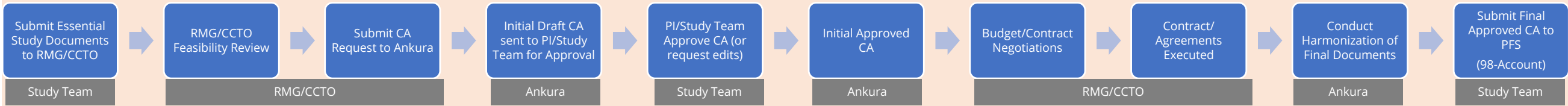
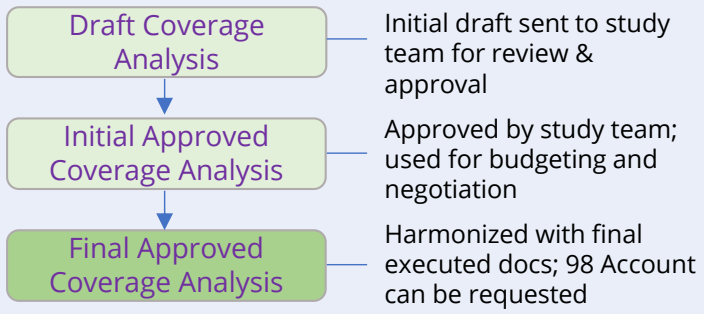


Coverage Analysis Process Summary



3-Stages of Coverage Analysis



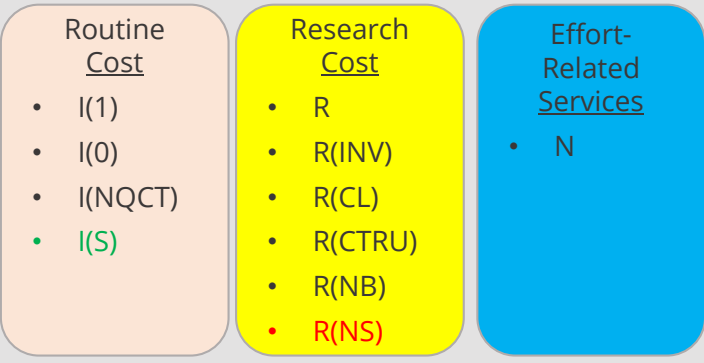
Workbook Billing Grid Sample

Billing Key		Bilable to Insurance		Research Paid Items	
(1) Bill to patient/insurance - Routine Cost in a CPT	(2) Bill to patient/insurance - Routine Cost which Sponsor has offered payment	(R) Research Paid Item - Clinical item or service that could generate a charge that is performed for research purposes and not billable per NCD 302.1 (i.e., paid by sponsor; item performed for research purposes only; promised free of charge in ICF)	(RCL) Research Paid Item - Central Lab Paid For by Study Sponsor	(RNS) Service not covered per Medicare billing rules and there is no sponsor offer for payment OR there is no external sponsor	(R) Research Paid Item - Provided by Sponsor
(3) SHC-CA-284	(4) Bill to patient/insurance - Investigational item/service in a CPT that is billable and is included in the study objectives	(R) Research Paid Item - Central Lab Paid For by Study Sponsor	(RNS) Service not covered per Medicare billing rules and there is no sponsor offer for payment OR there is no external sponsor	(R) Research Paid Item - Provided by Sponsor	(R) Research Paid Item - Provided by Sponsor
(5) Final Approved CA - Harmonized; All Clear for 98 Account v.1.0	(6) Bill to patient/insurance - Investigational item/service in a CPT that is billable and is included in the study objectives	(R) Research Paid Item - Central Lab Paid For by Study Sponsor	(RNS) Service not covered per Medicare billing rules and there is no sponsor offer for payment OR there is no external sponsor	(R) Research Paid Item - Provided by Sponsor	(R) Research Paid Item - Provided by Sponsor

Items and Services (As Listed in Study Protocol)	Items and Services (per CDM)	R Count	R(INV) Count	Service Code	CPT / HCPCS / DRG / APC Codes	Day of Tx	TP*	T24	T72	Initial Hospital Discharge	Day 30	Month 6* (± 30 Days)	Month 12* (± 60 Days)	Class	Analysis Grid Comments (Analysis of protocol-relevant services has been conducted according to NCD 302.1)	Final Review Comments
1. Informed Consent	Informed Consent			N/A	N/A	N								Protocol Sec. 3.2: "The IRB approved written informed consent form will be signed and dated by the subject and the individual obtaining the consent. The subject will be given a copy of the signed informed consent form; the original will be kept in the patient's file by the investigator."	This service is related to completion of documents or data collection and is not a billable event.	1) R Count, Billing Designations, and Codes are all CORRECT
2. Eligibility Criteria	Inclusion/Exclusion Criteria			N/A	N/A	N								Protocol Sec. 6.2: "Participants must meet all of the inclusion criteria and none of the exclusion criteria."	This service is related to completion of documents or data collection and is not a billable event.	1) R Count, Billing Designations, and Codes are all CORRECT
3. Baseline Characteristics/ Demographics	Demographics			N/A	N/A	N								Protocol Sec. 7.3: "If the donor heart meets the above criteria and is generated on OCS, baseline characteristics, demographics and other donor information will be collected at this site."	This service is related to completion of documents or data collection and is not a billable event.	1) R Count, Billing Designations, and Codes are all CORRECT
4. Medical & Cardiac History	Medical History & Cardiac History			N/A	N/A	N								Protocol Appendix 2: "Medical History and Cardiac History will be taken on the Day of Transplant."	This service is related to completion of documents or data collection and is not a billable event.	1) R Count, Billing Designations, and Codes are all CORRECT
5. Transplant Details	Heart Transplant			N/A	N/A	N								Protocol Sec. 8.1: "The following information concerning the transplant procedure will be collected: The organ recipient unique post-transplant patient identifier; Warm ischemic time as defined in this protocol; Total cross-clamp duration in minutes from donor or oc-clip application to removal of cross-clamp in the recipient; Pre-OCJ cold ischemia time (time from donor cross-clamp until start of perfusion on OCJ); Post-OCJ cold ischemia time (time from heart flush on OCJ until aortic cross-clamp removal in the recipient); Any surgical complications encountered during surgery."	This appears to be data collected from the medical record about the transplant/hospitalization.	1) R Count, Billing Designations, and Codes are all CORRECT

Billing Designations



PI/Study Team Review Check List

- Items/Services
- CPT Codes
- Timepoints/Milestones
- Billing Designations
- Study Team Comments/Checklist

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