

# CMS-NCI Oncology Pilot Project

## CMS National Coverage Decision (NCD) Anticancer Chemotherapy for Colorectal Cancer

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## CMS-NCI Oncology Pilot Project

- Background / Rationale for the Pilot Project
- Trials Selected & Dissemination of Information
- Update on trial accrual and Medicare beneficiary participation
- NCI Clinical Trial Information & Resources

# CMS-NCI Oncology Pilot Project

- Anti-cancer chemotherapeutic agents are eligible for coverage by CMS:
  - Used in accordance with **FDA-approved labeling** (section 1861(t)(2)(B) of the Social Security Act)
  - Off-label use in **authoritative drug compendia** listed in section 1861(t)(2)(B)(ii)(I) of the Social Security Act
  - **Medicare contractor determines an off-label use** is medically accepted based on guidance provided by the Secretary (section 1861(t)(2)(B)(ii)(II))

# CMS Coverage of Clinical Trials

	CMS 2000 Clinical Trials Policy	CMS 2005 Anti-Cancer NCD
What kinds of costs are covered?	<b>Routine costs</b> associated with the patients' medical care in the clinical trial.*	<b>Both routine and non-routine costs</b> associated with the patients' care in any of the nine trials are covered.
Does the policy pay for off-label use of anti-cancer drugs?	<b>Maybe.</b> Coverage of off-label use varies depending on whether the trial in question meets the policy's requirements.	<b>Yes,</b> off-label use is covered for the anticancer drugs in all nine trials.

\* More info at: [www.cms.hhs.gov/ClinicalTrialPolicies](http://www.cms.hhs.gov/ClinicalTrialPolicies)

## CMS-NCI Pilot: Inception of the Project

CMS and NCI entered into discussions to explore how the 2 agencies could align their resources & agency-specific goals to accelerate development of evidence for emerging cancer treatment regimens:

*CMS can collect data to see if reasonable and necessary criteria are met for off-label use of agents (data collected to inform payment decisions)*

*NCI sponsors trials as part of its research agenda to evaluate use of new agents in off-label indications in order to determine safety & efficacy*

Through discussions, proposed approach linking coverage to participants in specific trials developed

## CMS-NCI Pilot: Goals of the Project

- Offer consistent national coverage for these trials
- Ensure advancement in knowledge for these agents
- Accelerate development evidence for new / emerging cancer treatments
- Ensure beneficiaries rapid access to promising new uses of technologies under controlled clinical trial conditions
- Serve as potential model for additional coverage expansions in clinical trials for other anti-cancer agents by both CMS & other insurance carriers
- Encourage industry to invest in clinical studies that will expand knowledge base

## CMS-NCI Pilot: Why these Trials?

- CMS asked NCI to identify trials studying off-label uses of 4 agents important in CRC per the existing NCD for Anticancer Chemotherapy for Colorectal Cancer
  - 4 agents: oxaliplatin, irinotecan, bevacizumab, cetuximab
  - Trials with any of these agents in CRC & other cancers
  - Mix of Phase 1, 2, and 3 trials
  - Trials addressing questions likely to lead to important changes in therapy
  - Trials that were close to activating

# CMS-NCI Pilot: 9 Selected Trials

9 Trials Selected: 6 Colorectal and 3 Non-Colorectal

Phase 1/2	7325:	1 <sup>st</sup> Line Metastatic CRC (CWRU)
Phase 2	E4203:	1 <sup>st</sup> Line Metastatic CRC
Phase 3	E5202:	High-Risk Stage II Colon Cancer
	C80405:	1 <sup>st</sup> Line Metastatic CRC
	NSABP R-04:	Rectal Ca Adjuvant (Oxaliplatin Amend)
	E5204:	Rectal Ca Adjuvant
Phase 2	E2204:	Pancreatic Ca Adjuvant
Phase 3	RTOG-0522:	Stage III/IV Head & Neck Cancer
	S0502:	Metastatic / Unresectable GIST

## CMS-NCI Pilot: Dissemination of Information

- Web page updates of trial information on a regular basis
- Increasing awareness of these trials in conjunction with effort on promoting clinical trials awareness and understanding, including partnering with national colorectal cancer advocacy groups
  - Colon Cancer Alliance (CCA)
  - Colorectal Cancer Coalition (C3)
- Using various publications to highlight this pilot project and enhance participation of people > 65 years of age into these trials

