OCRICC Guidance Document for Investigators & Research Teams
MEDICARE COVERAGE ANALYSIS

INVESTIGATORS & RESEARCH TEAMS: PLEASE READ CAREFULLY

The Office of Clinical Research and Innovative Care Compliance (OCRICC) is responsible for performing a Medicare Coverage Analysis (MCA) for any services billed by a Froedtert Health Affiliate. The MCA is a critical activity to prevent Froedtert Health billing non-compliance and false claims. Medicare requires that you only bill for services that meet their requirements. The only way we know that is to perform an MCA against their policies and requirements. OCRICC manages claims as identified on the agreed-upon MCA. The purpose of this document is to provide research teams guidance that will help to expedite the MCA review.

Following the guidance outlined below will help to reduce delays in MCA turnaround and enhance the overall approval process.

General:

The key to compliant clinical research is exchange of clear, concise, and current information.

- It is critical that we have the current protocol, consent, and table of events in order to perform the MCA.
    - The protocol table of events can and should be used as a tool to communicate which Froedtert Health items/services you know will be paid outright by the study (marked 'R' for research), and which are considered routine care (marked 'SOC' for routine care) and should be evaluated for coverage against applicable Medicare rules. An example of what this looks like is found at the end of this document. **If SOC v R is not determined up front with the Principal Investigator and provided to OCRICC at time of MCA request, it will cause delays in turnaround of the MCA.**
    - Clearly identify the research activities that will be performed in MCW space (or other non-Froedtert Health space) and/or with MCW resources (or with other non-Froedtert Health resources).
    - If the sponsor provides a new or amended protocol, it is the research teams' responsibility to provide it to OCRICC as soon as possible. **Any changes to the protocol may change the MCA, and if you do not get the update to us promptly, it will cause delays in your administrative approval.**
- Evaluation against Medicare billing rules is the standard coverage determination process.
- Items cannot be billed to Medicare and then paid for by the sponsor only if denied. There has to be a consistent payer source for every service.
- Froedtert Health does not manage billing by payer. There are too many coverage policies across all payers and plans amid our patient population. For example, if Medicare will not pay for a service but a private insurance will, Froedtert Health cannot manage that.
- Patients are responsible for understanding coverage at their plan level.
- Froedtert Health cannot write off or discount a patient's co-insurance or deductible.

General - Coverage:

Medicare provides reimbursement for routine costs of items and services in qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials**. Some basic coverage requirements and guidelines are:**

- The trial must have therapeutic intent.
- Routine costs of clinical trials include all items and services that are otherwise generally available to Medicare beneficiaries.
- Existing National and Local Coverage Determinations (NCDs/LCDs) must be evaluated when determining coverage. If there is a National/Local Coverage determination that limits coverage or identifies non-

coverage for a diagnosis, it cannot be billed to Medicare. The MCA will reflect the service as not billable and request clarification of who will be liable - the study/sponsor or patient.

- Anything in the protocol that is identified as extra, non-essential, and/or optional are not generally medically necessary and cannot be billed.
- Items or services performed solely to satisfy data collection and analysis and are not used in the direct clinical management of the participant cannot be billed.
- The Medicare term "routine costs" comes close to being what the research community means by "standard of care", but it is not a one-for-one interchangeable concept. We are an academic medical center and are using innovative and cutting-edge therapies/treatments clinically that may be our standard, but not Medicare's standard.
- While many cancer cooperative group studies are designed to identify all services as considered routine care and billable, not all services are. Just because a service is not reimbursed by the cooperative group does not necessarily mean that the service is billable as routine care.
- Some cooperative groups provide a National Coverage Analysis. This document is seen as a tool and will be reviewed as part of the OCRICC MCA.
- Just because another institution is billing for a service does not mean they are billing correctly. OCRICC reviews our regions Medicare policies to determine coverage. If it is a gray area or the guidance is not clear, we will consider that when determining coverage.

