



Instructions for Organ Function / Late Effects (3504)

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Organ Function / Late Effects.

Organ Function / Late Effects

The Organ Function / Late Effects (3504) form captures various organ impairments / disorders that may occur post-infusion for both transplant and cellular therapy. This form will come due, starting at Day 100, for transplant recipients randomized to the Comprehensive Report Form (CRF) track. Additionally, this form will come due, starting at one-year, for cellular therapy recipients randomized to the CRF track.

Depending on the infusion type, questions capturing specific organ impairments / disorders will be enabled. Review Table 1 below for more information.

Table 1. Organ Impairments / Disorders Enabled Based on Infusion Type

Organ Impairment / Disorder	HCT or CT
Ipn or ARDS / IPS	HCT
Non-infectious pulmonary (Bronchiolitis obliterans, COP/BOOP, Diffuse alveolar hemorrhage , Other)	HCT
Endotracheal intubation or mechanical ventilation	HCT
Therapy used to prevent liver toxicity	HCT
Cirrhosis	HCT and CT
Non-infectious liver toxicity (VOD, medication toxicity, other)	HCT
TMA	HCT
Renal impairment / disorder	HCT and CT
Arrhythmia	HCT and CT
Cardiomyopathy	HCT and CT
Congestive heart failure	HCT and CT
Coronary artery disease	HCT and CT
Unstable angina	HCT and CT
Myocardial infarction	HCT and CT
Hypertension (HTN)	HCT
Pericarditis	HCT and CT

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Heart valve disease	HCT and CT
Deep vein thrombosis (DVT)	HCT and CT
Pulmonary embolism (PE)	HCT and CT
Hyperlipidemia	HCT
CNS hemorrhage	HCT
Encephalopathy (non-infectious)	HCT
Neuropathy	HCT
Seizures	HCT
Stroke	HCT
Diabetes	HCT and CT
Growth hormone deficiency / short stature	HCT
Hypothyroidism	HCT and CT
Pancreatitis	HCT and CT
Gonadal dysfunction	HCT and CT
Hemorrhagic cystitis / hematuria requiring medical intervention	HCT
Avascular necrosis	HCT and CT
Osteonecrosis of the jaw	HCT and CT
Osteoporosis	HCT and CT
Osteoporotic fracture	HCT and CT
Psychiatric impairment	HCT and CT
Cataracts	HCT
Iron overload	HCT
Mucositis	HCT
Other	HCT

Links to Sections of Form:

- QX: Question text header
- QX – X: Question text header
- QX – XX: Question text header

Manual Updates:

Sections of the Forms Instruction Manual are frequently updated. The most recent updates for the current manual version can be found below. For additional information, select the manual section and review the updated text.

To review the historical Manual Change History for this manual, reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/Remove/Modify	Description
3/27/2026	Organ Function / Late Effects (3504)	Add	Version 1 of the 3504: Organ Function / Late Effects section of the Forms Instructions Manual released. Version 1 corresponds to revision 1 of the Form 3504.

Q1 – 18: Pulmonary Function

Reporting Multiple Non-Infectious Interstitial Pneumonitis / Idiopathic Pneumonia Syndromes

Complete *Was non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) present through Date non-infectious IPn or ARDS / IPS resolved* questions to report multiple non-infectious interstitial pneumonitis / idiopathic pneumonia syndrome by adding an additional instance in the FormsNet3SM application.

Questions 1 – 2: Was non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) present? (*report infectious pneumonia in the infection section of the appropriate follow-up form*)

IPn refers to inflammation of the alveolar walls. Acute respiratory distress syndrome (ARDS) typically refers to fluid build-up within the alveoli. In either case, gas exchange is impaired resulting in oxygen deprivation. Both conditions can result from infectious or non-infectious causes.

Idiopathic pneumonia syndrome (IPS) refers to all non-infectious lung injuries that occur early after HCT (within 100 – 120 days) including: peri-engraftment respiratory distress syndrome (PERDS), interstitial pneumonitis without a pathogen, radiation / drug-induced lung injury, or transfusion-associated lung injury (TRALI).

Indicate if non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) in the reporting period.

- Non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) resolved in a prior reporting period and then recurred in the current reporting period.

If non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) was not present in the current reporting period or unknown if present, select **Not present**.

Report infectious pneumonia in the infection section of the appropriate follow-up form.

Questions 3 – 4: Select diagnostic methods for non-infectious IPn or ARDS / IPS (other than radiographic studies) (check all that apply)

Select all methods used to diagnose the non-infectious IPn or ARDS / IPS, excluding radiographic studies.

- **Bronchoalveolar lavage (BAL):** A procedure in which a bronchoscope is guided into the lower respiratory system. Fluid is emitted from the bronchoscope and then collected for further examination.
- **Transbronchial biopsy:** A procedure in which forceps on the end of the bronchoscope are used to collect lung tissue samples for further examination.
- **Open / thoracoscopic (video-assisted thoracic surgery, VATS) lung biopsy:** An open lung biopsy is a procedure in which an incision is made between the ribs to collect a sample of lung tissue for further examination. A thoracoscopic lung biopsy is a procedure in which an incision is made to the chest and an endoscope is used to collect samples of lung tissue.
- **Autopsy:** A post-mortem procedure used to determine the cause of death and to evaluate other disease present at the time of death.

- **Other diagnostic test:** If a diagnostic test, other than radiographic studies was performed, specify the test.
- **No diagnostic tests done:** If no diagnostic tests (other than radiographic studies) were performed, select this option.

Questions 5 – 6: Did non-infectious IPn or ARDS / IPS resolve?

Indicate if IPn or ARDS / IPS resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Reporting Multiple Non-Infectious Pulmonary Abnormalities

Complete *Was another non-infectious pulmonary abnormality present through Date non-infectious pulmonary abnormality resolved* questions to report multiple non-infectious pulmonary abnormalities by adding an additional instance in the FormsNet3SM application.

Questions 7 – 8: Was another non-infectious pulmonary abnormality present? (e.g., bronchiolitis obliterans, COP / BOOP, diffuse alveolar hemorrhage)

Indicate if any other non-infectious pulmonary abnormality was present in the current reporting period. See below for a list of other non-infectious pulmonary abnormalities.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with non-infectious pulmonary abnormality in the reporting period.
- Non-infectious pulmonary abnormality resolved in a prior reporting period and then recurred in the current reporting period.

If non-infectious pulmonary abnormality **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Non-infectious pulmonary abnormality was diagnosed pre-infusion and persisted into the Day 100 reporting period.

- Non-infectious pulmonary abnormality was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If non-infectious pulmonary abnormality was not present in the current reporting period or unknown if present, select **Not present**.

Questions 9 – 10: Select other non-infectious pulmonary abnormality experienced (e.g., bronchiolitis obliterans, COP / BOOP, diffuse alveolar hemorrhage)

Specify the other non-infectious pulmonary abnormality.