# CMS-NCI Pilot: Study Reimbursement Matrix Example (copy in handouts)

**SUMMARY REIMBURSEMENT MATRIX FOR:**  
**NSABP R-04 AFTER Amendment #2 - Phase III Study of Preop XRT and Capecitabine +/- Oxaliplatin vs Preop XRT and CVI 5-FU +/- Oxaliplatin For Resectable Rectal Cancer**  
 (Matrix Version: 2/3/06)

Study Agents	Agent Distribution & Timing of Test	Pharmaceutical/ Biotechnology Sponsor	Study Coverage	Medicare Coverage
Capecitabine (oral agent)	NSABP / Fisher Clinical Services	Yes (100%) Roche	N/A	No (funded by study)
5-Fluorouracil (IV)	Commercial	N/A	N/A	Yes
Oxaliplatin (IV)	NSABP / Fisher Clinical Services	Yes (100%) Sanofi-Aventis	N/A	No (funded by study)
Miscellaneous drugs - treatment support - IV medications	Commercial	N/A	N/A	Yes
Miscellaneous drugs - oral antiemetic agents given per Medicare Part B regulations only or oral agents given during an in-patient hospitalization	Commercial	N/A	N/A	Yes (per Medicare Part B only)
Miscellaneous drugs - oral prescription drugs per Medicare Part D regulations only	Commercial	N/A	N/A	Yes (per patient's Medicare Part D plan only -- special billing codes for this NCD do not apply to Medicare Part D)
<b>Pre-treatment and Randomization Tests</b>				
History / Physical Exam	Within 6 weeks of enrollment	N/A	N/A	Yes
CBC and WBC with differential; platelets	Within 6 weeks of enrollment	N/A	N/A	Yes
Bilirubin, AST, serum creatinine, alk phosphatase; creatinine clearance	Within 6 weeks of enrollment	N/A	N/A	Yes
CXR or thoracic CT scan	Within 6 weeks of enrollment	N/A	N/A	Yes
CT scan or MRI (abdomen & pelvis)	Within 6 weeks of enrollment	N/A	N/A	Yes
Complete colonoscopic exam; proctoscopy or sigmoidoscopy; transrectal US	Within 6 weeks of enrollment	N/A	N/A	Yes
RT simulation and field verification films	Prior to initiation of radiotherapy	N/A	N/A	Yes
QOL questionnaire	After consent & prior to randomization	Yes	N/A	No (funded by study)
Collection and preparation of clinical tissue from diagnostic biopsy	After registration & prior to initiation of therapy	N/A	N/A	Yes
Shipping of clinical tissue collected from diagnostic biopsy	N/A	N/A	Yes	No (funded by study)
<b>Research Tests</b>				
1. Collection, preparation, and shipping of serum. 2. Preparation and shipping of tissue samples in paraffin blocks for research. 3. Collection, preparation, and shipping of tissue in RNA later. 4. Research tests on tissue and blood at Central Labs (non-routine).	Collection/preparation and shipping of specimens after registration & prior to initiation of therapy and after completion of treatment and prior to surgery; the multiple research tests will be performed at Central Labs	Yes	Yes	No (funded by study)
<b>Treatment Tests and Physician Visits (including Follow-Up Tests/ visits)</b>				
History / Physical Exam, drug toxicity and AE assessment	Per Study Calendar	N/A	N/A	Yes
CBC with diff and platelets; total bilirubin (plus direct and indirect bilirubin, if needed); serum creatinine; AST, alkaline phosphatase	Per Study Calendar	N/A	N/A	Yes
CT scan or MRI of tumor/primary site	Per Study Calendar	N/A	N/A	Yes
Radiation Therapy Port Films and Radiation Therapy per protocol	Per Treatment Schedule	N/A	N/A	Yes
IV administration of study agents & all other clinical care, including laboratory tests and imaging studies, needed to provide study treatment per protocol specifications as well as to treat adverse events related to study treatment, including hospitalizations.	Per Treatment Schedule/ Study Calendar and as clinically indicated	N/A	N/A	Yes
Surgery	Per Study Calendar	N/A	N/A	Yes
Collection and preparation of clinical tissue during surgery	At time of surgery	N/A	N/A	Yes
Proctoscopy or sigmoidoscopy post-operatively in years 2 and 3	Per Study Calendar	Yes	N/A	No (funded by study)
QOL questionnaire	Per Study Calendar	Yes	N/A	No (funded by study)

