

Form 2043 R3.0: Multiple Sclerosis Pre-HSCT data

Center:

CRID:

Key Fields
Sequence Number: _____
Date Received: ____-____-____
CIBMTR Center Number: _____
CIBMTR Recipient ID: _____
EBMT Center Identification Code (CIC): _____
Today's Date: ____-____-____
Date of HSCT for which this form is being completed: ____-____-____

HSCT type: (check all that apply)

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related
- ☐ Syngeneic (identical twin)

Product Type: (check all that apply)

- ☐ Marrow
- ☐ PBSC
- ☐ Cord blood
- ☐ Other product

Specify: \_\_\_\_\_

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

Disease Assessment at Diagnosis	Questions: 1 - 13
---------------------------------	-------------------

1 What was the date of onset for the first Multiple Sclerosis (MS) symptom(s)? \_\_\_\_-\_\_\_\_-\_\_\_\_ ☐ Date unknown

2 What was the date of diagnosis of MS? \_\_\_\_-\_\_\_\_-\_\_\_\_ ☐ Date unknown

3 Are any of the recipient's family members also affected with MS?

- ☐ yes
- ☐ no
- ☐ Unknown

4 Monozygotic twin

- ☐ yes
- ☐ no
- ☐ Unknown

5 Dizygotic twin

- ☐ yes
- ☐ no
- ☐ Unknown

6 Other first degree relative (sibling, parent, child)

- ☐ yes
- ☐ no
- ☐ Unknown

7 Second degree relative (grandparent, aunt, uncle, first cousin)

- ☐ yes
- ☐ no
- ☐ Unknown

8 Other relative

- ☐ yes
- ☐ no
- ☐ Unknown

9 Specify relationship: \_\_\_\_\_

10 Was the diagnosis of MS corroborated by laboratory or radiological test results?

- ☐ yes
- ☐ no
- ☐ Unknown

# Form 2043 R3.0: Multiple Sclerosis Pre-HSCT data

Center:

CRID:

11 CSF oligoclonal bands present

☐ yes ☐ no ☐ Unknown

12 Elevated IgG index

☐ yes ☐ no ☐ Unknown

13 MRI brain lesions consistent with MS

☐ yes ☐ no ☐ Unknown

## Pre-HSCT Treatment for Multiple Sclerosis

Questions: 14 - 41

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)?

☐ yes ☐ no

15 Specify the date the first disease-modifying therapy started: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

16 Alemtuzumab (Campath)

☐ yes ☐ no ☐ Unknown

17 Azathioprine (Azasan, Imuran)

☐ yes ☐ no ☐ Unknown

18 Belimumab (LymphoStat-B)

☐ yes ☐ no ☐ Unknown

19 Cladribine (2-CdA, Leustatin)

☐ yes ☐ no ☐ Unknown

20 Corticosteroids (chronic use, not to treat acute relapse)

☐ yes ☐ no ☐ Unknown

21 Cyclophosphamide (CTX, Cytoxan, Neosar)

☐ yes ☐ no ☐ Unknown

22 Daclizumab (Zenapax, anti-CD25)

☐ yes ☐ no ☐ Unknown

23 Fingolimod (FTY720)

☐ yes ☐ no ☐ Unknown

24 Fumarate (oral) (BG00012)

☐ yes ☐ no ☐ Unknown

25 Glatiramer acetate (Copaxone) [previously copolymer-1]

☐ yes ☐ no ☐ Unknown

26 Immune globulin (IVIG, Gamimune, Gammagard)

☐ yes ☐ no ☐ Unknown

27 Interferon beta-1a (Avonex, Rebif)

☐ yes ☐ no ☐ Unknown

28 Interferon beta-1b (Betaseron)

☐ yes ☐ no ☐ Unknown

29 Laquinimod

☐ yes ☐ no ☐ Unknown

Form 2043 R3.0: Multiple Sclerosis Pre-HSCT data

Center:

CRID:

30 Methotrexate (MTX, Folex)

☐ yes ☐ no ☐ Unknown

31 Mitoxantrone (Novantrone)

☐ yes ☐ no ☐ Unknown

32 Natalizumab (Tysabri, Antegren)

☐ yes ☐ no ☐ Unknown

33 Mycophenolate mofetil (MMF, Cellcept)

☐ yes ☐ no ☐ Unknown

34 Rituximab (anti-CD20, Rituxan, MabThera)

☐ yes ☐ no ☐ Unknown

35 Sirolimus (Rapamune)

☐ yes ☐ no ☐ Unknown

36 Tacrolimus (FK 506, Prograf)

☐ yes ☐ no ☐ Unknown

37 Teriflunomide (oral) (HMR1726)

☐ yes ☐ no ☐ Unknown

38 Blinded randomized trial agent

☐ yes ☐ no ☐ Unknown

39 Specify trial agent: \_\_\_\_\_

40 Other treatment

☐ yes ☐ no ☐ Unknown

41 Specify other treatment: \_\_\_\_\_

Baseline Assessment for MS Performed at the Transplant Center

Questions: 42 - 65

42 Date of baseline evaluation: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

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:

