

Health Research Associates



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February 10, 2023

Centers for Medicare and Medicaid Services
Mail Stop C4-01-26
7500 Security Boulevard
Baltimore, MD 21244

RE: POTENTIALLY MISVALUED CODES (CPT 36514, CPT 36516 and CPT 36522)

- **CPT 36514, 36516, 36522: Inappropriate assigned clinical labor code (L042A) and need for creation of new clinical labor code (Therapeutic Apheresis Nurse Specialist)**
- **CPT 36514: Misvalued and missing supply items**

I am submitting this public nomination for the subject revisions of three potentially misvalued codes – therapeutic plasma exchange (TPE) (CPT 36514¹), lipoprotein apheresis (CPT 36516²) and extracorporeal photopheresis (ECP) (CPT 36522³). This public nomination is submitted on behalf of referring physicians and their patients who require these treatments on an outpatient basis but currently cannot find any non-facility service provider, and additionally on behalf of non-facility providers that would like to offer these services but currently cannot do so because of long standing undervaluation of certain direct practice expenses that in turn dictates Medicare Physician Fee Schedule (PFS) and non-Medicare payment rates that are inadequate to cover direct operating costs.

TPE and ECP constitute the two higher-volume procedures, each totaling roughly 175,000 to 200,000 procedures annually. Roughly one-half of TPE procedures are performed in the hospital outpatient setting; the balance are provided to hospital inpatients.

Under the Part B Hospital OPPS, the U.S. average CY 2023 Medicare payment rate for TPE/CPT 36514 performed in a hospital outpatient department is \$1,359.84. Under the Part B Physician Fee Schedule (PFS), the U.S. average CY 2023 Medicare payment rate for this same procedure performed in a non-facility (office or clinic) setting is \$571.00, which includes compensation of the supervising physician (1.81 RVUs) and malpractice insurance.

As addressed in more detail below, this current Medicare PFS payment rate does not sufficiently compensate non-facility providers for their direct and indirect non-physician costs to provide TPE, which importantly include the costs of therapeutic apheresis nurse labor and the disposable plasma exchange tubing set. As a consequence, and despite the fact

¹ Full CPT procedure code descriptor: Therapeutic apheresis; for plasmapheresis

² Full CPT procedure code descriptor: Therapeutic apheresis; with selective extracorporeal immunoadsorption, selective adsorption, or selective filtration and plasma reinfusion

³ Full CPT procedure code descriptor: Extracorporeal photopheresis

that TPE/CPT 36514 is safe, effective and covered by Medicare in the non-facility setting, there are virtually no U.S. TPE therapy providers, as evidenced by 2021 CMS claims data:

<u>Facility-based TPE physician claims⁴</u>	<u>Non-facility-based TPE physician claims</u>
23,015	398

As a consequence, virtually all outpatient TPE procedures are performed in the hospital outpatient setting, where the U.S. average CY 2023 Medicare payment rate is well over two-fold higher. Many physicians and other non-hospital-based providers have either investigated delivering TPE therapy in their non-facility setting, but cannot financially justify the operating losses they would sustain. Outpatients who require TPE therapy are referred to the higher-cost hospital outpatient treatment setting.

Similarly, the U.S. average Medicare PFS payment rate for ECP provided in the non-facility setting (\$1,379) is not sufficient to compensate providers for their operating costs. Below are 2021 facility-based and non-facility-based ECP physician claims:

<u>Facility-based ECP physician claims⁵</u>	<u>Non-facility-based ECP physician claims</u>
7,695	39

And again, virtually all outpatient ECP procedures are performed in the higher-cost hospital outpatient setting, as it is not financially possible for an office-based provider to do so. The U.S. average CY 2023 Medicare payment rate for ECP performed in the hospital outpatient department, exclusive of the physician professional fee, is \$4,160, three times higher than the current PFS payment rate for this same procedure.

As with TPE and ECP, inadequate reimbursement of non-hospital providers for lipoprotein apheresis is preventing otherwise willing non-facility-based providers from offering lipoprotein apheresis, forcing patients to travel instead to higher-cost facility-based providers to get their treatments.

Currently there are fewer than 10 non-facility-based providers of lipoprotein apheresis nationwide; many other providers that started this service have been forced to discontinue it and refer their patients to hospital-based lipoprotein apheresis providers, which are often hundreds of miles away and impractical or not possible for patients to access.

