Myeloma Pre-infusion Form

PATIENT IDENTIFICATION

Hospital: _____ UPN: _____ Name ID: _____ (optional)

AID (ANZTCT id): _____ Infusion date: __/__/__

PART A: DISEASE CLASSIFICATION

1. DIAGNOSIS

Date of diagnosis: __/__/__

Myeloma classification at diagnosis: _____

Heavy chain type	IgG IgA IgM IgD IgE No heavy chain
Light chain type	Kappa Lambda No light chain

Preceding or concurrent plasma cell disorder: Yes | No

If yes, specify disorder: _____

Date of diagnosis: __/__/__

Is this the patient's first cell infusion for this diagnosis?

- ☐ Yes – Complete Assessments at Initial Diagnosis and Disease status at infusion (sections 2 and 4 only)
- ☐ No – Complete Assessments at Last Evaluation and Disease status at infusion (sections 3 and 4 only)

2. ASSESSMENTS AT INITIAL MYELOMA DIAGNOSIS

Serum Calcium	mmol/L
Serum Creatinine	mmol/L
Serum Creatinine ULN	mmol/L
Haemoglobin	g/L
LDH	U/L
LDH ULN	U/L
Serum albumin	g/L
Serum β2-microglobulin	mg/L
Plasma cells in blood, morphologic	%
Plasma cells in blood, morphologic	x 10^6/L
Plasma cells in blood by flow cytometry	%

ISS staging at diagnosis	I II III unk
R-ISS staging at diagnosis	I II III unk
Durie-Salmon staging (if both R-ISS/ISS is unknown)	I II III unk A B

Were cytogenetics performed: Yes | No | Unk

Tested via FISH: Yes | No | Unk

- Results: Abnormalities identified | no abnormalities
- ISCN string: _____

Specify abnormalities: _____

Tested via karyotyping: Yes | No | Unk

- Results: Abnormalities identified | No evaluable metaphases | no abnormalities
- ISCN string: _____
- Specify abnormalities: _____

3. ASSESSMENTS AT LAST EVALUATION PRIOR TO PREPARATIVE TREATMENT / INFUSION

Serum Creatinine	mmol/L
Haemoglobin	g/L
Plasma cells in blood, morphologic	%
Plasma cells in blood, morphologic	x 10^6/L
Plasma cells in blood by flow cytometry	%

Were cytogenetics performed: Yes | No | Unk

Tested via FISH: Yes | No | Unk

- Results: Abnormalities identified | no abnormalities
- ISCN string: _____
- Specify abnormalities: _____

Tested via karyotyping: Yes | No | Unk

- Results: Abnormalities identified | No evaluable metaphases | no abnormalities
- ISCN string: _____
- Specify abnormalities: _____

4. Disease status at infusion

Disease status at infusion: _____

PART B: MULTIPLE MYELOMA

Is this the first cell therapy infusion for this indication?

- ☐ Yes - continue with the questions
- ☐ No - it is a subsequent infusion, go to the Disease Treatment questions

1. DIAGNOSIS AND ASSESSMENTS

Report lab values prior to first treatment for myeloma

Serum monoclonal protein (M-spike) or ☐ NA	g/L

Serum immunofixation:

M-spike type:

Heavy chain: _____ ☐ heavy chain only

Light chain: _____ ☐ light chain only

☐ no bands present

M-spike type(s)	Value	ULN
Serum free light chain- κ (kappa) mg/L		
Serum free light chain - λ (lambda) mg/L		

Serum quantitative immunoglobulins

	Value	ULN
IgG	g/L	g/L
IgA	g/L	g/L
IgM	g/L	g/L
IgD	g/L	g/L
IgE	g/L	g/L

	Value	Units
Urinary monoclonal protein (M-spike) / 24 hours		
Total urine protein in 24 hours		
Urine light chain	□ kappa □ lambda □NA	
Urine albumin / creatinine ratio		
Urine protein / creatinine ratio		

