Elements with asterisks (\*) are Core.

Suggested Timeline for Related Laboratory Assessments – every 90-120 days for the first year and every 6 months thereafter for 5 years and then yearly until normal.

Hepatic Assessments

1. \*Was a liver MRI performed?

☐ Yes

☐ No

☐ Unknown

\*If Yes, what was the liver iron content (LIC)?

☐ Known, by ☐ R2\* or ☐T2\*:

☐ Unknown

\*If Known, estimated LIC: \_\_ \_\_ \_\_ \* \_\_

☐ mg Fe/g liver dry weight

☐ g Fe/kg liver dry weigh

☐ umol Fe/g liver dry weight

1. Was a liver biopsy performed?

☐ Yes

☐ No

☐ Unknown

Yes, date of most recent liver biopsy: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

If yes, what was LIC? \_\_\_ mg Fe/gm liver dry wt

If the LIC is >22 mg Fe/gm dw, consider cardiac iron assessment by MRI

IF performed, was cardiac iron: *T2\*>20;*  *T2\*>10, <20;*  *T2\* <10;*

Was there evidence of fibrosis?

Yes

No

\*If Yes, identify type of fibrosis  Bridging  Periportal

Was there evidence of cirrhosis?

Yes

No

Was there evidence of hepatic inflammatory/hepatitis?

Yes

No

Is a copy of biopsy report attached?

Yes

No

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test | Normal | Result | Value | Significance | Comorbidities/  Comments |
| \*Iron |  | Data to be entered by site | Normal  Abnormal  Unknown | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| \*% Serum transferrin (% saturation) |  | Data to be entered by site | Normal  Abnormal  Unknown | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Soluble transferrin receptor |  | Data to be entered by site | Normal  Abnormal  Unknown | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Hepcidin |  | Data to be entered by site | Normal  Abnormal  Unknown | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| TIBC |  | Data to be entered by site | Normal  Abnormal  Unknown | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Serum ferritin |  | Data to be entered by site | Normal  Abnormal  Unknown | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |