

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

# Work Instruction - Coverage Analysis

Velos eResearch  
Version 10



Version: 1.0, 02/16/2018

## Work Instruction - Coverage Analysis

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Revision History			
Version/Amendment #:	Version Date:	Description:	Completed By:
Version 1.0	02/16/2018	Initial Release	VPR CTO

Documentation of Change History:

Version 1.0, 02/16/2018: VPR CTO initial release of version 10.0 work instructions;

# Work Instruction - Coverage Analysis

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## PURPOSE

The purpose of this work instruction is to provide guidance in completing the billing grid as part of the Coverage Analysis tab in Velos eResearch for studies that are entered into the system per the Standard Operating Procedure for Coverage Analysis (*SOP-005\_CoverageAnalysis.docx*). This is a continuation of the Billing Risk Review. Refer to the latest revision of the following documents which cover the Billing Risk Review process:

<b>Description</b>	<b>Document</b>
Work Instruction	Velos-WI-0400-Research Billing Risk.pdf
Standard Operating Procedure	SOP-004_ResearchBilling Risk.docx

## RESPONSIBILITY

**Clinical Trials Office Staff** - Designated CTO staff are responsible for performing the coverage analysis by reviewing human subject research studies that have a patient billing risk to ascertain the appropriate payer for services provided as part of the clinical research study. The following responsibilities also apply:

- Cancer Center CTO – provide coverage analysis support for all cancer-related studies. Submit the coverage analysis results to VPR CTO.
- VPR CTO – provide coverage analysis support for all studies that are not cancer-related. Submit coverage analysis results for cancer and non-cancer studies to the Office of Clinical Research (OCR) as part of the Institutional Review.

**Research Team (RT)** – Provide relevant documents and study information as requested by CTO staff. Communicate patient activity, services provided, and billing instructions to the appropriate billing entities.

**Principal Investigator (PI)** – Review completed coverage analysis for accuracy and to confirm agreement.

## ENTRY/PREREQUISITE CRITERIA

Prior to starting the Coverage Analysis in eResearch, the following must be completed:

- Billing Risk Questionnaire (BRQ) to help direct the coverage types and billing instructions
- Calendar of the study schedule of events/assessments must be completed in eResearch. If not completed, refer to the latest revision of the Velos *Work Instruction - Study Setup.docx* for instructions on completing a calendar.

## RELEVANT DOCUMENTS


The following documentation (as applicable) is referenced while completing the Coverage Analysis within eResearch. Note that *the finalized version* of various documents (\*) must be received before the Coverage Analysis can be completely finalized.

- Completed Billing Risk Questionnaire form (BRQ). (Refer to Velos-WI-0400– *Research Billing Risk.docx* for instructions on completing the form in eResearch).
- Research Protocol\*

## Work Instruction - Coverage Analysis

- Informed Consent Form\*
- Clinical Trial Agreement (CTA), Notice of Grant Award (NOGA) or other Funding Agreement\*
- Budget\*
- Documentation of the drug or device status with the FDA [e.g. Investigational New Drug (IND) number, Investigational Device Exemption (IDE) number, 510k approval], if available

### WORK INSTRUCTIONS

Role/Function	Description of Action								
<p><i>Coverage Analyst</i></p> <p><b>Navigate to Study Summary</b></p>	<ol style="list-style-type: none"> <li>1. Log-in to eResearch</li> <li>2. Click the MANAGE button from the toolbar and select SEARCH under the STUDIES option</li> <li>3. From the list of studies that appear, locate the desired study and click the Clipboard icon  for quick access to the Study &gt;&gt; Summary Page</li> </ol> <p>NOTE: Enter the study number in the <b>Search a Study</b> field, then click SEARCH to quickly locate the desired study.</p>								
<p><i>Coverage Analyst</i></p> <p><b>Navigate to the Coverage Analysis Tab</b></p>	<ol style="list-style-type: none"> <li>1. From the Study Summary tab, click the <b>Study Setup tab</b></li> <li>2. Locate the Calendar to be used for the Coverage Analysis and click on the Calendar Name</li> </ol> <div style="border: 1px solid #ccc; padding: 5px; margin: 10px 0;"> <p style="color: #c00000; font-weight: bold;">Associated Calendars</p> <p style="color: #c00000; font-weight: bold;">Calendars currently associated with this study are:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 80%;">Calendar Name</th> <th style="width: 20%;">Refresh M</th> </tr> </thead> <tbody> <tr> <td style="color: #c00000; text-decoration: underline;">StudyXYZ Schedule</td> <td></td> </tr> </tbody> </table> </div> <ol style="list-style-type: none"> <li>3. The Calendar selected will open to the Event-Visit Grid tab.</li> <li>4. Click on the <b>Coverage Analysis tab</b> to view the schedule below.</li> </ol> <div style="margin-top: 10px;"> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 25%;">Page Visits</td> <td style="width: 25%;">Event-Visit Grid</td> <td style="width: 25%; background-color: #cccccc;">Coverage Analysis</td> <td style="width: 25%;">Event Cost Item</td> </tr> </table> </div>	Calendar Name	Refresh M	StudyXYZ Schedule		Page Visits	Event-Visit Grid	Coverage Analysis	Event Cost Item
Calendar Name	Refresh M								
StudyXYZ Schedule									
Page Visits	Event-Visit Grid	Coverage Analysis	Event Cost Item						

# Work Instruction - Coverage Analysis

Define the Calendar | Select Events | Manage Visits | Event-Visit Grid | **Coverage Analysis** | Patient Cost Items | Milestones Setup

CTMS 16-0124 Calendar: CTMS 16-0124 - Patient Cale...

