

NYSDOH Epidiolex® Expanded Access for Treatment Resistant Epilepsy Appendix E

Patient Visit Schedule

Visit 1: (Week 0/Month 0 (baseline)): Historical seizure counts for each seizure type will be documented and evaluated for baseline.

- a. Seizure types will be classified prior to study entry via historical seizure counts over the past 4 weeks
- b. Physical and Neurological examination
- c. Vital signs
- d. Columbia Suicide Severity Rating Scale (C-SSRS) questionnaires will be conducted
- e. Weight and height will be recorded
- f. Urine pregnancy test if the patient is a female ≥ 9 years old.
- g. 12 lead ECG will be conducted
- h. Menstrual diary will be given to female patients who have reached menarche

Visit 2: (Week 2): This visit will be phone or email evaluations. The study team will assess for adverse effects and tolerability of CBD and also asking questions about seizure frequency. Adverse events will always be assessed and any concerns the patient may have answered.

Visit 3: (Week 4/Month 1):

- a. Physical and Neurological examination
- b. Vital signs
- c. C-SSRS questionnaires will be conducted
- d. AEs
- e. Weight and height will be recorded
- f. Seizure history evaluated
- g. Urine pregnancy test if the patient is a female ≥ 9 years old.
- h. LFT, BUN, creatinine, CBC, chemistry, and AED levels will be drawn
- i. Menstrual diary will be assessed when applicable

Visit 4: (Week 6): This visit will be phone or email evaluations. The study team will assess for adverse effects and tolerability of CBD and also asking questions about seizure frequency. Adverse events will always be assessed and any concerns the patient may have answered.

Visit 5: (Week 8/Month 2): will return for clinical evaluation, increase in medication as tolerated for next week.

- a. Physical and Neurological examination
- b. Vital signs
- c. C-SSRS questionnaires will be conducted
- d. AEs
- e. Weight and height will be recorded
- f. Seizure history evaluated
- g. Menstrual diary will be assessed when applicable
- h. Urine pregnancy test if the patient is a female ≥ 9 years old.

Visit 6: (Week 12/Month 3): will return for clinical evaluation, increase in medication as tolerated for next week, up to the maximum tolerated dose.

- a. Physical and Neurological examination
- b. Vital signs

- c. C-SSRS questionnaires will be conducted
- d. AEs
- e. Weight and height will be recorded
- f. Seizure history evaluated
- g. LFT, BUN, creatinine, CBC, chemistry and AED levels will be drawn
- h. Menstrual diary will be assessed when applicable
- i. 12 lead ECG will be conducted
- j. Urine pregnancy test if the patient is a female ≥ 9 years old.

Visit 7: (Week 24/ Month 6): will return for clinical evaluation, increase in medication (if needed) as tolerated for next week, up to the maximum tolerated dose.

- a. Physical and Neurological examination
- b. Vital signs
- c. C-SSRS questionnaires will be conducted
- d. AEs
- e. Weight and height will be recorded
- f. Seizure history evaluated
- g. Urine pregnancy test if the patient is a female ≥ 9 years old.
- h. LFT, BUN, creatinine, CBC, chemistry and AED levels drawn approximately 3½ to 4½ teaspoons for subjects over 6, and 1 ½ to 2 ½ teaspoons for subjects under 6
- i. Menstrual diary will be assessed when applicable

Visit 8: (Week 36 / Month 9): will return for clinical evaluation, increase in medication (if needed) as tolerated, up to the maximum tolerated dose.

- a. Physical and Neurological examination
- b. Vital signs
- c. C-SSRS questionnaires will be conducted
- d. AEs
- e. Weight and height will be recorded
- f. Seizure history evaluated
- g. Urine pregnancy test if the patient is a female ≥ 9 years old.
- h. LFT, BUN, creatinine, CBC, chemistry and AED levels drawn approximately 3½ to 4½ teaspoons for subjects over 6, and 1 ½ to 2 ½ teaspoons for subjects under 6 (based on the PI discretion)
- i. Menstrual diary will be assessed when applicable

Visit 9: (Week 48/Month 12): will return for clinical evaluation, increase in medication (if needed), up to the maximum tolerated dose. The patient will have the option to be weaned off medication or to continue to receive the medication from the manufacturer free of charge.

- a. Physical and Neurological examination
- b. Vital signs
- c. C-SSRS questionnaires will be conducted
- d. AEs
- e. Weight and height will be recorded
- f. Seizure history evaluated
- g. LFT, BUN, creatinine, CBC, chemistry and AED levels drawn (based on the PI discretion)
- h. Menstrual diary will be assessed when applicable
- i. Urine pregnancy test if the patient is a female > 9 years old.
- j. 12 lead ECG will be conducted