- **Bronchiolitis obliterans (BO):** An airway obstruction as a result of inflammation of the bronchioles. This complication typically occurs late after HCT. It is often a manifestation of chronic GVHD. If bronchiolitis obliterans is a result of chronic GVHD, confirm that bronchiolitis obliterans was also reported in the chronic GVHD section of the appropriate follow-up form.
- **Cryptogenic organizing pneumonia (COP) / Bronchiolitis obliterans with organizing pneumonia (BOOP):** An idiopathic form of pneumonia which affects different parts of the lungs including the bronchioles and alveoli. This complication typically occurs late after an infusion.
- **Diffuse alveolar hemorrhage (DAH):** Bleeding into the alveolar space typically resulting from an injury to the pulmonary blood vessels.
- **Other non-infectious pulmonary abnormality:** Any other non-infectious pulmonary abnormalities not already captured in the above categories. Do not report pleural effusions here.

Submitting Documentation of Diagnostic Methods

CIBMTR strongly encouraged attaching the report for the diagnostic method used. For further instructions on how to attach documents in FormsNet3SM, refer to the [Training Guide](#).

Questions 11 – 12: Select diagnostic methods for non-infectious pulmonary abnormality (other than radiographic studies) (check all that apply)

Select all methods used to diagnose the non-infectious pulmonary abnormality, excluding radiographic studies.

- **Bronchoalveolar lavage (BAL):** A procedure in which a bronchoscope is guided into the lower respiratory system. Fluid is emitted from the bronchoscope and then collected for further examination.
- **Transbronchial biopsy:** A procedure in which forceps on the end of the bronchoscope are used to collect lung tissue samples for further examination.
- **Open / thoracoscopic (video-assisted thoracic surgery, VATS) lung biopsy:** An open lung biopsy is a procedure in which an incision is made between the ribs to collect a sample of lung tissue for further examination. A thoracoscopic lung

biopsy is a procedure in which an incision is made to the chest and an endoscope is used to collect samples of lung tissue.

- **Autopsy:** A post-mortem procedure used to determine the cause of death and to evaluate other disease present at the time of death.
- **Other diagnostic test:** If a diagnostic test, other than radiographic studies was performed, specify the test.
- **No diagnostic tests done:** If no diagnostic tests (other than radiographic studies) were performed, select this option.

Questions 13 – 14: Did non-infectious pulmonary abnormality resolve?

Indicate if the non-infectious pulmonary abnormality resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

This question is disabled for diffuse alveolar hemorrhage.

Questions 15 – 16: Did the recipient receive endotracheal intubation or mechanical ventilation?

Endotracheal intubation or mechanical ventilation may be used for respiratory failure or for airway protection from severe mucositis.

Invasive positive pressure ventilation is delivered via an endotracheal tube. Do not include non-invasive positive pressure ventilation that is delivered through an alternate interface (e.g., facemask).

Indicate whether the recipient received endotracheal intubation or mechanical ventilation (invasive positive pressure ventilation) during the reporting period. If **Yes**, report the date when endotracheal intubation or mechanical ventilation was started. If the recipient was intubated multiple times within the reporting period, report the first date of intubation.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 17 – 18: Was the recipient successfully extubated?

Indicate if the recipient was successfully extubated during the reporting period. If **Yes**, report the date extubated. If the recipient was extubated multiple times within the reporting period, please report the last date extubated.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms.](#)

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q19 – 28: Liver Function

Questions 19 – 20: Specify therapy used to prevent liver toxicity (*check all that apply*)

Liver toxicities may be related to drugs / treatments, infection, GVHD, iron overload, cirrhosis, or sinusoidal obstructive syndrome (SOS) / veno-occlusive disease (VOD). Agents such as ursodiol may be given as prophylaxis against one or more of these transplant-related liver injuries. Agents given to prevent liver toxicity will generally be started prior to or during the preparative regimen and may be continued well after the infusion.

Select all therapy the recipient received intended to prevent liver toxicity during the reporting period, including therapy given during the preparative regimen. Report only agents given to prevent liver toxicities, not those given to treat a diagnosed liver injury or toxicity.

If **Other therapy** is selected, specify the therapy.

If therapy to prevent liver toxicity was not given in the reporting period, select **No therapy used.**

Liver Toxicity
 Liver toxicity questions are designed to collect information on the level of liver dysfunction unrelated to acute or chronic GVHD (e.g., chemotoxicity, cyclosporine toxicity, veno-occlusive disease [VOD]). Liver dysfunction may be determined by biopsy, viral culture, or suspected by clinical evidence.

Questions 21 – 22: Was cirrhosis present?

Cirrhosis is a degenerative disease in which fibrous tissue forms and the lobes become filled with fat. Cirrhosis may be diagnosed using a liver biopsy, but clinical symptoms (enlarged liver), blood tests, laparoscopy, or radiology imaging are often used to determine the diagnosis of cirrhosis when a liver biopsy is not necessary.

Indicate if cirrhosis was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with cirrhosis in the reporting period.

If cirrhosis **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report a recurrence of cirrhosis. Only the first occurrence is captured.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Cirrhosis was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- For cellular therapy, if cirrhosis was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

Do not report cirrhosis if it continued from a previous reporting period into the current reporting period, even if it was present.

If cirrhosis **Persisted**, report the onset date. For HCT, this date will be a date prior to the infusion (i.e., prior to Day 0). For cellular therapy, this date will either be a date prior to the infusion (i.e., prior to Day 0), or from the Day 100, or six-month reporting period, depending on when cirrhosis was first diagnosed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If cirrhosis was not present in the current reporting period or unknown if present, select **Not present**.

Reporting Multiple Non-Infectious Liver Toxicities

Complete *Was another non-infectious liver toxicity present* through *Date non-infectious liver toxicity resolved* questions to report multiple non-infectious liver toxicities by adding an additional instance in the FormsNet3SM application.

Questions 23 – 24: Was a non-infectious liver toxicity present? (excluding GVHD)

Indicate if a non-infectious liver toxicity, excluding GVHD, was present in the current reporting period. See below for a list of non-infectious liver toxicities.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with non-infectious liver toxicity in the reporting period.
- Non-infectious liver toxicity resolved in a prior reporting period and then recurred in the current reporting period.

If non-infectious liver toxicity **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Non-infectious liver toxicity was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Non-infectious liver toxicity was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If non-infectious liver toxicity was not present in the current reporting period or unknown if present, select **Not present**.

Questions 25 – 26: Select the non-infectious liver toxicity / etiology

Specify the non-infectious liver toxicity / etiology, excluding GVHD.

