MAYZENT (Siponimod) and First Dose Observations

PATIENT FAQs

Q. What type of clinician will be reading ECGs done as part of the baseline assessments and First Dose Observation?

A. Network clinicians are typically family practice, internal medicine or emergency clinicians; cardiology over-read will be done by a board certified cardiologist.

Q. Are baseline labs/blood work drawn on site?

A. Yes, baseline blood work is drawn on site. Samples are then sent to a lab for processing. Lab results are faxed to your prescribing neurologist as soon as they become available.

Q. Can a patient refuse to go through the baseline assessments?

A. It is important to complete the baseline testing requested by the neurologist. If you have any concerns with the testing, please be sure to discuss them with your neurologist.

Q. How do sites evaluate for discharge at the end of the 6-hour observation period?

A. The clinical protocol for the FDO has been developed independently by Concentra’s Medical Leadership team. Evidence considered in the development of this protocol included the new label for Mayzent as well as publically available data and Concentra’s clinical judgment.

Q. How long can site monitor a patient?

A. Sites are set up to monitor patients for 6 hours with the flexibility of extending monitoring for approximately two additional hours. If a patient does not meet discharge criteria at the end of the extended observation, the clinic will notify the neurologist and make arrangements to transfer the patient to the hospital. Please note the emergency services/hospital charges will be the responsibility of the patient’s insurance and the patient. In the event the patient does not have sufficient coverage then the Novartis Patient Assistance Program will review for medical copay eligibility.

Q. What is the interval for monitoring Heart Rate (HR) and Blood Pressure (BP)?

A. HR and BP are documented prior to dosing the patient along with the ECG and survey of medical history; medical staff at the clinic will evaluate all of these metrics to ensure they feel the patient is appropriate to initiate drug. If the patient is approved to initiate drug, HR and BP will be monitored twice in the first hour and every hour following throughout the course of the 6-hour observation period.

Q. Will Medicare pay for the labs and ECG?

A. Medicare will be billed for lab tests and ECG. Additional co-pay cost may apply for the ECG only.

Q. Are patients with Medicare and Medicaid (dual-eligible) covered by insurance for their first-dose observation?

A. The Assessment Network may accept dual-eligible patients in some cases as long as the patient has Medicare as their primary payer, but acceptance varies from location to location.
Q. Why do baseline assessments and the first-dose observation need to be completed in two appointments?

A. The first appointment will be for the baseline assessments and the second appointment will be scheduled at least 5 business days later for the first-dose observation. The prescribing neurologist will be faxed findings of the baseline assessments as soon as they are available to ensure the prescribing neurologist reviews the findings prior to any first-dose observation.

Q. What if my prescribing neurologist does not want the first-dose observation appointment set until after they received and acknowledged the results of the baseline ECG/lab?

A. This is at your prescriber’s discretion. This information should be shared with the GILENY Go Program.

Q. What if there is no Assessment Network location near me?

A. Your Patient Services Coordinator will assist you in finding a location or service to provide the observation.

Q. Why doesn't my prescribing neurologist have the ability to do the First Dose Observation?

A. The First Dose Observation process requires a well-equipped site and trained medical staff on hand for the entire 6-hour process. This process is typically performed at off-site observation locations.

Q. Will I need to have my blood work redrawn if I have to stop MAYZENT for more than one day?

A. This will depend on your prescribing neurologist's orders. Please follow up with your prescriber for information regarding the additional need for assessments.