TOOLKIT

Insurance Coverage of Clinical Trials Pre-Authorization and Denials/Appeals Management

ASCO® Research Community Forum

www.asco.org/research-community-forum

OVERVIEW

This Toolkit was developed as part of an initiative led by the American Society of Clinical Oncology's Research Community Forum (ASCO RCF) to develop tools and resources to assist oncology research programs with conducting insurance coverage analyses for clinical trials.

An ASCO RCF Working Group conceived of this Toolkit during an earlier initiative on clinical trial coverage analyses. The Working Group was led by Connie Szczepanek, and included Marjorie Good, Andrea Denicoff, Kelly Willenberg, Casey Dawson, Dr. Dax Kurbegov, and Patricia Hurley.

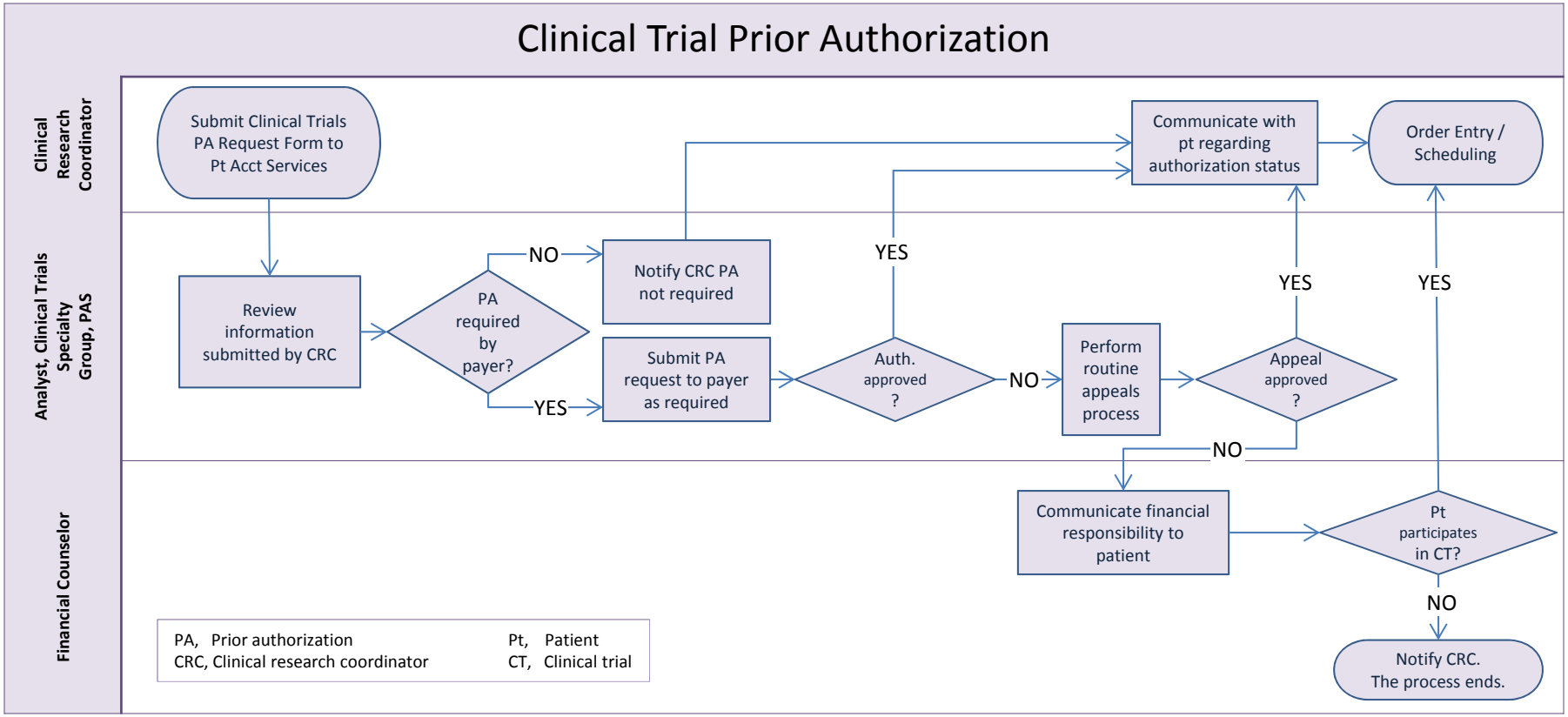
The Toolkit contains sample checklists, templates, and forms to assist research sites with effectively determining insurance coverage of clinical trials, dealing with coverage denials, and navigating the appeals process.