It is the responsibility of the research team to:

- Be familiar with the protocol before submitting an application to OCRICC, including **where** services are planned to occur (MCW or other non-Froedtert Health space versus within a Froedtert Health entity space) as well as **with what resources** (MCW or other non-Froedtert Health resources versus Froedtert Health resources).
- Clearly identify the Froedtert Health items/services that will be paid for by the Sponsor .
- Ensure the informed consent document, protocol, table of events, and CTA all align with what the sponsor is paying for. If there are conflicts or discrepancies, the research team should resolve them with the PI and sponsor prior to submitting an application to OCRICC.
- For all Category A and Category B device trials where FDA approval was obtained after January 1, 2015, the sponsor is responsible for obtaining approval from CMS. **This approval must be in place before submitting an application to OCRICC or the MCA cannot be completed, resulting in delays.**
- Find funding and update the ICF in the event the MCA identifies services that are not billable. The ICF must state that either the service will be paid by the study/sponsor or the participant will be liable. Most research teams will request that the sponsor pay for the item/service.
    - While rare, if the sponsor will not provide funding for the service and the research team is going to hold the participant liable, it is the responsibility of the Principal Investigator, or delegate, to inform the participant of their liability and to partner with the clinical department to obtain a Notice of Non-Coverage/Advanced Beneficiary Notice (ABN) or Hospital Issued Notification Of Non-coverage (HINN) for all Medicare patients. Beneficiary Notices and additional information can be found here: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html
      If an ABN or HINN is required and one is not obtained, the study will be liable.

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Escalation Process:

- If you receive an MCA that you believe is incorrect, first contact the OCRICC Nurse Consultant you are working with to discuss. They will help explain the coverage requirements and will make adjustments if applicable.
- If you are still not in agreement with the MCA, contact Bobbi Navarro, OCRICC Manager, at 414-805-6530.
- If you are still not in agreement, contact Nancy Schallert, Executive Director, via email at Nancy.Schallert@froedtert.com. Include the name of the PI, Study Title, and IRB# in the email along with the concern.

Example: SOCvR outlined on protocol table of events

[redacted]

Table 1: [redacted] **Schedule of Events: Screening Period, Treatment Period, and End of Treatment Visit**

	Study Activity	Screening		Treatment Period (28-Day Cycles)									End of Treatment Visit[1]
				Cycles 1 through 8						Cycles 9+			
		D -28 to -1	D -7 to -1	D 1[2]	D 4	D 8	D 11	D 15	D 22	D 1[2]	D 8	D 15	(± 3 days)
R	Informed consent	X											
R	Inclusion/exclusion criteria	X		X[3]									
S	Demographics	X											
S	Medical & surgical history	X											
S	Prior anti-myeloma therapies, radiotherapy, and surgeries[4]	X											
S	Prior medications & procedures[4]	X											
S	Disease diagnosis[5]	X											
S	Skeletal survey (X-ray)[6]	X											
S	Serum beta-2 microglobulin	X											
S	Height	X											
S	BMA and/or biopsy[7]	X											X
S	Physical exam[8]	X		X						X			X
S	Vital signs (BP, temp, RR, HR)[9]	X		X	X	X	X	X	X	X	X	X	X
S	Weight	X		X						X			X
R/P	12-Lead ECG (triplicate)[10]	X		X						X			X
S/R/P	Hematology[11]	X S		X[3] S	X R	X S	X R	X S	X S	X S	X S	X S	X S
S/R/P	Serum chemistry[12]	X S		X[3] S	X R	X S	X R	X S	X S	X S	X S	X S	X S
S	Urinalysis[13]	X		X[3]						X			X
R	Estimation of renal function[14]	X		X[3]	X	X	X	X	X	X	X	X	X
R	VTE history/monitoring[15]	X		X	X	X	X	X	X	X	X	X	X
R	Second primary malignancies[16]	X		X	X	X	X	X	X	X	X	X	X
S	EMP assessments[17]	X		X						X			X
S	ECOG performance status	X		X						X			X
R	Pregnancy counseling (see Pomalidomide Education and Counseling Guidance Document [Appendix D-2])	X		X						X			X
S	Pregnancy test for FCBP[18,19]	X[18]		Cycle 1 once weekly; Cycles 2+ once every 14 or 28 days[19]									X
S	Quantitative serum Ig levels[20]		X	X[3]						X			X

Hematology CBC

Chemistry

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[redacted]

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