Form Release Summary – Jan 2025

Contents

Solid Tumor Pre-Infusion Data (2059 R1)

- Solid Tumor Pre-infusion is a new data collection form to be used for cellular therapy (CT) and study recipients.
    - For cellular therapy recipients, Pre-Cellular Therapy Essential Data (4000 R10) is completed, **solid tumor** is selected as the primary indication.
    - Then, Pre-TED Disease Classification (2402 R9) is completed, if any of the **synovial sarcoma / bone sarcoma / myxoid round cell sarcoma** is selected as the solid tumor type, then Solid Tumor Pre-Infusion Data (F2059 R1) will come due.
    - As a new cellular therapy registry form, it will be implemented for corporate client Adaptimmune as part of CIBMTR study CS21-177:
        - CIBMTR Center Number = **US Center**
        - Consent status for submitting research data to CIBMTR = **Yes**
        - Name of Cellular Therapy Product = **Afamitresgene autoleucel**

- This new form consists of 102 questions capturing Subsequent Infusion, Disease Assessment at Diagnosis, Initial Therapy, Last Line of Therapy Prior to Collection, Bridging Therapy Prior to Infusion, Total Cumulative Exposure to Systemic Therapy / Radiation Therapy, and Disease Assessments at Last Evaluation.

Solid Tumor Response (3507 R1)

- Solid Tumor Response is a new data collection form to be used for cellular therapy (CT) and study recipients.
    - For cellular therapy recipients, Pre-Cellular Therapy Essential Data (4000 R10) is completed, **solid tumor** is selected as the primary indication.
    - Then, Pre-TED Disease Classification (2402 R9) is completed, if any of the **synovial sarcoma / bone sarcoma / myxoid round cell sarcoma** is selected as the solid tumor, that makes Solid Tumor Response form (3507 R1) come due.
    - Solid Tumor Response form (3507 R1) is completed in conjunction with the Post-Cellular Therapy Essential Data form (4100 R9) at each timepoint for cellular therapy recipients.

- It captures disease response occurring within the timeframe of each reporting period (i.e., at infusion, 100 days, 6 months, 1 year, 2 year and >2 years).
- As a new cellular therapy registry form, this new form will be implemented for corporate client Adaptimmune as part of CIBMTR study CS21-177:
  - CIBMTR Center Number = **US Center**
  - Consent status for submitting research data to CIBMTR = **Yes**
  - Name of Cellular Therapy Product = **Afamitresgene autoleucel**

- This new form consists of 9 questions capturing disease status at infusion, best response to infusion and current response.

CMS Registration (2554 R3)

Registration and Confirmation

- **"The recipient should be enrolled on the following study"**
  - Update: Removed an option **Myelodysplastic syndrome (MDS) (10-CMSMDS-1)** from the option list.
  - Rationale: Study no longer active.

- **"The recipient should be enrolled on the following study"**
  - Update: Added an option **CMS Innovation Center's Cell and Gene Therapy (CGT) Access Model for Sickle Cell Disease (SCD)** to the option list.
  - Rationale: This new option is added to collect required data related to recipients enrolled in the CMS Innovation Center's Cell and Gene Therapy (CGT) Access Model for Sickle Cell Disease (SCD).

- **"Does the recipient have Medicaid coverage?"**
  - Addition: New question.
  - Rationale: This new question will be answered for the recipients enrolled in CMS Innovation Center's Cell and Gene Therapy (CGT) and Sickle Cell Disease (SCD) to support Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare & Medicaid Services (CMS) project.

- **"Medicaid issuing state / territory"**
  - Addition: New question.
  - Rationale: This new question will be optional to support CMMI / CMS project.

- **"State Medicaid Beneficiary ID"**
  - Addition: New question.
  - Rationale: This new question will be optional to support CMMI / CMS project.

- **"Medicaid ID date issued"**
  - Addition: New question.
  - Rationale: This new question will be optional to support CMMI / CMS project.