Form 2553 R1.0: Veno-occlusive Disease (VOD) / Sinusoidal Obstruction Syndrome (SOS) Supplemental Data Collection Form

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

HCT type: (check all that apply)

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

Product type: (check all that apply)

- ☐ Bone marrow
- ☐ PBSC
- ☐ Single cord blood unit
- ☐ Multiple cord blood units
- ☐ Other product

Specify: _____

Visit

○ 100 day ○ 6 months

Diagnosis

Questions: 1 - 28

VOD/SOS Diagnosis

1 Was the date of diagnosis of VOD previously reported?

○ Yes ○ No

2 Date of diagnosis: __ __ __ __ - __ __- __ __

Specify how the diagnosis of VOD/SOS was made:

3 Was ultrasonography (with doppler) performed?

○ Yes ○ No

4 Date: __ __ __ __ - __ __- __ __

Specify results:

5 Normal

○ Yes ○ No

6 Reversal of portal venous flow (in at least 1 vein)

○ Yes ○ No

7 Other abnormality

○ Yes ○ No

8 Specify other abnormality: _____

Please submit documentation to the CIBMTR

9 Was a liver biopsy performed?

○ yes ○ no

10 Specify biopsy result

- ○ Positive (for signs of VOD)
- ○ Negative (for signs of VOD)
- ○ Inconclusive

11 Was an autopsy performed?

○ Yes ○ No

Specify signs and symptoms at diagnosis of VOD/SOS:

12 Ascites

○ Yes ○ No

13 Hepatomegaly

○ yes ○ no

14 Right upper quadrant pain

○ Yes ○ No

15 Weight gain (>2% over baseline at time of diagnosis of VOD/SOS)

○ Yes ○ No

16 Was there concurrent organ dysfunction at the time of diagnosis?

○ Yes ○ No

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Specify organ(s):

17 Kidney

○ yes ○ no

18 Did the recipient require renal replacement therapy?

○ Yes ○ No

19 Lungs

○ yes ○ no

20 Specify the oxygen requirements (at diagnosis of VOD/SOS)

○ Room air

○ Supplemental oxygen

○ Mechanical ventilation

○ Other oxygen requirement

21 Specify other oxygen requirement: _____

22 Date started: __ __ __ __ - __ __- __ __

23 Was the recipient successfully extubated?

○ Yes

○ No (mechanical ventilation ongoing)

24 Date extubated: __ __ __ __ - __ __- __ __

25 Other organ

○ yes ○ no

26 Specify other organ: _____

27 Recipient weight (at diagnosis of VOD/SOS)

○ Known ○ Unknown

28 Recipient weight: (at diagnosis of VOD/SOS) _____ ○ pounds ○ kilograms

Laboratory Studies at Diagnosis of VOD / SOS

Questions: 29 - 42

29 Total serum bilirubin (at diagnosis of VOD/SOS)

○ Known ○ Unknown

30 _____ ○ mg/dL ○ µmol/L

31 Date sample collected: __ __ __ __ - __ __- __ __

32 Serum creatinine (at diagnosis of VOD/SOS)

○ Known ○ Unknown

33 _____ ○ mg/dL ○ mmol/L ○ µmol/L

34 Date sample collected: __ __ __ __ - __ __- __ __

35 AST (SGOT) (at diagnosis of VOD/SOS)

○ Known ○ Unknown

36 _____ ○ U/L ○ µkat/L

37 Date sample collected: __ __ __ __ - __ __- __ __

38 Upper limit of normal for your institution: _____ ○ U/L ○ µkat/L

39 ALT (SGPT) (at diagnosis of VOD)

○ Known ○ Unknown

40 _____ ○ U/L ○ µkat/L

41 Date sample collected: __ __ __ __ - __ __- __ __

42 Upper limit of normal for your institution: _____ ○ U/L ○ µkat/L

Therapy for VOD / SOS

Questions: 43 - 98

Specify therapy given for VOD/SOS in this reporting period

43 Was therapy given?

○ yes ○ no

Specify therapy:

44 Defibrotide

○ Yes ○ No

45 Planned total daily dose: _____ mg/kg

46 Date started: __ __ __ __ - __ __- __ __

47 Was this therapy still being given at the date of last contact? (defibrotide)

○ Yes ○ No

48 Date stopped: __ __ __ __ - __ __- __ __

49 Recipient weight: (at initiation of therapy) _____ ○ pounds ○ kilograms

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Center: CRID:

Specify the lab results on the therapy start date:

50 Total serum bilirubin

○ Known ○ Unknown

51 _____ ○ mg/dL ○ µmol/L

52 Serum creatinine

○ Known ○ Unknown

53 _____ ○ mg/dL ○ mmol/L ○ µmol/L

54 Specify the oxygen requirements (at initiation of therapy)

○ Room air

○ Supplemental oxygen

○ Mechanical ventilation

○ Other oxygen requirement

55 Specify other oxygen requirement: _____

56 Specify the reason therapy stopped (defibrotide)

○ Complete resolution - (Total bilirubin <2 mg/dL, and resolution of associated organ dysfunction (Renal: Serum creatinine <1.5 x baseline or meeting ULN based on patient's age, Creatinine clearance/GFR >80% than initial value, Dialysis-independence; Pulmonary: O_2 saturation >90% on room air, No supplemental O_2 required, Ventilator-independence))

○ Completed prescribed course / end of treatment protocol

○ Discharge from hospital

○ Death

○ Side effect(s)

○ Other

57 Specify other reason: _____

Specify side effect(s)

58 Bleeding

○ Yes ○ No

Specify site(s) of bleeding:

59 Central nervous system (CNS)

○ Yes ○ No

60 Gastrointestinal (GI)

○ Yes ○ No

61 Pulmonary

○ yes ○ no

62 Other site

○ Yes ○ No

63 Specify other site: _____

64 Other side effect

○ Yes ○ No

65 Specify other side effect: _____

66 Anti-thrombin III

○ Yes ○ No

67 Date started: __ __ __ __ - __ __- __ __

68 Was this therapy still being given at the date of last contact? (anti-thrombin III)

○ Yes ○ No

69 Date stopped: __ __ __ __ - __ __- __ __

70 Diuretics

○ Yes ○ No

71 Date started: __ __ __ __ - __ __- __ __

72 Was this therapy still being given at the date of last contact? (diuretics)

○ Yes ○ No

73 Date stopped: __ __ __ __ - __ __- __ __

74 Heparin

○ yes ○ no

75 Date started: __ __ __ __ - __ __- __ __

76 Was this therapy still being given at the date of last contact? (heparin)

○ Yes ○ No

77 Date stopped: __ __ __ __ - __ __- __ __

78 Methylprednisolone

○ Yes ○ No

79 Date started: __ __ __ __ - __ __- __ __

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80 Was this therapy still being given at the date of last contact? (methylprednisolone)
Yes No