- **Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS):** Occurs following injury to the hepatic venous endothelium, resulting in hepatic venous outflow obstruction due to occlusion of the hepatic venules and sinusoids. This typically results in a distinctive triad of clinical signs including hepatomegaly with right upper quadrant tenderness, third space fluid retention (e.g., ascites), and jaundice with a cholestatic picture. For more information on

VOD / SOS including diagnostic criteria, refer to the [VOD / SOS section](#) of the Forms Instructions Manual.

- **Medication toxicity:** If the liver abnormality (i.e., abnormal LFT values) is associated with drug initiation, abnormalities improve with cessation, and / or there are no other causes for the change.
- **Other etiology:** Liver toxicity other than VOD / SOS or cirrhosis. Do not include hepatic infections or GVHD.
- **Unknown etiology:** If there is a liver toxicity; however, there is no information about the etiology of the non-infectious liver toxicity. This option should be used sparingly and only when no judgment can be made about the etiology of the reporting period.

Questions 27 – 28: Did non-infectious liver toxicity resolve?

Indicate if the non-infectious liver toxicity resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q29 – 39: Thrombotic Microangiopathy (TMA)

Reporting Multiple Thrombotic Microangiopathies

Complete *Was post-infusion thrombotic microangiopathy (TMA) or similar syndrome present through Date TMA resolved* questions to report multiple thrombotic microangiopathies by adding an additional instance in the FormsNet3SM application.

Questions 29 – 30: Was post-infusion thrombotic microangiopathy (TMA) or similar syndrome present? (includes microangiopathy, thrombotic purpura (TTP), hemolytic uremic syndrome (HUS))

Thrombotic microangiopathy (TMA) is a multifactorial condition where intravascular platelet activation, formation of thrombi, and microangiopathic hemolytic anemia occur due to generalized endothelial dysfunction. Organ injury, specifically the kidney, may

occur as a result of these processes.¹ Characteristics of thrombotic microangiopathy includes microangiopathic hemolysis, thrombocytopenia ($< 50 \times 10^9/L$), neurological changes, and pulmonary dysfunction. Other laboratory features include:

- LDH greater than the center-specific upper limit of normal
- Serum creatinine > 2 mg/dL or $>50\%$ rise over baseline
- Bilirubin is greater than twice the center-specific upper limit of normal

¹ Jodele, S., M. Davies, and B.L. Laskin. "Diagnostic and Risk Criteria for HSCT-associated Thrombotic Microangiopathy: A Study in Children and Young Adults." *Blood* 124.4 (2014): 645-53. Web.

Similar syndromes include:

- Microangiopathy: Disease of the capillaries where the capillaries bleed and slow the flow of blood due to thickening and weakening of capillary walls.
- Thrombotic purpura (TTP): Blood disorder where blood clots form in the small blood vessels of the body.
- Hemolytic uremic syndrome (HUS): Abnormal destruction of red blood cells which block the kidneys resulting in kidney failure. May be caused by *Escherichia coli*, other infections, and medications.

Indicate if TMA or a similar syndrome, such as microangiopathy, thrombotic purpura (TTP), and hemolytic uremic syndrome (HUS), was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with TMA or a similar syndrome in the reporting period.
- TMA or a similar syndrome resolved in a prior reporting period and then recurred in the current reporting period.

If TMA or a similar syndrome **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- TMA or a similar syndrome was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- TMA or a similar syndrome was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If TMA or a similar syndrome was not present in the current reporting period or unknown if present, select **Not present**.

Question 31: Specify signs and symptoms (check all that apply)

Report all TMA or a similar syndrome signs and symptoms at diagnosis or recurrence, if applicable.

Questions 32 – 35: Was TMA evaluated by biopsy?

Specify if biopsy was completed at diagnosis or recurrence, if applicable of TMA or a similar syndrome. If **Yes**, specify the results.

If a biopsy was not completed or unknown, select **No**.

Questions 36 – 37: Specify therapy given for TMA (check all that apply)

Report therapy given in the reporting period for TMA or a similar syndrome. Select all that apply.

If **Other therapy** is selected, specify the treatment.

If therapy was not given, select **None**.

Questions 38 – 39: Did TMA resolved? (normalization of renal function, LDH, and resolution or improvement in renal and / or neurologic dysfunction)

Indicate if TMA or a similar syndrome resolved during the reporting period. If **Yes**, report the first date when the following criteria was met:

- Renal function normalized by institutional guidelines
- LDH normalized by institutional guidelines
- Improvement or resolution in renal and / or neurologic dysfunction

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)
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Q40 – 53: Renal Impairment / Disorder

Reporting Multiple Renal Impairments / Disorders

Complete *Was a renal impairment / disorder present* through *Date renal impairment / disorder resolved* questions to report multiple renal impairments / disorders by adding an additional instance in the FormsNet3SM application.

Questions 40 – 41: Was a renal impairment / disorder present?

Symptoms of renal failure include dehydration, nausea, blood in the urine, and / or swelling of extremities. Acute kidney failure is classified as three stages:

- Stage 1
 - Serum creatinine is 1.5 – 1.9 x baseline, or
 - ≥ 0.3 mg / dL (≥ 26.5 μmol / L) increase
- Stage 2
 - Serum creatinine is 2.0 – 2.9 x baseline
- Stage 3
 - Serum creatinine is 3.0 x baseline, or
 - Increase serum creatinine ≥ 4.0 mg / dL (≥ 353.6 μmol / L), or
 - The start of renal replacement therapy, or
 - In recipients < 18 years, decrease in eGFR to < 35 ml / min / 1.73 m²

Kidney failure is considered chronic when there is persistent decrease in glomerular filtration to < 60 ml / min / 1.73 m² for three or more months.

Indicate if a renal impairment / disorder (stage 2 or 3 acute kidney failure and / or chronic kidney failure) was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with a renal impairment / disorder in the reporting period.
- Renal impairment / disorder resolved in a prior reporting period and then recurred in the current reporting period.

If the renal impairment / disorder **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Renal impairment / disorder was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Renal impairment / disorder was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.
- For cellular therapy, if the renal impairment / disorder was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

If the renal impairment / disorder was not present in the current reporting period or unknown if present, select **Not present**.

Do not report stage 1 acute kidney failure.

Questions 42 – 44: Did the recipient experience acute renal failure requiring dialysis?

Indicate if the recipient experienced stage 2 or 3 acute kidney failure, requiring dialysis (for less than three months) in the current reporting period. If **Yes**, specify the dialysis start date for acute kidney failure.

If dialysis was started in a prior reporting period and continued into the current reporting period, report the start date as **Previously reported**. If dialysis was stopped in prior reporting period but restarted in the current reporting period, report the start date as the date when dialysis was restarted.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 45 – 46: Was the recipient still on dialysis for acute renal failure at the date of last contact?

