

OHF CARE CENTERS STANDARDS

Standards for Certification & Certification Process

Summary

The OHF advocates for standardized care in managing primary hyperoxaluria (PH) through its Care Center Network. Certified centers, listed on the OHF website, offer comprehensive PH services. Led by a director with guidance from the Care Center Network Steering Committee, Certification Committee, composed of PH care experts, manages the certification process involving application, surveys, and patient record reviews. This living document undergoes annual review and updates by the Steering Committee.

Member Certification

Membership within the OHF Care Center Network signifies a commitment to delivering standardized and comprehensive care for PH. This voluntary certification demonstrates the center's dedication to providing excellence in care for individuals and families affected by PH, ultimately enhancing the quality of patient care and reducing global disparities.

Vision of OHF Care Center Network

To provide outstanding, comprehensive care for individuals with PH, integrating medical, educational, and research initiatives. Our aim is to enhance the quality of life for patients and their families, advance scientific understanding of PH, and contribute to the development of innovative treatments. Through collaboration with the PH community, healthcare professionals, and researchers, we strive to improve outcomes, promote education, and ultimately work towards a cure for PH.

OHF Care Center Network Requirements for Care & Services

Members of the OHF Care Center Network are committed to delivering comprehensive sub-specialty care and clinical services for individuals and families affected by Primary Hyperoxaluria (PH). Each sub-specialist is expected to adhere to OHF Care Center Best Practices. The following providers must be accessible during visits, either in-person or remotely as appropriate:

- 1. Center Director:**
 - A nephrologist specializing in PH, overseeing patient diagnosis and treatment.
 - Expected to be committed to dedicating time to improving hyperoxaluria care and collaborating through the OHF Care Center Network
 - May also serve as the center director.
- 2. Urology Specialist(s):**

- Experienced in treating PH patients, with potential dual roles as the center director.
3. **Administrative Contact:**
 - Knowledgeable in patient care coordination, expected to be committed to dedicating time to improving hyperoxaluria care and collaborating through the OHF Care Center Network.
 - Preferably a nurse or nurse practitioner.
 4. **Dialysis Teams and Transplant Teams**

The following sub-specialty and clinical services must be available as needed during visits:

1. **OHF Registry Data Entry:**
 - a. Systems and faculty to ensure annual patient data entry into the OHF Registry.
2. **Registered Dietitians:**
 - a. Available for patient and family meetings during center visits.
3. **Social Workers:**
 - a. Available for patient and family support.
4. **Genetic Counselors:**
 - a. Available for patient and family guidance.
5. **Ancillary Faculty for Managing Less Common PH Complications:**
 - a. Including radiology/imaging specialists, and cardiology.

Provision of Care:

Care will align with the 2023 Best Practices outlined by the OHF Care Center Steering Committee. Key measures for care include coordination and communication:

- A written summary with recommendations sent to the patient's primary provider at the time of diagnosis.
- A written summary with recommendations sent to the patient's primary provider at each appointment.
- Disease-specific information/resources available/sent to primary providers.
- Patients/families receive a copy of the note/summary sent to their primary provider, electronically if preferred.

Nephrology

Nephrologists will help lead your team in creating patients' personalized health plans. These experts will specialize in the diagnosis and treatment of hyperoxaluria.

Urology

Urologists will be available at all center appointments.
Urologists may be the primary specialist who manages patients' care teams as certified centers.

Radiology/Imaging

Ultrasound, CT, and X-ray will all be available for imaging to aid in the management and treatment of kidney stones and other symptoms of primary hyperoxaluria.

Dialysis Care

Clinicians trained in dialysis will be available at all centers.
They will have the expertise to provide education about self-care choices that allows those with primary hyperoxaluria to live as full a life as possible.

Transplant Team

Transplant teams may be composed of experts at each center, and will include nephrologists and hepatologists specializing in kidney/liver transplant in addition to other medical support staff.

Cardiology

All patients have access to cardiology as needed.
Patients have an ECG done at least annually.
Patients receive a printed copy of their ECG to use in emergencies.
Every patient receives cardiac imaging (cMRI if available and appropriate, echo if cMRI is unavailable, not appropriate or if q6 mos evaluations are needed) at least annually.
Cardiac medications are started with evidence of cardiac dysfunction or fibrosis or by age 10yo with normal findings.
Patients taking ACEi or ARB have their BUN, creatinine and electrolytes checked annually.

Nutrition

A registered or licensed dietitian (RD) or nutritionist is part of your team and is an expert in identifying and treating disease-related malnutrition and in conducting medical nutrition therapy.
The RD is able to help each family develop a nutrition plan, helping to prevent obesity or treat underweight.
Intake of calcium is assessed at each visit and supplements encouraged as needed.
Swallowing, constipation, GERD and gastroparesis is assessed at each visit.