81 Date stopped: __ __ __ __ - __ __- __ __

82 N-acetylcysteine
Yes No

83 Date started: __ __ __ __ - __ __- __ __

84 Was this therapy still being given at the date of last contact? (N-acetylcysteine)
Yes No

85 Date stopped: __ __ __ __ - __ __- __ __

86 Tissue plasminogen activator (TPA)
Yes No

87 Date started: __ __ __ __ - __ __- __ __

88 Was this therapy still being given at the date of last contact? (TPA)
Yes No

89 Date stopped: __ __ __ __ - __ __- __ __

90 Ursodiol
Yes No

91 Date started: __ __ __ __ - __ __- __ __

92 Was this therapy still being given at the date of last contact? (ursodiol)
Yes No

93 Date stopped: __ __ __ __ - __ __- __ __

94 Other therapy
yes no

95 Specify other therapy: _____

96 Date started: __ __ __ __ - __ __- __ __

97 Was this therapy still being given at the date of last contact? (other therapy)
Yes No

98 Date stopped: __ __ __ __ - __ __- __ __

Maximum Severity of VOD / SOS in this Reporting Period

Questions: 99 - 112

99 Maximum recipient weight
Known Unknown

100 Maximum recipient weight: _____ pounds kilograms

101 Maximum total serum bilirubin
Known Unknown

102 _____ mg/dL µmol/L

103 Date sample collected: __ __ __ __ - __ __- __ __

104 Maximum serum creatinine
Known Unknown

105 _____ mg/dL mmol/L µmol/L

106 Date sample collected: __ __ __ __ - __ __- __ __

107 Was the recipient placed on dialysis?
Yes No

108 Date dialysis started: __ __ __ __ - __ __- __ __

109 Was the recipient still on dialysis at the date of last contact?
Yes No

110 Date dialysis stopped: __ __ __ __ - __ __- __ __

111 Specify the maximum oxygen requirements
Room air
Supplemental oxygen
Mechanical ventilation
Other oxygen requirement

112 Specify other maximum oxygen requirement: _____

Current Status

Questions: 113 - 145

113 Recipient weight (most recent)
Known Unknown

114 Recipient weight: (most recent) _____ pounds kilograms

115 Date documented: __ __ __ __ - __ __- __ __

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Specify the lab results at the date of last contact

116 Total serum bilirubin

○ Known ○ Unknown

117 _____ ○ mg/dL ○ µmol/L

118 Date sample collected: __ __ __ __ - __ __- __ __

119 Serum creatinine

○ Known ○ Unknown

120 _____ ○ mg/dL ○ mmol/L ○ µmol/L

121 Date sample collected: __ __ __ __ - __ __- __ __

122 Specify the oxygen requirements (at date of last contact)

○ Room air

○ Supplemental oxygen

○ Mechanical ventilation

○ Other oxygen requirement

123 Specify other oxygen requirement: _____

VOD/SOS Status

124 Did VOD / SOS resolve?

○ Yes ○ No

125 Date resolved: __ __ __ __ - __ __- __ __

126 Did VOD / SOS symptoms recur?

○ Yes ○ No

127 Date of recurrence: __ __ __ __ - __ __- __ __

VOD/SOS Symptoms at Recurrence

128 Increased bilirubin

○ Yes ○ No

129 Ascites

○ Yes ○ No

130 Weight gain (>2% over baseline at time of recurrence)

○ Yes ○ No

131 Hepatomegaly

○ yes ○ no

132 Right upper quadrant pain

○ Yes ○ No

133 Other symptom

○ Yes ○ No

134 Specify other symptom: _____

135 Was therapy given for recurrent VOD?

○ yes ○ no

136 Anti-thrombin III

○ Yes ○ No

137 Defibrotide

○ Yes ○ No

138 Diuretics

○ Yes ○ No

139 Heparin

○ yes ○ no

140 Methylprednisolone

○ Yes ○ No

141 N-acetylcysteine

○ Yes ○ No

142 Tissue plasminogen activator (TPA)

○ Yes ○ No

143 Ursodiol

○ Yes ○ No

144 Other drug

○ yes ○ no

145 Specify other drug: _____

Management of Late Sequelae

Questions: 146 - 153

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146 Was management of late sequelae required?
Yes No

147 Variceal banding
Yes No

148 Transjugular Intrahepatic Portosystemic Shunt (TIPS)
Yes No

149 Paracentesis
Yes No

150 Thoracentesis
Yes No

151 Was the recipient dialysis dependent?
Yes No

152 Other late sequelae
Yes No

153 Specify other late sequelae: _____

Hospital Stay

Questions: 154 - 163

154 Was the intent to complete the HCT procedure (conditioning, infusion, and period of recovery from neutropenia) as an outpatient?
Yes No

155 Did the recipient require an unplanned admission?
Yes No

156 Was the recipient admitted to ICU during their hospital stay?
Yes No

157 First date of ICU stay: __ __ __ __ - __ __- __ __

158 End date of ICU stay: __ __ __ __ - __ __- __ __

159 Was the recipient discharged prior to the date of contact?
Yes No

160 Date first discharged from hospital post-HCT: __ __ __ __ - __ __- __ __

161 Total number of inpatient days (day 0 to day 100) in first 100 days post-HCT: _____

162 Discharge status
Discharged to home Hospice Rehabilitation Other

163 Specify other discharge status: _____

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __- __ __