Specify if the recipient was still on dialysis for acute kidney failure on the contact date for the current reporting period. If **No**, specify the dialysis end date.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 47 – 49: Did the recipient experience chronic renal failure requiring dialysis?

Indicate if the recipient experienced chronic kidney failure, requiring dialysis in the current reporting period. If **Yes**, specify the dialysis start date for chronic kidney failure.

If dialysis was started in a prior reporting period and continued into the current reporting period, report the start date as **Previously reported**. If dialysis was stopped in prior reporting period but restarted in the current reporting period, report the start date as the date when dialysis was restarted.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 50 – 51: Was the recipient still on dialysis for chronic renal failure at the date of last contact?

Specify if the recipient was still on dialysis for chronic kidney failure on the contact date for the current reporting period. If **No**, specify the dialysis end date.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 52 – 53: Did the renal impairment / disorder resolve?

Indicate if the renal impairment / disorder is resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q54 – 89: Cardiac Impairment / Disorder

Reporting Multiple Arrhythmias
Complete *Was arrhythmia present* through *Date arrhythmia resolved* questions to report multiple arrhythmias by adding an additional instance in the FormsNet3SM application.

Questions 54 – 55: Was arrhythmia present?

Arrhythmia includes atrial fibrillation or flutter, sick sinus syndrome, and ventricular arrhythmia.

Indicate if an arrhythmia was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with arrhythmia in the reporting period.
- Arrhythmia resolved in a prior reporting period and then recurred in the current reporting period.

If the arrhythmia **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Arrhythmia was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Arrhythmia was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.
- For cellular therapy, if the arrhythmia was diagnosed pre-infusion and persisted in the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

If the arrhythmia was not present in the current reporting period or unknown if present, select **Not present**.

Questions 56 – 57: Specify arrhythmia

Specify the arrhythmia type. If **Other arrhythmia** is selected, specify.

Questions 58 – 59: Did the arrhythmia resolve?

Indicate if the arrhythmia is resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Reporting Multiple Cardiomyopathies

Complete *Was cardiomyopathy present* through *Date cardiomyopathy resolved* questions to report multiple cardiomyopathies by adding an additional instance in the FormsNet3SM application.

Questions 60 – 61: Was cardiomyopathy present?

Cardiomyopathy is a disease of the heart muscle that makes it more difficult for the heart to pump blood to the rest of the body.

Indicate if cardiomyopathy was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with cardiomyopathy in the reporting period.
- Cardiomyopathy resolved in a prior reporting period and then recurred in the current reporting period.

If cardiomyopathy **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Cardiomyopathy was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Cardiomyopathy was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.
- For cellular therapy, if cardiomyopathy was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

If cardiomyopathy was not present in the current reporting period or unknown if present, select **Not present**.

Questions 62 – 63: Did the cardiomyopathy resolve?

Indicate if cardiomyopathy is resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 64 – 65: Was congestive heart failure present?

Congestive heart failure (CHF) is the inability of the heart to supply oxygenated blood to meet the body's needs, with an ejection fraction < 40%.

Indicate if congestive heart failure was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with congestive heart failure in the reporting period.

If congestive heart failure **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report a recurrence of congestive heart failure. Only the first occurrence is captured.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Congestive heart failure was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- For cellular therapy, if congestive heart failure was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

Do not report congestive heart failure if it continued from a previous reporting period into the current reporting period, even if it was present.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If congestive heart failure was not present in the current reporting period or unknown if present, select **Not present**.

Question 66: Specify ejection fraction

If congestive heart failure **Developed**, report the ejection fraction from diagnosis. If congestive heart failure **Persisted** pre-infusion into the Day 100 reporting period, report the ejection fraction from diagnosis (i.e., the pre-infusion ejection fraction).

Question 67: Specify symptomatic or asymptomatic

Indicate if the recipient was **Symptomatic** or **Asymptomatic** in the current reporting period.

Questions 68 – 69: Did the congestive heart failure resolve?

Indicate if congestive heart failure is resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Reporting Multiple Coronary Artery Diseases

Complete *Was coronary artery disease present through Date coronary artery disease onset* questions to report multiple coronary artery diseases by adding an additional instance in the FormsNet3SM application.

Questions 70 – 71: Was coronary artery disease present?

Coronary artery disease is the damage or disease in the major blood vessels of the heart. Coronary artery disease is also known as CAD and atherosclerotic heart disease.

Indicate if coronary artery disease was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with coronary artery disease in the reporting period.
- Coronary artery disease resolved in a prior reporting period and then recurred in the current reporting period.

If coronary artery disease **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Coronary artery disease was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Coronary artery disease was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.
- For cellular therapy, if coronary artery disease was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

If coronary artery disease was not present in the current reporting period or unknown if present, select **Not present**.

Reporting Multiple Unstable Anginas

Complete *Was unstable angina present through Date unstable angina resolved* questions to report multiple unstable anginas by adding an additional instance in the FormsNet3SM application.

Questions 72 – 73: Was unstable angina present?

Unstable angina is sometimes called acute coronary syndromes and results in unexpected chest pain due to reduce blood flow and oxygen to the heart.

Indicate if unstable angina was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with unstable angina in the reporting period.
- Unstable angina resolved in a prior reporting period and then recurred in the current reporting period.

If unstable angina **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Unstable angina was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Unstable angina was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.
- For cellular therapy, if unstable angina was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

If unstable angina was not present in the current reporting period or unknown if present, select **Not present**.

Questions 74 – 75: Did unstable angina resolve?

Indicate if unstable angina resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Question 76: Did the recipient experience a myocardial infarction?

Myocardial infarction (MI) is an obstruction in the coronary artery resulting in damage / necrosis to the cardiac muscle.

Indicate if the recipient experienced a myocardial infarction in the current reporting period. The intent of this question is to capture each instance of a myocardial infarction occurring in the reporting period.

If the recipient did not have a myocardial infarction in the current reporting period or is unknown, select **No**.

Reporting Multiple Myocardial Infarctions

Complete *Date of myocardial infarction onset* question to report multiple myocardial infarctions by adding an additional instance in the FormsNet3SM application.

Question 77: Date of myocardial infarction onset

Specify the date of the myocardial infarction. If multiple myocardial infarctions occurred in one day, only one instance is required to capture the myocardial infarctions occurring that day; multiple instances for the same day are not required.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Reporting Multiple Hypertensions Requiring Therapy

Complete *Was hypertension (HTN) requiring therapy present* through *Date HTN requiring therapy resolved* questions to report multiple hypertension requiring therapy by adding an additional instance in the FormsNet3SM application

Questions 78 – 79: Was hypertension (HTN) requiring therapy present?

Hypertension, also known as high blood pressure, is a condition where the blood pressure against the artery walls is too high, which increases the risk of stroke and heart disease.

Indicate if hypertension requiring therapy was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with hypertension requiring treatment in the reporting period.
- Hypertension requiring treatment resolved in a prior reporting period and then recurred in the current reporting period.

