

Expanding Access in Minnesota

Update for Never Surrender Inc.

April 2025

With deep gratitude to Never Surrender Inc., the Sean M. Healey & AMG Center for ALS (Healey & AMG Center) at Mass General has successfully established and launched an Expanded Access Protocol (EAP) program site with our colleagues at the University of Minnesota (UMN) and continues to build upon the existing program at Essentia Health.

Your foundational support provides an effective runway for these programs to get up and running. These sites have successfully participated in three EAPs and treated 11 people living with ALS (5 participants enrolled and 2 investigational products at UMN and 6 participants enrolled and 1 investigational product at Essentia Health). These initial efforts set the stage for expansion based on the needs of the patients seen at these sites.

A total of 43 sites nationwide are offering EAP programs. This network has provided 693 participants with access to 21 investigational products. The Mayo Clinic in Rochester is also offering an EAP program, increasing the number of people in Minnesota receiving access through Healey Center EAPs to 14 participants!

The EAP programs at UMN and Essentia Health are key components of our nationwide network of clinical researchers seeking to identify the most effective therapies for ALS. Several of these promising therapies are being tested in the HEALEY ALS Platform Trial. The platform trial is a revolutionary new approach to evaluating therapies by allowing multiple therapies to be tested simultaneously and continuously, speeding the pace of discovery. To address the pace of participation, in 2024 we launched Acceleration Centers of Enrollment, leveraging our strongest HEALEY ALS Platform Trials sites to ensure everyone with ALS can access the best treatments, enroll in the most appropriate clinical trial and receive the care and support every individual and their family needs throughout their journey with this disease. UMN was identified as part of this pilot initiative alongside Northwestern Medicine and the Healey & AMG Center for ALS at Mass General.

EAPs give patients who are not eligible to participate in clinical trials the opportunity to access the same treatments and contribute to research. A key component of the EAP program is the collection of safety and biomarker data, which informs important research findings. Through published papers in

prominent medical journals, our researchers advance the scientific body of knowledge necessary to keep moving the field forward and bring us ever closer to finding cures for ALS.

Your foundational support allows us to include more individuals in research and pursue novel approaches to therapy development. All of this work provides invaluable data that allows us to more precisely target disease pathways.

Impact of Philanthropy

Support from Never Surrender, Inc. enabled UMN and Essentia Health to initiate these EAP programs efficiently and has given patients with ALS, who have been unable to enroll in ongoing clinical trials, the opportunity to gain access to cutting-edge investigational therapies. There has been tremendous interest from patients seen at UMN, Essentia Health and regionally.

In addition to funding from Never Surrender, Inc., the individual NIH funded EAPs come with a per-participant budget to support site activities. The site initiation funds have allowed UMN and Essentia Health to hire new staff who are dedicated to EAPs, which makes expanding this program to future EAPs possible. Furthermore, we are deeply committed to continuing our pursuit of governmental funding as well as philanthropic funds from additional sources.

Collaboration and Communication

- Patients have expressed hope and tremendous gratitude for being able to participate in this EAP program. Below is a quote received from a thankful EAP participant:
"I am very happy to be a part of this program. It gives me hope and I know I am helping others in the future. My health and well-being are truly better because I have faith that these drugs will help me. It's hard to tell if these drugs are making a difference, but I have hope they do make a difference and extend my time. My friends think that I'm upbeat for the situation I'm in, so I try to keep a very positive attitude about my future and my efforts to try new things as I go forward. Thank you for all your help and support."
- We are proud to report that the Healey & AMG Center monthly EAP webinar series has been well-received by the ALS community, with over 4,000 YouTube views and hundreds of questions answered to date. In 2024, we hosted 12 EAP webinars featuring 18 guest speakers with an average of 83 live attendees and 242 subsequent YouTube views per webinar. Thank you, David, Sandy and Dr. Walk for joining us in November!
- We meet on a regular basis with Dr. David Walk, Dr. Amber Erikson and their teams to receive updates on the group's progress and to provide guidance.
- Our manuscript on [An Expanded Access Protocol of RNS60 in Amyotrophic Lateral Sclerosis](#) was published in Muscle & Nerve in March 2025.

Thanks to Never Surrender Inc., more people living with ALS in Minnesota now have access to promising investigational drugs.