

Protocol Title: Real World Administration of Zepatier (Grazoprevir plus Elbasvir) in Chronic Hemodialysis Patients with Hepatitis C Infection. Strategies for Identification of Candidate Hemodialysis Patients, Obtainment of Insurance Approval, Treatment Guidelines, and Laboratory and Clinical Monitoring During Therapy Directed to Nephrologists

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Statistical Plan: The planned primary analysis will be the proportion of patients who following treatment have achieved a sustained viral remission (SVR) at 12 weeks following completion of treatment. Secondary analyses will determine (a) proportion of patients for whom third party approval for Zepatier treatment was successfully obtained (b) logistic barriers to getting third party approval (c) adverse events with treatment. The design of the protocol does not require any specific statistical methods to test these hypotheses. A sample size to determine adequate statistical power is not applicable to this protocol since there is only one treatment group and the outcome is binary (SVR at 12 weeks achieved or not achieved). The projected sample size of 25 patients chosen for this study will be adequate to test the hypothesis and meet the objectives of his study.