If hypertension requiring treatment **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Hypertension requiring treatment was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Hypertension requiring treatment was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If hypertension requiring treatment was not present in the current reporting period or unknown if present, select **Not present**.

Questions 80 – 81: Was the recipient still receiving therapy for HTN at the date of contact for this reporting period?

Specify if the recipient was still receiving treatment for hypertension at the contact date for the current reporting period.

If the recipient was no longer receiving treatment at the contact date, select **No** and specify the therapy completion date.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

HTN Requiring Therapy Resolution

Did HTN requiring therapy resolve is disabled.

Questions 82 – 83: Did HTN requiring therapy resolve?

Indicate if hypertension requiring therapy resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Reporting Multiple Pericarditides

Complete *Was pericarditis present* through *Date pericarditis resolved* questions to report multiple pericarditides by adding an additional instance in the FormsNet3SM application

Questions 84 – 85: Was pericarditis present?

Pericarditis is the swelling and irritation of pericardium.

Indicate if pericarditis was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with pericarditis in the reporting period.
- Pericarditis resolved in a prior reporting period and then recurred in the current reporting period.

If pericarditis **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory

assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Pericarditis was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Pericarditis was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.
- For cellular therapy, if pericarditis was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

If pericarditis was not present in the current reporting period or unknown if present, select **Not present**.

Questions 86 – 87: Did pericarditis resolve?

Indicate if pericarditis resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Reporting Multiple Heart Valve Diseases

Complete *Was heart valve disease present* through *Date of heart valve disease onset* questions to report multiple heart valve diseases by adding an additional instance in the FormsNet3SM application

Questions 88 – 89: Was heart valve disease present?

Heart valve disease is the presence of one or more of the following:

- Moderate or severe degree of valve stenosis or insufficiency as determined by an echo, whether the valve is mitral, aortic, tricuspid, or pulmonary
- Prosthetic mitral or aortic valve
- Symptomatic mitral valve prolapse

Indicate if heart valve disease was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with heart valve disease in the reporting period.
- Heart valve disease resolved in a prior reporting period and then recurred in the current reporting period.

If heart valve disease **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Heart valve disease was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Heart valve disease was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.
- For cellular therapy, if heart valve disease was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

If heart valve disease was not present in the current reporting period or unknown if present, select **Not present**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q90 – 104: Vascular Impairment / Disorder

Question 90: Did the recipient experience a deep vein thrombosis (DVT)? (excluding pulmonary embolism)

A deep vein thrombosis (DVT) is the development of a blood clot in a deep vein.

Indicate if the recipient experienced a deep vein thrombosis, excluding a pulmonary embolism, in the current reporting period. The intent of this question is to capture each instance of deep vein thrombosis occurring in the reporting period.

If the recipient did not have a deep vein thrombosis in the current reporting period or is unknown, select **No**.

Reporting Multiple Deep Vein Thromboses

Complete *Date of DVT onset* through *Was the DVT catheter related* questions to report multiple deep vein thromboses by adding an additional instance in the FormsNet3SM application

Question 91: Date of DVT onset

Specify the date of the deep vein thrombosis.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Question 92: Was the DVT catheter related?

Specify if the deep vein thrombosis was catheter related. This information is typically documented within the results of the ultrasound.

Question 93: Did the recipient experience a pulmonary embolism (PE)?

A pulmonary embolism (PE) is the development of a blood clot in the arteries of the lung.

Indicate if the recipient experienced a pulmonary embolism in the current reporting period. The intent of this question is to capture each instance of a pulmonary embolism occurring in the reporting period.

If the recipient did not have a pulmonary embolism in the current reporting period or is unknown, select **No**.

Reporting Multiple Pulmonary Embolisms

Complete *Date of PE onset* through *Was the PE catheter related* questions to report multiple pulmonary embolisms by adding an additional instance in the FormsNet3SM application

Question 94: Date of PE onset

Specify the date of the pulmonary embolism.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Question 95: Was the PE catheter related?

Specify if the pulmonary embolism was catheter related. This information is typically documented within the results of the ultrasound.

Reporting Multiple Hyperlipidemias

Complete *Was hyperlipidemia present through Date therapy for hyperlipidemia stopped* questions to report multiple hyperlipidemias by adding an additional instance in the FormsNet3SM application

Questions 96 – 97: Was hyperlipidemia present? (*high total cholesterol, low high-density lipoprotein cholesterol, high low-density lipoprotein cholesterol, and / or high triglyceride levels*)

Hyperlipidemia is high levels of lipids (fat particles) in the blood and is typically diagnosed by a lipid panel.

Indicate if hyperlipidemia was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with hyperlipidemia in the reporting period.
- Hyperlipidemia resolved in a prior reporting period and then recurred in the current reporting period.

If hyperlipidemia **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Hyperlipidemia was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Hyperlipidemia was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If hyperlipidemia was not present in the current reporting period or unknown if present, select **Not present**.

Questions 97 – 101: Specify which lipids were assessed (check all that apply)

Indicate which lipids were assessed and specify the results and units of measurement. Select all that apply.

If hyperlipidemia **Developed** (first diagnosis or recurrence), report the labs from the initial diagnosis / recurrence.

If hyperlipidemia **Persisted**, report the most recent lab values in the current reporting period.

Question 102: Was therapy received to treat hyperlipidemia

Specify if therapy to treat hyperlipidemia was received in the current reporting period.

If therapy was not received or is unknown, select **No**.

Questions 103 – 104: Was the recipient still receiving therapy for hyperlipidemia at the date of contact for this reporting period?

Specify if the recipient was still receiving hyperlipidemia treatment at the contact date for the current reporting period.

If the recipient was no longer receiving treatment at the contact date, select **No** and specify the therapy completion date.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q105 – 118: Neurological Impairment / Disorder

Question 105: Did the recipient experience a CNS hemorrhage?

A CNS hemorrhage is bleeding within the central nervous system.

Indicate if the recipient experienced a CNS hemorrhage in the current reporting period. The intent of this question is to capture each instance of a CNS hemorrhage occurring in the reporting period.

If the recipient did not have a CNS hemorrhage in the current reporting period or is unknown, select **No**.

Reporting Multiple CNS Hemorrhages

Complete *Date of CNS hemorrhage onset* question to report multiple CNS hemorrhages by adding an additional instance in the FormsNet3SM application

Question 106: Date of CNS hemorrhage onset

Specify the date of the CNS hemorrhage.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Reporting Multiple Non-Infectious Encephalopathies

Complete *Was non-infectious encephalopathy present* through *Date non-infectious encephalopathy resolved* questions to report multiple non-infectious encephalopathies by adding an additional instance in the FormsNet3SM application

Questions 107 – 108: Was non-infectious encephalopathy present?

