Kaiser Permanente's Experience in Coverage and Conduct of Oncology Clinical Trials

IOM/ASCO Implementation Planning Workshop

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March 21, 2011

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Kaiser Permanente: Coverage and Conduct of Clinical Trials Overview

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- Largest private integrated delivery system in the US
- Not-for-profit Health Plan, 31 not-for-profit community hospitals
- 15,000 Permanente physicians, organized in 8 Permanente Medical Groups, in a mutually exclusive partnership and contractual relationship with Kaiser Foundation Health Plan and Hospitals
- 8.8 million members, in 8 states and District of Columbia (>2.5% of the US pop)
- As health plan/insurer, KP meets and often exceeds industry standard and jurisdictional requirements re coverage for clinical trials (table attached).
- As a care delivery system, well positioned to accrue patients for clinical trials, and conduct clinical trials
  - Heterogeneous, ethnically diverse patient population representative of the US Census population at large
  - Direct access to stable, remarkably loyal patient population and their physicians
  - Multispecialty group practice with fully-dedicated oncologists
  - Substantial investment in clinical trials infrastructure, data systems,
  - Unified EMR/EHR with complete capture of prescribed, dispensed and administered meds

- Jurisdictional requirements form the basis of minimum coverage for Clinical Trials
- Kaiser Permanente provides coverage for “Routine Care” generally defined as care that would be covered for non Clinical Trial procedures and services (e.g. laboratory, x-ray, office visits)
- Kaiser Permanente provides coverage of clinical trials with therapeutic value, not those intended to evaluate the safety, toxicity or efficacy of the Service
- In some cases, Kaiser Permanente provides coverage that exceeds jurisdictional requirements:
  - KP provides coverage for clinical trials beyond cancer.
  - KP California regions covers phases I-IV as long as trial meets other criteria
  - KP California regions provide coverage for travel in some circumstances

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Summary of Coverage by KP Region

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	Jurisdictional Requirements	KP EOC Language (Summarized)
California	▪ California Health and Safety Code 1370.6 – Clinical trials for Members diagnosed with cancer and accepted into a Phase I, II, III or IV clinical trial for cancer. Coverage applies to "routine patient care costs related to the clinical trial," as defined.	▪ Phase I, II, III, or IV clinical trial for cancer when referred by Plan Physician, or Non–Plan Physician ▪ Routine services that would be covered if they were not provided in connection with a clinical trial ▪ Clinical trial has a therapeutic intent ▪ Involves a drug that is exempt under federal regulations from a new drug application, or trial is approved by designated agency
Northwest	▪ OR: NA ▪ WA: NA	▪ Routine care costs not provided by the clinical trial (x-rays, doctor visits, lab tests, etc) when plan physicians provide or arrange for care
Colorado	▪ Based on legislation that was introduced and passed during the 2009 session	▪ Cover routine patient care costs while the covered person participates in a clinical trial ▪ Routine patient care cost means all items and services that are a benefit under a health coverage plan that would be covered if the covered person were not involved in either the experimental or the control arms of a clinical trial

Regional Comparison for Coverage of Clinical Trials

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	Jurisdictional Requirements	KP EOC Language (Summarized)
MAS/DC	▪ D.C. code 31-2993.02 – Must cover routine patient care costs of a health care ervice, item or drug for qualified member participating in an approved clinical trial if the service, item or drug would have been covered outside of a clinical trial setting	▪ Routine patient care for an approved clinical trial undertaken for the purposes of the prevention, early detection, treatment, or monitoring of cancer, chronic disease, or life-threatening illness
MAS/MD	▪ MD Ins. Code 15-827; MD Code, Health – Gen. 17-706 (aa) Member's costs in a clinical trial as a result of: 1) treatment provided for a life-threatening condition; or 2) prevention, early detection, and treatment studies on cancer	▪ Routine in-patient and out-patient costs ▪ Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer or any other life-threatening condition ▪ "Patient costs" mean the cost of a medically necessary Service that is incurred as a result of the treatment being provided to the member for purposes of the clinical trial
MAS/VA	▪ Code of VA 38.2-3418.8 and 38.2-4319. Patient's costs, as specified, incurred during participation in clinical trials for treatment studies on cancer, including ovarian cancer trials.	▪ Routine in-patient and out-patient costs ▪ Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer or any other life-threatening condition ▪ "Patient costs" mean the cost of a medically necessary Service that is incurred as a result of the treatment being provided to the member for purposes of the clinical trial

