



# Pearl Jam – How to Rock It in Clinical Trials

Kelly M Willenberg, DBA, RN, CHRC, CHC, CCRP

# Objectives – PEARL Jam

- ▶ Plan a solid budget process for a return on investment
- ▶ Evaluate your negotiation skills
- ▶ Assemble stakeholders
- ▶ Refine your study start up process
- ▶ List the needs and value of CTMS systems



# Plan a Solid Budget Process For a Return on Investment

3

4

# The Sheet of Music or the Necessary Documents

## Protocol

- ✓ Final Version
- ✓ Ask if there is an anticipated or pending amendment

## Sponsor's Budget

- ✓ Budget drives the contract language
- ✓ Request changes to be called out during negotiations

## Investigational Product/Device

- ✓ Verify Version
- ✓ Obtain copy of drug/device user manual
- ✓ Obtain copy of investigators brochure (IB)

## Draft ICF

- ✓ Verify any language
- ✓ Verify subject injury language

## Coverage Analysis

- ✓ Drives budget, contract and budget
- ✓ Accurately identifies costs

# Trial Specific Start-Up and Site Costs

## ► Start-Up Costs

- Reading the protocol and completing the feasibility evaluation
- Training (i.e., protocol training for study staff, eCRF training)
- Sponsor required equipment QC
- Staff time for tasks such as service agreements
- Site Initiation Visit
- Regulatory time and effort for IRB submission

## ► Site Costs

- Ancillary dept. start up costs and annual fees (i.e., IRB Fees, Investigational Pharmacy Fees, Lab Fees)
- Coverage analysis fee
- Amendment Fees (i.e., staff time for regulatory staff submission, IRB fees, budget amendment fee, contract amendment fee)
- Close out fees

# Remember Fixed Costs vs Variable

- ▶ Protocol Amendments
- ▶ Re-consenting for revised ICF
- ▶ IRB renewals and annual reviews
- ▶ ICF Translations
- ▶ Safety reports and submissions
- ▶ Excessive SAE submission or external AE/SAE review
- ▶ Medicare Coverage Analysis
- ▶ Conference calls and meetings
- ▶ Study extension
- ▶ Study Close Out
- ▶ Patient Costs
- ▶ Staff Time
- ▶ Monitor Visits including Remote Monitoring
- ▶ CRF data input or changes
- ▶ Change orders
- ▶ Cost of living adjustments
- ▶ Study Feasibility
- ▶ Site Qualifications
- ▶ Site Initiation

# Staff Time

- ▶ Consent (multiple)
- ▶ Evaluation of inclusion / exclusion criteria
- ▶ Patient registration
- ▶ CRF completion / Data entry
- ▶ Adverse event monitoring / recording
- ▶ Disease History
- ▶ Concomitant meds
- ▶ Phone calls / Follow-ups
- ▶ RECIST measurements (outside of normal measurements)
- ▶ Central lab coordination
- ▶ IVRS calls / randomization
- ▶ Procurement (Slides, Samples)
- ▶ EKG transmissions / Scans to central lab
- ▶ Photographs
- ▶ Administration / Collection of surveys and evaluations
- ▶ Clinician completed assessments and evaluations
- ▶ Diary training / review
- ▶ Medication compliance
- ▶ Subject training e.g. self admin

# Physician Fee Schedule Overview

- ▶ Designed to provide information on services covered by the Medicare Physician Fee Schedule (MPFS).
- ▶ Provides more than 10,000 physician services, the associated relative value units (RVU's), a fee schedule indicator and various payment policy indicators needed for payment adjustment (i.e., payment of assistant in surgery, team surgery, etc.). The Physician Fee Schedule look-up website is designed to take you through the selection steps prior to the display of information.
- ▶ The site allows you to:
  - ▶ Search pricing amounts, various payment policy indicators, RVU's, and GPCI's by a single procedure code, a range and a list of procedure codes.
  - ▶ Search for the national payment amount, a specific Medicare Administrative Contractor (MAC) or a specific MCA locality. Each page has associated Help/Hint available to complete your selections.



