

Health Research Associates



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

By email: PE_Price_Input_Update@cms.hhs.gov

RE: POTENTIALLY MISVALUED CODE (CPT 36514)

- **Misvalued cell separator system (EQ084) price and utilization rate**

Dear CMS,

I am submitting this public nomination for the subject revision of a potentially misvalued code: therapeutic plasma exchange (TPE) (CPT 36514¹). This public nomination is submitted both on behalf of (1) physicians who would like to refer their patients to non-facility providers but currently cannot find any non-facility service provider, and (2) non-facility health care providers that would like to offer TPE (CPT 36514) but currently cannot do so because of long-standing undervaluation of direct practice expenses, which in turn dictates Medicare Physician Fee Schedule (PFS) and non-Medicare payment rates that are inadequate to cover their direct operating costs.

Background

Roughly 100,000 TPE procedures are performed annually to treat a wide spectrum of acute and chronic inflammatory, autoimmune and alloimmune disorders. Roughly 75% of TPE procedures are performed in the hospital outpatient setting, with the balance provided to hospital inpatients.²

Under the Part B Hospital OPPS, the U.S. average CY 2025 Medicare payment rate for TPE/CPT 36514 performed in a hospital outpatient department is \$1,639.28, not including compensation for the supervising physician. Under the Part B Physician Fee Schedule (PFS), the U.S. average CY 2025 Medicare payment rate for this same procedure performed in a non-facility (office or clinic) setting is \$663.43,³ which includes compensation of the supervising physician and malpractice insurance.

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

² Definitive Healthcare LLC. U.S. hospital outpatient and inpatient TPE claims, 2023.

³ 20.51 relative value units (RVUs) with a finalized CY 2025 conversion factor of \$32.3465

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, the cell separator system (CMS code EQ084) and several other dedicated equipment items. As a consequence, and despite the fact that TPE/CPT 36514 is safe, effective and covered by Medicare in the non-facility setting, there are exceedingly few non-facility TPE therapy providers or procedures billed to Medicare, as evidenced by 2023 CMS claims data:⁴

<u>Facility-based TPE physician claims⁵</u>	<u>Non-facility-based TPE physician claims</u>
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20,204

397

More than 98% of outpatient TPE procedures are performed in the hospital outpatient setting, where the U.S. average CY 2025 Medicare payment rate is nearly 2.5-fold higher than in the non-facility setting. Over the last decade, I have learned of or directly heard from a number of physicians who would like to provide TPE and have investigated delivering TPE therapy in their non-facility setting, but cannot financially justify the operating losses that they would sustain at the current non-facility payment rate. The resulting absence of non-facility Medicare providers forces referring physicians to direct their patients, including Medicare beneficiaries, to the higher-cost hospital outpatient treatment setting.

The enabling technology used to perform TPE procedures is the cell separator system (EQ084). These FDA-cleared devices separate liquid blood plasma from blood cellular components (red blood cells, platelets, leukocytes, etc.), with subsequent discard of the plasma phase and replacement with human albumin solutions or donor plasma. Below is the current information in the CMS Equipment File on which the cost or price per procedure is calculated:

cms_code	description	useful_life	price	utilization_rate	minutes_ per_year	nf_time
EQ084	cell separator system	6	81656.397	0.5	150000	176

Need for updated price for EQ084

The current average sales price (ASP) of cell separator systems is \$93,231.35, just under \$11,600 higher than the price identified in the Equipment File. This ASP is based on the ASP for all fourth quarter 2024 U.S. sales of the Spectra Optia cell separator system (Terumo BCT). The Spectra Optia system accounts for an estimated 93% of the U.S. cell

⁴ CY 2025 PFS Final Rule 2023 Utilization Data Crosswalked to CY 2025
<https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notice/cms-1807-f>

⁵ This value represents physicians' professional supervision claims for TPE for both hospital outpatient and inpatient TPE procedures; thus it does not equate with numbers of OPPI procedures

separator market; other commercial cell separator devices utilized for performance of TPE⁶ collectively account for an estimated 7% of the U.S. market.⁷

Copies of all fourth quarter 2024 invoices are separately appended.

