Considerations for stopping NA in HBV finite treatment

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Considerations related to stopping NA in Finite Treatment Duration Studies for Chronic HBV

• **EASL/AASLD current guidelines** – are they still relevant for new approaches?
  • HBeAg loss in HBeAg+ patients
  • Prolonged NA suppression in HBeAg- patients

• If using HBsAg lowering strategies, is there a **target HBsAg** level that should be reached prior to stopping?
  • Would this be different for direct acting HBsAg lowering agents vs immunomodulators?

• Incorporate a **consolidation phase**? For a low HBsAg level, or HBsAg / HBeAg loss?

• Need for **additional biomarkers** to identify patients with higher chance of FC?

• Expect HBV **DNA rebound after NA stop** to contribute to the ultimate response?

• Could criteria be influenced by **patient’s characteristics** (age, race)
Restart of NA should be considered taking into account the dynamics of HBV DNA and/or ALT values.

Abnormal test confirmed 4 weeks apart

- Signs of decreasing liver function based on laboratory findings (e.g., INR, direct bilirubin) or clinical assessment (e.g., ascites, hepatic encephalopathy).
- HBV DNA > 2000 IU/mL and ALT > 5xULN *
- HBV DNA > 20,000 IU/mL
- Confirmed HBeAg seroreversion (HBeAg positive after it was negative at NA completion)

Yes

Restart of NA should be considered taking into account the dynamics of HBV DNA and/or ALT values.

No

Monitoring without restarting NA

*At anytime an ALT flare (≥3xULN and ≥ 3xNadir) will trigger weekly visits until stabilization