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Owner Amanda Bigler:
Manager, Clinical
Compliance
Area Clinical Services -
All
Lines Of Business D-SNP,
Medicare

Coverage of Clinical Trials (Chapter 4, Section 10.7), CL-116

Purpose:

To maintain compliance with the National Coverage Determinations (NCD) for clinical trials.

Policy:

The Health Plan navigates members enrolled in qualifying clinical trials to obtain services and understand their benefit.

Procedure:

1. For clinical trials covered under the clinical trials NCD 310.1, original Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled with The Health Plan, 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. [Medicare Chapter 4, Section 10.7](#)
2. This policy does not withdraw Medicare coverage for items and services that may be covered according to LCDs or the regulations on category B investigational device exemptions (IDE). The Health Plan may contact the Medicare administrative contractor (MAC) for information about qualification and payment for clinical trial items and services.
3. The Health Plan pays the enrollee the difference between original Medicare cost-sharing incurred for qualified clinical trial items and services and The Health 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.
4. The Health Plan does not choose the clinical trial or clinical trial items and services to which

this policy applies.

5. The Health Plan owes the difference even if the enrollee has not yet paid the clinical trial provider.
6. The enrollee's in-network cost-sharing portion also must be included in The Health Plan's out-of-pocket maximum calculation.
7. To be eligible for reimbursement, an enrollee (or providers acting on the enrollee's behalf) must notify The Health Plan that the enrollee received a qualified clinical trial service and provide documentation of the cost-sharing incurred, such as a provider bill.
8. The Health Plan is permitted to seek the enrollee's original Medicare cost-sharing information directly from the clinical trial providers.
9. The Health Plan's enrollees are free to participate in any qualifying clinical trial that is open to beneficiaries in original Medicare.
10. The Health Plan does not require prior authorization for participation in a Medicare-qualified clinical trial.
11. The Health Plan does not require enrollees to pay the original Medicare cost-sharing amount for routine care services before being compensated by The Health Plan for the difference or unduly delaying any required cost-sharing refund.
12. Enrollees have the right to choose the clinical trials(s) in which they want to participate.
13. The Health Plan may request, but not require, enrollees to notify The Health Plan in advance when they choose to participate in Medicare qualified clinical trials..

All Revision Dates

10/28/2022, 11/18/2021, 8/21/2020, 8/27/2019, 11/1/2016

Approval Signatures

Step Description	Approver	Date
EMT	Jeff Knight: President & CEO	10/25/2023
MDOC	Robert Cross: Medical Director	10/25/2023
	Heather Jones: Director, Utilization Management	9/25/2023
	Amanda Bigler: Manager, Clinical Compliance	9/20/2023