Kelly Willenberg and Associates contributed to the development of this Toolkit and some of the resources are adapted, with permission, from materials used in their training and consulting services.

Disclaimer: This Toolkit contains templates and resources that are provided as examples only for research programs to consider as they formulate their own letters and forms.

TOOLKIT CONTENT

Process Flow Overview



CHECKLIST
Clinical Trial Commercial Payer Coverage

Adapted with Permission from Kelly Willenberg and Associates

- ❑ **Coverage:**
  - Is the condition / services covered under the patient's health plan benefits?
    - Obtain health plan's coverage documents and medical management policies
    - Establish communication with the health plan

- ❑ **Approved Clinical Trial:**
  - Does the trial meet criteria as an approved clinical trial? A phase I,II,III, OR IV clinical trial conducted in relation to the prevention, detection, or treatment or cancer or life-threatening disease or condition that is:
    - A federally funded or approved clinical trial[1],
    - The trial is conducted under an investigational new drug application (IND) review by the Food & Drug Administration, OR
    - The trial is a drug trial that is exempt from having an IND application

- ❑ **Qualified Individual:**
  - Is the patient eligible to participate in the clinical trial?
  - Is the patient being treated for a cancer or other life-threatening disease or condition?

- ❑ **Routine Patient Care Costs**
  - Has a coverage analysis been completed to identify routine patient care costs and those costs to be paid for by the sponsor or another funding source?

- ❑ **Network**
  - Is/are the provider(s) within the patient's plan network requirements?
  - Are any single case agreements needed?

- ❑ **Prior Authorization & Referrals:**
  - What are the plan's Prior Authorization or referral requirements?
  - Has prior authorization requests been sent to the health plan?
    - Complete "Clinical Trial Prior Authorization Form" and packet and submit to health plan
    - Submit all subsequent items / services for prior authorization as applicable

[1]An approved clinical trial is one that is approved or funded (including in-kind contributions) by one of the following: National Institutes of Health (NIH), Agency for Health Care Research & Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Cooperative Groups, Department of Defense (DOD), Department of Veterans Affairs (DVA), qualified non-governmental research entity identified in the guidelines by the NIH for center support grants and studies/investigations conducted by DVA, DOD or the Department of Energy (DOE).

SAMPLE COVER LETTER
Commercial Insurance Company for Coverage of Clinical Trials

Adapted with Permission from Kelly Willenberg and Associates

(Date)

(Name of Contact Person at Insurance Company)
(Insurance Company's Name)
(Address)
(City, State, Zip Code)

Re: ***(Patient's Name)***
(Date of Birth)
(Patient's Insurance ID Number)

Dear ***(Name of Contact Person at Insurance Company – Utilization Management Medical Director),***

(Insert patient's name) has been under my care since ***(insert date)*** for evaluation and treatment of ***(insert condition),*** which is a life threatening condition left untreated. ***(Give brief medical history emphasizing the most recent events that led to consideration of enrolling patient into the clinical trial).***

(Insert patient's name) meets eligibility criteria for the ***(insert name of clinical trial)***. The ***(insert name of clinical trial)*** clinical trial's main objective are to: ***(list main objectives)***.

Further, ***(Insert patient's name)*** participation in the ***(Insert Clinical Trial Name)*** meet all criteria for health plan coverage as indicated by the Affordable Care Act which requires health plans to cover routine patient costs incurred by qualified individuals who are participating in an approved clinical trial (ACT). Specifically, the aforementioned criteria is met by the following:

- ***(Insert patient's name)*** is covered for treatment of this condition under the plan's benefits.
- ***(Insert patient's name)*** meets eligibility criteria for this clinical trial.
- ***(Insert Clinical Trial Name)*** is an ACT because ***(list reason(s) the trial meets ACT criteria, for example)***:
    - ***(Insert Phase I, Phase II, Phase III or Phase IV clinical trial).***
    - ***(The trial is being conducted in relation to the prevention, detection or treatment for cancer or other life threatening disease or condition).***
    - ***(The trial is federally funded and/or conducted under an Investigational New Drug (IND) application review by the Food and Drug Administration (FDA) or IND exemption)***

I have included in the packet, attached to this letter, a Clinical Trial Authorization Request Form and the following information: ***(list all information attached)***

I ask that you consider authorizing ***(Insert patient's name)*** participation and coverage in the above-mentioned clinical trial including coverage of all associated routine care items and services. I would like to enroll her/him into the clinical trial by ***(insert date)***. Should you have any questions, please call me at ***(insert phone number)***.