Regional Comparison for Coverage of Clinical Trials

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	Jurisdictional Requirements	EOC Language (Summarized)
Georgia	▪ Required to provide coverage for "routine patient care costs" associated with "approved clinical trial programs" for the treatment of children's cancer. Approved clinical trial programs are Phase II and Phase III prescription drug clinical trials located in Georgia, as approved by the FDA or the National Cancer Institute for the treatment of cancer in children (underage 19) only.	▪ Phase I, II, III, or IV clinical trial for cancer ▪ Routine services that would be covered if they were not provided in connection with a clinical trial ▪ Clinical trial has a therapeutic intent ▪ Involves a drug that is exempt under federal regulations from a new drug application, or trial is approved by designated agency
Ohio	▪ ORC 3923.80: Routine care for patients enrolled in eligible cancer clinical trials	▪ Routine Patient Care associated with an "Eligible Cancer Clinical Trial" ▪ Routine services that would be covered if they were not provided in connection with a clinical trial ▪ Authorized by a Plan Physician. "Routine Patient Care" ▪ Specific exclusions for travel/lodging and other services/items
Hawaii	▪ NA	▪ Routine services that would be covered if they were not provided in connection with a clinical trial ▪ Excludes Experimental or investigational Services: Defines as services provided as part of a Phase I or Phase II clinical trial, as the experimental or research arm of a Phase III clinical trial, or in any other manner that is intended to evaluate the safety, toxicity, or efficacy of the Services.

KP Unique Assets for Conduct of Oncology Clinical Trials

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- Community based, reflecting US population and not a selected cohort of high economic, social and educational status
- Diversity- NCAL and most sites have ≥25-30% minority accrual, 30% ≥65 yo
- Same EMR, including national Chemorx order sets
- Excellent long term follow up rates
- Excellent access and submission for tissue banks/libraries
- Commitment to Phase III NCI trials,(represents >75% of patients enrolled in OCT)
- Committed >100 FTEs to OCTs Conduct
- Budgets >10 million dollars for OCTs Staff
- Enrolled 660 pts/yr to NCI Co-op Phase II, III
- Follow over 4,000 active patients on OCTs, the vast majority NCI Co-op patients

Kaiser Permanente Regions
Active in NCI Cooperative Group Treatment Trials

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- KP Northern California, Southern California , Northwest (Oregon and Washington)
- KP Colorado, Hawaii, Mid-Atlantic (Maryland, Virginia and the District of Columbia

KP Regions' New Accrual to NCI Cooperative Groups Treatment Trials in 2009

KPSC	144
KPNW	53
KPNC	359
KPColo	79
KPHawaii	7
KPMidAtlantic	18
Total	660

- No Academic Medical Center in 2009 enrolled more than 139 patients into the NCI Cooperative group SWOG/CTSU plus NSABP solely from the AMC (only with added totals of community affiliates)

KP Regions Access to NCI Cooperative Groups

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- **KPNorCal**- Main member NSABP, Main member SWOG, CTSU, Affiliate RTOG
- **KPSoCal**- Main member NSABP, affiliate in SWOG with KPNC, CTSU
- **KP Colorado-** Affiliate in NSABP+SWOG with KPNC, CTSU
- **KP Hawaii-** Affiliated with KPNC in NSABP and SWOG, CTSU
- **KPNW**- Member CCOP, NorthWest CCOP
- **KP MidAtlantic-** In Development

- **NSABP-**
  - KPNCAL Main Member with KPCOL, KPHawaii
  - KPSCAL Main Member
  - KPNW CCOP Member
  - KPMAS CTSU Member
- **SWOG-**
  - KPNCAL Main Member with KPCol, KPHawai, KPSCal affiliates
  - KPNW CCOP Member

KP Regions Individually Establish Coverage Policies for Out-of-Plan OCT Coverage

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- Routine care covered, and patient referred to out-of-plan Oncology Clinical Trial, if:
  - Treating physician feels trial has reasonable potential to benefit the patient compared to standard treatment offered
  - Trial is a quality trial with qualified investigators
  - Goal of trial is not primarily to determine toxicity or dosing
  - Internal KP trial not available, or less beneficial

KP/NCI Opportunities for Enhanced Participation in OCT

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- Assist Integrated Care Delivery Systems (like KP) and/or developing Accountable Care Organizations to develop OCT programs and to enroll patients into NCI Cooperative Group trials:
  - Provide adequate support (currently 20% of cost)
  - Reward/recognize OCT enrolling physicians in community or in academia
  - Streamline review regulatory processes
  - De emphasize redundant slow accruing single site phase II trials that compete with important phase III national trials. Incent AMCs to increase NCI Cooperative Group enrollment