Non-infectious encephalopathy is the damage or disease of the brain. Symptoms include memory loss, personality changes, and declining ability to concentrate and reason.

Indicate if non-infectious encephalopathy was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with non-infectious encephalopathy in the reporting period.
- Non-infectious encephalopathy disease resolved in a prior reporting period and then recurred in the current reporting period.

If non-infectious encephalopathy **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Non-infectious encephalopathy was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Non-infectious encephalopathy was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If non-infectious encephalopathy was not present in the current reporting period or unknown if present, select **Not present**.

Questions 109 – 110: Did non-infectious encephalopathy resolve?

Indicate if non-infectious encephalopathy resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Reporting Multiple Neuropathies

Complete *Was neuropathy present* through *Date neuropathy resolved* questions to report multiple neuropathies by adding an additional instance in the FormsNet3SM application

Questions 111 – 112: Was neuropathy present?

Neuropathy is also known as nerve damage, typically in hands and feet, which causes pain, weakness, and numbness.

Indicate if neuropathy was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with neuropathy in the reporting period.
- Neuropathy disease resolved in a prior reporting period and then recurred in the current reporting period.

If neuropathy **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Neuropathy was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Neuropathy was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If neuropathy was not present in the current reporting period or unknown if present, select **Not present**.

Questions 113 – 114: Did neuropathy resolve?

Indicate if neuropathy resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Question 115: Did the recipient experience a seizure(s)?

Seizures are sudden, involuntary muscle contractions due to hyperexcitation of neurons.

Indicate if the recipient experienced a seizure(s) in the current reporting period. The intent of this question is to capture each instance of a myocardial infarction occurring in the reporting period.

If the recipient did not have a seizure in the current reporting period or is unknown, select **No**.

Reporting Multiple Seizures

Complete *Date of a seizure(s) onset* question to report multiple seizures by adding an additional instance in the FormsNet3SM application

Question 116: Date of a seizure(s) onset

Specify the date of the seizure. If multiple seizures occurred in one day, only one instance is required to capture the seizures occurring that day; multiple instances for the same day are not required.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Question 117: Did the recipient experience a stroke / transient ischemic attack?

A stroke / transient ischemic attack is the loss of brain function due to a disturbance in the blood supply to the brain.

Indicate if the recipient experienced a stroke / transient ischemic attack in the current reporting period. The intent of this question is to capture each instance of a myocardial infarction occurring in the reporting period.

If the recipient did not have a stroke / transient ischemic attack in the current reporting period or is unknown, select **No**.

Reporting Multiple Strokes / Transient Ischemic Attacks
Complete *Date of stroke / transient ischemic attack onset* question to report multiple strokes / transient ischemic attacks by adding an additional instance in the FormsNet3SM application

Question 116: Date of stroke / transient ischemic attack onset

Specify the date of the stroke / transient ischemic attack. If the recipient experienced different kinds of strokes in the reporting period, report a separate instance for each stroke type.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q119 – 133: Endocrine Impairment / Disorder

Reporting Multiple Diabetes / Hyperglycemias Requiring Chronic Treatment
Complete *Was diabetes / hyperglycemia requiring chronic treatment present* through *Date diabetes / hyperglycemia requiring chronic treatment resolved* questions to report

multiple diabetes / hyperglycemias requiring chronic treatment by adding an additional instance in the FormsNet3SM application

Questions 119 – 120: Was diabetes / hyperglycemia requiring chronic treatment present?

Diabetes / hyperglycemia is also known as high blood glucose levels.

Indicate if diabetes / hyperglycemia requiring chronic treatment was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with diabetes / hyperglycemia requiring chronic treatment in the reporting period.
- Diabetes / hyperglycemia requiring chronic treatment resolved in a prior reporting period and then recurred in the current reporting period.

If diabetes / hyperglycemia requiring chronic treatment **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Diabetes / hyperglycemia requiring chronic treatment was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Diabetes / hyperglycemia requiring chronic treatment was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.
- For cellular therapy, if diabetes / hyperglycemia requiring chronic treatment was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

If diabetes / hyperglycemia requiring chronic treatment was not present in the current reporting period or unknown if present, select **Not present**.

Questions 121 – 122: Was the recipient still receiving therapy for diabetes / hyperglycemia at the date of contact for this reporting period?

Specify if the recipient was still receiving treatment for diabetes / hyperglycemia at the contact date for the current reporting period.

If the recipient was no longer receiving treatment at the contact date, select **No** and specify the therapy completion date.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Diabetes / Hyperglycemia Requiring Chronic Treatment Resolution
Did diabetes / hyperglycemia requiring chronic treatment resolve is disabled.

Questions 123 – 124: Did diabetes / hyperglycemia requiring chronic treatment resolve?

Indicate if diabetes / hyperglycemia chronic treatment resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 125 – 126: Was growth hormone deficiency / short stature present?

Growth hormone deficiency / short stature is a condition in which the body does not produce enough growth hormone / a reduced overall rate of growth.

Indicate if growth hormone deficiency / short stature was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with growth hormone deficiency / short stature in the reporting period.

If growth hormone deficiency / short stature **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report a recurrence of growth hormone deficiency / short stature. Only the first occurrence is captured.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

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Report **Persisted** in the following scenarios:

- Growth hormone deficiency / short stature was diagnosed pre-infusion and persisted into the Day 100 reporting period.

Do not report growth hormone deficiency / short stature if it continued from a previous reporting period into the current reporting period, even if it was present.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If growth hormone deficiency / short stature was not present in the current reporting period or unknown if present, select **Not present**.

Question 127: Was therapy given for hormone deficiency / short stature?

Specify if therapy was given for hormone deficiency / short stature in the current reporting period.

If therapy was not received or is unknown, select **No**.

Questions 128 – 129: Was the recipient still receiving therapy for hormone deficiency / short stature at the date of contact for this reporting period?

Specify if the recipient was still receiving hormone deficiency / short stature treatment at the contact date for the current reporting period.

If the recipient was no longer receiving treatment at the contact date, select **No** and specify the therapy completion date.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 130 – 131: Was hypothyroidism requiring replacement therapy present?

Hypothyroidism is a decreased activity of the thyroid gland. Diagnosis of hypothyroidism includes high levels of thyroid-stimulating hormone (TSH). Symptoms include fatigue, depression, weakness, weight gain, musculoskeletal pain, decreased taste, hoarseness, and / or puffy face.

Indicate if hypothyroidism requiring replacement therapy was present in the current reporting period.

Report **Developed** in the following scenarios:

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- This is the first time the recipient was diagnosed with hypothyroidism requiring replacement therapy in the reporting period.

