| CMS Manual System | Department of Health & Human Services (DHHS) |
|---|---|
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| **Transmittal 3241** | **Date: April 24, 2015** |
| | **Change Request 9002** |

**Transmittal 3142, dated December 5, 2014, is being rescinded and replaced by Transmittal 3241 to remove BR 9002-04.4 and BR 9002-04.4.1. The Medicare Claims Processing Manual, Chapter 32, Section 340.2, Claims Processing Requirements for TMVR for MR Services on Professional Claims, is changed to delete text concerning billing TMVR for MR with modifier -62. All other information remains the same.**

**SUBJECT: Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD)**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to inform contractors payment shall be allowed for Transcatheter Mitral Valve Repair for (TMVR) under Coverage with Evidence Development.

**EFFECTIVE DATE: August 7, 2014**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: April 6, 2015**

***Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.***

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|---|---|
| R | 32/Table of Contents |
| N | 32/340/ Transcatheter Mitral Valve Repair (TMVR) |
| N | 32/340.1/ Coding Requirements for TMVR for MR Claims Furnished on or After August 7, 2014 |
| N | 32/340.2/ Claims Processing Requirements for TMVR for MR Services on Professional Claims |
| N | 32/340.3 /Claims Processing Requirements for TMVR for MR Services on Inpatient Hospital Claims |
| N | 32/340.4/Claims Processing Requirements for TMVR for MR Services for Medicare Advantage (MA) Plan Participants |

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements**
**Manual Instruction**

# Attachment - Business Requirements

| Pub. 100-04 | Transmittal: 3241 | Date: April 24, 2015 | Change Request: 9002 |
|---|---|---|---|

**Transmittal 3142, dated December 5, 2014, is being rescinded and replaced by Transmittal 3241 to remove BR 9002-04.4 and BR 9002-04.4.1. The Medicare Claims Processing Manual, Chapter 32, Section 340.2, Claims Processing Requirements for TMVR for MR Services on Professional Claims, is changed to delete text concerning billing TMVR for MR with modifier -62. All other information remains the same.**

**SUBJECT: Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD)**

**EFFECTIVE DATE: August 7, 2014**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: April 6, 2015**

## I. GENERAL INFORMATION

**A. Background:** Transcatheter Mitral Valve Repair (TMVR) is a new technology for use in treating mitral regurgitation (MR). MR occurs when the leaflets of the mitral valve do not close properly and blood flows from the left ventricle back into the left atrium, causing the heart to work harder to pump, in turn causing enlargement of the left ventricle and potential heart failure. Abbott's MitraClip, the only Food and Drug Administration (FDA)-approved TMVR device, involves clipping together a portion of the mitral valve leaflets. No national coverage determination (NCD) existed for TMVR for MR prior to August 7, 2014.

