10.7 – Clinical Trials

(Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

10.7.1 – Payment for Services

(Rev. 121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

For clinical trials covered under the Clinical Trials National Coverage Determination 310.1 (NCD) (NCD manual, Pub. 100-03, Part 4, *section* 310), *original* Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in MA plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials. All other *original* Medicare rules apply.

Refer to the Medicare Clinical Trial Policy at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA and for more information on the definition of routine costs and the clinical trial Medicare qualification process. This policy does not withdraw Medicare coverage for items and services that may be covered according to Local Coverage Determinations (LCDs) or the regulations on category B investigational device exemptions *(IDE)* found in 42 CFR 405, Subpart B, 411.15, and 411.406. MAOs may contact the Medicare Administrative Contractor (MAC) for information about qualification and payment for clinical trial items and services.

MAOs pay the enrollee the difference between original Medicare cost-sharing incurred for qualified clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services. This cost-sharing reduction requirement

applies to all qualifying clinical trials as defined in the NCD manual, Pub. 100-03, Part 4, *section* 310.1. MAOs may not choose the clinical trial or clinical trial items and services to which this policy applies. The MAO owes the difference even if the enrollee has not yet paid the clinical trial provider. Additionally, the enrollee's in-network cost-sharing portion also must be included in the plan's out-of-pocket maximum calculation.

To be eligible for reimbursement, *an enrollee* (or providers acting on *the enrollee's* behalf) must notify their plan that *the enrollee* received *a qualified clinical trial service* and provide documentation of the cost-sharing incurred, such as a provider bill. MAOs also are permitted to seek the MA enrollee's original Medicare cost-sharing information directly from clinical trial providers.

MA enrollees are free to participate in any qualifying clinical trial that is open to beneficiaries in original Medicare. If an MAO conducts its own clinical trial, the MAO can explain to its enrollees the benefits of participating in its clinical trial; however, the MAO may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial, even if the MAO believes it is sponsoring a clinical trial of a similar nature. Examples of impediments to an enrollee's participation include, but are not limited to, requiring enrollees to pay the original Medicare cost-sharing amount for routine care services before being compensated by the MAO for the difference or unduly delaying any required cost-sharing refund. Enrollees retain the right to choose the clinical trial(s) in which they wish to participate. However, an *MAO* may request, but not require, enrollees to notify the plan in advance when they choose to participate in Medicare-qualified clinical trials.

10.7.2 – Payment for Investigational Device Exemption (IDE) Studies

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MAOs are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in CMS-approved Category A and Category B *IDE studies*. *The MAO is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage.*

CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. A listing of all CMS-approved Category A IDE studies and Category B IDE studies will be posted on the CMS Coverage webpage site located at: http://www.cms.hhs.gov/center/coverage.asp and published in the Federal Register.

10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)

(Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

In National Coverage Determinations (NCDs) requiring CED, Medicare covers items and services in CMS-approved CED studies. MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service (see 42 CFR 422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development webpage (see http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html). Billing instructions are issued for each NCD.

10.7.4 – Claims *Processing* Instructions for Clinical Studies

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Complete requirements for *claims processing* and payment *for clinical studies* may be found in the Medicare Claims Processing Manual, Transmittal *2955* (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2955CP.pdf*).