

CMS-NCI Oncology Pilot Project

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

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Note - representatives from the U.S. Food and Drug Administration and cancer advocates participate in meetings on an ad-hoc basis

- Background / Rationale for the Pilot Project**
- Trials Selected**
- Coverage to be Provided**
- Dissemination of Information**

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-NCI Pilot: Existing Cost Coverage

Routine Cost Coverage in Trials per Current Medicare NCD for Clinical Trials (Sept. 2000)

NOT Covered

- Investigational item itself
- Items provided solely to satisfy data collection and analysis (e.g., monthly CT scans for condition usually requiring a single scan)
- Items & services usually provided by research sponsors free of charge

Covered

- Conventional care
- Items/services required solely for provision of the investigational item & clinically appropriate monitoring or prevention of complications
- Items needed for reasonable and necessary care arising from the provision of an item or service (e.g., complications)

CMS-NCI Pilot: Issues with Current NCD Clinical Trials Coverage



- **Regional variability in interpretation of routine costs by local contractors**
- **Cost of anti-cancer drugs for off-label indications is determined by local contractors**
- **Non-routine costs are not covered**
- **Not associated with particular trials, but class of qualifying trials (although NIH trials are automatically qualified)**

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 specific 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 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 nearly ready to begin patient enrollment**

9 Trials Selected: 6 Colorectal and 3 Non-Colorectal

CMS-NCI Pilot: 6 Colorectal Trials

Phase 1/2	7325:	1st Line Met CRC (CWRU)
Phase 2	E4203:	1st Line Met CRC
Phase 3	E5202:	High-Risk Stage II Colon
	C80405:	1st Line Met CRC
	NSABP R-04:	Rectal Adjuvant (Oxaliplatin Amendment)
	E5204:	Rectal Adjuvant

CMS-NCI Pilot: 3 Non-Colorectal Trials



Phase 2 **E2204:** **Pancreatic Adjuvant**

Phase 3 **RTOG-0522:** **Stage III/IV Head & Neck**

S0502: **Metastatic / Unresectable
GIST**

CMS-NCI Pilot: Coverage for Project

All routine & non-routine costs associated with these trials as long as a “benefit category” exists & item is not prohibited by statute or national non-coverage decision

- Coverage by national decision**
- ↓ variability by regional contractors**
- Includes tests / evaluations for pretreatment & randomization tests to support eligibility**
- Includes treatments, all on-going tests / imaging evaluations during therapy and follow-up, as well as complications from treatment**

CMS-NCI Pilot: Coverage for Project

- ❑ **Special code modifiers to be used for claims processing for these specific trials:**
 - QV for routine costs,
 - QR for non-routine costs
 - V70.7 after dx to indicate trial covered by CMS NCD
- ❑ **Billing algorithm simplified (depend on appropriate cancer dx, not how frequently test is being ordered); CMS acceptance bill should be quick**
- ❑ **Self-administered questionnaires (item without a “benefit category”) could be covered as a bundled benefit under a Comprehensive Visit**
- ❑ **Co-pays cannot be waived by CMS**

CMS-NCI Pilot: CMS Information on Project



- CMS website information on the project for public**
http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd
NCD for Anti-Cancer Chemotherapy for Colorectal Cancer (110.17)

- Monthly Conference Calls with CMS Contractor Medical Directors**

- CMS website information on project for Medicare Providers (MedLearn Matters)**
<http://www.cms.hhs.gov/medlearn/matters/mmarticles/2005/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/manuals/pm_trans/r588cp.pdf

- CMS national meetings with CMS Regional Contractors**

CMS-NCI Pilot: NCI & Cooperative Groups Information on Project



- General Information Sheet for Physicians being created with protocol-specific reimbursement matrix; including links to CMS Reference materials**
- General Information Sheet for Patients being developed**
- General Information Sheet also to help patients referred to another physician or center for protocol tests (on any of the 9 trials) get the tests coded & billed appropriately**
- Add information to NCI & Cooperative Group websites**
- Information exchange with ASCO, ACCC, other organizations**

Study #	Study Title	Phase	Study Status (Sept. 1, 2005)	Anticipated Date for Study to Open	Location of Participating Sites
C80405	Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab, or Cetuximab, or with the combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum	Phase 3	Protocol Approved – Study to open Sept 2005	Sept 2005	Nationwide
E2204	An Intergroup Randomized Phase II Study of Bevacizumab or Cetuximab in Combination with Gemcitabine and in Combination with Chemoradiation (Capecitabine and Radiation) in Patients with Completely-Resected Pancreatic Carcinoma	Randomized Phase 2	Protocol in Review	Fall 2005	Limited Regions
E4203	Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer	Randomized Phase 2	Study Open	July 14, 2005	Limited Regions
E5202	Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers	Phase 3	Study Open	August 4, 2005	Nationwide
E5204	Intergroup Randomized Phase III Study of Post-Operative Oxaliplatin, 5-Fluorouracil and Leucovorin with or without Bevacizumab in Patients with Stage II or III Rectal Cancer Receiving Pre-Operative Radiation and a 5-Fluorouracil-Based Regimen	Phase 3	Protocol in Development	Winter 2005	Nationwide
NSABP-R-04	A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum	Phase 3	Open study - Amendment Approved – Opening of Study Amendment Pending	Fall 2005	Nationwide
RTOG-0522	Phase III Trial of Concurrent Accelerated Radiation & Cisplatin vs Concurrent Accelerated Radiation, Cisplatin, & Cetuximab (Followed by Surgery for Selected Patients) for Stage III & IV Head & Neck Carcinomas	Phase 3	Protocol Under Review at Central IRB	Fall 2005	Nationwide
S0502	Phase III Randomized Study of Imatinib, with or without Bevacizumab, in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors	Phase 3	Protocol in Review	Fall 2005	Nationwide
7325	Dose-Dense and Dose-Intense Alternating Irinotecan/Capecitabine & Oxaliplatin/Capecitabine: Phase I in Solid Tumors and Phase II with Bevacizumab as First-Line Therapy of Advanced Colorectal Cancer	Phase 1/2	Protocol in Review	Fall 2005	Single Institution

CMS-NCI Pilot



Updated Trial List with Status

Studies in various stages of development

NCAB Meeting – Sept 20, 2005