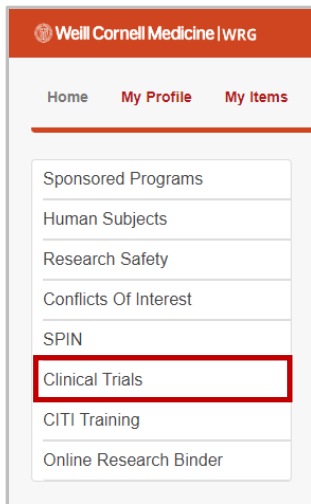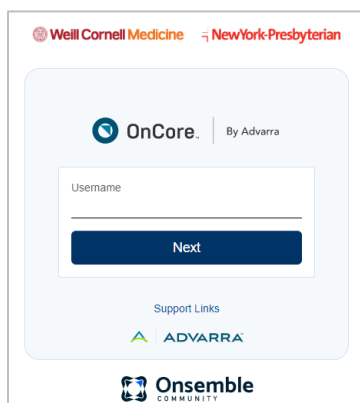# COVERAGE ANALYSIS REVIEW

1. **Go to** wrg.weill.cornell.edu and log into Weill Research Gateway using your CWID and password.
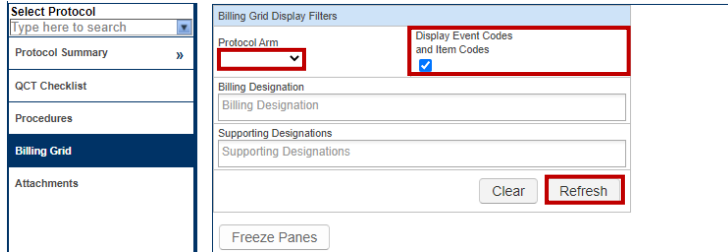2. Click on **Clinical Trials** on the left-hand panel to access OnCore.

3. You will be automatically directed to OnCore, where you will log in by **re-entering your CWID**. You will be prompted to authenticate using DUO if you're not on the VPN.

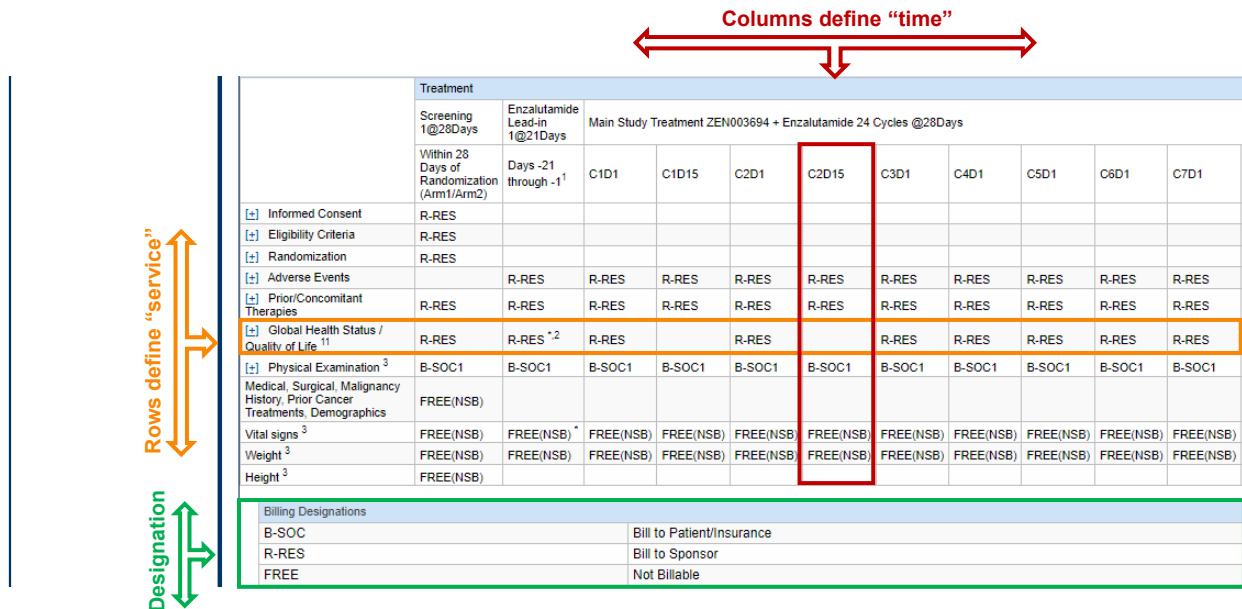4. To review the Coverage Analysis, Protocol, Informed Consent, and Budget, please follow the following steps:
    a. Click **Menu**.
    b. Hover over **Financials Console**.
    c. Click the **Coverage Analysis Console**.
        i. Clicking the ★ will populate this menu option in your header
    d. Enter the protocol number in the **Select Protocol** text box.
    e. Click **Billing Grid** on the left-hand panel.

    i.   Utilize the **Billing Grid Display Filters box.** Use the pulldown to display the appropriate version/**protocol arm** of the coverage analysis for review.

    ii.   Click **Display Event Codes and Item Codes** to see the Event Codes in the Billing Grid, then click **Refresh**.

