



CLINICAL TRIAL POLICY

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CMS Clinical Trial Policy

BACKGROUND

- **Executive Memorandum, June, 2000**
- **National Coverage Determination (NCD), September, 2001**
- **Reconsideration completed, October, 2007**

CMS Clinical Trial Policy

GOALS

- Allow Medicare beneficiaries to **participate** in research studies;
- Encourage the conduct of research studies that **add to the knowledge base** about the efficient, appropriate, and effective use of products and technologies in the **Medicare population**, thus improving the quality of care that Medicare beneficiaries receive; and,
- Allow Medicare beneficiaries to receive care that may have a health benefit, but for which **evidence for the effectiveness of the treatment or service is insufficient to allow for full, unrestricted coverage.**

CMS Clinical Trial Policy

OVERVIEW

- **Covered items & services**
 - Routine costs (clinical care)
 - Benefit Category
- **Non-covered items and services**
 - Specific technology being investigated
 - Completion of case report forms
 - If provided free of charge to any subjects
 - Excludes indigent patients
- **Reconsideration, October, 2007**
 - Coverage with Evidence Development (CED)
 - Investigational item that is currently covered

CMS Clinical Trial Policy

OVERVIEW

- **Co-pays in fee-for service plans**
 - 20% co-pay applicable
- **Co-pays in Medicare Advantage Organization (MAO) Plans**
 - 20% co-pay applicable (since providers are paid on a fee-for-service basis)
- **How co-pays affect enrollment, retention, and generalizability**
 - Under-represents beneficiaries enrolled in MAO plans
 - Impairs masking of subjects and providers if co-pays differ between the investigational items and services

Clinical Trials Covered Under the Medicare Anti-Cancer NCD

- **January 28, 2005 NCD No. CAG-00179N**
- **Covers the off-label use of anti-cancer drugs**
- **Nine specific NCI sponsored clinical trials**
- **Investigational drugs**
 - **Oxaliplatin (Eloxatin™)**
 - **Ironotecan (Camptosar®)**
 - **Cetuximab (Erbix™)**
 - **Bevacizumab (Avastin™)**

Clinical Trials Covered Under the Medicare Anti-Cancer NCD

- **Pilot Project**
 - **Actively working to assist NCI in developing tools for investigators to assure consistency in Medicare coverage across the country.**
- **Coordination between the Agencies**
 - **Billing instructions for investigators**
 - **Claims processing instructions for Medicare contractors**

Clinical Trials

<u>Study ID (Phase)</u>	<u>Cancer Type</u>
C80405 (III)	Colon
E2204 (II)	Pancreatic
E4203 (II)	Colorectal
E5202 (III)	Colon
E5204 (III)	Rectal
NSABP-R-04 (III)	Rectal
RTOG-0522 (III)	Head & Neck
S0502 (III)	Gastrointestinal
7325 (I/II)	Colorectal/Solid Tumors

CLINICAL TRIAL ENROLLMENT

Study ID	Maximum Planned Accrual	Total Accrual (as of 3/31/08)	Total subjects > 64 years old (%)
C80405	2,289	1,279	444 (34.7)
E2204	126	130	45 (34.6)
E4203	246	108	38 (35.2)
E5202	3,610	1,041	387 (37.2)
E5204	2,100	184	24 (13)
NSABP-R-04	1,606	851	246 (28.9)
RTOG-0522	720	503	109 (21.7)
S0502	572	Opened 4/15/08	-
7325	50	8	2 (25)

ENROLLMENT by AGE & USE of MEDICARE

Study ID	Total Accrual (as of 3/31/08)	Total subjects Medicare eligible (%)	Total Medicare subjects using Medicare
C80405	1,279	444 (34.7)	371
E2204	130	45 (34.6)	34
E4203	108	38 (35.2)	24
E5202	1,041	387 (37.2)	277
E5204	184	24 (13)	20
NSABP-R-04	851	246 (28.9)	175
RTOG-0522	503	109 (21.7)	98
S0502	Opened 4/15/08	-	-
7325	8	2 (25)	0

Trial Accrual of Medicare Subjects by Ethnicity/Race

Study ID	Hispanic/Latino	Black/African American	Total Medicare eligible subjects
C80405	24	39	444
E2204	2	4	45
E4203	2	4	38
E5202	21	20	387
E5204	0	1	24
NSABP-R-04	8	7	246
RTOG-0522	4	4	109
S0502	Opened 4/15/08	-	-
7325	0	1	2

Trial Accrual of Medicare Subjects

- Enrollment occurred between 2004 and 2008
- Maximum planned accrual = 11,319
- Accrual as of March 31, 2008 = 4104
- Accrual of Medicare Subjects = 1,295
- 31.6% of the subjects are 65 years of age and older (Medicare eligible)
- Only 999 (77.1%) of the Medicare subjects are using Medicare for payment
- Medicare is paying the clinical costs of 24.3% of subjects enrolled thus far (999 of 4104)

NCI AND MEDICARE

- <http://www.cancer.gov/clinicaltrials/developments/NCD179N>
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