Sincerely,
(Doctor's Name)

CLINICAL TRIAL PRIOR AUTHORIZATION REQUEST FORM

Request Date:	**Request Type:** Routine or Urgent/Expedited
Insurance Information	
Insurer's Name & Address:	**Insurer's Fax#:**
Provider Information	**Patient Information**
Provider's Name & Address:	**Patient's Name & Address:**
Provider's Tax ID #:	**Patient's Insurance Member ID#:**
Provider's Office Contact Name:	**Patient's Medical Record #:**
Phone #:	**Birth Date:**
Fax #:	**Request Date:**
ICD-9 Code(s):	
CPT/HCPCS Code(s):	
Clinical Trial Information	
Clinical Trial Name/Title:	
Clinical Trial Sponsor Name:	**Principal Investigator's Name:**
Clinical Trial location(s) of service: (check one) ☐ Inpatient ☐ Outpatient ☐ Both Inpatient and Outpatient	**Clinical Trial Phase:** (check one) ☐ Drug Trial Phase: I, II, III, IV (circle one) ☐ Device Trial ☐ Other:
Clinical Trial Funding Source(s):	**ClinicalTrial.gov Number:** **Investigational New Drug (IND) Number:** **Investigation Device Exemption (IDE) Number:**
Clinical Trial Objectives/Aims:	
Patient Clinical Information	
Diagnosis:	
Patient accepted into the Clinical Trial: Yes, No or Workup in Progress (circle one)	
Documents Attached	
❑ Cover Letter ❑ Clinical Trial Synopsis / www.ClinicalTrials.gov NCT# ❑ Clinical Trial Institutional Review Board (IRB) approval letter and number ❑ IRB approved Informed Consent Form, signed by the patient ❑ Coverage Analysis (list of items & services that the trial will and will NOT cover) ❑ IND/IDE Number or IND Exemption documentation ❑ Medical Records ❑ Reference materials as listed below:	

Adapted with Permission from Kelly Willenberg and Associates

CHECKLIST

Clinical Trial Commercial Payer Authorization Request

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- ❑ Cover Letter
- ❑ Protocol Synopsis / www.clinicaltrials.gov
- ❑ Clinical Trial Institutional Review Board (IRB) approval letter and number
- ❑ IRB approved Informed Consent Form, signed by the patient
- ❑ Coverage Analysis (list of items & services that the trial itself will and will NOT cover)
- ❑ IND/IDE Number or IND Exemption documentation
- ❑ Medical Records
- ❑ Other reference materials

SAMPLE APPEAL LETTER
Commercial Insurance Company for Coverage of Clinical Trials

Adapted with Permission from Kelly Willenberg and Associates

(Date)

(Name of Contact Person at Insurance Company)
(Insurance Company's Name)
(Address)
(City, State, Zip Code)

Re: ***(Patient's Name)***
(Date of Birth)
(Patient's Insurance ID Number)

Dear ***(Name of Contact Person at Insurance Company – Utilization Management Medical Director),***

(Insert patient's name) has received a denial for the ***(insert clinical trial name / treatment)*** because it is believed that the clinical trial / treatment is ***(insert specific reason for the denial as detailed in the denial letter)***.