- ☐ relapsing remitting
- ☐ secondary progressive
- ☐ primary progressive
- ☐ progressive relapsing
- ☐ Unknown

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

☐ yes ☐ no ☐ Unknown

EDSS assessment(s) (1)

Questions: 46 - 47

46 Date of EDSS assessment: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

47 EDSS: \_\_\_\_\_

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

☐ yes ☐ no ☐ Unknown

Form 2043 R3.0: Multiple Sclerosis Pre-HSCT data

Center: CRID:

49

Pyramidal

score unknown

50

Cerebellar

score unknown

51

Brainstem

score unknown

52

Sensory

score unknown

53

Bowel and bladder

score unknown

54

Visual

score unknown

55

Cerebral:

score unknown

56

Other function:

score unknown

57

Specify other function:

58

Specify the EDSS at baseline assessment:

EDSS unknown

59

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

yes

no

Unknown

60

Date of baseline MRI:

Date unknown

61

Are T2 lesions present on the MRI?

yes

no

62

Specify number of T2 lesions:

number unknown

63

Was gadolinium contrast used for this assesment?

yes

no

64

Are gadolinium-enhancing lesions present on the MRI?

yes

no

65

Specify number of lesions:

number unknown

Stem Cell Mobilization for Autologous HSCTQuestions: 66 - 70

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 71.

66

Did the recipient receive treatment, prior to any stem cell harvest, to enhance the autologous product collection for this HSCT?

yes

no

Specify treatment(s):

67

Cyclophosphamide

yes

no

68

Growth factors

yes

no

69

Other mobilization chemotherapy

yes

no

70

Specify other chemotherapy:

Most Recent Disease Assessment Prior to the Start of the Preparative (Conditioning) RegimenQuestions: 71 - 95

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.

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

71

Date of evaluation prior to the preparative regimen:

72

Specify the number of relapses of MS that occurred after the start of mobilization and the start of the preparative regimen:

number unknown

# Form 2043 R3.0: Multiple Sclerosis Pre-HSCT data

Center:

CRID:

**73** Did the recipient experience worsening disability or continuous progression of MS between mobilization and the start of the preparative regimen?

☐ yes ☐ no ☐ Unknown

**74** Was a MRI scan of the brain conducted prior to the preparative regimen?

☐ yes ☐ no ☐ Unknown

**75** Date of most recent MRI performed prior to the preparative regimen: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**76** Does the radiology report include a comparison with the baseline MRI?

☐ yes ☐ no

**77** Are T2 lesions present on the MRI?

☐ yes ☐ no

**78** Specify the number of T2 lesions: \_\_\_\_\_ ☐ number unknown

**79** Was gadolinium contrast used for this assessment?

☐ yes ☐ no

**80** Are gadolinium-enhancing lesions present on the MRI?

☐ yes ☐ no

**81** Specify the number of gadolinium-enhancing lesions: \_\_\_\_\_ ☐ number unknown

**82** In comparison to the baseline MRI, does the radiology report state evidence of new or enlarged T2 lesions?

☐ yes ☐ no

**83** In comparison to the baseline MRI, does the radiology report state evidence of any new or enlarged gadolinium-enhancing lesions?

☐ yes ☐ no

**84** In comparison to the baseline MRI, does the radiology report a change in the overall burden of MS-specific lesions?

☐ improvement of lesion burden

☐ worsening of lesion burden

☐ mixed response

**85** Was the Kurtze functional systems scale conducted prior to the preparative regimen?

(not including any FSS reported at question 48)

☐ yes ☐ no ☐ Unknown

**86** Pyramidal: \_\_\_\_\_ ☐ score unknown

**87** Cerebellar: \_\_\_\_\_ ☐ score unknown

**88** Brainstem: \_\_\_\_\_ ☐ score unknown

**89** Sensory: \_\_\_\_\_ ☐ score unknown

**90** Bowel and bladder: \_\_\_\_\_ ☐ score unknown

**91** Visual: \_\_\_\_\_ ☐ score unknown

**92** Cerebral: \_\_\_\_\_ ☐ score unknown

**93** Other function: \_\_\_\_\_ ☐ score unknown

**94** Specify other function: \_\_\_\_\_

**95** 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 signature lines below.

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Phone number: \_\_\_\_\_ Fax number: \_\_\_\_\_

# Form 2043 R3.0: Multiple Sclerosis Pre-HSCT data

Center:

CRID:

E-mail address: \_\_\_\_\_