⁴ These are physician supervision claims for TPE, which do not equate with numbers of OPPS procedures

⁵ These are physician supervision claims for ECP, which may not equate with numbers of OPPS procedures

***CPT 36514, 36516, 36522: Inappropriate assignment of RN/LPN labor code (L051A);
Need for new clinical labor code (Therapeutic Apheresis Nurse Specialist) that reflects
highly specialized training, skills, work functions and median salary***

The extracorporeal blood therapy procedures CPT 36514, CPT 36516 and CPT 36522 are variously used to treat serious hematological, oncologic, neurological, rheumatologic, cardiac and autoimmune disorders. While each of these procedures are used to treat a different subset of these disorders and involves the use of a different type of enabling technology, the skill and experience requirements to perform them are very similar. In fact, many therapeutic apheresis nurse specialists are trained and capable of performing two or all three procedures.

Therapeutic apheresis nurse specialists are generally RNs, but they can also be LPNs, LVNs or other licensed medical personnel. They must have the requisite training, knowledge-based skills and experience to perform these complex procedures on patients who often have serious comorbidities that can result in hemodynamic instability over the course of the procedure. Therapeutic apheresis specialists must be skilled in evaluating patients and managing clinical issues and adverse events that commonly arise during the procedure, particularly in patients with comorbid anemia, renal failure, cardiovascular disease, serum protein abnormalities or other risk factors.⁶

Below are key work functions involved in the performance of TPE (CPT 36514), ECP (CPT 36522) and lipoprotein apheresis (CPT 36516):

- Advanced Vascular Access assessment
- Advanced venipuncture skills for high blood flow procedures
- Advanced skills for accessing and caring for implantable ports
- Pre-procedure assessment for hemodynamic stability and contraindications to apheresis procedures
- Management of the extracorporeal blood circuit
- Advanced troubleshooting and optimization skills to complete the procedure.
- Advanced patient assessment skills throughout the procedure to identify and manage adverse events, as per facility's SOP
- Management of rapid blood product infusion
- Medication administration: both infusion of medications and knowledge about medications used as adjunct treatments and potential drug interactions or effects of the therapeutic apheresis procedure on circulating drug levels.

⁶ Chhibber V and King KE. Management of the therapeutic apheresis patient (Chapter 12). In: *Apheresis: Principles and Practice, 3rd Edition*. Bethesda, MD: AABB Press, 2010.

While position postings often use the same terminology (e.g. “apheresis RN”), the skill set, experience and work functions required for a therapeutic apheresis specialist are sharply differentiated from those of “apheresis nurses” who work in donor blood facilities to collect blood components, including platelets, red blood cells and other cellular and acellular blood components, using similar types of centrifugation-based apheresis equipment from *healthy volunteer donors*. These blood component collection activities are not therapeutic medical procedures, and of course are not associated with CPT procedure codes or billed to insurers.

Commensurate with the lesser demands of the non-therapeutic blood collection procedures they perform on healthy volunteer blood donors, the salary range for non-clinical “apheresis nurses,” who work in non-medical settings including donor blood centers, bloodmobiles and offsite locations in the community, is significantly lower than the salary range for therapeutic apheresis nurse specialists.

The CY 2023 rate per minute for the clinical labor code L042A (RN/LPN) currently assigned for CPT 36514, 36516 and 36522 is \$0.525, which is scheduled to increase to \$0.63 in CY 2025. According to Fresenius Medical Care, which is the largest provider of therapeutic apheresis services in the U.S.,⁷ the mean base salary for therapeutic apheresis nurses is \$50 per hour, with much variation geographically in accordance with local wage rates and qualified personnel availability.⁸ This corresponds with an annual base salary of \$104,000; with application of CMS’ benefits multiplier (1.366), this translates to a wage rate of \$1.14 per minute.

Separately, ZipRecruiter, a national employment recruiting firm, estimates that the national average base salary for an apheresis RN is currently \$49 per hour, or \$101,488 annually.⁹ A second national employment recruiting firm, Glassdoor, estimates a \$96,407 median annual income for an apheresis RN.¹⁰ Application of the benefits multiplier yields rates of \$1.11 and \$1.06 per minute, respectively.

To resolve this wide disparity between the \$0.525 (terminating at \$0.63) rate per minute that presently applies for CPT 36514/16/22 and the \$1.06 to \$1.14 rates per minute reflected in these data, I propose that CMS coordinate with the Department of Labor to:

1. Create a new clinical labor code and descriptor, which specifically identifies this highly specialized job function, e.g. Therapeutic Apheresis Nurse Specialist) and
2. Complete an investigation to establish a mean annual base salary for U.S. therapeutic apheresis nurse specialists, for adjustment with CMS’ 1.366 benefits multiplier and conversion to a rate per minute.