Calendar Status: Work in Progress

Search Event Clear Search

Event	CPT code	Visit 1 : Screening (Pre-Consent)	Visit 2 : Pre-Procedure	Visit 3 : Procedure	Visit 4 : Post Procedure
Demographics			R		
Medical History		R			
Physical Examination - Comprehensive	99381-99387		SOC		
BUN URINE	82565				R
QOL - Quality of Life - Questionnaire			R		
Radiographic procedure	76499			Invoice-R	Invoice-R
Unlisted Event - 1				R	R
Adverse Events				R	R
Patient Compensation					

Coverage Analyst

## Assign Coverage Types

- Use the determinations from the Billing Risk Questionnaire and the funding agreement (contract/grant) to assign the appropriate Coverage Types to each Event on the Calendar.
  - Refer to *SOP-005\_CoverageAnalysis* for guidance on performing a Coverage Analysis.
  - A drop down menu to select the Coverage Types can be accessed through **Events** section or the **Visit** time points

Calendar Status: Work in Progress

Search Event Clear Search

Event	CPT code	Visit 1 : Screening (Pre-Consent)
Inclusion/Exclusion		NB R
Informed Consent - Pre-Screening		R
Demographics		R
Medical History		NB R
Physical Examination - Comprehensive	99381-99387	S
BUN URINE	82565	R
QOL - Quality of Life - Questionnaire		
Radiographic procedure	76499	

Dropdown menu options: R, Invoice-R, SOC, NB, Q0, Q1

- Click within the EVENT GRID row to open the **Edit Coverage Analysis for Event** details window.
  - Repeat this step for each EVENT listed on the Calendar.

Edit Coverage Analysis for Event: ECG/EKG

Event: ECG/EKG



D Coverage Type	Event Coverage	Apply to All Visits	Screening	Visit 1	Visit 2
			Q1	Invoice-R	NB
E Coverage Notes					

e-Signature \* Submit

## Work Instruction - Coverage Analysis

Refer to the screenshot above for the following steps

3. Verify that Coverage Types are being assigned for the correct Event [A].
4. IF the Coverage Types are the SAME for that Event for each Visit, Select the Coverage Type under Apply to All Visits [B].
5. IF the Coverage Types are DIFFERENT per Visit, then select the correct Coverage Type under each Visit listed for that Event [C].  
USE the Coverage Type legend [D] as a guide, if needed
6. PROVIDE Coverage Notes [E] as needed.
  - a. Notes can be documented for each time the Event occurs under Event Coverage, or per Visit.
  - b. Notes can be used to specify specific labs that were rolled up into one Event line item.
7. Enter your **e-Signature** and click **SUBMIT** to apply the edits.
  - a. Repeat this process for each EVENT listed on the Calendar
8. REVIEW the Calendar once again looking for "X's" that remain without Coverage Types.
  - a. CORRECT any omissions or errors that may exist.
  - b. IF none found, mark those events with "NB" and notify the Budget Analyst.

 NOTE: The Coverage Analysis may be exported to MS Excel for easy viewing. 

*Below is an example of a completed Coverage Analysis in eResearch. Note how the system presents the Coverage Notes differently between a note for the entire Event (ex. Pregnancy Test-Serum = Females Only) and a note for an Event per Visit (ex. Physical Examination-Brief at Screening Visit).*

# Work Instruction - Coverage Analysis

CTMS 16-0124 Calendar: CTMS 16-0124 - Patient Calendar

Calendar Status: Work in Progress

Search Event Clear Search



Event	Visit 4 - Post Procedure	Visit 5 - 6 week follow-up	Visit 6 - 12 week follow-up	Visit 7 - 18 week follow-up	Visit 8 - 24 Week follow-up	Visit 9 - 39 Week follow-up	Visit 10 - 52 Week follow-up	Coverage Notes
Demographics								
Medical History								
Physical Examination - Comprehensive		SOC	SOC	SOC	SOC	SOC	SOC	Only if completed as SOC
BUN URINE	R	R	R					
QOL - Quality of Life - Questionnaire			R		R	SOC	R	
Radiographic procedure	Invoice-R	Invoice-R	Invoice-R		Invoice-R		Invoice-R	
Unlisted Event - 1	R	R	R				R	
Adverse Events	R	R	R	R	R	SOC	R	
Patient Compensation		R	R	R	R	SOC	R	
Study Coordinator - Complex - Personnel	R	R	R	R	R	SOC	R	
Administrative Assistant - Personnel	R	R	R	R	R	SOC	R	
Principal Investigator - Complex - Personnel	R	R	R	R	R	SOC	R	

1 - 1-4 draws completed over 4 hours  
2 - Compensation doubled for this visit

## Coverage Analyst

## Coverage Analysis Completion

**NOTE:** Perform the following tasks if the Coverage Analysis has not already been sent and reviewed by the RT

- When the Coverage Analysis is complete, DOWNLOAD to either  or  (example of download provided below).

