CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

EBMT
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European Group for Blood and Marrow Transplantation

Multiple Sclerosis Pre-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

EBMT Center Identification Code (CIC):

Today's Date: Month Day 2 0 Year

Date of HSCT for which this form is being completed: 🕮 Month Day 2 0 Year

HSCT type: ☐ autologous ☐ allogeneic, unrelated ☐ allogeneic, related ☐ syngeneic (identical twin)

Product type: ☐ marrow ☐ PBSC ☐ cord blood ☐ other product, specify: _____

This form must be accompanied by Form 2000 – Recipient Baseline Data. All information in the box above, including the date, should be identical with the corresponding Form 2000. Information should come from an actual examination by the Transplant Center physician, or the physician who is following the recipient pre-HSCT, or abstraction of the recipient's medical records.

Questions followed by the book symbol 🕮 indicate additional information necessary to complete the question is referenced in the forms instruction manual.

If this is a report of a second or subsequent transplant, check here ☐ and continue with question 42.

Disease Assessment at Diagnosis

1. What was the date of onset for the first Multiple Sclerosis (MS) symptom(s)? Month Day Year ☐ date unknown

2. What was the date of diagnosis of MS? Month Day Year ☐ date unknown

3. Are any of the recipient's family members also affected with MS?
   1 ☐ yes → Specify the family members:
   2 ☐ no
   3 ☐ unknown

   4. 1 ☐ yes 2 ☐ no 3 ☐ unknown Monozygotic twin
   5. 1 ☐ yes 2 ☐ no 3 ☐ unknown Dizygotic twin
   6. 1 ☐ yes 2 ☐ no 3 ☐ unknown Other first degree relative (sibling, parent, child)
   7. 1 ☐ yes 2 ☐ no 3 ☐ unknown Second degree relative (grandparent, aunt, uncle, first cousin)
   8. 1 ☐ yes 2 ☐ no 3 ☐ unknown Other relative → 9. Specify relationship: _____

Laboratory Studies at Diagnosis

Specify results of tests performed prior to any first treatment given for MS.

10. Was the diagnosis of MS corroborated by laboratory or radiological test results?
    1 ☐ yes → Specify which test measures indicated MS:
    2 ☐ no
    3 ☐ unknown

    11. 1 ☐ yes 2 ☐ no 3 ☐ unknown CSF oligoclonal bands present
    12. 1 ☐ yes 2 ☐ no 3 ☐ unknown Elevated IgG index
    13. 1 ☐ yes 2 ☐ no 3 ☐ unknown MRI brain lesions consistent with MS

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Mail this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the transplant center.

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Pre-HSCT Treatment for Multiple Sclerosis

14. Did the recipient receive any disease-modifying treatments between the time of diagnosis and prior to mobilization for stem cell collection (or prior to the preparative regimen if mobilization was not done)?

1 ☐ yes → **Continue with table below**

2 ☐ no → **Continue with question 42**

15. Specify the date the first disease-modifying therapy started: | | Month | | | Day | | | | Year |

Indicate all treatments for MS that the recipient received prior to mobilization for stem cell collection (or prior to the preparative regimen if mobilization was not done):