If hypothyroidism requiring replacement therapy **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report a recurrence of hypothyroidism requiring replacement therapy. Only the first occurrence is captured.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Hypothyroidism requiring replacement therapy was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- For cellular therapy, if hypothyroidism requiring replacement therapy was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

Do not report hypothyroidism requiring replacement therapy if it continued from a previous reporting period into the current reporting period, even if it was present.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If hypothyroidism requiring replacement therapy was not present in the current reporting period or unknown if present, select **Not present**.

Questions 132 – 133: Was pancreatitis present?

Pancreatitis is the inflammation of the pancreas.

Indicate if pancreatitis were present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with pancreatitis in the reporting period.

If pancreatitis **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report a recurrence of pancreatitis. Only the first occurrence is captured.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Pancreatitis was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- For cellular therapy, if pancreatitis was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

Do not report pancreatitis if it continued from a previous reporting period into the current reporting period, even if it was present.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If pancreatitis was not present in the current reporting period or unknown if present, select **Not present**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q134 – 139: Genitourinary Impairment / Disorder

Questions 134 – 135: Was gonadal dysfunction requiring hormone replacement present? (*testosterone or estrogen*)

Gonadal dysfunction requiring hormone replacement affects both males and females. Males experience decreased spermatogenesis and females may experience early symptoms of menopause, including amenorrhea. Low levels of follicle stimulating

hormone (FSH), luteinizing hormone (LH), and / or testosterone may require hormone replacement therapy.

Indicate if gonadal dysfunction requiring hormone replacement was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with gonadal dysfunction requiring hormone replacement in the reporting period.

If gonadal dysfunction requiring hormone replacement **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report a recurrence of gonadal dysfunction requiring hormone replacement. Only the first occurrence is captured.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Gonadal dysfunction requiring hormone replacement was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- For cellular therapy, if gonadal dysfunction requiring hormone replacement was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

Do not report gonadal dysfunction requiring hormone replacement if it continued from a previous reporting period into the current reporting period, even if it was present.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If gonadal dysfunction requiring hormone replacement was not present in the current reporting period or unknown if present, select **Not present**.

Questions 136 – 137: Was hemorrhagic cystitis / hematuria requiring medical intervention present? (catheterization of bladder, extra transfusions, urology consult)

Hemorrhagic cystitis / hematuria is characterized by bleeding and inflammation of the bladder wall. Hemorrhagic cystitis may result from systemic chemotherapy or radiation therapy and / or some viral infections (e.g., BK virus).

Indicate if hemorrhagic cystitis / hematuria requiring medical intervention (i.e., catheterization of bladder, extra transfusions, urology consultation) was present in the current reporting period. Report cases with macroscopic (visible to the naked eye) or gross hematuria (WHO Grade III and IV hemorrhagic cystitis). If the etiology is infectious, also report the infection on the appropriate follow-up form.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with hemorrhagic cystitis / hematuria requiring medical intervention in the reporting period.
- Hemorrhagic cystitis / hematuria requiring medical intervention resolved in a prior reporting period and then recurred in the current reporting period.

If hemorrhagic cystitis / hematuria requiring medical intervention **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Hemorrhagic cystitis / hematuria requiring medical intervention was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Hemorrhagic cystitis / hematuria requiring medical intervention was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If hemorrhagic cystitis / hematuria requiring medical intervention was not present in the current reporting period or unknown if present, select **Not present**.

Questions 138 – 139: Did hemorrhagic cystitis / hematuria requiring medical intervention resolve?

Indicate if hemorrhagic cystitis / hematuria requiring medical intervention resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q140 – 149: Musculoskeletal Impairment / Disorder

Question 140: Did the recipient experience avascular necrosis?

Avascular necrosis, also known as coagulation necrosis or ischemic necrosis, is localized tissue death due to inadequate oxygen to the cells.

Indicate if the recipient experienced avascular necrosis in the current reporting period. The intent of this question is to capture each instance of avascular necrosis occurring in the reporting period.

If the recipient did not have avascular necrosis in the current reporting period or is unknown, select **No**.

Reporting Multiple Avascular Necroses

Complete *Date of avascular necrosis onset* through *Date of avascular necrosis surgery* questions to report multiple avascular necroses by adding an additional instance in the FormsNet3SM application

Question 141: Date of avascular necrosis onset

Specify the date of the avascular necrosis.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 142 – 143: Did the recipient have surgery for avascular necrosis during this reporting period?

Indicate if the recipient required surgery for avascular necrosis during the current reporting period. If **Yes**, specify the surgery date.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Reporting Multiple Osteonecroses of the Jaw

Complete *Was osteonecrosis of the jaw present* through *Date of osteonecrosis of the jaw onset* questions to report multiple osteonecroses of the jaw by adding an additional instance in the FormsNet3SM application

Questions 144 – 145: Was osteonecrosis of the jaw present?

Osteonecrosis of the jaw is when jaw bones weaken and die due to potent antiresorptive medications such as bisphosphonates or RANKL inhibitors, infection, steroid use, and cancer treatment, including radiation.

Indicate if osteonecrosis of the jaw was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with osteonecrosis of the jaw in the reporting period.
- Osteonecrosis of the jaw resolved in a prior reporting period and then recurred in the current reporting period.

If osteonecrosis of the jaw **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Osteonecrosis of the jaw was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Osteonecrosis of the jaw was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.
- For cellular therapy, if osteonecrosis of the jaw was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

If osteonecrosis of the jaw was not present in the current reporting period or unknown if present, select **Not present**.

Questions 146 – 147: Was osteoporosis present?

Osteoporosis is where the bones become weak and brittle due to losing bone mass faster than it is created from aging.

Indicate if osteoporosis was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with osteoporosis in the reporting period.

If osteoporosis **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report a recurrence of osteoporosis. Only the first occurrence is captured.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Osteoporosis was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- For cellular therapy, if osteoporosis was diagnosed pre-infusion and persisted into the one-year reporting period (without resolution since the pre-infusion diagnosis) as this form will not come due until the one-year reporting period.

Do not report osteoporosis if it continued from a previous reporting period into the current reporting period, even if it was present.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If osteoporosis was not present in the current reporting period or unknown if present select **Not present**.

Question 148: Did the recipient experience an osteoporotic fracture?

Osteoporotic fracture is where a fracture occurs due to low bone mineral density.

Indicate if the recipient experienced an osteoporotic fracture in the current reporting period. The intent of this question is to capture each instance of an osteoporotic fracture occurring in the reporting period.

If the recipient did not have an osteoporotic fracture in the current reporting period or is unknown, select **No**.

Reporting Multiple Osteoporotic Fractures

Complete *Date of osteoporotic fracture* question to report multiple osteoporotic fractures by adding an additional instance in the FormsNet3SM application

Question 149: Date of osteoporotic fracture

Specify the date of the osteoporotic fracture.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q150 – 152: Psychiatric Impairment / Disorder

Reporting Multiple Psychiatric Impairments / Disorders

Complete *Date of psychiatric impairment / disorder onset* through *Specify psychiatric impairment / disorder* questions to report multiple psychiatric impairments / disorders by adding an additional instance in the FormsNet3SM application.