# Physician Fee Look Up

The screenshot shows the CMS.gov website. At the top left is the CMS.gov logo and the text "Centers for Medicare & Medicaid Services". To the right are links for "About CMS" and "Newsroom". Below this is a navigation menu with links for "Medicare", "Medicaid/CHIP", "Medicare-Medicaid Coordination", "Private Insurance", "Innovation Center", "Regulations & Guidance", and "Re". The "Medicare" link is underlined. Below the navigation menu is the heading "Medicare". A search bar is highlighted with a yellow background and contains the text "Physician Fee Schedule" with a magnifying glass icon to its right. Below the search bar is a paragraph of text: "People with Medicare, family members, and caregivers should visit [Medicare.gov](https://www.medicare.gov), the Official U.S. Government Site for People with Medicare, for the latest information on Medicare enrollment, benefits, and other helpful tools." Below this paragraph is a section titled "Medicare Fee-for-Service Payment" which contains two links: "[Physician Fee Schedule](#)" and "[Physician Fee Schedule Look-Up Tool](#)". Both links are highlighted with a yellow background and circled in red.

**CMS.gov** Centers for Medicare & Medicaid Services [About CMS](#) [Newsroom](#)

[Medicare](#) [Medicaid/CHIP](#) [Medicare-Medicaid Coordination](#) [Private Insurance](#) [Innovation Center](#) [Regulations & Guidance](#) [Re](#)

## Medicare

Physician Fee Schedule


People with Medicare, family members, and caregivers should visit [Medicare.gov](https://www.medicare.gov), the Official U.S. Government Site for People with Medicare, for the latest information on Medicare enrollment, benefits, and other helpful tools.


### Medicare Fee-for-Service Payment

[Physician Fee Schedule](#)


[Physician Fee Schedule Look-Up Tool](#)


# Fee Look Up – Technical

**Year**  
2022  [See notes for selected year](#)


**Type of Information**  
All 

Select Healthcare Common Procedural Coding System (HCPCS) criteria.

**HCPCS Criteria** **HCPCS Code**  
Single HCPCS Code  93306

**Modifier**  
TC Technical Component 

Select Medicare Administrative Contractor (MAC) option.

**MAC Option**  
All MACs 

**Search fees**

# Fee Look Up – Technical

## Search Results

Showing 1-10 of 113

Items per page: **10** 25 50 100

HCPCS Code ▲	Modifier ▲	Short Description ◆	Mac Locality ▲	Non-Facility Price ◆	Facility Price ◆	Non-Facility Limiting Charge ◆	Facility Limiting Charge ◆	GPCI Work ◆	GPCI PE ◆
93306	TC	Tte w/doppler complete	0000000	\$134.62	NA	\$147.07	NA	1.000	1.000
93306	TC	Tte w/doppler complete	0111205	\$178.31	NA	\$194.80	NA	1.077	1.329
93306	TC	Tte w/doppler complete	0111206	\$178.31	NA	\$194.80	NA	1.077	1.329
93306	TC	Tte w/doppler complete	0111207	\$178.31	NA	\$194.80	NA	1.077	1.329
93306	TC	Tte w/doppler complete	0111209	\$185.51	NA	\$202.67	NA	1.096	1.383

# Fee Look Up – Professional

2022 [See notes for selected year](#)

**Type of Information**  
All

Select Healthcare Common Procedural Coding System (HCPCS) criteria.

**HCPCS Criteria**      **HCPCS Code**  
Single HCPCS Code      93306

**Modifier**  
26 Professional Component

Select Medicare Administrative Contractor (MAC) option.