**B. Policy:** On August 7, 2014, the Centers for Medicare and Medicaid services (CMS) issued a final decision memorandum covering TMVR for MR under Coverage with Evidence Development (CED) when the treatment is furnished for an FDA-approved indication with an FDA-approved device as follows: (1) Treatment of significant, symptomatic, degenerative MR when furnished according to an FDA-approved indication and all CMS coverage criteria are met, and, (2) TMVR for MR uses not expressly listed as FDA-approved indications but only within the context of an FDA-approved, randomized clinical trial that meets all CMS coverage criteria. TMVR is non-covered outside CED or for non-MR indications.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| 9002 - 04.1 | Effective for claims with dates of service on or after August 7, 2014, contractors shall allow payment for TMVR for MR under CED only as outlined in Pub 100-03, chapter 1, section 20.33, of the NCD Manual and chapter 32, section 340, Medicare Claims Processing Manual, Pub.100-04. | X | X | | | X | X | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | | | | | | | | | | |
| 9002 - 04.2 | Effective for claims with dates of service on or after August 7, 2014, contractors shall recognize HCPCS codes 0343T, 0344T, and 0345T when billed for TMVR for MR.<br><br>NOTE: Effective for claims with dates of service on or after January 1, 2015, HCPCS code 0343T is replaced by HCPCS code 33418 and HCPCS code 0344T is replaced by HCPCS code 33419. | | X | | | | | | | |
| 9002 - 04.2.1 | Effective for claims with dates of service on or after August 7, 2014, contractors shall apply contractor pricing to claims containing HCPCS codes 0343T, 0344T, and 0345T when billing for TMVR for MR.<br><br>NOTE: Effective January 1, 2015, HCPCS codes 33418 and 33419 will be paid based on the 2015 Medicare Physician Fee Schedule. | | X | | | | | | | |
| 9002 - 04.3 | Effective for claims with dates of service on or after August 7, 2014, contractors shall pay TMVR for MR claim lines for HCPCS codes 0343T(33418), 0344T(33419), and 0345T only when services are provided in place of service (POS) 21, Inpatient Hospital. | | X | | | | | | | |
| 9002 - 04.3.1 | Effective for claims with dates of service on or after August 7, 2014, contractors shall line-item deny TMVR for MR claim lines with a POS code other than 21 with the following messages:<br><br>Claim Adjustment Reason Code (CARC) 58: Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present<br><br>Medicare Summary Notice (MSN) 21.25: This service was denied because Medicare only covers this service in certain settings. | | X | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | Spanish Version: El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."<br><br>Group Code –Contractual Obligation (CO). | | | | | | | | | |
| 9002-04.4 | This requirement was deleted. | | | | | | | | | |
| 9002-04.4.1 | This requirement was deleted. | | | | | | | | | |
| 9002 – 04.5 | Effective for claims with dates of service on or after August 7, 2014, contractors shall pay TMVR for MR claim lines HCPCS codes 0343T(33418), 0344T(33419), and 0345T only when billed with an 8-digit national clinical trial (NCT) number. | | X | | | | | | | |
| 9002 – 04.5.1 | For claims with dates of service on or after August 7, 2014, contractors shall return TMVR for MR claim lines as unprocessable when billed without an 8-digit NCT number using the following messages:<br><br>CARC 16: Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)<br><br>RARC MA50: Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.<br><br>Group Code-Contractual Obligation (CO). | | X | | | | | | | |
| 9002 – 04.6 | For claims with dates of service on or after August 7, 2014, contractors shall pay TMVR for MR claim lines for HCPCS codes 0343T(33418), 0344T(33419), and 0345T only when billed with modifier -Q0. | | X | | | | X | | | |
| 9002 - 04.6.1 | For claims with dates of service on or after August 7, 2014, contractors shall return claim lines for TMVR for MR as unprocessable when billed without the -Q0 modifier with the following | | X | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | messages:<br><br>CARC 4: The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.<br><br>RARC N517: Resubmit a new claim with the requested information.<br><br>Group Code-Contractual Obligation (CO). | | | | | | | | | |
