



Ensuring Only Clinical Trial Services Receive Fee-for-Service (FFS) Payment on Claims Billed for Managed Care Beneficiaries – JA6455

Note: MLN Matters® article MM6455 was revised to include a note, which is included on page 2 below. All other information is the same.

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Contractors Affected

- Fiscal Intermediaries (FIs)
- Part A/B Medicare Administrative Contractors (A/B MACs)

Provider Types Affected Hospitals submitting outpatient claims to Medicare FIs and A/B MACs for outpatient clinical trial services provided to Medicare beneficiaries enrolled in managed care plans



- Change Request (CR) 6455 provides additional clarification about billing and processing claims for outpatient clinical trial services to managed care enrollees.
- CR6455 updates Medicare system editing to ensure accurate billing, and ultimately correct pricing of clinical trial services provided to managed care beneficiaries.

Provider Needs to Know...

- For beneficiaries enrolled in a managed care plan, institutional providers, like hospitals, must not bill outpatient clinical trial services and non-clinical trial services on the same claim.
- If covered outpatient services unrelated to the clinical trial are rendered during the same day/stay for a Medicare managed care patient, the provider must **ONLY** bill the clinical trial services to Medicare to be processed as though the services were rendered to a Medicare FFS patient.

- This allows the Medicare claims processing system to pay for the services on a FFS-basis and not apply the deductible when the patient is found to be in a managed care plan.
- Any outpatient services unrelated to the clinical trial should be billed to the managed care plan.
- Hospitals should ensure that their billing staffs are aware of this change.
- Medicare contractors will reject line items that are not related to the clinical trial and, therefore, not payable under FFS for managed care enrollees.
- Contractors will use the following messages when line-item rejecting:
 - **Medicare Summary Notice 11.1** - "Our records show that you are enrolled in a Medicare health plan. Your provider must bill this service to the plan."
 - **Claim Adjustment Reason Code 24** – "Charges are covered under a capitation agreement/managed care plan."
 - **Group Code CO** – Contractual Obligation.

Note: Providers who are not required to report Healthcare Common Procedure Coding System (HCPCS) codes (or for revenue codes that do not require a HCPCS code) will report a Not Otherwise Classified (NOC) code when reporting lines related to the clinical trial for a managed care beneficiary. By doing so, the provider is able to report the appropriate clinical trial HCPCS modifier (Q0 or Q1) for the NOC line.

Background

- The Centers for Medicare & Medicaid Services (CMS) has recognized a need to provide additional clarification about billing and processing clinical trial services.
- Medicare policy is to pay for covered clinical trial services furnished to beneficiaries enrolled in managed care plans.
- The clinical trial coding requirements for managed care enrollee claims are the same as those for regular Medicare FFS claims.
- However, for beneficiaries enrolled in a managed care plan, institutional providers must not bill outpatient clinical trial services and non-clinical trial services on the same claim.

Operational Impact N/A

Reference Materials The related MLN Matters® article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6455.pdf> on the CMS website.

The official instruction (CR6455) issued regarding this change may be found at <http://www.cms.hhs.gov/Transmittals/downloads/R1723CP.pdf> on the CMS website.
