

Public Comments on Hepatitis C Criteria for West Virginia DUR Board Meeting, May 22nd 2024

Thank you for the opportunity to provide public comments on the prior authorization criteria for Hepatitis C agents, and for EPCLUSA® (sofosbuvir/velpatasvir) in particular. My name is Nancy Njuguna, BPharm, Medical Value Evidence Liaison with Gilead Sciences. I humbly request that the requirements for patients to access these curative therapies be updated:

- a) To reflect FDA- approved product labeling for EPCLUSA.
- b) To allow providers to deliver care to their patients without undue hurdles.

Resistance testing in patients with Genotype 3 (GT3) and addition of ribavirin

- The FDA- approved product labeling for EPCLUSA¹ (Section 2.2) is for 12 weeks of EPCLUSA in treatment-naïve and treatment-experienced patients without cirrhosis and with compensated cirrhosis (Child-Pugh A), without regard to genotype or prevalence of baseline resistance-associated substitutions.
- This is consistent with findings from the Phase 3 clinical trial program.²
- The requirement for resistance testing in patients with GT3 has the potential to delay time to cure as patients may fall out of care, while remaining viremic awaiting results.

Patient-Provider Agreement – Hepatitis C

- The agreement includes language that might be stigmatizing to patients in active addiction^{3,4}, and active or recent drug use or a concern for reinfection is not a contraindication to HCV treatment⁵.
- This is of particular importance given that injection drug use (IDU) is the most common risk factor for HCV infection in North America and Europe⁵, with an HCV seroprevalence of 18% to 88% depending on geographic location⁶ and duration of IDU exposure⁷.
- In the SIMPLIFY⁸ open-label, single-arm, phase 4, multicenter trial in persons with drug use within the last 6 months (including a subset on medication- assisted treatment (MAT) for opioid use disorder, and with 74% of all participants with drug use in the past 30 days), 94% of participants achieved SVR-12. These data are included in the EPCLUSA Prescribing Information.

Requirements for Hepatitis A and B Vaccination

- It is unclear on what basis this requirement is imposed.
- Furthermore, given that these vaccines are recommended in childhood⁹, it may not be feasible to require patients to provide documentation.

Thank you for the opportunity to provide comments for the committee's consideration.

References

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