



Exagamglogene autotemcel (Casgevy®) Post-Infusion Supplemental Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: _____

YYYY MM DD

Visit

100 day

6 months

1 year

2 years

>2 years, Specify: _____

Report all findings SINCE DATE OF LAST REPORT unless otherwise specified.

Exagamglogene autotemcel (Casgevy®)

1. Did the recipient experience any infection event?

- Yes
- No
- Unknown

2. Did the recipient experience a grade 3 or higher bleeding event?

- Yes – **Go to question 3**
- No – **Go to question 8**

Copy and complete questions 3 – 7 to report all bleeding events.

3. Specify the bleeding event

- Epistaxis – **Go to question 5**
- Hematuria – **Go to question 5**
- Intracranial hemorrhage – **Go to question 5**
- Lower GI hemorrhage or rectal bleeding – **Go to question 5**
- Menorrhagia – **Go to question 5**
- Upper GI hemorrhage – **Go to question 5**
- Other bleeding event – **Go to question 4**

4. Specify other bleeding event: _____

5. Date of bleeding event

- Known – **Go to question 6**
- Unknown – **Go to question 7**

6. Date of bleeding event: _____ - _____ - _____
YYYY MM DD

7. Was the recipient hospitalized (or in hospital) for this event?

- Yes
- No
- Unknown

Copy and complete questions 3 – 7 to report all bleeding events.

Hepatic Assessments

8. Did the recipient have hepatomegaly? *(sickle cell disease only)*

- Yes
- No

Splenic Assessments

9. Complete red blood cell count (RBC): *(transfusion-dependent thalassemia only)* _____.

- $\square \times 10^3/\mu\text{L} (\times 10^9/\text{L}) (\times 10^3/\text{mm}^3)$
- $\square \times 10^6/\mu\text{L} (\times 10^{12}/\text{L})$

10. Date sample drawn: _____ - _____ - _____
 YYYY MM DD

11. Did the recipient have splenomegaly? *(sickle cell disease only)*

- Yes
- No

Pain

12. Were non-narcotic analgesics administered? *(sickle cell disease only)*

- Yes
- No
- Unknown

Other Symptoms

13. Did the recipient experience a hemoglobin level <8 g/dL lasting for more than three months? *(occurring after Day +100)*

- Yes
- No
- Previously reported
- Unknown

New non-malignant hematologic disorder

14. Did autoimmune hemolytic anemia develop or persist?

- Yes – **Go to question 15**
- No – **Go to question 18**

Unknown – **Go to question 18**

15. Was the date of onset previously reported?

Yes – **Go to question 17**

No – **Go to question 16**

16. Date of autoimmune hemolytic anemia onset: _____ - _____ - _____

YYYY

MM

DD

17. Status

Ongoing

Resolved

18. Did aplastic anemia develop or persist?

Yes – **Go to question 19**

No – **Go to question 22**

Unknown – **Go to question 22**

19. Was the date of onset previously reported?

Yes – **Go to question 21**

No – **Go to question 20**

20. Date of aplastic anemia onset: _____ - _____ - _____

YYYY

MM

DD

21. Status

Ongoing

Resolved

22. Did immune thrombocytopenia develop or persist?

Yes – **Go to question 23**

No – **Go to question 26**

Unknown – **Go to question 26**

23. Was the date of onset previously reported?

Yes – **Go to question 25**

No – **Go to question 24**

CIBMTR Center Number: _____

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24. Date of immune thrombocytopenia onset: _____ - _____ - _____
YYYY MM DD

25. Status

- Ongoing
- Resolved

26. Did another new non-malignant hematologic disorder develop or persist?

- Yes – **Go to question 27**
- No – **Go to question 31**
- Unknown – **Go to question 31**

27. Specify other: _____

28. Was the date of onset previously reported?

- Yes – **Go to question 30**
- No – **Go to question 29**

29. Date of other new non-malignant hematologic onset: _____ - _____ - _____

YYYY DD MM

30. Status

- Ongoing
- Resolved

Solid tumor TNM classification

31. Did the recipient develop a solid tumor new malignancy? (*also complete Subsequent Neoplasms Form 3500*)

- Yes – **Go to question 32**
- No – **Go to End of Form**

32. Solid tumor – (T) tumor

- TX
- T0
- T1a
- T1b
- T2a
- T2b
- T3a

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- T3b
- T4a
- T4b
- Unknown

33. Solid tumor – (N) lymph node

- NX
- N0
- N1
- N1a
- N1b
- N1c
- N2
- N2a
- N2b
- N2c
- N3
- Unknown

34. Solid tumor – (M) metastasis

- M0
- M1
- M1a
- M1b
- M1c
- Unknown