Plasma cells in BM aspirate (flow cytometry)	%
Plasma cells in BM aspirate (morphologic)	%
Plasma cells in BM biopsy	%

Immunohistochemical stains were performed: Yes | No | Unk

CD138	Pos | Neg | Unk
CD38	Pos | Neg | Unk

Gene expression profile was performed? Yes | No

Considered High-risk myeloma? Yes | No

Was imaging performed: Yes | No

Type of imaging: ☐ CT ☐ PET/CT ☐ MRI

Positive for myeloma involvement: Yes | No

Areas of involvement: _____

Date of scan: __/__/__or ☐ unknown

2. DISEASE TREATMENT

If this is a subsequent infusion and a prior treatment have already been reported for the previous infusion, only report treatment given following the previous infusion to the current infusion

Treatment was given after diagnosis: Yes | No

Total number of lines: ____

Complete the following as many times as required for each line given

Systemic therapy: Yes | No

Date started: __/__/__ Date ended: __/__/__

Specify regimen: _____

Additional agents: _____

Reason therapy stopped: _____

This therapy line given to mobilised cells: Yes | No

Radiation therapy: Yes | No

Date started: __/__/__ Date ended: __/__/__

Total dose: _____ ☐ Gy ☐ cGy

PART B: MULTIPLE MYELOMA continued

DISEASE TREATMENT continued

Cell therapy: Y | N if yes, complete CT form

Best haematologic response to this line of therapy

- ☐ Stringent complete response (sCR)
- ☐ Complete response (CR)
- ☐ Very good partial response (VGPR)
- ☐ Partial response (PR)
- ☐ No response (NR) / stable disease (SD)
- ☐ Progressive disease (PD)
- ☐ Relapse from CR (Rel) (untreated)
- ☐ Unknown

Date of haematologic assessment: ___ /___ /___

Disease relapse/progress following this therapy: Yes | No

Date of relapse: __/__/__

3. DISEASE ASSESSMENT AT LAST EVALUATION PRIOR TO PREPARATIVE TREATMENT / INFUSION

Serum β2-microglobulin	mg/L
Plasma cells in blood by flow cytometry	%
Plasma cells in blood, morphologic	%
Plasma cells in blood, morphologic	x 10^6/L
Serum albumin	g/L

Serum monoclonal protein (M-spike) (from electrophoresis)	g/L

Serum immunofixation, specify bands present

Original monoclonal bands: Yes | No

New monoclonal (or oligoclonal) bands: Yes | No

Serum free light chain	Value	ULN
- κ (kappa)	mg/L	mg/L
- λ (lambda)	mg/L	mg/L

	Value	Units
Urinary monoclonal protein (M-spike)/24 hrs		

Urinary immunofixation, specify bands present

Original monoclonal bands: Yes | No

New monoclonal (or oligoclonal) bands: Yes | No

	Value	Units
Total urine protein in 24 hours		
Urine albumin / creatinine ratio		
Urine protein / creatinine ratio		

Minimal residual disease (MRD) was assessed Yes | No | Unk

	Pos/Neg/ND	Sample source	Sensitivity
NGS			
Next Gen Flow			

Plasma cells in BM aspirate by flow cytometry	%
Plasma cells in BM aspirate, morphologic	%
Plasma cells in BM biopsy	%

Were cytogenetics performed: Yes | No | Unk

Tested via FISH: Yes | No | Unk

- Results: Abnormalities identified | no abnormalities
- ISCN string: _____
- Specify abnormalities: _____

Tested via karyotyping: Yes | No | Unk

- Results: Abnormalities identified | No evaluable metaphases | no abnormalities
- ISCN string: _____
- Specify abnormalities: _____

Did patient receive dialysis: Yes | No

Date of dialysis: __/__/__

Was imaging performed: Yes | No

Type of imaging: ☐ CT ☐ PET/CT ☐ MRI

Positive for myeloma involvement: Yes | No

Areas of involvement: _____

Date of scan: __/__/__