HL7® FHIR® CodeX Listening Session: Oncology Clinical Pathways and Prior Authorization

June 26, 2020
Agenda

01 Introduction
5 minutes
Steve Bratt, PhD
FHIR™ CodeX Accelerator Lead, MITRE

02 Health System Perspective
15 minutes
Larry Shulman, MD
Deputy Director for Clinical Services, Abramson Cancer Center, University of Pennsylvania
Peter Gabriel, MD, MSE
Chief Oncology Informatics Officer for Penn Medicine Cancer Service

03 Payer Perspective
15 minutes
Melanie Combs-Dyer
Director of Innovation, Mettle Solutions, LLC

04 Pathway Vendor Perspective
15 minutes
Tyler Haydell
Senior Product Manager, Flatiron Health

05 Discussion and Q&A
40 minutes

[Image of CodeX logo]
mCODE ™ Standard: minimal Common Oncology Data Elements

- Small, stable set of critical data elements
- Driven by oncology experts
- Standardized for collection and sharing, using FHIR
- Better cancer care and research

Community: A new HL7 FHIR Accelerator

A community and platform accelerating interoperable data modeling and implementation around FHIR and mCODE, leading to step-change improvements in cancer care and research

http://hl7.org/CodeX
**CodeX Use-Case-Based Projects**

0. mCODE++ Extraction
1. EHR Endpoints for Cancer Clinical Trials (ICAREdata)
2. Integrated Trial Matching for Cancer Patients and Providers
3. Cancer Registry Reporting
4. Radiation Therapy Treatment Data for Cancer

5. Oncology Clinical Pathways
7. Alternative Payment Model Data Reporting for Cancer
8. Drug Value Based Agreements for Cancer

Active Community Development
Active Community Planning
In Discovery
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Pathways in Cancer Medicine: A Growing Imperative

Lawrence N Shulman, MD  
Deputy Director for Clinical Services  

Peter Gabriel, MD  
Chief Oncology Informatics Officer  

Abramson Cancer Center  
University of Pennsylvania  

July 2020
Pathways…..The Imperative

- Rapid increasing complexity of cancer care
  - Newly FDA approved treatments
  - New data

- Reduction in variation *(paraphrasing Brent James – Intermountain Health)*
  - “It is more important to do it the same than that you do it right – when you do it the same:”
    - Error rates fall
    - Costs fall
    - You can apply scientific analysis to improvement

- Payor pressures
  - Pre-authorization process
  - NCCN guidelines
Pathway Work - Themes

- Clinical process, operations
  - New patient intake
  - Initial diagnostics
  - Expedited treatment pathway for patients with spinal cord and brain metastases

- Treatment related
  - Surgery, medical oncology, radiation oncology

- Post-treatment surveillance
  - Follow-up scheduling coordination reducing redundancy
  - Imaging
  - Dedicated survivorship care
Survival for Colon Cancer – On and Off Pathway

**Stage III Adjuvant**
- Disease-Free Survival (%)
- 344 pts on pathway
- 89 pts off pathway

**Metastatic**
- Overall Survival (%)
- 412 pts on pathway
- 65 pts off pathway

Figure 1. Disease-free survival according to pathway status for patients with stage III disease who were initiating an adjuvant line of therapy.

Figure 2. Overall survival according to pathway status for patients with metastatic disease who were initiating first-line therapy.

Hoverman J Oncology Practice 2011
## Colon Cancer Pathways and Cost

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<th>Adjuvant</th>
<th>Metastatic</th>
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<tbody>
<tr>
<td></td>
<td>On-pathway (80 pts)</td>
<td>Off-Pathway (70 pts)</td>
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<tr>
<td>Cost/case</td>
<td>103K</td>
<td>156K</td>
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<tr>
<td>Cost PP/PM</td>
<td>5.9K</td>
<td>9.1K</td>
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<td>Chemo Cost</td>
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<tr>
<td>Chemo related adm/pt</td>
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<td>0.30</td>
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</table>