16. 1 ☐ yes 2 ☐ no 3 ☐ unknown Alemtuzumab (Campath)
17. 1 ☐ yes 2 ☐ no 3 ☐ unknown Azathioprine (Azasan, Imuran)
18. 1 ☐ yes 2 ☐ no 3 ☐ unknown Belimumab (LymphoStat-B)
19. 1 ☐ yes 2 ☐ no 3 ☐ unknown Cladribine (2-CdA, Leustatin)
20. 1 ☐ yes 2 ☐ no 3 ☐ unknown Corticosteroids 🕮 (chronic use, not to treat acute relapse)
21. 1 ☐ yes 2 ☐ no 3 ☐ unknown Cyclophosphamide (CTX, Cytoxan, Neosar)
22. 1 ☐ yes 2 ☐ no 3 ☐ unknown Daclizumab (Zenapax, anti-CD25)
23. 1 ☐ yes 2 ☐ no 3 ☐ unknown Fingolimod (FTY720)
24. 1 ☐ yes 2 ☐ no 3 ☐ unknown Fumarate (oral) (BG00012)
25. 1 ☐ yes 2 ☐ no 3 ☐ unknown Glatiramer acetate (Copaxone) [previously copolymer-1]
26. 1 ☐ yes 2 ☐ no 3 ☐ unknown Immune globulin (IVIG, Gamimune, Gammagard)
27. 1 ☐ yes 2 ☐ no 3 ☐ unknown Interferon beta-1a (Avonex, Rebif)
28. 1 ☐ yes 2 ☐ no 3 ☐ unknown Interferon beta-1b (Betaseron)
29. 1 ☐ yes 2 ☐ no 3 ☐ unknown Laquinimod
30. 1 ☐ yes 2 ☐ no 3 ☐ unknown Methotrexate (MTX, Folex)
31. 1 ☐ yes 2 ☐ no 3 ☐ unknown Mitoxantrone (Novantrone)
32. 1 ☐ yes 2 ☐ no 3 ☐ unknown Natalizumab (Tysabri, Antegren)
33. 1 ☐ yes 2 ☐ no 3 ☐ unknown Mycophenolate mofetil (MMF, Cellcept)
34. 1 ☐ yes 2 ☐ no 3 ☐ unknown Rituximab (anti-CD20, Rituxan, MabThera)
35. 1 ☐ yes 2 ☐ no 3 ☐ unknown Sirolimus (Rapamune)
36. 1 ☐ yes 2 ☐ no 3 ☐ unknown Tacrolimus (FK 506, Prograf)
37. 1 ☐ yes 2 ☐ no 3 ☐ unknown Teriflunomide (oral) (HMR1726)
38. 1 ☐ yes 2 ☐ no 3 ☐ unknown Blinded randomized trial agent → 39. Specify trial agent: _____
40. 1 ☐ yes 2 ☐ no 3 ☐ unknown Other treatment → 41. Specify other treatment: _____

Baseline Assessment for MS Performed at the Transplant Center

Information reported in this section should come from the recipient's first evaluation performed at the transplant center. For autologous HSCT recipients, the baseline assessment is typically ≤ 4 weeks prior to mobilization for stem cell collection.

42. Date of baseline evaluation: | | Month | | | Day | | | | Year |

43. Specify the number of relapses of MS during the 1-year period prior to the baseline assessment: | | ☐ number unknown

44. Specify the disease course during the 2-year period prior to the baseline assessment:

1 ☐ relapsing remitting
2 ☐ secondary progressive
3 ☐ primary progressive
4 ☐ progressive relapsing
5 ☐ unknown

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45. Was the Kurtzke Expanded Disability Status Scale (EDSS) assessed by a neurologist during the 2-year period prior to the baseline assessment?

1 ☐ yes → 2 ☐ no 3 ☐ unknown

	Month	Day	Year		
46. Date of EDSS assessment:				47. EDSS:	.
48. Date of EDSS assessment:				49. EDSS:	.
50. Date of EDSS assessment:				51. EDSS:	.
52. Date of EDSS assessment:				53. EDSS:	.
54. Date of EDSS assessment:				55. EDSS:	.

56. Were the Kurtzke Functional Systems Scores (FSS) assessed by a neurologist during the baseline assessment?

1 ☐ yes → 2 ☐ no 3 ☐ unknown

Specify the following FSS scores:

57. Pyramidal:		☐ score unknown
58. Cerebellar:		☐ score unknown
59. Brainstem:		☐ score unknown
60. Sensory:		☐ score unknown
61. Bowel and bladder:		☐ score unknown
62. Visual:		☐ score unknown
63. Cerebral:		☐ score unknown
64. Other function:		65. Specify other function: _____ ☐ score unknown

66. Specify the EDSS at baseline assessment: | | . | | ☐ EDSS unknown

67. Was a MRI scan of the brain conducted during the baseline assessment?

1 ☐ yes → 2 ☐ no 3 ☐ unknown

68. Date of baseline MRI: Month | | Day | | Year | | | | ☐ date unknown

69. Are T2 lesions present on the MRI?

1 ☐ yes → 2 ☐ no

70. Specify number of T2 lesions: | | ☐ number unknown

71. Was gadolinium contrast used for this assessment?

1 ☐ yes → 2 ☐ no

72. Are gadolinium-enhancing lesions present on the MRI?

1 ☐ yes → 2 ☐ no

73. Specify number of lesions: | | ☐ number unknown

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Stem Cell Mobilization for Autologous HSCT

This section records pre-mobilization information for autologous HSCTs only; if this report is for an allogeneic HSCT, or if the autologous HSCT did not use mobilization, check here ☐ and continue with question 79.