**MAC Option**  
All MACs

[Search fees](#)

# Fee Look Up – Professional

## Search Results

Showing 1-10 of 113

Items per page: **10** 25 50 100

HCPCS Code ▲	Modifier ▲	Short Description ▼	Mac Locality ▲	Non-Facility Price ▼	Facility Price ▼	Non-Facility Limiting Charge ▼	Facility Limiting Charge ▼	GPCI Work ▼	GPCI PE ▼
93306	26	Tte w/doppler complete	0000000	\$70.25	\$70.25	\$76.75	\$76.75	1.000	1.000
93306	26	Tte w/doppler complete	0111205	\$79.12	\$79.12	\$86.44	\$86.44	1.077	1.329
93306	26	Tte w/doppler complete	0111206	\$79.12	\$79.12	\$86.44	\$86.44	1.077	1.329
93306	26	Tte w/doppler complete	0111207	\$79.12	\$79.12	\$86.44	\$86.44	1.077	1.329
93306	26	Tte w/doppler complete	0111209	\$80.98	\$80.98	\$88.47	\$88.47	1.096	1.383
93306	26	Tte w/doppler complete	0111251	\$75.57	\$75.57	\$82.57	\$82.57	1.044	1.220

# Physician Fee Schedule Look Up Tool Links

- ▶ Physician Fee Schedule Look-Up Tool Link:
  - ▶ <https://www.cms.gov/medicare/physician-fee-schedule/search>
- ▶ Physician Fee Schedule Guide PDF Link:
  - ▶ <https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf>

# Clinical Activities

- Conventional Care vs. Research
  - E&M Visits
  - Drug administration costs
    - Route, Pre-meds
  - Labs
    - Venipuncture / Line Placement
    - Shipping/Handling
- Radiology
  - Associated tests (BUN/Cr), 3D interpretation, contrast agents
  - Confirmation scans
- Pathology
- Sampling (PK, PG, Biomarkers, Etc.)
- Cardiology (EKG, ECHO, MUGA)

# Pharmacy Costs

- Protocol review and Study Set-up
- Drug Storage
- Pharmacy dispensing / mixing of investigational products
- Used vial storage
- Randomization
- MAR reconciliation
- Inventory
- Billing as necessary
- Monitor visits



# Hidden Costs

- ▶ Delayed study start-up
- ▶ Delayed IRB approval
- ▶ Time to review and implement changes due to amendments or safety reports
- ▶ Pre-screening activities not otherwise compensated
- ▶ Screen failures higher than expected
- ▶ Lower than expected enrollment
- ▶ High early termination or dropout rates
- ▶ Unscheduled visits
- ▶ Uncompensated monitoring visits or remote monitoring
- ▶ Monitor Changes
- ▶ Additional sponsor or CRO requests that are not planned
- ▶ Preparation for and involvement in Audits
- ▶ Other costs and time that are not specifically compensated for in the per subject compensation

# Evaluate Your Negotiation Skills

18

# Be Realistic in Budget Negotiation



1

Establish rapport and be reasonable. Lead with your WANT but know your NEED/bottom line.

2

Negotiate in Good Faith (put yourself in the other party's shoes). Diffuse dialogue whenever possible.

3

Provide reasonable alternatives, realizing you may need to sacrifice a "want" to gain a "need".

4

Make relatively small changes in position rather than drastic sacrifices. If a CRO causes excessive delays, contact the sponsor directly.

# Assemble Stakeholders

20

# Stakeholders in the Process

- ▶ Principal Investigator
- ▶ Clinical Research Coordinator
- ▶ IRB process or vendors
- ▶ Budget negotiators
- ▶ Clinical Trial Agreement negotiators
- ▶ Project Accounting/Grant administration
- ▶ Health Information Management/IT
- ▶ Registration/Scheduling/Authorizations/Denials
- ▶ Offsite facilities providing Clinical Trial services



# Thank you

Kelly Willenberg, DBA, RN, CHRC, CHC, CCRP

[Kelly@kellywillenberg.com](mailto:Kelly@kellywillenberg.com)

864-473-7209

<https://kellywillenberg.com/>