Criteria for Centers Applying for

Certification

Care Center Network Certification Committee

The OHF Care Center Network Certification Committee, in pursuit of its overarching mission, is dedicated to achieving the following key objectives:

- 1. Identifying and Certifying Comprehensive PH Care Centers:**
 - a. Rigorously assess and certify healthcare centers that demonstrate excellence in providing comprehensive care for individuals with primary hyperoxaluria.
 - b. Collaborate with recognized experts to establish stringent criteria ensuring the highest standards of care.
- 2. Communicating Certification Status to the PH Community and Stakeholders:**
 - a. Effectively disseminate information regarding certified care centers to the primary hyperoxaluria community, patients, families, and relevant stakeholders.
 - b. Utilize various communication channels, including the OHF website, press releases, and social media, to ensure widespread awareness.
- 3. Ensuring Consistent and Fair Application Evaluation:**
 - a. Develop and maintain transparent, standardized evaluation processes to ensure fairness and equity in assessing certification and data use applications.
 - b. Regularly review and update evaluation criteria to reflect advancements in medical practices and standards.
- 4. Monitoring Certified Centers:**
 - a. Implement a robust monitoring system to continuously assess the performance and adherence of certified centers to established care standards.
 - b. Facilitate ongoing communication with certified centers to address any emerging challenges and foster a culture of continuous improvement.
- 5. Offering Guidance to Centers Seeking OHF CC Network Certification:**
 - a. Provide comprehensive guidance and support to centers in the process of seeking OHF CC Network certification.
 - b. Offer resources, educational materials, and mentorship to assist centers in meeting and exceeding certification criteria.

The OHF Care Center Certification Committee will consider a center eligible for certification if it meets the following criteria:

Provides care according to current best practices and publications, as demonstrated on the Care Center Application, substantiated by site visit and supported by patient

reported outcomes in the Primary Hyperoxaluria Registry and parent/patient responses in the Clinical Experiences survey.

As an OHF Care Center Network Member, each center is expected to:

- Provide complete and accurate information during the certification process and during its term of certification.
- Provide an OHF annual report.
- Encourage/enable patients/families to annually participate in scheduled OHF Care Center Network initiatives and update their profile in the OHF Registry.
- Encourage/enable patients/families to complete the Clinical Experience Survey.
- Foster collaboration between OHF Care Center Network sites, and attend quarterly Network meetings.

Continuing Criteria for Membership

Maintain membership by agreeing to the following terms:

- Publicly share membership of the OHF Care Center Network.
- Ensure that comments and suggestions from the Certification Committee remain confidential and are shared only with the applicant(s), followed up annually.
- Keep evaluations and comments from patients/parents on Clinical Experiences surveys confidential, sharing them only with the Certification Committee and other participating centers.
- Provide up-to-date information on care and services, ensuring that it is regularly updated, at least annually.
- Maintain clear and open channels of communication with OHF and the OHF CCN Certification Committee, including during site initiation meeting after successful application for Network membership.

Benefits of Certification as a Certified Primary Hyperoxaluria Care Center

Benefits for members of the Care Center Network include the opportunity for collaboration with other certified centers, access to educational resources, and participation in OHF educational and conference opportunities. OHF Care Center Network membership is valid for 5 years and can be renewed if requirements are consistently met. Additionally, members will be listed on the OHF website.

For centers initially unable to obtain certification, the OHF Care Center Certification Committee provides guidance, allowing them to reapply after 1 year without restarting the process, addressing previous deficiencies. If, after this period, the requirements are still not met, the application process begins anew. The Certification Committee holds exclusive authority over application acceptance, and applying centers have the option to appeal. All information related to certification is kept confidential.

Application Process

The process to obtain certification as a member of the OHF Care Center Network is summarized as follows and is detailed in the Care Center application.

- Complete the online application for certification as a member of the OHF Care Center Network
- Comply with the decisions and recommendations of the OHF Care Center Certification Committee, which will be evaluated annually
- Agree to encourage and enable patients and families to register, and annually update, information in both OHF Registry and the Clinical Experiences Surveys.

Annual Review by Certification Committee

Certification will be granted for 5 years, providing that members:

- Provide an updated OHF annual report.
- Continue to provide care and services in alignment with the OHF Care Center Network best practices and guidelines.
- Continue to encourage/enable their parents/patients to be a part of and update information in the OHF Registry.
- Demonstrate continued quality improvement and compliance with recommendations made by the Certification Committee, which will be reviewed annually.

At the end of a 5-year cycle, members will again be evaluated for recertification.

Centers Unable to Receive Certification

Centers committed to providing comprehensive primary hyperoxaluria care, not yet meeting certification criteria, will receive recommendations from the Certification Committee. They can reapply after 1 year without starting over, addressing prior deficiencies. If they still can't meet requirements after 1 year, the application process restarts. The Certification Committee has sole authority over application acceptance and certification approval.

Revocation of Certification

If the Certification Committee finds that certification requirements are not maintained (e.g., care deviates from OHF best practices and guidelines or annual information isn't provided), membership may be revoked. Members will receive guidance, a 6-12 month period to comply, and if requirements are met within that time, membership is retained. Failure to meet requirements within 6-12 months leads to membership revocation and a need to restart the application process.