Select Protocol	Billing Grid Display Filters	
Type here to search	Protocol Arm	Display Event Codes and Item Codes ☑
Protocol Summary »	Billing Designation	
QCT Checklist	Billing Designation	
Procedures	Supporting Designations	
Billing Grid	Supporting Designations	
Attachments	Clear Refresh	
	Freeze Panes	

5. **Column** headings are service intervals defined by the investigator (days, weeks, months, cycles, etc.) to reflect the planned timing/interval of when services will be rendered after enrollment in the study.

6. **Row** headings are service categories defined in the protocol and/or budget. CPT codes should accompany clinical services under each row heading.

7. **Designation** codes are added to complete the billing grid.
   a. **B-SOC** indicates that the service is medically necessary routine/standard-of-care service and may be billed to the patient or their insurance.
   b. **R-RES** indicates that services designated in the informed consent form and budget are paid for by the research sponsor or private or internal funds. These are not to be billed to the patient or their insurance.
   c. **Free** would be listed for services or products provided directly by the study sponsor and, therefore, not billable.
      i. **Free/NSB** would be listed for services that are 'not separately billed' and bundled ('vitals' when done outside the physical examination).

Columns define "time"

	Screening 1@28Days	Enzalutamide Lead-in 1@21Days	Main Study Treatment ZEN003694 + Enzalutamide 24 Cycles @28Days								
	Within 28 Days of Randomization (Arm1/Arm2)	Days -21 through -1[1]	C1D1	C1D15	C2D1	C2D15	C3D1	C4D1	C5D1	C6D1	C7D1
[+] Informed Consent	R-RES										
[+] Eligibility Criteria	R-RES										
[+] Randomization	R-RES										
[+] Adverse Events		R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
[+] Prior/Concomitant Therapies	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
[+] Global Health Status / Quality of Life [11]	R-RES	R-RES *,[2]	R-RES		R-RES		R-RES	R-RES	R-RES	R-RES	R-RES
[+] Physical Examination [3]	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1
Medical, Surgical, Malignancy History, Prior Cancer Treatments, Demographics	FREE(NSB)										
Vital signs [3]	FREE(NSB)	FREE(NSB) *	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)
Weight [3]	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)
Height [3]	FREE(NSB)										

Rows define "service"

Designation

Billing Designations	
B-SOC	Bill to Patient/Insurance
R-RES	Bill to Sponsor
FREE	Not Billable

8. Click the **[+]** hyperlink or **Expand All** to view the linked charges from the Charge Master.

[+] IDEAL Image Transfer	R-RES			R-RES		R-RES	R-RES	
[+] Archival Tumor Tissue Collection [7]	R-RES							
Fresh Tumor Tissue Biopsy (procedure) [6]	R-RES							
[+] Fresh Tissue Handling	R-RES							
ZEN003694 [PO] Investigational Pharmacy Preparation [10]								
Enzalutamide [PO] Investigational Pharmacy Preparation		R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
[+] Survival status and subsequent therapy [15]								
Expand All Collapse All								

9. After the row(s) have been expanded
   a. Click (bottom right) **View Excel** to view the Coverage Analysis in an Excel format.
   b. Whichever format you choose to review the Coverage Analysis, check that the clinical services with **R-RES** and **B-SOC** designation codes have the correct **CPT code or CPT code range**. This is what Epic looks for, and then it assigns the procedure to be billed to insurance or the study.
      i. CPT codes must be listed and reviewed for all clinical procedures.
         1. If a clinical procedure is **missing a CPT code or lists the incorrect CPT code**, the coverage analysis needs to **go back to the Coverage Analysis builder** and then resubmitted for review. Email the Coverage Analysis Builder with the list of changes /corrections.
         2. To find the name of the appropriate builder, reference the OnCore-generated email with the subject line "[OnCore] Action Required: Coverage Analysis Signoff." The builder is included in this email, and the builder's name is stated in the body of the email: "Sent from OnCore on behalf of XXXX." You can also navigate Menu > Protocol > PC console and view the Staff tab.

