentech, grants and personal fees from Astra Zeneca, grants and personal fees from Sanofi Regeneron, from HAEA MAB, during the














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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.