- ADD any additional study identifying information to the downloaded document.

**CAUTION:** Any event names which have been modified will not export with the customized name, and will need to be updated prior to sending out or finalization.

- EMAIL the downloaded document to the Principal Investigator for review and confirmation of agreement.
  - The PI may confirm agreement via email.
- PROVIDE the following completed documents to the VPR CTO
  - Coverage Analysis (Billing Grid)
  - Billing Risk Questionnaire form

## Work Instruction - Coverage Analysis

<i>Exported Coverage Analysis</i>							
Coverage Analysis for Calendar: Study XYZ Schedule							
Event	CPT code	Additional Codes	Screening	Visit 1	Visit 2	Visit 3	Coverage Notes
CBC	85025-85027		X Q1		X R		
Concomitant Medications		• Research Code - CONMD	X R	X R	X R	X R	
CT Scan - Without Contrast	70450, 71250, 74150		X R	X Q1		X R	
ECG/EKG	93000, 93005, 93010		X Q1	X Invoice-R	X NB	X Invoice-R	
Inclusion/Exclusion		• Research Code - INCEX	X R				
Physical Examination - Brief	99201-99205, 99211-99215		X R §1	X R	X R	X R	
Pregnancy Test - Serum	84703		X R			X R	Females Only
X=Event-Visit selected  R=Research Invoice-R=Invoice-R SOC=Standard of Care NB=NonBillable Q0=QCT-Investigational Q1=QCT-Routine  § 1 – Review Medical Hx							
<p><i>VPR CTO</i></p> <p><b><i>Submit to OCR for Institutional Review</i></b></p>	<ol style="list-style-type: none"> <li>1. Receives the Billing Risk Questionnaire form and Coverage Analysis (Billing Grid) from Coverage Analyst.</li> <li>2. SUBMITS the results of the Billing Risk review to the Office of Clinical Research (OCR).</li> </ol>						

### EXIT CRITERIA

Upon conclusion of this work instruction, Coverage Analysis is complete. Presuming all other processes related to the Billing Risk review are complete, the study is released to the Office of Clinical Research.

### APPENDIX A: ROLES & RESPONSIBILITIES

RACI Chart	Vice President of Research - Clinical Trial Office							Research Team	
	CTO Director	Budget Analyst Team			Medical Records Coding Team			Study Entry Team	Principal Investigator
FINANCIAL MANAGEMENT		Lead	Senior	Intermediate	Lead	Senior	Intermediate		
- Coverage Analysis									
- Assign Coverage Types	-	-	-	-	R	R	R	C	R, A, C
- Coverage Analysis Completion	-	I	I	I	R	R	R	C	R, A, C
- Submit to OCR for Institutional Review	-	-	-	-	R	R	R	C	A, I

Under each function, define either the function or role and assign R, A, C or I  
 R = Responsible party  
 A = Accountable party  
 C = consulting party  
 I = party to be kept informed

### APPENDIX B: DEFINITIONS

#### Coverage Types

The following coverage types are the billing codes to be used on the billing grid for the coverage analysis:

- **Invoice-R** – *Research* event that must be invoiced to Sponsor or funding agency for payment.
- **NB** – *Non-Billable* – Event is not billable to funding sponsor or to third party payer.



## Work Instruction - Coverage Analysis

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- **Q0** – *Investigational* item/service in Qualified Clinical Trial (QCT) reported to a third party payer. Must be billed with V70.7 diagnosis code, Q0 modifier and NCT# (ClinicalTrials.gov registration number).
- **Q1** – *Routine* item/service in a Qualified Clinical Trial (QCT) billed to a third party payer. Must be billed with V70.7 diagnosis code, Q1 modifier and NCT# (ClinicalTrials.gov registration number).
- **R** – *Research* – Research charge being covered by Sponsor or funding agency, but does not require specific invoicing. May also include (ex. Informed Consent, Eligibility Criteria, Concomitant Medications, Medical History, Questionnaires, etc).
- **SOC** – *Standard of Care* - Conventional care procedure being charged as part of a non-qualified clinical trial to a third party payer; no additional codes or modifiers needed.

### **REFERENCES**

[CMS NCD 310.1 Clinical Trial Policy](#)

[Novitas Clinical Trials and Devices](#)

HOP 7.7.1, [Budgeting & Billing for Clinical Services Provided as Part of Research Involving Human Subjects](#)

OCR Policy 1.3.2. [Clinical Trial Billing](#)

SOP-005\_CoverageAnalysis

**END OF DOCUMENT**