I am writing to you with information regarding the clinical trial and the associated routine care items and services that would occur regardless of ***(Insert patient's name)*** participation in the aforementioned clinical trial. ***(Give brief, yet specific description of the clinical trial and associated treatment and why you believe it should be approved.)***

Specifically, I have included ***(list several journal articles, national guidelines, professional organization's care guidelines, as applicable)*** supporting the routine care items and services associated with this clinical trial for your consideration including the following ***(bullet point list the evidence with a brief synopsis of denied items)***:

- *X scans every 3 months – NCCN Guidelines for X Carcinoma Version 1.2015 state X scans are indicated every 3 months*
- *X Drug for 6 cycles – NCCN Guidelines for X Carcinoma Version 1.2015 state X drug is indicated every X*

(Insert patient's name) meets eligibility criteria for the aforementioned clinical trial. Further, ***(Insert patient's name)*** participation in the ***(Insert Clinical Trial Name)*** meet all criteria for health plan coverage as indicated by the Affordable Care Act which requires health plans to cover routine patient costs incurred by qualified individuals who are participating in an approved clinical trial (ACT). Specifically, the aforementioned criteria is met by the following:

- *(**Insert patient's name)*** is covered for treatment of this condition under the plan's benefits.
- ***(Insert patient's name)*** meets eligibility criteria for this clinical trial.
- ***(Insert Clinical Trial Name)*** is an ACT because ***(list reason(s) the trial meets ACT criteria, for example)***:
    - ***(Insert Phase I, Phase II, Phase III or Phase IV clinical trial).***
    - ***(The trial is being conducted in relation to the prevention, detection or treatment for cancer or other life threatening disease or condition).***
    - ***(The trial is federally funded and/or conducted under an Investigational New Drug (IND) application review by the Food and Drug Administration (FDA) or IND exemption)***

I ask that you reconsider authorizing ***(Insert patient's name)*** participation and coverage in the above-mentioned clinical trial including coverage of all associated routine care items and services. I would like to enroll her/him into the clinical trial by ***(insert date)***. Should you have any questions, please call me at ***(insert phone number)***.

Sincerely,
(Doctor's Name)

TEMPLATE EXAMPLE

Clinical Trial Coverage Analysis

A sample coverage analysis (CA) template is provided that features potential structural elements of a CA and sample content designed for teaching purposes. This coverage analysis template emerged from the American Society of Clinical Oncology (ASCO) and National Cancer Institute (NCI) Clinical Trial Coverage Analysis Training Symposium discussions. Symposium participants reviewed the SWOG CA template and process for completion of a CA. The SWOG team shared experiences with identifying deemed and qualified status for studies, assigning billing Current Procedural Terminology (CPT) codes to procedures and laboratory tests, reviewing National Comprehensive Cancer Network (NCCN) guidelines, and providing billing justifications. A recommendation was made for NCI's National Clinical Trials Network (NCTN) and Community Oncology Research Program (NCORP) Research Bases to build on SWOG's template and experiences in order to develop a standardized National Coverage Analysis (NCA).

**Disclaimer: The national coverage analysis is a part of a process that should include a thorough review of local coverage decisions, a review of medical necessity, physicians' orders, and a claim review prior to submission to payers. This template should not be considered an exclusive approach to a proper billing compliance program and should be evaluated at the local coverage level with each trial opened.*

Source: Szczepanek CM, Hurley P, Good MJ, et al., Journal of Oncology Practice. DOI: 10.1200/JOP.2016.020313

PROTOCOL XXXXX Version Date: 1/15/2017

TEMPLATE EXAMPLE CLINICAL TRIAL COVERAGE ANALYSIS

Is the study a deemed trial? ☒ Yes ☐ No
Is the study a qualifying clinical trial? ☒ Yes ☐ No