⁷ Fresenius Medical Care provides some 32,000 therapeutic apheresis treatments annually. Accessed at: <https://fmcna.com/physician-solutions/practice-management/apheresis-services/>

⁸ Darinka Povrzenic, Vice President, Clinical OPS, Fresenius Medical Care. Personal communication by email. Ms. Povrzenic may be reached at Darinka.povrzenic@fmc-na.com.

⁹ ZipRecruiter. Apheresis RN Salary. Accessed 2/9/2023 at: <https://www.ziprecruiter.com/Salaries/Apheresis-RN-Salary>

¹⁰ Glassdoor. Apheresis RN Salaries. Accessed 2/7/2023 at: https://www.glassdoor.com/Salaries/apheresis-rn-salary-SRCH_KO0,12.htm

CPT 36514: Mis-valuation of two supply items

Two supply items in the Supply file which are utilized in the performance of each TPE procedure are misvalued. These items are identified below with their supply code, current price, and the average selling price (ASP) that represents information provided by the two manufacturers (Terumo BCT and Fresenius Kabi/Fenwal) that, according to independent market research,¹¹ account for 96% of the U.S. market:

cms_code	Description	Price (existing) ¹²	ASP
SC085	Tubing set, plasma exchange	\$186.12	\$248.77
SC084	Tubing set, blood warmer	\$8.01	\$14.71

These ASP values represent a unit sales volume-weighted average of the Q4 2022 ASP of Terumo BCT's *Spectra Optia* Exchange Set and the full-year 2022 ASP for Fresenius Kabi/Fenwal's Amicus Exchange Kit. These data supplied to me for purposes of calculating the overall ASPs in the above table are sensitive. However, representatives of each manufacturer indicated that they will be happy to directly provide their unit sales and ASPs to CMS. Their email and phone contact information is provided in the footnote below.¹³

Terumo BCT and Fresenius Kabi/Fenwal supply these items to well over 1,000 U.S. provider customers, corresponding with many thousands of invoices each year. Attached is a sample invoice from each manufacturer with the customer identity redacted for privacy purposes.

If you have any questions or additional information needs, please contact me at 626-665-1898 or kberman626@outlook.com.

Sincerely,



Keith Berman, MPH, MBA

Attachment: Sample Plasma Exchange Tubing Set and Blood Warmer Invoices

¹¹ GlobalData plc. U.S. Hospital SKU Level Trackers (June 2020).

¹² CMS-1770-F_PUF_Supply

¹³ **Terumo BCT:** Carly Newton (Manager, Therapy Access), Carly.Newton@terumobct.com (email), 720-548-0429. **Fresenius Kabi/Fenwal:** Jeremy McGough (Sales Manager, Therapeutic Apheresis), Jeremy.McGough@fresenius-kabi.com, 314-722-0393.

Sample Plasma Exchange Tubing Set and Blood Warmer Invoices from Terumo BCT and Fresenius Kabi/Fenwal



Terumo BCT, Inc.
10811 West Collins Avenue
Lakewood CO 80215
USA
Tel : 877-339-4228 Fax : 866-715-6768

Invoice

Reprint

<p>Ship-to Customer : [REDACTED] [REDACTED] [REDACTED] USA</p> <p>Sold-to Customer : [REDACTED] [REDACTED] [REDACTED] [REDACTED]</p>	<p>Invoice # : 5110816143 Customer Ref : 95488427 Invoice Date : 02/07/2023 Currency : USD Order No. : 2598397 Delivery No. : 81759001 Terms of Payment : Net 30 Days</p> <p>Customer PO No. : [REDACTED] Contact Person : [REDACTED] Contact No. : [REDACTED]</p> <p>Total Including Tax & Freight : 1,573.59</p>
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<p>Shipping Conditions : Ground Gross Weight : 6.600 KG Warehouse Code : US02</p>	<p>Incoterms : [REDACTED] Description : Ex Works Shipping Date : 02/07/2023</p>
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IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT CUSTOMER SUPPORT AT 877-339-4228.

Material/Description	Quantity	Unit Price	Total Price
12220 SPECTRA OPTIA EXCHANGE SET,EA 950217 Batch Number : 2301116141 Expiration Date : 01/01/2025 EAN: 05020583122208	1CS	1,573.59	1,573.59
Amount Before Tax			1,573.59
Total Amount Owed			1,573.59

If you seek reimbursement from a governmental healthcare program, you must accurately report all costs in compliance with the program's requirements.