## CMS-NCI Trial Accrual Data (all 9 trials)

Trial activation dates	1st trial activated July 2004 and 9 <sup>th</sup> trial in April 2008
Maximum planned accrual as described in each trial	11,271
Total accrual as of April 1, 2009	6,059 (54% of total accrual)
Accrual of patients age >64 (Medicare eligible)	1,873 (31%)
Medicare eligible using Medicare as a Method of Payment	1,405 (23%)
Medicare eligible using Medicare for payment in trials	75% (1,405 of 1,873)

# Clinical Trial Enrollment (as of 3/31/09)

NCI Trial # (Cancer Type)	Total Accrual (Planned)	Total Accrual > age 64 (%)
7325 (CRC)	11 (50)	4 (36%)
C80405 (CRC)	1484 (2016)	510 (34%)
E2204 (Pancreatic)	137 (126)	45 (33%)
E4203 (CRC)	126 (246)	46 (37%)
E5202 (CRC)	1808 (3610)	669 (37%)
E5204 (Rectal)	344 (2100)	56 (16%)
NSABP-R-04 (Rectal)	1201 (1606)	349 (29%)
RTOG-0522 (H & N)	942 (945)	193 (20%)
S0502* (GI Stromal)	6 (572)	1 (17%)

\* Trial activated April 2008

Trials in blue are open to accrual

## CMS-NCI Pilot: Information on Project

- CMS website information on the project for public
  - [http://www.cms.hhs.gov/mcd/index\\_list.asp?list\\_type=ncd](http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd)
  - NCD for Anti-Cancer Chemotherapy for Colorectal Cancer (110.17)
- CMS website information on project for Medicare Providers (MedLearn Matters)
  - <http://www.cms.hhs.gov/MedlearnMattersArticles/downloads/MM3742.pdf>
- CMS website information on business requirements for billing offices (Change Request 3742 in Transmittal 588 of Medicare Pub. 100-04, Medicare Claims Processing):
  - <http://www.cms.hhs.gov/transmittals/downloads/R588CP.pdf>
- NCI web page with information on this project:
  - <http://www.cancer.gov/clinicaltrials/developments/NCD179N>

## NCI Clinical Trials Information & Resources

- Search NCI's clinical trials database at:
  - <http://www.cancer.gov/clinicaltrials/search>
- Clinical trial information, education, & results:
  - <http://www.cancer.gov/clinicaltrials>
- Get live, online assistance from the NCI's LiveHelp service for clinical trials or cancer information:
  - <https://cissecure.nci.nih.gov/livehelp/welcome.asp>
- Toll-free phone assistance for clinical trials and cancer information via NCI's Cancer Information Service at:
  - 1-800-4-CANCER (1-800-422-6237)
  - <http://www.cancer.gov/help>

## NCI Clinical Trial Training

- Provided clinical trials training to DoD TRICARE contractors to help them search NCI trials database and better understand cancer trials as their health care benefits provide prospective coverage of NCI-sponsored cancer prevention and treatment trials for TRICARE beneficiaries.
- Future training planned for DoD TRICARE contractors - date not set yet, so if Medicare contractors wish to send staff to free NCI training, please send email to:
  - Andrea Denicoff, RN, MS, ANP at the NCI at
  - Email: [denicofa@mail.nih.gov](mailto:denicofa@mail.nih.gov)
  - Phone: 301-496-2522

## References

- Murthy, VH, et al (2004). Participation in Cancer Clinical Trials: Race, Sex, and Age-Based Disparities. *JAMA*, 291 (22), 2720-2726.
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- Unger, JM, et al (2006). Impact of the Year 2000 Medicare Policy Change on Older Patient Enrollment to Cancer Clinical Trials. *JCO*, 24 (1), 141-144.