	Treatment										
	Screening 1@28Days	Enzalutamide Lead-in 1@21Days	Main Study Treatment ZEN003694 + Enzalutamide 24 Cycles @28Days								
	Within 28 Days of Randomization (Arm1/Arm2)	Days -21 through -1 [1]	C1D1	C1D15	C2D1	C2D15	C3D1	C4D1	C5D1	C6D1	C7D1
[-] Informed Consent	R-RES										
*INFORMED CONSENT PROCESS	R-RES										
[-] Eligibility Criteria	R-RES										
*INCLUSION/EXCLUSION CRITERIA - ELIGIBILITY REVIEW	R-RES										
[-] Randomization	R-RES										
*RANDOMIZATION	R-RES										
[-] Adverse Events		R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
*ADVERSE EVENTS/AE ASSESSMENT		R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
[-] Prior/Concomitant Therapies	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
*CONCOMITANT MEDICATIONS/CONMED ASSESSMENT	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
[-] Global Health Status / Quality of Life [11]	R-RES	R-RES [*,2]	R-RES		R-RES		R-RES	R-RES	R-RES	R-RES	R-RES
*QUESTIONNAIRE (EACH)	R-RES	R-RES	R-RES		R-RES		R-RES	R-RES	R-RES	R-RES	R-RES
[-] Physical Examination [3]	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1
OFFICE VISIT, INPATIENT AND OUTPATIENT, INCLUDING CONSULTATIONS 99202-05, 99212-15, 99221-23, 99231-33, 99238-39, 99241-45, 99251-55	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1
Medical, Surgical, Malignancy History, Prior Cancer Treatments, Demographics	FREE(NSB)										
Vital signs [3]	FREE(NSB)	FREE(NSB) [*]	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)
Weight [3]	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)
Height [3]	FREE(NSB)										

10. Review the clinical services with **R-RES** and **B-SOC** designation codes on the Billing Grid to **ensure they match the informed consent form and budget**.
    a. To view the protocol, informed consent form, and budget,
        i. Click the **Attachments** tab on the left-hand panel, then click on the **link for the protocol.** If you do not have access to view the protocol document in WRG-HS, email jctoctms@med.cornell.edu, who will upload the protocol into OnCore. The informed consent form and budget should be uploaded in this section. If missing, contact the **Coverage Analysis Builder** to request that they upload these documents.

Contract No.:		Protocol No.:		Library:			Sponsor:	
Protocol Target Accrual:				PI:				Accrual To Date:
RC Total Accrual Goal (Upper):								
Short Title:							Status:	

Select Protocol
Type here to search

Protocol Summary »		**Coverage Analysis Attachment Details**					
QCT Checklist		Document Type	File Name / URL	Description	Version Date	Created Date	Created User
Procedures		Coverage Analysis - Budget					
Billing Grid		Coverage Analysis - Informed Consent Form					
Attachments		Coverage Analysis - Informed Consent Form					

Protocol Attachment Details					
Document Type	File Name / URL		Description	Version Date	Created Date	Created User
Investigator Brochure					
Other Research Documents					
Other Research Documents					
Other Research Documents					
Protocol					

11. Lastly, if there are services for Radiology and/or Pathology, export the Coverage Analysis to Excel (bottom right, **View Excel**). Click the checkmarks for Include Events and Items, Event Codes and Item Codes, and Include Footnotes.

Export Options ✕

Include Events and Items ☑
Include Event Codes and Item Codes ☑
Include Footnotes ☑
Include QCT Checklist on additional tab ☐

Export

Email the billing grid and protocol to Radiology (Grazyna Dabrowska, grd2005@med.cornell.edu (primary) or Maria Calvelo, mac2106@med.cornell.edu) and/or Pathology (Alexandria Nunez, aln2006@med.cornell.edu) for review. **Communicate any suggested changes made by Radiology and/or Pathology back to the Coverage Analysis Builder.**

12. The review is complete if:
    a. All Visits and Billing designations on the Coverage Analysis match the study protocol, informed consent, and budget.
    b. Clinical services with R-RES and B-SOC designation codes have appropriate CPT codes.
    c. Radiology and/or Pathology has approved the review of their services for said study, if applicable.
13. To Signoff, click **Menu**.
14. Hover over **Forms/Calendar**.
15. Click **Specifications**.
16. Click **Coverage Analysis Signoff** in the bottom right-hand corner.