Questions 150 – 152: Was a psychiatric impairment / disorder present?

Psychiatric impairment / disorders include depression, anxiety, and post-traumatic stress disorder.

- Depression: A mood disorder resulting in persistent feeling of sadness and loss of interest. Common treatments include antidepressant, anxiolytic, and antipsychotic medications. Common names include Amitriptyline, Bupropion (Wellbutrin), Buspirone, and Abilify.

- Anxiety: A disorder characterized by feelings of worry, anxiety, or fear which are strong enough to interfere with daily activities. Common medications include Duloxetine (Cymbalta), Diazepam (Valium), Buspirone, Pregabalin (Lyrica).
- Post-traumatic stress disorder (PTSD): A condition triggered by seeing or experiencing a traumatic event.

Indicate if depression, anxiety, or PTSD, requiring treatment, was present in the current reporting period.

Report **Developed** if this is the first time the recipient was diagnosed with depression, anxiety, or PTSD, requiring treatment, in the reporting period.

If depression, anxiety, or PTSD, requiring treatment **Developed**, report the onset date and specify the psychiatric impairment / disorder. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report the following:

- A recurrence of depression, anxiety, or PTSD, requiring treatment. Only the first occurrence is captured.
- Depression, anxiety, or PTSD, requiring treatment was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Depression, anxiety, or PTSD, requiring treatment continued from a previous reporting period into the current reporting period.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If depression, anxiety, and / or PTSD, requiring treatment, was not present in the current reporting period or unknown if present, select **Not present**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q153 – 167: Other Impairment / Disorder

Questions 153 – 154: Were cataracts present?

Cataracts are the loss of transparency in the lens of the eye.

Indicate if cataracts were present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with cataracts in the reporting period.

If cataracts **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report a recurrence of cataracts. Only the first occurrence is captured.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Cataracts were diagnosed pre-infusion and persisted into the Day 100 reporting period.

Do not report cataracts if it continued from a previous reporting period into the current reporting period, even if it was present.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If cataracts were not present in the current reporting period or unknown if present, select **Not present**.

Reporting Multiple Iron Overloads Requiring Therapy

Complete *Was iron overload requiring therapy present* through *Date iron overload requiring therapy resolved* questions to report multiple iron overloads requiring therapy by adding an additional instance in the FormsNet3SM application

Questions 155 – 156: Was iron overload requiring therapy present?

Iron overload is a condition characterized by having too much iron in the body. Therapy includes phlebotomy and iron chelation.

Indicate if iron overload requiring therapy was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with iron overload requiring therapy in the reporting period.
- Iron overload requiring therapy in a prior reporting period and then recurred in the current reporting period.

If iron overload requiring therapy **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Iron overload requiring therapy was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- Iron overload requiring therapy was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If iron overload requiring therapy was not present in the current reporting period or unknown if present, select **Not present**.

Questions 157 – 158: Specify therapy given for iron overload (*check all that apply*)

Indicate the therapy given for iron overload in the current reporting period. Select all therapies. If **Other therapy** is selected, specify.

Questions 159 – 160: Was the recipient still receiving therapy for iron overload at the date of contact for this reporting period?

Specify if the recipient was still receiving iron overload therapy at the contact date for the current reporting period. If **No**, specify the therapy end date.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Iron Overload Requiring Therapy Resolution

Did iron overload requiring therapy resolve is disabled.

Questions 161 – 162: Did iron overload requiring therapy resolve?

Indicate if iron overload requiring therapy resolved during the reporting period. If **Yes**, report the resolution date. The resolution date is the date when the notes specify the condition as resolved and / or medications to treat the condition were completed.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Questions 163 – 164: Was mucositis requiring therapy present?

Mucositis is the inflammation and ulceration of mucous membranes that line the digestive tract, usually due to chemotherapy and radiotherapy. Specify if mucositis was present in the current reporting period.

Indicate if mucositis requiring therapy was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with mucositis in the reporting period.

If mucositis **Developed**, report the onset date. If the diagnosis was determined at an outside center and no documentation of a clinical, pathological, or laboratory assessment is available, the dictated date of diagnosis within a physician note may be reported.

Do not report a recurrence of mucositis. Only the first occurrence is captured.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

Report **Persisted** in the following scenarios:

- Mucositis was diagnosed pre-infusion and persisted into the Day 100 reporting period.

Do not report mucositis if it continued from a previous reporting period into the current reporting period, even if it was present.

For more information regarding reporting partial or unknown dates, see [General Instructions, General Guidelines for Completing Forms](#).

If mucositis was not present in the current reporting period or unknown if present, select **Not present**.

This question is only enabled for the Day 100 reporting period.

Questions 165: Specify maximum OMS grade

Report the maximum OMS grade in the reporting period using the following guidelines:

- **0 (none)**: Normal mucosa with no mucositis
- **I (mild)**: Oral soreness, erythema
- **II (moderate)**: Oral erythema, ulcers, solid diet tolerated
- **III (severe)**: Oral ulcers, liquid diet only
- **IV (life-threatening)**: Oral ulcers, oral alimentation impossible

Reporting Multiple Other Impairments / Disorders

Complete *Was another impairment / disorder present* through *Specify other impairment / disorder* questions to report multiple other impairments / disorders by adding an additional instance in the FormsNet3SM application

Questions 166 – 167: Was another impairment / disorder present?

An other impairment / disorder should be reported for any clinically significant impairment / disorder that is not listed above.

Specify if an other impairment / disorder was present in the current reporting period.

Report **Developed** in the following scenarios:

- This is the first time the recipient was diagnosed with the other impairment / disorder in the reporting period.
- The other impairment / disorder resolved in a prior reporting period and then recurred in the current reporting period.

Report **Persisted** in the following scenarios:

- The other impairment / disorder was diagnosed pre-infusion and persisted into the Day 100 reporting period.
- The other impairment / disorder was diagnosed (or persisted) in the prior reporting period and persisted into the current reporting period.

If the other impairment / disorder was not present in the current reporting period or unknown if present, select **Not present**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q168 – 172: Solid Organ Transplant

Questions 168 – 172: Has the recipient received a solid organ transplant?

Indicate whether the recipient received a solid organ transplant during the current reporting period. If **Yes**, specify the organ transplanted. If **Other organ** is reported, specify the organ. Additionally, report the solid organ transplant date and specify the type of the solid organ donor.

If the exact transplant date is not known, use the guidelines for reporting partial or unknown dates in General Instructions, General Guidelines for Completing Forms.

If the recipient did not receive a solid organ transplant during the reporting period or it is unknown, select **No**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)