74. Did the recipient receive treatment, prior to any stem cell harvest, to enhance the autologous product collection for this HSCT?
    1 ☐ yes → Specify treatment(s): *(select all that apply)*
    2 ☐ no
    75. 1 ☐ yes 2 ☐ no Cyclophosphamide
    76. 1 ☐ yes 2 ☐ no Growth factors → **Report details on form 2006 – HSCT Infusion**
    77. 1 ☐ yes 2 ☐ no Other mobilization chemotherapy → 78 Specify other chemotherapy: _____

Most Recent Disease Assessment Prior to the Start of the Preparative (Conditioning) Regimen

Information for this section should come from the most recent evaluation performed ≤ 2 weeks prior to the preparative regimen. If the recipient was not evaluated prior to the preparative regimen, check here ☐ and continue with the signature lines at question 104.

For recipients of autologous cells who underwent mobilization for stem cell collection, a second disease assessment is required prior to the preparative regimen.

79. Date of evaluation prior to the preparative regimen: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

80. Specify the number of relapses of MS that occurred after the start of mobilization and the start of the preparative regimen: 🕮 ☐☐ ☐ number unknown

81. Did the recipient experience worsening disability or continuous progression of MS between mobilization and the start of the preparative regimen?
    1 ☐ yes
    2 ☐ no
    3 ☐ unknown

82. Was a MRI scan of the brain conducted as part of the disease assessment prior to the preparative regimen (not including the baseline MRI reported at question 67)?
    1 ☐ yes →
    2 ☐ no
    3 ☐ unknown

    83. Date of most recent MRI performed prior to the preparative regimen: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

    84. Does the radiology report include a comparison with the baseline MRI?
        1 ☐ yes → **Continue with question 87**
        2 ☐ no → **Complete questions 85–89, then continue at question 93.**

    85. Are T2 lesions present on the MRI?
        1 ☐ yes → 86. Specify the number of T2 lesions: ☐☐ ☐ number unknown
        2 ☐ no

    87. Was gadolinium contrast used for this assessment?
        1 ☐ yes → 88. Are gadolinium-enhancing lesions present on the MRI?
            1 ☐ yes → 89. Specify the number of gadolinium-enhancing lesions: ☐☐ ☐ number unknown
            2 ☐ no
        2 ☐ no

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90. In comparison to the baseline MRI, does the radiology report state evidence of new or enlarged T2 lesions?
    1 ☐ yes
    2 ☐ no
91. In comparison to the baseline MRI, does the radiology report state evidence of any new or enlarged gadolinium-enhancing lesions?
    1 ☐ yes
    2 ☐ no
92. In comparison to the baseline MRI, does the radiology report a change in the overall burden of MS-specific lesions?
    1 ☐ improvement of lesion burden
    2 ☐ worsening of lesion burden
    3 ☐ mixed response

93. Were the Kurtzke Functional Systems Scores (FSS) assessed by a neurologist prior to the preparative regimen (not including any FSS reported at question 56)?
    1 ☐ yes → Specify the following FSS scores:
    2 ☐ no
    3 ☐ unknown

94. Pyramidal:		☐ score unknown
95. Cerebellar:		☐ score unknown
96. Brainstem:		☐ score unknown
97. Sensory:		☐ score unknown
98. Bowel and bladder:		☐ score unknown
99. Visual:		☐ score unknown
100. Cerebral:		☐ score unknown
101. Other function:		102. Specify other function: _____ ☐ score unknown

103. Specify the most recent EDSS assessed prior to the preparative regimen: | | . | | ☐ EDSS unknown

If the person completing this form is a Neurologist, check here ☐ and continue with the signautre lines below.

104. Signed: _____
Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____

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