| 9002 - 04.7 | For claims with dates of service on or after August 7, 2014, contractors shall pay TMVR for MR claim lines for HCPCS codes 0343T(33418), 0344T(33419), and 0345T only when billed with ICD-9 diagnosis code 424.0 (ICD-10 I34.0 or I34.8) and secondary ICD-9 diagnosis code V70.7 (ICD-10 Z00.6). | | X | | | | X | | | |
| 9002 - 04.7.1 | For claims with dates of service on or after August 7, 2014, contractors shall deny TMVR for MR claim lines when billed without the ICD-9 or ICD-10 (once ICD-10 is implemented) diagnosis codes required in BR 9002-04.7<br><br>CARC 50: These are non-covered services because this is not deemed a “medical necessity” by the payer.<br><br>RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.<br><br>Group Code: Contractual Obligation (CO).<br><br>MSN 15.20: The following policies [NCD 20.33] | | X | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | were used when we made this decision<br><br>Spanish Version: 15.20- Las siguientes políticas [NCD 20.33]fueron utilizadas cuando se tomó esta decisión | | | | | | | | | |
| 9002 - 04.8 | Effective for inpatient hospital discharges on or after August 7, 2014, contractors shall allow payment for TMVR for MR under CED only when billed with the following procedure, diagnosis, and clinical trial codes:<br><br>• ICD-9 procedure code 35.97 - Percutaneous mitral valve repair with implant (ICD-10 02UG3JZ)<br><br>• ICD-9 in the primary diagnosis code field 424.0 – mitral valve disorder (ICD-10 I34.0, or I34.8)<br><br>• ICD-9 in any of the secondary diagnosis code fields V70.7 - Exam-clinical trial (Examination of participant in clinical trial) (ICD-10 Z00.6)<br><br>• Condition code 30 - Qualifying Clinical Trials<br><br>• Value code D4 - Clinical Trial Number Assigned by NLM/NIH with a*n 8-digit clinicaltrials.gov identifier number listed on the CMS website* | X | | | | X | | | | |
| 9002 - 04.8.1 | Effective for inpatient hospital discharges on or after August 7, 2014, contractors shall deny claims for TMVR for MR with the following messages when any of the procedure, diagnosis, or trial codes in BR .8 are not present:<br><br>• CARC 50: These are non-covered services because this is not deemed a “medical necessity” by the payer.<br><br>• RARC N386: This decision was based on a National Coverage Determination (NCD). An | X | | | | X | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.<br><br>• Group Code: Contractual Obligation (CO)<br><br>• MSN 15.20: The following policies [NCD 20.33] were used when we made this decision<br><br>Spanish Version: MSN 15.20: Las siguientes políticas [NCD 20.33], fueron utilizadas cuando se tomó esta decisión. | | | | | | | | | |
| 9002 - 04.9 | Contractors shall note the appropriate ICD-10 codes listed below. Contractors shall track the ICD-10 code/edits (and add the code(s)/edit(s) to their system when applicable) and ensure that the updated edit is functional as part of ICD-10 implementation.<br><br>• ICD-10 procedure code 02UG3JZ – supplement mitral valve with synthetic substitute, percutaneous approach<br><br>• ICD-10 primary diagnosis codes I34.0 – nonrheumatic mitral (valve) insufficiency, I34.8 – other nonrheumatic mitral valve disorders<br><br>• ICD-10 secondary diagnosis code Z00.6 - Encounter for examination for normal comparison and control in clinical research program<br><br>**NOTE: You will not receive a separate Change Request to implement ICD-10 edits.** | X | X | | | X | X | | | |
| 9002 - 04.10 | Effective for claims with discharge dates or dates of service on and after August 7, 2014, through the implementation of this CR, contractors shall not | X | X | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | search for TMVR for MR claims but may adjust claims that are brought to their attention. | | | | | | | | | |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| 9002 - 04.11 | MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | X | | | |

## IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|

**Section B: All other recommendations and supporting information:** N/A

## V. CONTACTS

**Pre-Implementation Contact(s):** Sarah Fulton, 410-786-2749 or sarah.fulton@cms.hhs.gov (Coverage), Patricia Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov (Coverage), Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage), Cami DiGiacomo, 410-786-5888 or cami.digiacomo@cms.hhs.gov (Institutional Claims Processing), Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Practitioner Claims Processing)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

**VI. FUNDING**

**Section A: For Medicare Administrative Contractors (MACs):**
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 0**

# Medicare Claims Processing Manual

## Chapter 32 – Billing Requirements for Special Services

**Table of Contents**
***(Rev. 3241, Issued: 04-24-15)***

## *340 – Transcatheter Mitral Valve Repair (TMVR)*

***(Rev. 3241, Issued: 04-24-15, Effective: 08-07-14, Implementation: 04-06-15)***

*Transcatheter Mitral Valve Repair (TMVR) is used in the treatment of mitral regurgitation (MR). A TMVR device involves clipping together a portion of the mitral valve leaflets as treatment for reducing MR. Currently, Abbott Vascular's MitraClip® is the only device with Food and Drug Administration (FDA)-approval.*

*For services furnished on or after August 7, 2014, the Centers for Medicare & Medicaid Services (CMS) covers TMVR for MR when furnished under coverage with evidence development (CED) when the treatment is furnished for an FDA-approved indication with an FDA-approved device as follows: (1) Treatment of significant, symptomatic, degenerative MR when furnished according to an FDA-approved indication and all CMS coverage criteria are met, and, (2) TMVR for MR uses not expressly listed as FDA-approved indications but only within the context of an FDA-approved, randomized clinical trial that meets all CMS coverage criteria. TMVR is non-covered outside CED or for non-MR indications. For more detailed information see Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 20, Section 20.33.*

## *340.1 – Coding Requirements for TMVR for MR Claims Furnished on or After August 7, 2014*

***(Rev. 3241, Issued: 04-24-15, Effective: 08-07-14, Implementation: 04-06-15)***

***Current Procedural Terminology (CPT) Codes for TMVR for MR Claims***

*0343T - Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; initial prosthesis. (Note: 0343T will be replaced by CPT code 33418 effective January 1, 2015.)*

*0344T - Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure). (Note: 0344T will be replaced by CPT code 33419 effective January 1, 2015.)*

*0345T - Transcatheter mitral valve repair percutaneous approach via the coronary sinus*

*33418 - Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis. (Note: CPT code 33418 is effective January 1, 2015.)*

*33419 - Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session. (List separately in addition to code for primary procedure.) (Note: CPT code 33419 is effective January 1, 2015.)*

***ICD-9 Procedure Code for TMVR for MR Claims***

*35.97 - Percutaneous mitral valve repair with implant*

***ICD-10 Procedure Code for TMVR for MR Claims***

*02UG3JZ – Supplement mitral valve with synthetic substitute, percutaneous approach*

***ICD-9 Diagnosis Code for TMVR for MR Claims***

*424.0 – Mitral valve disorder*

***ICD-10 Diagnosis Codes for TMVR for MR***

*I34.0 – Nonrheumatic mitral (valve) insufficiency or*
*I34.8 – Other nonrheumatic mitral valve disorders*

## *340.2 – Claims Processing Requirements for TMVR for MR Services on Professional Claims*

***(Rev. 3241, Issued: 04-24-15, Effective: 08-07-14, Implementation: 04-06-15)***

***Professional Claims Place of Service (POS) Codes for TMVR for MR Claims***

*Effective for claims with dates of service on and after August 7, 2014, place of service (POS) code 21 shall be used for TMVR for MR services. All other POS codes shall be denied.*

*The following messages shall be used when Medicare contractors deny TMVR for MR claims for POS:*

*Claim Adjustment Reason Code (CARC) 58: "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."*

*Group Code: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)*

*Medicare Summary Notice (MSN) 21.25: "This service was denied because Medicare only covers this service in certain settings."*

*Spanish Version: El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."*

***Professional Claims Modifiers for TMVR for MR Claims***

*Effective for claims with dates of service on or after August 7, 2014, contractors shall pay claim lines for TMVR for MR billed with CPT codes 0343T, 0344T, and 0345T in a clinical trial when billed with modifier -Q0. (Effective January 1, 2015, CPT codes 33418 and 33419 replace CPT codes 0343T and 0344T, respectively.) TMVR for MR claim lines in a clinical trial billed without modifier -Q0 shall be returned as unprocessable.*

*The following messages shall be used when Medicare contractors return TMVR for MR claim lines in a clinical trial billed without modifier -Q0 as unprocessable:*

*CARC 4: "The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."*

*RARC N517: "Resubmit a new claim with the requested information."*

*Group Code: CO "(Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)"*

***Professional Clinical Trial Diagnostic Coding for TMVR for MR Claims***

*Effective for claims with dates of service on or after August 7, 2014, contractors shall pay claim lines for TMVR for MR billed with CPT codes 0343T, 0344T, and 0345T in a clinical trial when billed with ICD-9 diagnosis code 424.0 (ICD-10 I34.0 or I34.8) and secondary ICD-9 diagnosis code V70.7 (ICD-10=Z00.6). (Effective January 1, 2015, CPT codes 33418 and 33419 replace CPT codes 0343T and 0344T, respectively.) TMVR for*

