SCANLY®
HOME OCT Monitoring Program

Physician Responsibilities Acknowledgement

Service Description

Notal Vision® provides a remote retinal imaging service using the SCANLY® Home OCT program. This program is approved for use by patients with wet or neovascular age-related macular degeneration ("nvAMD") to help improve personalized care and diagnoses for these patients as outlined in the Food and Drug Administration ("FDA"), Indication for Use, listed on below.

The Home OCT service provided by Notal Vision's Monitoring Center ("Monitoring Center") must be ordered/prescribed by an eye care professional and is intended for patients with the FDA Indication for Use. To perform the test, a device is provided to the patient by Notal Vision for daily scanning and analysis. Access to the patient's scan and related analysis is provided to the ordering physician or other authorized health care professional via the secure database which may be accessed via the SCANLY Portal located at: https://notalvision.info/OCTanalysis ("Portal").

Physician and Practice Responsibilities

The ordering physician is responsible for determining and then setting individual patient specific notification criteria in the SCANLY Portal and for acting on any notifications and the scan information that is provided by or made accessible to the physician by the Monitoring Center. The Food and Drug Administration ("FDA") requires the ordering physician to regularly review patient data in the Portal. Notal Vision is not

responsible for interpreting scan information or for communicating any interpretation or diagnosis to the referred patient.

Patient scans are transmitted to a secure database accessible for review via the internet by the physician and/or the physician's practice at any time. **Review and use of such test results is solely the responsibility of the ordering/prescribing physician, and the physician's practice and affiliated authorized health care professionals.** Please note that patients typically transmit new scans to Notal Vision for analysis at various intervals and times during each 30-day testing period.

As the ordering physician, you acknowledge the following:

1. You and your practice are responsible for timely review of scan data and for acting on the results to the extent necessary in you or their professional judgement;
2. You and your practice are responsible for immediately notifying the Monitoring Center if they become aware of a patient's device not working as intended;
3. You and your practice are responsible for notifying Notal Vision in the event they become aware of any change in the patient's medical condition or any other information relevant to the performance of the service. These may necessitate the termination of the SCANLY program;
4. You and your practice will immediately notify the Monitoring Center if Portal notifications are not

working as intended notifications are not being sent or not being received.

5. You and your practice are responsible for the immediate reporting of any adverse events related to the SCANLY device.
6. You and your practice are required to provide updated contact information in the event that patient management or staffing changes in order for the Monitoring Center to communicate required information and scan results;
7. When submitting orders for the service, you and your practice will make efforts to provide correct, complete, and legible information for the patient;
8. All patient scanning results can and should be reviewed at: notalvision.info/OCTanalysis;
9. When/if the ordering/prescribing physician changes, this information must be conveyed to the Monitoring Center in a timely manner;
10. When/if the patient's diagnosis changes such that diagnostic testing is no longer necessary as determined by the patient's physician, this information will be conveyed to the Monitoring Center in a timely manner with direction to terminate the service; and
11. Questions regarding patients can be relayed to Notal Vision's Practice Engagement unit by phone at 866-203-1188, or via email at practiceengagement@notalvision.com

FDA Indication for Use: *The SCANLY Home Optical Coherence Tomography (OCT) System is an Artificial Intelligence (AI)-based Home Use device indicated for visualization of intraretinal and subretinal hypo-reflective*

spaces in a 10 by 10-degrees area centered on the point of fixation of eyes diagnosed with neovascular age-related macular degeneration (NV-AMD). In addition, it provides segmentation and an estimation of the volume of hypo-reflective spaces. The SCANLY Home OCT device is intended for imaging at home between regularly scheduled clinic assessments and not intended to be used to make treatment decisions or replace standard-of care regularly scheduled examinations and clinical testing as needed, including in-office imaging and assessments for changes in vision, by an ophthalmologist.