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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-20 One-Time Notification | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 473 | Date: APRIL 24, 2009 |
| | Change Request 6326 |

Subject: Deductible Application on Clinical Trial Claims

I. SUMMARY OF CHANGES: This Change Request (CR) is updating the claims processing system to correctly apply or not apply the deductible on clinical trial claims. Deductible application for clinical trials does not apply to Managed Care beneficiaries.

Clarification

Effective Date: Dates of service on or after September 19, 2000

Implementation Date: October 5, 2009

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/revise 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 |
|-------|--|
| N/A | |

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: 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.

IV. ATTACHMENTS:

One-Time Notification

**Unless otherwise specified, the effective date is the date of service.*

Attachment – One-Time Notification

| | | | |
|-------------|------------------|----------------------|----------------------|
| Pub. 100-20 | Transmittal: 473 | Date: April 24, 2009 | Change Request: 6326 |
|-------------|------------------|----------------------|----------------------|

SUBJECT: Deductible Application on Clinical Trial Claims

Effective Date: Dates of service on or after September 19, 2000

Implementation Date: October 5, 2009

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) was recently made aware that clinical trial services provided to Medicare beneficiaries are not properly reimbursed when paid under certain payment methodologies due to deductible inadvertently being applied or in some cases not applied when it should.

B. Policy: For dates of service on or after September 19, 2000, and until notified otherwise by CMS, Medicare contractors will pay for covered clinical trial services furnished to beneficiaries enrolled in managed care plans. Medicare contractors determine payment for covered clinical trial services furnished to beneficiaries enrolled in managed care plans in accordance with applicable fee for service rules, except that beneficiaries are not responsible for the Part A or Part B deductibles (i.e., assume the Part A or Part B deductible has been met). Managed care enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules. The Medicare deductible applies to fee for service Medicare clinical trial claims.

Note: CMS will be issuing separate billing instruction that will coincide with this sensitive and controversial instruction to allow the split billing of outpatient clinical trial claims to allow proper payment and deductible application.

II. BUSINESS REQUIREMENTS TABLE

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | | |
|----------|--|---|-----------------------|---------------------------|----------------------------|------------------|------------------------------|--|--|--|-----------|--|
| | | A / B M A C | D M M A C | F I I E R | C A R I E R | R H H I | Shared-System Maintainers | | | | OTH ER | |
| | | F I S S | M I C S | V M S | C M W F | | | | | | | |
| 6326.1.1 | The CWF shall not apply the Medicare deductible to clinical trial claims containing condition code 30, secondary diagnosis code V707 and the beneficiary is enrolled in a Medicare Advantage Plan (Plan Option Code A, B, or C). | | | | | | | | | | X | |
| 6326.1.2 | The CWF shall apply the Medicare deductible to clinical trial claims containing condition code 30, secondary diagnosis code V707 and the beneficiary is | | | | | | | | | | X | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|------------|--|---|-------------|--------|---------------------------------|-------------|---------------------------|-------------|-------------|-------------|---------------------------------------|
| | | A / B | D M E | F I | C A R R I E R | R H I | Shared-System Maintainers | | | | O T H E R |
| | | | | | | | F I S S | M C S | V M S | C W F | |
| | NOT enrolled in a Medicare Advantage Plan (Plan Option Code 1, 2 or 4). | | | | | | | | | | |
| 6326.1.3 | The CWF shall apply the Medicare deductible to clinical trial claims containing condition code 30, secondary diagnosis code V707 and the beneficiary is not enrolled in a Part C Plan (Fee For Service Beneficiary). | | | | | | | | | | X |
| 6326.2 | CWF shall create a new error code to reject OPSS claims with condition code 30, with secondary diagnosis code V707, without condition code MA, and a positive GHOD file exists in CWF. | | | | | | | | | | X |
| 6326.2.1 | Based off of the CWF reject, FISS shall append condition code 'MA' to these claims. 'MA' – Managed care enrollee (verified within CWF). | | | | | | X | | | | |
| 6326.2.1.1 | FISS shall recycle claims with 'MA' payer only condition code. | | | | | | X | | | | |
| 6326.3 | The IOCE shall recognize the new payer only condition code, 'MA,' as being applicable only to claims for managed care beneficiaries. | | | | | | | | | | IOCE |
| 6326.4 | For claims with the new 'MA' payer only condition code, the IOCE shall assign Payment Adjustment Flag (PAF) #4 (Do not apply deductible) to all lines. | | | | | | | | | | IOCE |
| 6326.5 | The OPSS Pricer shall not apply deductible (i.e., assume the Part B deductible has been met) when pricing a line that is assigned a PAF #4. | | | | | | | | | | OP S P r i c e r |
| 6326.6 | The OPSS Pricer shall correctly calculate the reimbursement and coinsurance on each line that has deductible not applied (line with PAF #4 present). | | | | | | | | | | OP S P r i c e r |
| 6326.7 | The shared system maintainers shall bypass overlap edits for outpatient claims when overlapping another outpatient claim from the same provider, for the same dates of service when either the processed or suspended claim is for a clinical trial (with condition code 30 and a secondary diagnosis code of V707). | | | | | | X | | | | X |
| 6326.8 | Contractors shall adjust any claims brought to their | X | | X | | | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|--------|-------------|---|-------------|--------|---------------------------------|-------------|------------------------------|-------------|-------------|-------------|-----------|
| | | A / B | D M E | F I | C A R R I E R | R H I | Shared-System Maintainers | | | | OTH ER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| | attention. | | | | | | | | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|--------|-------------|---|-------------|--------|---------------------------------|-------------|------------------------------|-------------|-------------|-------------|-----------|
| | | A / B | D M E | F I | C A R R I E R | R H I | Shared-System Maintainers | | | | OTH ER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| | None. | | | | | | | | | | |

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements:
"Should" denotes a recommendation.

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|--|
| 6326.1.2 6326.1.3 | The following CWF edits have been identified for modification: 2216 (for outpatient claims) and 46#W (for inpatient claims). |
| 6326.2 | For purposes of this error code, only the following TOBs shall be applied: 12X, 13X and 76X. |

Section B: For all other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s):

Institutional Claims Processing:

Joe Bryson at 410-4786-2986 or joseph.bryson@cms.hhs.gov

Valeri Ritter at 410-786-8652 or valeri.ritter@cms.hhs.gov

Post-Implementation Contact(s): Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers and Regional Home Health Carriers (RHHs)*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: 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.