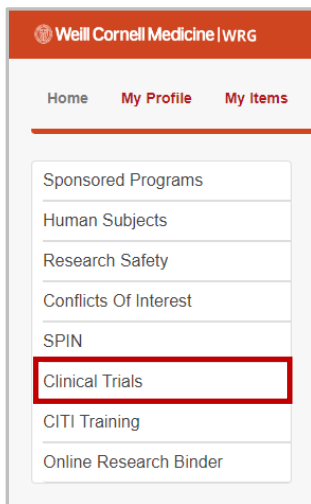
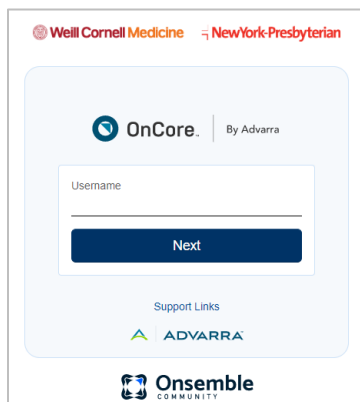


## COVERAGE ANALYSIS REVIEW

1. Go to [wrg.weill.cornell.edu](http://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.

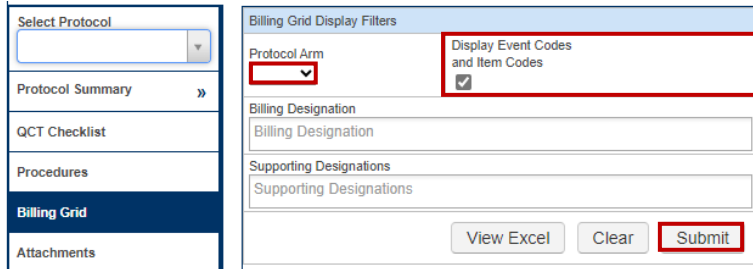


3. You will be automatically directed to OnCore, where you will log in by **re-entering your CWID**. You will be prompted to authenticate using **DUO** if you're not on the VPN.



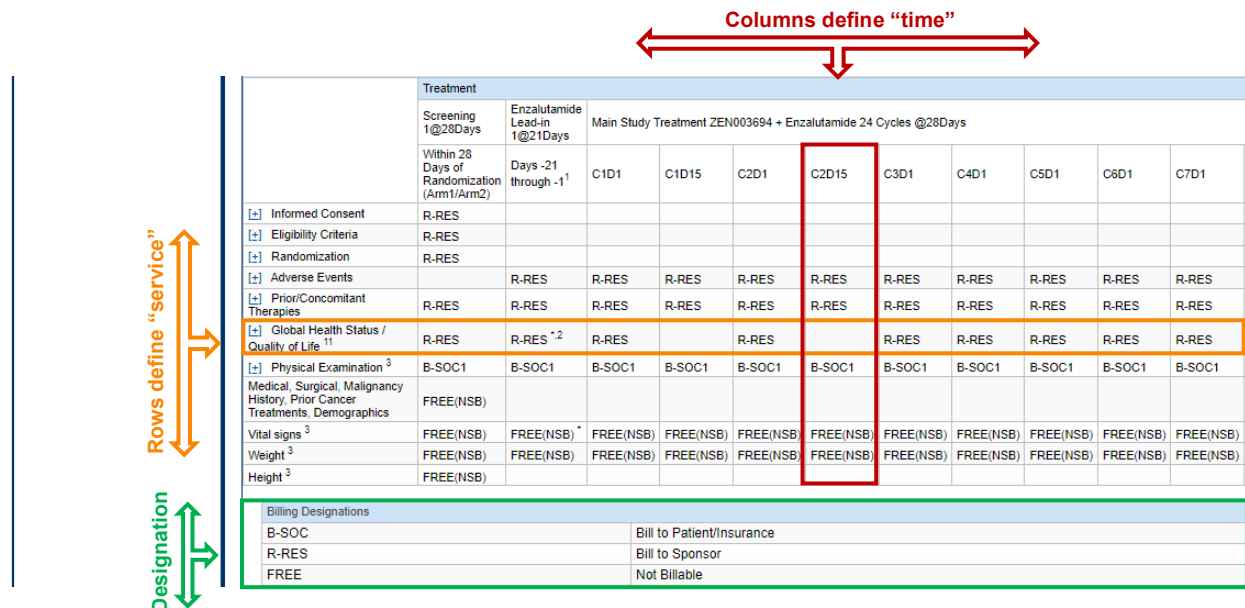
4. To review the Coverage Analysis, Protocol, Informed Consent, and Budget, please follow the following steps:
  - a. Click **Menu**.
  - b. Hover over **Financials Console**.
  - c. Click the **Coverage Analysis Console**.
    - i. Clicking the ★ will populate this menu option in your header
  - d. 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 **Submit**.



- 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.
- Row** headings are service categories defined in the protocol and/or budget. CPT codes should accompany clinical services under each row heading.
- Designation** codes are added to complete the billing grid.
  - B-SOC** indicates that the service is medically necessary routine/standard-of-care service and may be billed to the patient or their insurance.
  - 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.
  - Free** would be listed for services or products provided directly by the study sponsor and, therefore, not billable.
    - Free/NSB** would be listed for services that are 'not separately billed' and bundled ('vitals' when done outside the physical examination).

**Columns define "time"**



	Treatment		Main Study Treatment ZEN003694 + Enzalutamide 24 Cycles @28Days								
	Screening 1@28Days	Enzalutamide Lead-in 1@21Days	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 <sup>11</sup>	R-RES	R-RES <sup>2</sup>	R-RES		R-RES		R-RES	R-RES	R-RES	R-RES	R-RES
[+] Physical Examination <sup>3</sup>	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 <sup>3</sup>	FREE(NSB)	FREE(NSB) <sup>4</sup>	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)
Weight <sup>3</sup>	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)
Height <sup>3</sup>	FREE(NSB)										

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



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](mailto: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:

<b>Select Protocol</b>	<b>Coverage Analysis Attachment Details</b>					
Type here to search	<b>Document Type</b>	<b>File Name / URL</b>	<b>Description</b>	<b>Version Date</b>	<b>Created Date</b>	<b>Created User</b>
Protocol Summary »	Coverage Analysis - Budget					
QCT Checklist	Coverage Analysis - Informed Consent Form					
Procedures	Coverage Analysis - Informed Consent Form					
Billing Grid						
<b>Attachments</b>	<b>Protocol Attachment Details</b>					
	<b>Document Type</b>	<b>File Name / URL</b>	<b>Description</b>	<b>Version Date</b>	<b>Created Date</b>	<b>Created User</b>
	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 (top left, **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

Email the billing grid and protocol to Radiology (Grazyna Dabrowska, [grd2005@med.cornell.edu](mailto:grd2005@med.cornell.edu) (primary) or Maria Calvelo, [mac2106@med.cornell.edu](mailto:mac2106@med.cornell.edu)) and/or Pathology (Alexandria Nunez, [aln2006@med.cornell.edu](mailto: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.