Coverage Analysis Process Summary

Submit Essential Study Documents to RMG/CCTO	RMG/CCTO Feasibility Review	Submit CA Request to Ankura	Initial Draft CA sent to PI/Study Team for Approval	PI/Study Team Approve CA (or request edits)	Initial Approved CA	Budget/Contract Negotiations	Contract/ Agreements Executed	Conduct Harmonization of Final Documents	Submit Final Approved CA to PFS (98-Account)
Study Team	RMG/CCTO		Ankura	Study Team	Ankura	RMG/CCTO		Ankura	Study Team

3-Stages of Coverage Analysis 1

- **Draft Coverage Analysis** — Initial draft sent to study team for review & approval
- **Initial Approved Coverage Analysis** — Approved by study team; used for budgeting and negotiation
- **Final Approved Coverage Analysis** — Harmonized with final executed docs; 98 Account can be requested

Billing Designations 2

Routine Cost	Research Cost	Effort-Related Services
• I(1)	• R	• N
• I(0)	• R(INV)	
• I(NQCT)	• R(CL)	
• I(S)	• R(CTRU)	
	• R(NB)	
	• R(NS)	

Workbook Billing Grid Sample

Stanford HEALTH CARE / STANFORD MEDICINE — ankura COLLABORATION DRIVES RESULTS

Internal Budget 01/29/2021 Dr. Yasuhiro Shudo 211700 FINAL, Final Approved CA 03/05/2021

Modified Workbook Version 6.1 dated 10/19/20

Clinical Trial Coverage Analysis

IRB (eProtocol) or RedCap (CCTO) Number : 59080

The Portable Organ Care System (OCS™) Heart For Resuscitation, Preservation and Assessment of Hearts from Donors after Circulatory Death Continued Access Protocol (OCS DCD Heart CAP)

This coverage analysis is intended as a general guideline for use in determining which clinical research items and services are billable to third party payers based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare or other payer must be supported by medical necessity.

BILLING KEY: ----------> (Legend)	Billable to Insurance		Research Paid Items		
	I(1): Bill to patient/insurance - Routine Cost in a QCT	I(S): Bill to patient/insurance - Routine Cost which Sponsor has offered payment	R: Research Paid Item/Service --Clinical item or service that could generate a charge that is performed for research purposes and not billable per NCD 310.1 (i.e., paid by sponsor; item performed for research purposes only; promised free of charge in ICF)	R(CL): Research Paid Item – Central Lab Paid for by Study Sponsor	R(NS): Service is not covered per Medicare billing rules and there is no sponsor offer for payment OR there is no external sponsor
SHC-CA-284	I(0): Bill to patient/insurance - Investigational item/Service in a QCT that is billable and is included in the study objectives			R(CTRU): Research Paid Item - Rendered in Stanford CTRU	No Charge in Billing System
Final Approved CA - Harmonized; All Clear for 98 Account — v1.0 — 03/05/21	I(NQCT): Billable to Patient/Insurance - SOC item Rendered in Non-QCT - Billable as conventional care in a non QCT or in a clinical trial that does need to qualify for coverage		R(INV): Clinical item or service that could generate a charge that is performed for research purposes and not billable per NCD 310.1, paid upon receipt of an invoice	R(NB): Research Paid Item - Provided by Sponsor	N: Item that does not generate a charge in Billing System (i.e., forms, questionnaires, bundled services, informed Consent)

	Items and Services (As Listed in Study Protocol)	Items and Services (per CDM) (LF): Lab Fees (PF): Pro Fees (TF): Tech Fees (Rd): Radiology (Sp): Supplies	RCount (# of Research Paid Occurrences)	R(INV) Count (# of Research Paid Invoiceable Items)	Service Code	CPT / HCPCS / DRG / APC Codes	DCD Transplanted Recipient Schedule of Assessments: Day of Tx	T0*	T24	T72	Initial Hospital Discharge	Day 30	Month 6* (± 30 Days)	Month 12* (± 60 Days)	Citations	Analysis Grid Comments (Analysis of protocol-required services has been conducted according to NCD 310.1)	Please Confirm the Following: 1) R Count (number of occurrences paid by Research for this item/service) 2) Billing Designations (the designation determined) 3) CPT/Service Code (the appropriate codes/levels are selected) - If all is correct and accurate. - If a change or update is needed. A comment (in the column to the right) is required	Stanford Review Comments: Must Include: 1. The change or update requested 2. The date of change/update request 3. Your initials
1	Informed Consent	Informed Consent			N/A	N/A	N								Protocol Sec. 13.2; "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.	Y - 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.	Y - 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 preserved on OCS, baseline characteristics, demographics and other donor information will be collected at this visit."	This service is related to completion of documents or data collection and is not a billable event.	Y - 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.	Y - 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 cross clamp application to removal of cross clamp in the recipient); Pre-OCS cold ischemia time (time from donor cross clamp until start of perfusion on OCS); Post-OCS cold ischemia time (time from heart flush on OCS 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.	Y - R Count, Billing Designations, and Codes are all CORRECT	

PI/Study Team Review Check List

☐ **Items/Services** 3 ☐ **CPT Codes** 4 ☐ **Timepoints/Milestones** 5 ☐ **Billing Designations** 6 ☐ **Study Team Comments/Checklist** 7