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 |