*MR claim lines in a clinical trial billed without ICD-9 diagnosis code 424.0 (ICD-10 I34.0 or I34.8) and secondary ICD-9 diagnosis code V70.7 (ICD-10=Z00.6) shall be denied.*

*The following messages shall be used when Medicare contractors deny TMVR for MR claim lines in a clinical trial billed without secondary ICD-9 diagnosis code V70.7(ICD-10=Z00.6):*

*CARC 50: These are non-covered services because this is not deemed a "medical necessity" by the payer.*

*RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD Group Code: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)*

*MSN 15.20: The following policies [NCD 20.33]] were used when we made this decision*

*Spanish Version: MSN 15.20: Las siguientes políticas [NCD 20.33] fueron utilizadas cuando se tomó esta decisión.*

***Mandatory National Clinical Trial (NCT) Number for TMVR for MR Claims***

*Effective for claims with dates of service on or after August 7, 2014, contractors shall pay TMVR for MR claim lines billed with CPT codes 0343T, 0344T, and 0345T in a clinical trial only when billed with an 8-digit national clinical trial (NCT) number. (Effective January 1, 2015, CPT codes 33418 and 33419 replace CPT codes 0343T and 0344T, respectively.) Contractors shall accept the numeric, 8-digit NCT number preceded by the two alpha characters of "CT" when placed in Field 19 of paper Form CMS-1500, or when entered WITHOUT the "CT" prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4).* ***NOTE****: The "CT" prefix is required on a paper claim, but it is not required on an electronic claim. TMVR for MR claim lines in a clinical trial billed without an 8-digit NCT number shall be returned as unprocessable.*

*The following messages shall be used when Medicare contractors return TMVR for MR claim lines as unprocessable when billed without an 8-digit NCT number:*

*CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"*

*RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."*

*Group Code: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)*

## *340.3 - Claims Processing Requirements for TMVR for MR Services on Inpatient Hospital Claims*

***(Rev. 3241, Issued: 04-24-15, Effective: 08-07-14, Implementation: 04-06-15)***

*Inpatient hospitals shall bill for TMVR for MR on an 11X type of bill (TOB) effective for discharges on or after August 7, 2014. Refer to Section 69 of this chapter for further guidance on billing under CED.*

*In addition to the ICD-9/10 procedure and diagnosis codes mentioned above, inpatient hospital discharges for TMVR for MR shall be covered when billed with the following clinical trial coding:*

- *Secondary ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6*
- *Condition Code 30*
- *Value code D4 - Clinical Trial Number Assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website*

*Inpatient hospital discharges for TMVR for MR shall be denied when billed without the ICD-9/10 diagnosis, procedure codes and clinical trial coding mentioned above. Claims that do not include these required codes shall be rejected with the following messages:*

*CARC 50: These are non-covered services because this is not deemed a "medical necessity" by the payer.*

*RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.*

*Group Code: CO (Contractual Obligation) assigning financial liability to the provider*

*MSN 15.20: The following policies [NCD 20.33] were used when we made this decision*

*Spanish Version: MSN 15.20 - Las siguientes políticas [NCD 20.33] fueron utilizadas cuando se tomó esta decisión.*

## *340.4 - Claims Processing Requirements for TMVR for MR Services for Medicare Advantage (MA) Plan Participants*

***(Rev. 3241, Issued: 04-24-15, Effective: 08-07-14, Implementation: 04-06-15)***

*Medicare Advantage (MA) plans are responsible for payment of TMVR for MR services on behalf of MA plan participants. Medicare coverage for TMVR for MR is based on clinical trial policy in section 310.1 of the NCD Manual (Routine Costs in Clinical Trials), in section 1861(a)(1)(A) of the Social Security Act (the Act), and in section 1861(a)(1)(E) of the Act for the CED policy.*