Hoverman J Oncology Practice 2011
Utilization of Clinical Pathways Can Reduce Drug Spend Within the Oncology Care Model

Andrew Hertler, MD¹; Sang Chau, PharmD¹; Rani Khetarpal, MBA²; Ed Bassin, PhD¹; Jeff Dang, PhD¹; Daniel Koppel, MS¹; Vijay Damarla, MD, MPH²; and James Wade, MD²

A resource. In October 2017, NCH’s pathway program was officially launched at CCSI for OCM-attributed patients. The practice initially wished to integrate NCH pathways into their electronic medical record (EMR), which was determined to be technically feasible. However, the practice shared their EMR with a local hospital. The hospital approval process for the integration, as well as the cost to the practice by the EMR vendor to perform the integration, proved prohibitive to the practice. Therefore, NCH care
FIG 2. (A) Median per-patient per-month drug spend (risk-adjusted 4-quarter average) for Cancer Care Specialists of Illinois (CCSI) compared with the median of all Oncology Care Model (OCM) participating practices. (B) Percent difference in per-patient per-month drug spend for CCSI relative to OCM median. Q, quarter.
Pathways and Electronic Health Records – 1

- Most pathway applications poorly integrated with EHRs or not integrated at all

- Clinicians “live” in the EHR
  - Hard to live a “schizophrenic” existence in 2 systems

- Pathway integration must decrease work and friction, not increase, or they will not be successful or sustainable
Pathways and Electronic Health Records – 2

- Lack of structured data elements in the EHR makes pathways decision support and automation difficult (hence the need for mCODE)

- Lack of standardized chemotherapy regimen build makes integration hard (need to map the recommendations from the pathways app to actual protocols in each institution’s EHR) – efforts to standardize (e.g. what NCCN is doing) needed

- Need to support two types of clinicians
  - the generalist who needs legitimate guidance
  - the sub-specialist who knows what he/she wants to do and needs to select and justify it with minimal friction
And what about the Payors?.....

- National Comprehensive Cancer Network (NCCN)
  - 30 major US cancer centers
  - Expert panels for all major cancers create guidelines
  - Guidelines updated at least annually, but more often as new data becomes available
  - Compendium utilized by many payors to determine what is covered

- Pre-authorizations
  - Designed to reduce low value care
  - Major pain point for providers
  - Adds significantly to administrative cost of care for both providers and payors
Pre-authorizations

- Guidelines and pre-authorizations based on clinical data
  - Cancer type
  - Stage
  - Biomarkers
  - Intent of treatment
  - Other clinical data – prior treatments, etc

- All of these data in the EHR but not necessarily as structured data

- Pre-authorizations performed person to person
  - Repeating data that are in the EHR
  - Approval and treatment often delayed significantly
What if …… ??……………..

- Pathway needed data were present in EHR in structured data

- Pathways drove NCCN concordant care – provider picks concordant treatment plan in EHR

- Data extracted from EHR and transmitted automatically to payor IS infrastructure

- If clinical data and treatment plan match NCCN compendium in payor database, then an instantaneous approval is given

- If not standard peer-to-peer review occurs
Thank You
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Mettle Solutions
Prior Authorization Pilot and
Payer Uniformity Project

Two Initiatives to Reduce Provider Burden

Melanie Combs-Dyer
Director of Innovation
Mettle Solutions is a Health IT solutions vendor with expertise in:

• Interoperability standards and specifications,
• Medical documentation exchange, and
• Reducing physician administrative burden.

Mettle Solutions holds a contract with CMS to pilot test ePrior Authorization on FHIR* in the Medicare FFS Program

* FHIR = Fast Healthcare Interoperability Resources
Mettle’s active participation in HL7 Da Vinci

- Payer Data Exchange (PDex)
- Payer Coverage Decision Exchange (PCDE)
- Prior Authorization Support (PAS)
- Clinical Data Exchange (CDex)
- Coverage Requirements Discovery (CRD)
- Documentation Templates and Coverage Rules (DTR)
- Data Exchange for Quality Measures (DEQM)
- Gaps in Care and Information
- Post-Acute Order and Durable Medical Equipment (DME) Order

Documentation Requirements Lookup Service (DRLS)
The Problem: Prior Authorization

Delays in Care
Delays in care could occur if a provider does not understand what data elements need to be documented in the medical record for an item/service that requires prior authorization.

