PROTOCOL FOR EVALUATION, TREATMENT, AND FOLLOW-UP OF CHRONIC HEPATITIS B- 2025

Standard Operating Procedure for the Management of Chronic Hepatitis B among Tibetans by Primary Care Physicians

GUIDELINES FOR TREATING CHRONIC HEPATITIS B:

Treat all adults and adolescents (>=12 years) with CHB (including pregnant women and girls, and women of reproductive age) with:

1.	**Evidence of significant fibrosis (>=F2)** based on APRI score of >0.5 or transient elastography (Fibroscan) value of > 7kPa or **Evidence of cirrhosis (F4)** based on clinical criteria or an APRI score of >1 or transient elastography (fibroscan) value of >12.5kPa Regardless of HBV DNA or ALT levels. *Note: Clinical features of decompensated cirrhosis: portal hypertension (ascites, variceal haemorrhage and hepatic encephalopathy), coagulopathy or liver insufficiency (jaundice). Other clinical features of advanced liver disease and cirrhosis may include: hepatomegaly, splenomegaly, pruritus, fatigue, arthralgia, palmar erythema and oedema.* **OR**
2.	HBV DNA >2,000 IU/ml **and** an ALT level above the upper limit of normal (ULN) *Note: For ALT>ULN, take the upper limit of your respective labs (Ideally the machine should be calibrated). If the laboratory ULN is not known then take ULN of ALT as 35U/L for men and 25U/L for women.* *Note: For adolescents, this should be based on ALT >ULN on at least 2 occasions in a 6- to 12- month period.* **OR**
3.	Presence of any of the following: (regardless of APRI score, HBV DNA or ALT level) • **Co-infections** (eg. HIV, hepatitis D, hepatitis C) • **Family history** of liver cancer or cirrhosis • **Immune suppression** (eg. long-term steroids, solid organ or stem cell transplant) • **Co-morbidities** (eg. diabetes, metabolic dysfunction-associated steatotic liver disease) • **Extra-hepatic manifestations** (eg. glomerulonephritis or vasculitis)

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (MTCT) OF HEPATITIS B:

INTERVENTION	DETAILS	TIMING
Newborn Prophylaxis (Active-Passive Immunization)	All infants born to HBsAg positive mothers must receive both: **1.Hepatitis B Immune Globulin (HBIG)** (Passive immunity) **2.Hepatitis B Vaccine:** Birth dose followed by 3 additional doses	HBIG: Must be administered within **12hours of birth.** Hepatis B Vaccine-Birth dose must be administered within **24hours of birth.**
Maternal Antiviral Prophylaxis	Recommended for mothers with: **HBV DNA viral load of >200,000 IU/mL** OR **HBeAg positive**	**Second Trimester-**Preferably around **28 weeks.** To be continued until **at least delivery or completion of infant HBV vaccination series.** (*Provided the antiviral was started solely for the prevention of MTCT because she had a high viral load (HBV DNA > 200,000 IU/mL) or HBeAg positive but otherwise had inactive liver disease (normal ALT, no cirrhosis).* Monitor closely for at least **6 months postpartum** to detect and manage a flare.
Drug of Choice	**Tenofovir Disoproxil Fumarate (TDF)**	Note: For those already on antiviral therapy: TDF should be continued; ETV or TAF should be switched to TDF at first antenatal visit.

Note: Breastfeeding is not contraindicated among women taking TDF.

Selection of Antivirals for Chronic Hepatitis B
Antiviral drug of choice: 1. Tenofovir alafenamide (TAF) 25mg 2. Tenofovir disoproxil fumarate (TDF) 300mg: -If TAF is unavailable or unaffordable -Drug of choice in pregnant females 3. Entecavir: children aged 2 to 11 years

Baseline Evaluation of Patients with Chronic Hepatitis B	
1	Complete history (including family history of cirrhosis or HCC) and physical examination (evaluate for signs and symptoms of cirrhosis)
2	Full LFTs
3	CBC
4	HBV-DNA (Quantitative)
5	HBeAg
6	AFP
7	Serum Creatinine
8	Ultrasound Liver
9	Anti-HCV
10	HIV with pre and post-test counselling
Optional Test	
11	PT/INR
12	Fibro-scan

Monitoring of Patients - RECEIVING TREATMENT		
Cirrhosis- Monitor every **6months**	1.	CBC
	2	LFT
	3	AFP
	4	HBV DNA Level
	5	Creatinine
	6	Ultrasound abdomen
		APRI Score
		Monitor for treatment adherence at each visit
Non cirrhosis- Monitor **annually**	1	CBC
	2	LFT
	3	AFP
	4	HBV DNA Level
	5	Creatinine
	6	Ultrasound abdomen
	7	Fibroscan/ Shear Wave Elastography if available
		APRI Score
		Monitor for treatment adherence at each visit
		**NOTE: For persistently undetectable HBV DNA levels: HBsAg (Quantitative test) is advised.*
Monitoring of Patients – NOT YET RECEIVING TREATMENT		
Monitor: Every **6months** **(Preferred)** **Annually (Minimum)**	1	CBC
	2	LFT
	3	AFP
	4	HBV DNA Level
	5	USG abdomen
	6	Fibroscan/ Shear Wave Elastography if available
		APRI Score

When to Refer	
1	Acute Flare
2	All Cirrhosis (Decompensated/ Compensated)
3	Co-infection with HCV or HDV or HIV
4	Immune suppression (eg. long-term steroids, solid organ or stem cell transplant)
5	Co-morbidities (eg. diabetes, metabolic dysfunction-associated steatotic liver disease)
6	Extra-hepatic manifestations (eg. glomerulonephritis or vasculitis)
7	Treatment failure
8	SOL liver (Space occupying lesions)
9	Patients opting for IFT (interferon therapy)
10	Pregnancy

When to Stop Treatment?

(Advisable to seek expert opinion before stopping)

Antiviral therapy is lifelong. Discontinuation can be considered exceptionally for:

1. People without evidence of cirrhosis [based on clinical criteria or non-invasive test (APRI or Fibroscan) score];

AND

2. Persistently normal ALT levels and persistently undetectable HBV DNA levels;

AND

3. Who can be followed carefully after discontinuation and long term for reactivation;

AND

4a. For previously HBeAg positive patients: Evidence of HbeAg Loss and seroconversion to Anti HBe and after completion of atleast one additional year of treatment.

OR

4b. For previously HBeAg negative patients: Persistent HBsAg loss and after completion of atleast one additional year of treatment.