Agenda

• Background
• Current status of studies
• Overview of Forms
Background
What is CMS?

• Centers for Medicare & Medicaid Services (CMS) is a federal agency within the U.S. Department of Health and Human Services (HHS).

• Administers many programs including Medicare.
What is CED?

• Coverage with Evidence Development (CED) is a mechanism by which CMS can provide coverage and encourage clinical studies that will lead to solid evidence for future decision making.

• National Coverage Determination (NCD)

• Relatively rare mechanism used when:
  – Safety has been assured
  – Service has high potential of benefit
  – Significant barriers to conduct of trials exist
MDS Decision

• CMS decision in Summer of 2010
• CIBMTR put together a proposal to CMS
• Enrollment began in December 2010
• Updates have been provided to CMS
• Enrollment continues
Additional Diseases

• Transplants in the older population continues to increase for a variety of diseases
• BMT community continued to work with CMS to consider other CED/NCD
• Decisions have been made for:
  – Sickle Cell (development)
  – Myelofibrosis (Active Nov 2016)
  – Multiple Myeloma (development)
Data Submission for MDS and MF
Required Data

• Centers must designate willingness to participate in CRF submission for CED
• Participating recipients must sign database consent form
• Standard reporting
  – CRID assignment form 2804/2814
  – Pre-TED form 2400/2402
  – Comprehensive report forms - necessary for study objectives.
Additional Required Forms

• MDS and MF
  – Registration form 2554 (on demand once CRID form 2804/2814 completed)

• MF
  – Eligibility form 2555 (due when MF selected on form 2554)
  – Pre HCT form 2556 (due when MF selected on form 2402)
  – Post HCT form 2557 (due when MF selected on form 2402)
CMS Registration Form
Form 2554
Registration Form 2554

1. The recipient should be enrolled on the following study:
   - Myelodysplasia (16-CMS-MF)
   - Myelodysplastic syndrome (MDS) (10-CMSMD5-1)
   - Multiple myeloma

2. Has the recipient signed an IRB / Ethics Committee-approved consent form for participation in the study?
   - Yes (patient consented)
   - No (patient declined)

3. Date form was signed:

4. Does the recipient have Medicare coverage?
   - Yes
   - No

Completed by:

First Name:
Last Name:
E-mail address:
Date:

Registration Information
Registration Form continued

Complete and return this form to the CIBMTR for each eligible patient.

1. The recipient should be enrolled on the following study:
   - Myelofibrosis (16-CMS-MF)
   - Myelodysplastic syndrome (MDS) (10-CMSMDS-1)
   - Multiple myeloma
Registration Form continued

2. Has the recipient signed an IRB / Ethics Committee-approved consent form for participation in the study?
   - Yes (patient consented)
   - No (patient declined)

3. Date form was signed:
Registration Form continued

4. Does the recipient have Medicare coverage?
   - [ ] Yes
   - [ ] No
Myelofibrosis (MF) Forms
Form 2555, Form 2556 and Form 2557
Myelofibrosis (MF) Eligibility Form
Form 2555
Eligibility Form 2555

| CIBMTR Center Number (CCN): | [Redacted] |
| CIBMTR Research ID: | [Redacted] |
| Event date: | [Redacted] |

### Inclusion Criteria

1. Did the recipient have an eligible diagnosis?
   - Primary myelofibrosis
   - Post-polycythemia vera myelofibrosis
   - Post-essential thrombocythemia myelofibrosis

2. Has the recipient ever had Int-2 or high-risk disease as determined by the DIPSS?
   - Yes – Go to question 3
   - No – Go signature line

3. Date assessed: [Redacted]

4. Specify donor:
   - 6 HLA-matched related (not monozygotic twin)
   - 6 HLA-A, B, C, DRB1 unrelated
   - Haploidentical

### Exclusion Criteria

5. Is the planned product an umbilical cord blood unit(s)?
   - Yes
   - No

6. Is the planned donor a mismatched unrelated donor?
   - Yes
   - No

7. Did the recipient have an overlap syndrome?
   - Yes
   - No

Completed by:

- First Name: [Redacted]
- Last Name: [Redacted]
- E-mail address: [Redacted]
- Date: [Redacted]
Inclusion Criteria

1. Did the recipient have an eligible diagnosis?
   - Primary myelofibrosis
   - Post-polycythemia vera myelofibrosis
   - Post-essential thrombocytopenia myelofibrosis

Indicate the recipient’s diagnosis
Inclusion Criteria

2. Has the recipient ever had Int-2 or high-risk disease as determined by the DIPSS?
   - Yes – Go to question 3
   - No – Go signature line

3. Date assessed: 

Indicate if the recipient has ever been diagnosed with int-2 or high risk disease as determined by the DIPSS.

*Please note: DIPSS test required before recipient registration

If yes, enter the date assessed in YYYY/MM/DD format.
Inclusion Criteria

4. Specify donor:
   - 6/6 HLA-matched related (not monozygotic twin)
   - 8/8 HLA-A, -B, -C, -DRB1 unrelated
   - Haploidentical
Exclusion Criteria

5. Is the planned product an umbilical cord blood unit(s)?
   - Yes
   - No

6. Is the planned donor a mismatched unrelated donor?
   - Yes
   - No
Exclusion Criteria

7. Did the recipient have an overlap syndrome?
   - Yes
   - No

List of Overlap Syndrome:
- Myelodysplastic/myeloproliferative neoplasms (MDS/MPN)
- Chronic myelomonocytic leukemia (CMML)
- Atypical chronic myeloid leukemia (aCML), BCR-ABL1−
- Juvenile myelomonocytic leukemia (JMML)
- MDS/MPN with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
- MDS/MPN, unclassifiable
Myelofibrosis (MF) Pre and Post HCT Form Form 2556 and 2557
Pre and Post HCT MF Forms

• Required forms
• Forms Instruction Manual
• Under Infection and Miscellaneous Manuals
Key Reminders

• Registration
  – MDS forms in FN; Form 2517 replaced
    • Form 2554
    • Form 2400/2402
  – MF forms
    • Form 2554
    • Form 2555
    • Form 2400/2402
Key Reminders

• MF will require additional forms
  – Pre HCT form 2556
  – Post HCT form 2557

• MDS and MF require CRF forms

• If the MDS or MF recipient will submit to Medicare they must be registered
Contact with Questions

General CMS related questions
Rae Besser rbesser@nmdp.org or
763-406-4847
Cynthia Kunakom ckunakom@nmdp.org
763-406-8285
MF Form 2556 and 2557 related questions
Contact your CRC
Questions?