CMS-NCI Oncology Pilot Project

CMS National Coverage Decision (NCD) for Colorectal Cancer

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Cancer Care Delivery Systems
Note - representatives from the U.S. Food and Drug Administration and cancer advocates participate in meetings on an ad-hoc basis
CMS-NCl Oncology Pilot Project

- 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)

NCAB Meeting – Sept 20, 2005
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 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

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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**

<table>
<thead>
<tr>
<th>Phase 1/2</th>
<th>7325:</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; Line Met CRC (CWRU)</th>
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<tbody>
<tr>
<td>Phase 2</td>
<td>E4203:</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; Line Met CRC</td>
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<tr>
<td>Phase 3</td>
<td>E5202:</td>
<td>High-Risk Stage II Colon</td>
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<tr>
<td></td>
<td>C80405:</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; Line Met CRC</td>
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<td>NSABP</td>
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<td>R-04: Rectal Adjuvant</td>
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<td></td>
<td></td>
<td>E5204: Rectal Adjuvant</td>
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</tbody>
</table>

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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
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-NCl 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 Mattters)

- CMS website information on business requirements for billing offices (Change Request 3742 in Transmittal 588 of Medicare Pub. 100-04, Medicare Claims Processing):

- CMS national meetings with CMS Regional Contractors

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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

NCAB Meeting – Sept 20, 2005
<table>
<thead>
<tr>
<th>Study #</th>
<th>Study Title</th>
<th>Phase</th>
<th>Study Status (Sept. 1, 2003)</th>
<th>Anticipated Date for Study to Open</th>
<th>Location of Participating Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>C80405</td>
<td>Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab or Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum</td>
<td>Phase 3</td>
<td>Protocol Approved – Study to open Sept 2005</td>
<td>Sept 2005</td>
<td>Nationwide</td>
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<tr>
<td>E2204</td>
<td>An Intergroup Randomized Phase II Study of Bevacizumab or Cetuximab in Combination with Gemcitabine and in Combination with Chemoradiation (Capetabine and Radiation) in Patients with Completely-Resected Pancreatic Carcinoma</td>
<td>Randomized Phase 2</td>
<td>Protocol in Review</td>
<td>Fall 2005</td>
<td>Limited Regions</td>
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<tr>
<td>E4203</td>
<td>Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer</td>
<td>Randomized Phase 2</td>
<td>Study Open</td>
<td>July 14, 2005</td>
<td>Limited Regions</td>
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<tr>
<td>E5202</td>
<td>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</td>
<td>Phase 3</td>
<td>Study Open</td>
<td>August 4, 2005</td>
<td>Nationwide</td>
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<tr>
<td>E5204</td>
<td>Intergroup Randomized Phase III Study of Post-Operative Oxaliplatin, S-Fluorouracil and Leucovorin with or without Bevacizumab in Patients with Stage II or III Rectal Cancer Receiving Pre-Operative Radiation and a S-Fluorouracil-Based Regimen</td>
<td>Phase 3</td>
<td>Protocol in Development</td>
<td>Winter 2005</td>
<td>Nationwide</td>
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<tr>
<td>NSABP-R-04</td>
<td>A Clinical Trial Comparing Preoperative Radiation Therapy and Capetabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion S-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum</td>
<td>Phase 3</td>
<td>Open study - Amendment Approved – Opening of Study Amendment Pending</td>
<td>Fall 2005</td>
<td>Nationwide</td>
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<tr>
<td>RTOG-0522</td>
<td>Phase III Trial of Concurrent Accelerated Radiation &amp; Cisplatin vs Concurrent Accelerated Radiation, Cisplatin, &amp; Cetuximab (Followed by Surgery for Selected Patients) for Stage III &amp; IV Head &amp; Neck Carcinomas</td>
<td>Phase 3</td>
<td>Protocol Under Review at Central IRB</td>
<td>Fall 2005</td>
<td>Nationwide</td>
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<tr>
<td>S0502</td>
<td>Phase III Randomized Study of Imatinib, with or without Bevacizumab, in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors</td>
<td>Phase 3</td>
<td>Protocol in Review</td>
<td>Fall 2005</td>
<td>Nationwide</td>
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<tr>
<td>7325</td>
<td>Dose-Dense and Dose-Intense Alternating Irinotecan/Capetabine &amp; Oxaliplatin/Capetabine: Phase I in Solid Tumors and Phase II with Bevacizumab as First-Line Therapy of Advanced Colorectal Carcinoma</td>
<td>Phase 1/2</td>
<td>Protocol in Review</td>
<td>Fall 2005</td>
<td>Single Institution</td>
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