I ask that CMS update its price for the cell separator system (EQ084) to **\$93,321.35**, to more accurately reflect its current mean acquisition cost.

Need to correct the cell separator system (EQ084) utilization rate

Both average procedure time (176 minutes) and useful life (6 years) for the cell separator system cited in the Equipment File are accurate. However, the current utilization rate factor (0.5) in the Equipment File for EQ084 very substantially overstates the actual average utilization of these therapeutic blood separation devices.

Below for calendar year 2024 are the numbers of operational cell separator devices and number of therapeutic apheresis procedures reported by five large hospital TPE providers, including the three largest-volume hospitals in the U.S. As there is substantial cost associated with the purchase and maintenance of each cell separator device, these and other high-volume institutional TPE providers place a particular priority on operational efficiency to maximize the number of procedures that can be performed per device. **Across all five providers on a procedure volume-weighted basis, there was a mean of 181 procedures performed on each cell separator device in calendar year 2024.**

Institution	Cell separators (EQ084) in use	Number of procedures (2024)	Procedures per device (2024)
UC San Diego Medical Center ⁸	25	3,882	155
Johns Hopkins Hospital ⁹	11	2,706	246
Methodist Hospital (Houston) ¹⁰	11	2,598	236
University of Pennsylvania Hospital ¹¹	17	2,040	120
William P Clements Jr University Hospital ¹²	9	2,016	224
Volume-weighted mean procedures per device:			181

⁶ Prismaflex (Baxter Healthcare), Amicus (Fresenius Kabi) and NxStage System One (Fresenius Medical Care)

⁷ U.S. hospital utilization data. Spectra Optia, Prismaflex, NxStage System One, Amicus cell separator systems. GlobalData Plc. 2020.

⁸ Jerel Malong (Apheresis Nurse Manager); email: jmalong@health.ucsd.edu

⁹ Sonja Vozniak (Hemapheresis Nurse Manager); email: sscott3@jhmi.edu

¹⁰ AJ Musharbash (Apheresis Manager); email: amusharbash@houstonmethodist.org

¹¹ Caitlin Cahill (Nurse Manager, Apheresis Unit); email: caitlin.cahill@pennmedicine.upenn.edu

¹² Bridget Scott (Apheresis Unit Nurse); email: bridget.scott@utsouthwestern.edu

Applying this mean of 181 TPE procedures per year per cell separator system (EQ084) and an intra-procedure time of 176 minutes, we calculate the procedure minutes per device per year:

$181 \text{ procedures/year} \times 176 \text{ minutes/procedure} = \mathbf{31,856 \text{ minutes per cell separator system per year.}}$

Based on 150,000 minutes per year, the utilization rate for EQ084 is as follows:

$31,856 \text{ minutes per EQ084 device per year} / 150,000 \text{ minutes per year} = 0.212 \cong \mathbf{0.21.}$

The current 0.5 utilization rate identified in the Equipment File for EQ084 implies that a mean of 426 TPE procedures are performed per year on a single EQ084 device ($150,000 \times 0.5 = 75,000$ minutes per device per year divided by 176 intra-procedure minutes per device = 426 procedures per year). This current presumptive device utilization rate is more than two-fold (135%) higher than the actual mean utilization rate of 181 procedures per cell separator system reported by our sample of high-volume, high-efficiency hospitals.

I ask that CMS revise the utilization rate for EQ084 (cell separator system) from 0.5 to **0.21** to reflect real-world utilization of this device type by efficient, high-volume institutional providers.

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

Sincerely,

A handwritten signature in green ink that reads "Keith Berman".

Keith Berman, MPH, MBA

Attachment: EQ084_Q4 2024 U.S. invoices_Spectra Optia_Terumo BCT