

BMT CTN PROTOCOL #0102

A Trial of Tandem Autologous Stem Cell Transplants +/- Post Second Autologous Transplant Maintenance Therapy Versus Single Autologous Stem Cell Transplant Followed by Matched Sibling Non-myeloablative Allogeneic Stem Cell Transplant for Patients with Multiple Myeloma

#0102 FORMS SUBMISSION SCHEDULES

- ◆ Segment A
- ◆ Segment B – Allogeneic Stem Cell Transplant
- ◆ Segment B – 2nd Autologous Transplant and Dexamethasone/
Thalidomide Maintenance Therapy

**BMT CTN PROTOCOL #0102
Forms Submission Schedule – Segment A**

FORM	Prior to Transplant	Day 0	Day 28	Day 100	Day 365
Eligibility (Segment A) Transplant	X				
Eligibility (Segment B-Treatment Arm Assignment)	X ¹	X			
Myeloma Status		X			
Toxicity			X		
Follow-up Status			X	X ²	
Specimen Acquisition		X			
Health Quality of Life³		X			
Progression/Relapse		Submit after progression or relapse			
Infection		Submit after each infectious event			
Unexpected, Grade 3-5 Adverse Event		Submit after each unexpected, grade 3-5 adverse event			
Re-Admission/Hospitalization		Submit after each hospitalization			
Death		Submit in the event of the patient's death			
CIBMTR Day 100 Report⁴			X ⁵	X ^{6,7}	
CIBMTR Follow-up⁸					X ^{2,7}

Protocol # 0102 Table Notes:

- ¹To be completed either at the time of first registration or as soon as evaluation of all potential donors is complete, whichever comes first. Must be completed prior to the Segment B Post-Autologous Transplant Checklist.
- ²If second transplant before Day 100, complete the form using patient status between Day 29 and day of second transplant.
- ³Includes FACT-BMT and SF-36.
- ⁴Includes Core, Disease and Graft Inserts.
- ⁵Includes pre-transplant information (Q1-287) of Day 100 Core Form only.
- ⁶Includes post-transplant information of Day 100 Core Form, and Disease and Graft Inserts.
- ⁷Or day prior to second transplant.
- ⁸Includes Core and Disease Follow-up Forms.

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Forms Submission Schedule – Segment B – Allogeneic Stem Cell Transplant

	Prior to 2 nd Transplant	Day 0	Weeks (Days) Post-transplant			Day 90	Day 100	Day 120	Months (Days) Post-transplant										
			4	8	12				6	9	12	18	24	30	36				
			(28)	(56)	(84)				(180)	(270)	(365)	(540)	(730)	(900)	(1095)				
Post-1st Autologous Transplant Checklist	X																		
Transplant		X																	
Myeloma Status		X ¹		X				X	X	X	X	X	X	X	X	X	X		
Acute GVHD			Submit weekly until Day 100																
Follow-up GVHD						X		X			X		X				X		
Toxicity			X	X	X			X			X	X	X	X	X	X	X		
NST Hematopoiesis			X	X	X			X			X								
Follow-Up Status			X				X			X			X				X		
Specimen Acquisition		X		X					X	X	X	X	X	X	X	X	X		
Health Quality of Life²		X							X		X		X				X		
Donor Toxicity		X	X																
Single Transplant Follow-up⁷									X		X		X				X		
Progression/Relapse									Submit after progression or relapse										
Infection									Submit after each infectious event										
Unexpected, Grade 3-5 Adverse Event									Submit after each unexpected, grade 3-5 adverse event										
Re-admission/Hospitalization									Submit after each hospitalization										
Death									Submit in the event of the patient's death										
Secondary Graft Failure									Submit in the event of secondary graft failure										
CIBMTR Day 100 Rpt³			X ⁴					X ⁵											
CIBMTR Follow-Up⁶											X		X				X		

(Protocol # 0102 Table Notes on the next page).

Protocol # 0102 Table Notes:

- ¹ Must be assessed within two weeks of second intervention.
- ² Includes FACT-BMT and SF-36.
- ³ Includes Core, Disease and Graft Inserts.
- ⁴ Includes pre-transplant information (Q1-287) of Day 100 Core Form Only.
- ⁵ Includes post-transplant information of Day 100 Core Form, and Disease and Graft Inserts.
- ⁶ Includes Core and Disease Follow-up Forms.

BMT CTN PROTOCOL #0102
Forms Submission Schedule – Segment B – 2nd Autologous Transplant and Dexamethasone/Thalidomide Maintenance Therapy (If Applicable)

FORM	Prior to 2 nd Transplant	D a y 0	Weeks (Days) Post-Transplant		D a y 60	D a y 100	Months (Days) Post-Transplant													
			4	8			12	6	9	12	18	24	30	36						
			(28)	(56)			(84)	(180)	(270)	(365)	(540)	(730)	(900)	(1095)						
Post-1 st Autologous Transplant Checklist	X																			
Post-2 nd Autologous Transplant Checklist					X ¹															
Transplant		X																		
Myeloma Status		X ³		X					X	X	X	X	X	X	X	X	X	X	X	X
Sibling Information		X																		
Medication ⁴					X ²		X		X	X	X	X								
Toxicity			X	X		X		X		X	X	X	X	X	X	X	X	X	X	X
Follow-up Status			X				X		X		X		X							X
Specimen Acquisition		X		X					X	X	X	X	X	X	X	X	X	X	X	X
Health Quality of Life ⁵		X							X		X		X							X
Single Transplant Follow-up ¹⁰									X		X		X							X
Progression/Relapse	Submit after progression or relapse																			
Infection	Submit after each infectious event																			
Unexpected, Grade 3-5 Adverse Event	Submit after each unexpected, grade 3-5 adverse event																			
Re-admission/Hospitalization	Submit after each hospitalization																			
Death	Submit in the event of a patient's death																			
CIBMTR Day 100 Report ⁶			X ⁷						X ⁸											
CIBMTR Follow-up ⁹													X			X				X

(Protocol # 0102 Table Notes on the next page).

Protocol # 0102 Table Notes:

¹Or after recovery from the second-autologous transplant, but at least 60 days post-2nd autologous transplant.

²To be completed on the day of drug initiation for patients randomized to dexamethasone and thalidomide maintenance therapy, but at least 60 days post-2nd autologous transplant.

³Must be assessed within 2 weeks of second intervention.

⁴For patients randomized to dexamethasone and thalidomide maintenance therapy.

⁵Includes FACT-BMT and SF-36.

⁶Includes Core, Disease and Graft Inserts.

⁷Includes pre-transplant information (Q1-287) of Day 100 Core Form only.

⁸Includes post-transplant information of Day 100 Core Form, and Disease and Graft Inserts.

⁹Includes Core and Disease Follow-up Forms for patients who do not have a second transplant.