User Frustration
Providers can be confused by the lack of uniformity in what needs to be documented in the medical record for different payers.

Improper Payments
Insufficient documentation in the medical record can lead to improper payments.

High Appeal Rates
Denials due to insufficient documentation can drive up appeals.

Excess Payer Costs
Today’s manual process is expensive for payers.
Prior Authorization (for Medical services) – current process
Mettle’s **basic** Medical-ePA solution

Mettle ePA App is integrated into provider’s EHR or practice management system.

Mettle ePA App provides a Single Interface to all participating payers.
Mettle’s Medical-ePA+ solution

Payer’s IT team/vendor* can build into their systems:
- Documentation Requirement Lookup Service (DRLS),
- Status Tracking, and/or
- Quick-Response capabilities

Where payer has DRLS capabilities, the Mettle “Prefill” feature will auto-pull all needed documentation into PA Request

* Mettle can be the vendor
DETAILED VIEW of Mettle’s Medical ePA+

1. Request for Bene’s payer end-point
2. End-point response
3. DRLS Request – FHIR
4. DRLS Response – FHIR
5. ePA Request – FHIR bundle
6a. ePA Response – X12
6b. Supporting Documentation
7. ePA Response – X12
8. ePA FHIR Server

- Payer Directory
- SMART on FHIR App
- CRD / DTR Server
- CDS Services
- DRLS Services
- CRD / DTR Server and CDS Services
- CQL
- HL7 FHIR Resources

Supporting Documentation

- X12 275 with documentation
- X12 278 PA Request
- X12 278 PA Response
- X12
- Documentation Repository
- Review System
- Payer Systems

- CRD / DTR Server
- CDS Services
- HL7 FHIR Resources
In July 2020, Mettle plans to begin enrolling providers in a pilot test of the Mettle Medical ePA app
Who can enroll in the Mettle ePrior Auth pilot?

Mettle Solutions is seeking providers who:

- Submit 5 or more NON-DRUG prior authorization requests (on average) per month
- Use an EHR or Practice Management System that has a FHIR server
- Are willing to download and install the Mettle ePrior Auth app in their EHR or practice management system
  
  note: Mettle does not charge the provider any fees to download or use the Mettle ePrior Auth app

Step 1: Express interest in joining the pilot

by sending an email to melanie.combs-dyer@mettles.com including:

  o Provider Organization’s name
  o Number of NPIs at this provider organization
  o Organization’s Primary Contact name, phone number, email address
  o Goal date for submitting the Onboarding Form
Mettle’s Payer Uniformity Project

Goal: Develop A Process Whereby Payers Can Work Together to Develop Common Sets Of Required Data Elements

- Solicit Da Vinci Payers
  Mettle Solutions will ask all Da Vinci Payers if they wish to participate in a Payer Uniformity Team

- Top 10 Prior Auth Items/Services
  The team identifies the Top 10 Items/Services for which Prior Authorization is Required

- Gather/Review Documentation Elements
  One item/service at a time, the team will:
  - Gather the data elements required by each payer
  - Reach consensus on a uniform set of documentation elements
  - Request new USCDI elements where missing

Questions

Email: Melanie.Combs-Dyer@mettles.com
Phone: (410) 878-2192
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• Market Trends & Where We are Today
• Vision: CDS = Prior Auth at PoC
• Where Flatiron is Investing
• Need for Interoperability/Standards
Market Trends

1. Rapid pace of new drug approvals is making it overwhelming for generalists to keep up

2. Drugs make up majority of cost of care in oncology

3. Transition from reimbursement approval based on NCCN Guidelines to approval based on payer-specific preferences within NCCN Guidelines

Clinical decision support and prior authorization are the primary tools used to support oncologists as they face these changes
Where we are today