STUDY CALENDAR PROTOCOL XXXXX

Procedure	CPT Code	Baseline	Treatment Cycle 1	2	3	4	5	6	7	8	Justification
EVALUATION AND MANAGEMENT											
Physical Exam	XXXXX	RC				RC				RC	Reasonable and necessary to monitor patient health per NCCN Guidelines Version 3.2014; billable as Routine Care per NCD 310.1 (routine costs of qualifying clinical trials).
Weight and Performance Status		RC				RC				RC	
Toxicity Notation		PD	PD	PD	PD	PD	PD	PD	PD	PD	Toxicity Notation recorded per protocol cost supported by per-accrual payments made to sites.
LABORATORY											
CBC, Differential, Platelets	XXXXX	RC	RC	RC	RC	RC	RC	RC	RC	RC	Reasonable and necessary to monitor patient health per NCCN Guidelines Version 3.2014; billable as Routine Care per NCD 310.1 (routine costs of qualifying clinical trials).
Serum Bilirubin	XXXXX	RC	RC	RC	RC	RC	RC	RC	RC	RC	
SGOT or SGPT	XXXXX	RC	RC	RC	RC	RC	RC	RC	RC	RC	
Serum Creatinine/Calc CrCl	XXXXX	RC	RC	RC	RC	RC	RC	RC	RC	RC	
LDH	XXXXX	RC	RC	RC	RC	RC	RC	RC	RC	RC	
Albumin	XXXXX	PD	PD	PD	PD	PD	PD	PD	PD	PD	Not billable. Payment made to sites.
TSH	XXXXX	PD	PD	PD	PD	PD	PD	PD	PD	PD	Not billable. Payment made to sites.
FT3/FT4	XXXXX	PD	PD	PD	PD	PD	PD	PD	PD	PD	Not billable. Payment made to sites.
SCANS AND PROCEDURES											
CT or MRI for Disease Assessment	XXXXX	RC				RC				RC	Scans are to assess and monitor disease progression, and results directly determine patients' course of treatment. NCCN Guidelines Version 3.2014 support use of CT/MRI scans to monitor disease progression in NSCLC. Medicare allows billing of CT Scans under NCD 220.1, and MRI scans under 220.2; in addition, as routine costs of a qualifying clinical trial, on-study scans are billable under NCD 310.1.
EKG	XXXXX	RC				RC				RC	EKG to be performed as clinically indicated and are considered billable as a routine cost of a qualifying clinical trial under NCD 310.1.
SPECIMENS											
Tissue for Biomarker Profiling		PD				PD				PD	Not billable. Payment made to sites for specimen submission.
Tissue for Banking		PD				PD				PD	Not billable. Payment made to sites for specimen submission.
Blood for Banking		PD				PD				PD	Not billable. Payment made to sites for specimen submission.
TREATMENT											
A		PD	PD	PD	PD	PD	PD	PD	PD	PD	Investigational drug provided by study sponsor.
B		RC	RC	RC	RC	RC	RC	RC	RC	RC	Billable, commercial drug.
The National Coverage Decision 310.1 and the NCCN Clinical Practice Guidelines were used to provide this coverage analysis. This is provided as a communication tool without guarantee. Each site is responsible to conduct, verify, and/or add to this coverage analysis in compliance with their institutional guidelines and local coverage decisions.											

LEGEND: RC, routine care, likely billable; PD, study paid/provided

**Disclaimer: The national coverage analysis is a part of a process that should include a thorough review of local coverage decisions, a review of medical necessity, physicians' orders, and a claim review prior to submission to payers. This template should not be considered an exclusive approach to a proper billing compliance program and should be evaluated at the local coverage level with each trial opened.*

GLOSSARY OF TERMS

Coverage analysis: A document that identifies all clinical items or services associated with a particular clinical trial. This includes identification of the financially accountable party for items or services, such as the trial sponsor, patient, or a third party payor.

Financial Counseling: Financial counselors are patient advocates whose role is to contact insurance companies to determine benefits and review insurance coverage details. Counselors can provide a cost estimate of proposed treatment and can be a resource to patients for interpretation of medical bills, resolution of financial questions, and for any other financial concerns.

Insurance verification*:* A process that includes checking to ensure that patients' health care benefits cover required procedures. The patient's insurance company is contacted to verify coverage levels and benefit information.

Medical necessity/Medically Necessary: Health care services or supplies needed to diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine.

Peer-to-peer consultation: A conversation between a physician at an insurance company and the patient's attending physician.

Plan limitations: Every health plan includes a section called the *limitations and exclusions*. This is a list of medical services and equipment a health plan **won't** pay for.

Post-Service Appeal: An appeal to a non-payment or reduction in payment on the received in response to a billing after treating the patient.

Pre-Service Appeal: An appeal to a denial of a pre-authorization request.

Qualifying clinical trial: A trial that meets the requirements set forth in Clinical Trial Policy (NCD 310.1) by the Center for Medicare and Medicaid Services (CMS).

Routine costs in a clinical trial: NCD310.10 - Items or services that are typically provided absent a clinical trial (e.g., conventional care); items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and; items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.