Federal Tax ID: 84-1155788
Florida Permit Number: 26:1348
Please Direct Inquiries To:
Customer Support: (877) 339-4228 Fax: (866) 715-6768
Credit Dept.: (877) 339-4228 Fax: (303) 231-4103

Forwarder:
Terumo BCT, Inc.
C/O Acme Dist Centers, Inc.
18101 E. Colfax Avenue
Aurora, CO 80011

Please Remit Payments To:
Terumo BCT
Department 7087
CAROL STREAM, IL
60122-7087

See Terms and Conditions at site: <http://www.terumobct.com/location/north-america/Documents/Ordering-Information-Terms-Conditions.pdf>

6 Spectra Optia Exchange tubing sets per case



Terumo BCT, Inc.
10811 West Collins Avenue
Lakewood CO 80215
USA
Tel : 877-339-4228 Fax : 866-715-6768

Invoice

Ship-to Customer : [REDACTED] Sold-to Customer : [REDACTED]	Invoice # : 5110810339 Customer Ref : [REDACTED] Invoice Date : 01/05/2023 Currency : USD Order No. : 2592321 Delivery No. : 81739151 Terms of Payment : Net 30 Days Customer PO No. : [REDACTED] Contact Person : [REDACTED] Contact No. : [REDACTED] Total Including Tax & Freight : 1,661.92
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Shipping Conditions : Ground Gross Weight : 6.800 KG Warehouse Code : US02	Incoterms : [REDACTED] Description : Ex Works Shipping Date : 01/05/2023
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IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT CUSTOMER SUPPORT AT 877-339-4228.

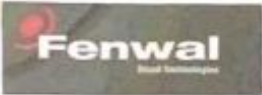
Material/Description	Quantity	Unit Price	Total Price
IFT40410 ASTO TUBE,BD WARMING W/PRE-SP 5030706 Batch Number : 32075792 EAN: 04260114140016 AstoTUBE Set	2CS	830.96	1,661.92
Expiration Date : 02/17/2025			
Amount Before Tax			1,661.92
Total Amount Owed			1,661.92

If you seek reimbursement from a governmental healthcare program, you must accurately report all costs in compliance with the program's requirements.

Federal Tax ID: 84-1155788 Florida Permit Number: 28:1348 Please Direct Inquiries To: Customer Support: (877) 339-4228 Credit Dept.: (877) 339-4228	Forwarder: Terumo BCT, Inc. C/O Acme Dist Centers, Inc. 18101 E. Colfax Avenue Aurora, CO 80011	Please Remit Payments To: Terumo BCT Department 7087 CAROL STREAM, IL 60122-7087
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See Terms and Conditions at site: <http://www.terumobct.com/location/north-america/Documents/Ordering-Information-Terms-Conditions.pdf>


50 Asto Tube blood warming devices per case

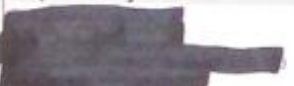


Fenwal Inc.
Three Corporate Drive
LAKE ZURICH IL 60047-8930
USA


Page 1 of 1
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Order Confirmation

Sold-To-Party


Ship-To-Party


Information

Sales Order No. 1224048
Document Date 11/17/2022
Customer No. 
Currency USD
Contact Person PI_CONNECT

Header Information					
Purchase Order No:	GL004	Purchase Order Date:			
Gross Weight:	42.760 LB	Net Weight:	41.896 LB		
Volume:	3.458 FT3				
Terms of payment:	Prepayment Required				
Terms of Delivery:	PPD DESTINATION				

Item	Material	Quantity	UOM	Quantity per UOM	UOM Price	Amount
10	X6R2349	1.00	CS	6 EA	1,365.00 USD	1,365.00
	AMICUS EXCHANGE KIT - THERAPEUTICS					
	Batch:	FA22G28018				
	Sales Tax (%)	8.25	%			
20	4B7891X	1.00	CS	14 EA	140.42 USD	140.42
	ACD-A IN 1000ML PLASTICCONTAINER					
	Batch:	Y392945				
	Sales Tax (%)	0	%			
Items total:						1,505.42
Shipping / Hand		0.54	USD	1 LB	427.60	23.09
Sales Tax:						112.61
Final amount:						1,641.12

Please note that we are unable to apply shipping and handling charges to your carrier account. Any applicable shipping charges will be applied directly to your invoice.

Signature _____

Date _____

Visit www.myfreseniuskabi.com/us to access tools that enable you to place, view and track your orders. You can also reference and print invoices. Sign up today.