1. Physician orders a regimen in the EHR

2. Prior auth staff see regimen has been ordered, search the patient’s chart to find data needed for the auth, and submit prior auth

3. If payer prefers another treatment, staff must go back to the physician to determine if appropriate to change order or if peer-to-peer is needed

Current system is labor intensive, error prone, and delays time to treatment for patients - one of the top challenges for oncologists today
Vision: CDS = Prior Auth at Point of Care

When ordering a regimen in the EHR:

- Physician sees all information needed to choose best treatment for patient
- All data needed for authorization is sent to the payer
- Physician receives response for the auth in real-time

Realizing this vision will accelerate time to treatment for patients, reduce administrative costs, and increase compliance with evidence-based care
About this patient

Non-Small Cell Lung Cancer

CLINICAL FACTORS FOUND IN EHR

- CLINICAL STAGE IIIB: cT2a, cN1, cM0
- PATHOLOGIC STAGE IIIA: pT3, pN1

ADD CLINICAL FACTORS

- TREATMENT SETTING: Advanced
- LINE OF THERAPY: First Line
- EGFR MUTATION: Positive

RESOURCES

- NCCN Guidelines® Homepage
- UpToDate®

Clinical Trials

1

INV 20193055 EA5163. A Randomized, Phase III Study of Firstline Immunotherapy Alone or in Combination with Chemotherapy in Lung Cancer

Preferred regimens

2

PAYER #2

NCCN_NSCLC27: Erlotinib PO(150 QD)D1-28 Q28D
1 NCCN recommended indication

NCCN • PAYER #1 • PRACTICE

NCCN_NSCLC66: Osimertinib PO(80 QD)D1-28 Q28D
1 NCCN recommended indication

Other regimens

1

NCCN_NSCLC60: Afatinib PO(40 QD)D1-28 Q28D
1 NCCN recommended indication
NCCN_NS_C66: Osimertinib PO(80 QD)D1-28 Q28D

This regimen must be given within NCCN’s recommended uses in order to be considered guideline concordant. Please accurately represents this patient’s clinical characteristics.

1 NCCN recommended indication:

- **Treatment Setting:** Advanced
- **Line of Therapy:** First Line
- **Histology:** Adenocarcinoma (with mixed subtypes), Large cell carcinoma, Squamous cell carcinoma
- **EGFR Mutation:** Positive

This regimen is preferred by NCCN, Payer #1 and Practice for this indication.

Other treatments available for this clinical indication:

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REGIMEN</th>
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<tbody>
<tr>
<td>Payer #2</td>
<td>NCCN_NS_C27: Erlotinib PO(150 QD)D1-28 Q28D</td>
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</tbody>
</table>
Need for Interoperability/Standards

Unsustainable to build and maintain a bespoke integration between each EHR and payer
Adoption of common standards, terminology, and APIs enable each EHR/payer to develop and scale 1 integration.
DISCUSSION AND Q&A
CodeX Community of Practice

July 31, 2010  12:00 EDT
Topic: Oncology Clinical Pathways: Prior Authorization

Interested in learning more?

Minutes, recording and slides for this meeting
Oncology Clinical Pathways: Prior Authorization
CodeX Community of practice
Other CodeX use cases

https://confluence.hl7.org/display/COD/CodeX+Home

go google HL7 FHIR CodeX Confluence

For more information contact
Carmela Couderc (ccouderc@mitre.org) or Jim O’Connor (joconnor@mitre.org)
CodeX
Oncology Clinical Pathways & Prior Authorization

Crossing the Chasm

HL7® FHIR® oncology standard: mCODE
Standardized Prior Authorization process (HL7 DaVinci Accelerator)
Shared Pathway Definitions between provider and payer

For more information contact
Carmela Couderc (ccouderc@mitre.org) or Jim O’Connor (joconnor@mitre.org)
Leveraging the mCODE™ standard (minimal Common Oncology Data Elements), CodeX will expand around this core to encompass additional use cases, accelerating opportunities to create a learning health system based on interoperable data and improved patient care.

Learn more www.hl7.org/codex/