Lifespan
Delivering health with care.

Clinical Trials Quarterly

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Lifespan

Office of Research Administration

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Building a Complete and Accurate Coverage Analysis

What is a Coverage Analysis and why do we need it?

The Coverage Analysis (CA) is a document prepared to ensure compliant clinical research billing. A CA identifies all clinical items or services in a study protocol Schedule of Events (SoE), including identification of the financially accountable party; study sponsor (S), and patient/third-party payor (RC). It also identifies items or services that are not billable (NB), such as study questionnaires, informed consent, and medical history.

The CTO requires a completed CA for all industry-sponsored clinical trials, and also for non-industry studies where there are Lifespan billable items in the protocol. This includes federal, foundation, and department funded studies.

All studies with Lifespan billable items will be entered by the CTO into the LifeChart system, and all bills for associated patients must be reviewed by the study coordinator on a regular basis.

On pages 2-3 is an example of a study SoE and the corresponding CA. The vertical column on the left is where you will enter the clinical items and services listed in the protocol SoE, and the horizontal line across the top is where you will enter the study timeline. In the corresponding box, you will indicate which tests or services are occurring on each date of the timeline, and whether they are S, NB, or RC.

RC = Routine Care. These are charges billable to the patient or their insurance, and are performed regardless of the patient's participation in the study as part of their routine care.

NB = Not Billable. Items that cannot be charged to the study or to the patient or their insurance. *Note: This includes items that are reflected in staff time and effort, such as the informed consent or the administration of questionnaires.*

S = Sponsor. Items that are paid for by the Sponsor as part of the study budget.

In Next Quarter's Issue:

"Patient Injury Language in the Informed Consent Document and the Clinical Trial Agreement".

Note: Volume 1 Issue 2 was scheduled to include an article on the Internal Budget. This article will be featured in a future issue.

Helpful Hints for Completing the Coverage Analysis

- ✓ Use the notes section for clarification, such as: who is doing the venipuncture, where labs are going for processing (local or central), who is doing an EKG (research staff or heart station), urine pregnancy (lab or kits?).
- ✓ The PI must sign the CA before submission to the CTO.
- ✓ Enter the NCT # for the study in the lower right hand corner.
- ✓ Be sure to include all of the study procedures and the entire timeline of the study
- ✓ If there is more than 1 cohort for a study, submit each one a separate coverage analysis document. They will be entered into LifeChart separately.
- ✓ Indicate any procedures that are part of a physician or staff member's time and effort
- ✓ The more information you include, the faster the study can be reviewed and approved by the CTO.

Study Procedures Table

Study Name: APEX6
Protocol #4462
Sponsor: ABC123 Pharma LLC

Study Procedure	Screening	Randomization	Week 2 (Day 15) ±2	Week 8 (Day 57) ±2	Week 16 (Day 113) ±7	EOT (Day 127) ±7
Informed Consent	X					
Medical History	X					
Physical Exam	X					X
Vital Signs	X					X
Hematology and Chemistry	X		X		X	
Urinalysis	X	X		X		
Serum HcG	X					
12-lead ECG	X					
MRI			X		X	X
2-Min Walk Test	X					X
Questionnaire	X					X

	A	B	C	D	E	F	G	H	I	J	K
1	Coverage Analysis (EXAMPLE ONLY)										
2											
3		CPT Codes			Treatment (your study's timeline HERE↓)						
4			Screening	Randomization	Week 2 (Day 15) ±2	Week 8 (Day 57) ±2	Week 16 (Day 113) ±7	EOT (Day127) ±7	Comments		
5											
6	Procedures (your study's schedule of events HERE↓)										
7	Informed Consent		NB						The completion of this form is not a billable event		
8	Medical History		NB						Collection of this data is not billable		
9	Physical Exam		S					S	Performed by PI, part of time and effort	←	Note clarifies that the patient will not be registered for an office visit. Therefore there is no Lifespan billable charge. The cost is in the time and effort of the Investigator.
10	Vital Signs		NB					NB	Performed by research nurse, part of time and effort		
11	Hematology and Chemistry		S		S		S		Screening sent to central lab, all others local lab. Venipuncture perfomed by phlebotomist.	←	Note clarifies that labs after screening and venipuncture are Lifespan billable charges, to be entered into LifeChart.
12	Urinalysis		S	S		S			Performed by research staff with sponsor-provided kits	←	Note clarifies that there will not be Lifespan charges, as the kits are provided by the Sponsor. The cost is in the time and effort of the staff member.
13	Serum HcG		S						Test on females of childbearing potential only - central lab. Research nurse doing venipuncture.	←	Note clarifies that labs and venipuncture are not Lifespan billable charges, and won't be entered into LifeChart.
14	12 lead ECG		S						Performed by research nurse, read by PI. Part of time and effort.		
15	MRI				S		S	S	Test is paid for by the sponsor according to the budget & informed consent.		
16	2-Min Walk Test		S					S	Performed by Research Staff, part of time and effort		
17	Questionnaire		NB					NB	Collection of this data is not billable		
18	Other										
19	Investigational drug APEX6-122 provided by sponsor										
20	NB-not a billable item										
21	RC- Routine Costs bill to subject insurance										
22	S - Paid by Sponsor/Study										

Items to Note:

- Our new indirect rate for non-federal clinical trial agreements as of October 1, 2015, is 30% across all affiliates.
- At the close of an active clinical trial, the remaining balance of funds will be assessed the applicable indirect costs.
- Your Research Administrator can provide the research discount rate for Lifespan tests and procedures. Call or email Gina or Kim-Marie Lawrence.
- The new Industry-Sponsored Clinical Trial Internal Budget template has been released. It can be found at http://www.lifespan.org/grants-and-funding-general-forms.html.
- A memo regarding Lifespan's stance on patient injury language in the informed consent and the clinical trial agreement was sent to the research community in January. If you need a copy please contact Gina.
- Training is available at your site! Call or email Gina Johnson.