THERAPEUTIC APHERESIS

A Guide to Billing and Securing Appropriate Reimbursement

2024 Edition

ASFA
American Society for Apheresis

The American Society for Apheresis would like to thank and recognize the members of its Public Affairs and Advocacy Committee for their participation in the development of this Guide:

Chairs:

Susan Knight, MBA, CNMT, FACHE

Chet Andrzejewski, PhD, MD, FCAP

Committee Members:

Nicole Aqui, MD

Jan C. Hofmann, MD, MPH, MSc

Tina S. Ipe, MD, MPH

Yanhua Li, MD, MS, FCAP

Walter Linz, MD, MBA

Kristin Ricci, MD

Gustaaf de Ridder, MD, PhD

Nicole De Simone, MD, MPH

Leah M. Stone, JD

Ding Wen Wu, MD, PhD, FCAP

Prepared by:

Keith Berman, MPH, MBA
Health Research Associates
Sierra Madre, California
(626) 665-1898
kberman626@outlook.com

The American Society for Apheresis provides this guide as a resource to help you communicate more effectively with your billing staff about:

- Use of billing codes – the "language" of insurance claims and communications – to more accurately bill payers for your services
- How insurance billing and payment works in different treatment settings for the types of therapeutic apheresis procedures you perform

We hope you find this guide to be a useful tool as you work to minimize and resolve problems which may arise with insurance coverage or payment for your therapeutic apheresis services.

Important – Please Note:

The information provided in this guide is for illustrative purposes only, and does not constitute billing, reimbursement or legal advice. Neither the American Society for Apheresis nor any of its members or supporters makes any representation or warranty concerning this information or its completeness, accuracy or timeliness. No entity involved in the preparation of this guide makes any representation about the likelihood of success in obtaining insurance coverage or reimbursement for any service.

It is solely the responsibility of the provider to determine and submit appropriate codes, charges and other documentation in claims for services rendered.

For citation purposes, please use the following:

ASFA Public Affairs and Advocacy Committee. Therapeutic Apheresis: A Guide to Billing and Securing Appropriate Reimbursement, 2024 Edition. Knight S, Andrzejewski Jr C, et al (eds.). Vancouver, BC: American Society for Apheresis, 2024; 34 pages. Available from the ASFA website at: http://www.apheresis.org/?page=ApheresisReimbursement.

Contents

Preface

The members of the American Society for Apheresis (ASFA) Public Affairs and Advocacy Committee are pleased to share with the Society's membership the latest update to **Therapeutic Apheresis: A Guide to Billing and Securing Appropriate Reimbursement**. Below are listed the significant changes that appear in the 2024 edition of the Reimbursement Guide:

- All Medicare payment rates for products and hospital and physician services have been updated to reflect the current 2024 rate schedules.
- Referenced Medicare regulations and other resources, including the bibliography for further reading, have been updated.
- Medicare payment for physician supervision of apheresis treatment provided in hospital inpatient or outpatient settings.
- Medicare payment changes for office-based therapeutic plasma exchange.
- Updated FDA-approved indications for lipoprotein apheresis.
- Autologous T-cell collections for chimeric antigen receptor (CAR) T-cell therapy.

The committee encourages the membership to contact the Society regarding any problems, errors, omissions or additional information which a member believes should be included in future editions of the document so that these items can be addressed by the committee. In addition, the committee is interested in receiving feedback from members about potential reimbursement issues that they have encountered as relates to information provided in the current edition of the Guide.

The committee wishes to thank Keith Berman for his extensive work in creating and updating this (and prior) versions of the Guide, and members of the ASFA Head Office for their ongoing work and significant support of this endeavor.

Sincerely,

Members of the Public Affairs and Advocacy Committee

Introduction: The Insurance Billing Process

As a provider of therapeutic apheresis services, you rely on payment from a variety of public and commercial insurers, with varying coverage and payment policies.

Insurance **coverage** of different types of therapeutic apheresis procedures is discussed in several sections of this guide.

To secure appropriate **payment**, your billing staff must assure that the insurance claim is complete and accurate. In certain instances, the claim must be customized to conform with the requirements of a particular insurer, or to alert that insurer to a contractual agreement.

The mechanics of the insurance billing process for apheresis services can be subdivided on the basis of:

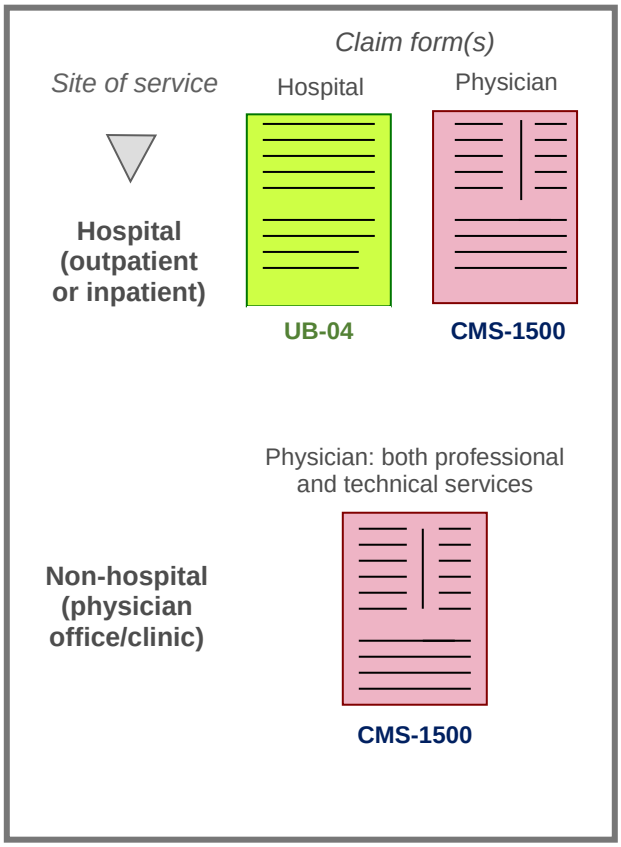
- **The treatment setting** in which the service is performed (hospital vs. physician office/physician-directed clinic);
- **The provider** that is submitting a service claim (**physician** or **hospital**).

Therapeutic apheresis services provided in the **hospital inpatient or outpatient** setting generally involves completion and separate submission of ***two*** claim forms:

- The ***CMS-1500*** by the **physician**, to facilitate payment for the physician's supervision of the procedure; and
- The ***UB-04*** by the **hospital**, to facilitate payment for the technical service itself (including nurse or technician performing the procedure, supplies, equipment amortization, replacement fluid, facility overhead, etc.).

When the procedure is performed in a **physician office or clinic**, only a ***single*** CMS-1500 claim form is required to bill both the technical and professional services.

Claim Forms Submitted Depend on the Site of Service



The two "universal" insurance claim forms:

UB-04	Hospital claim form
CMS-1500	Physician office/clinic claim form

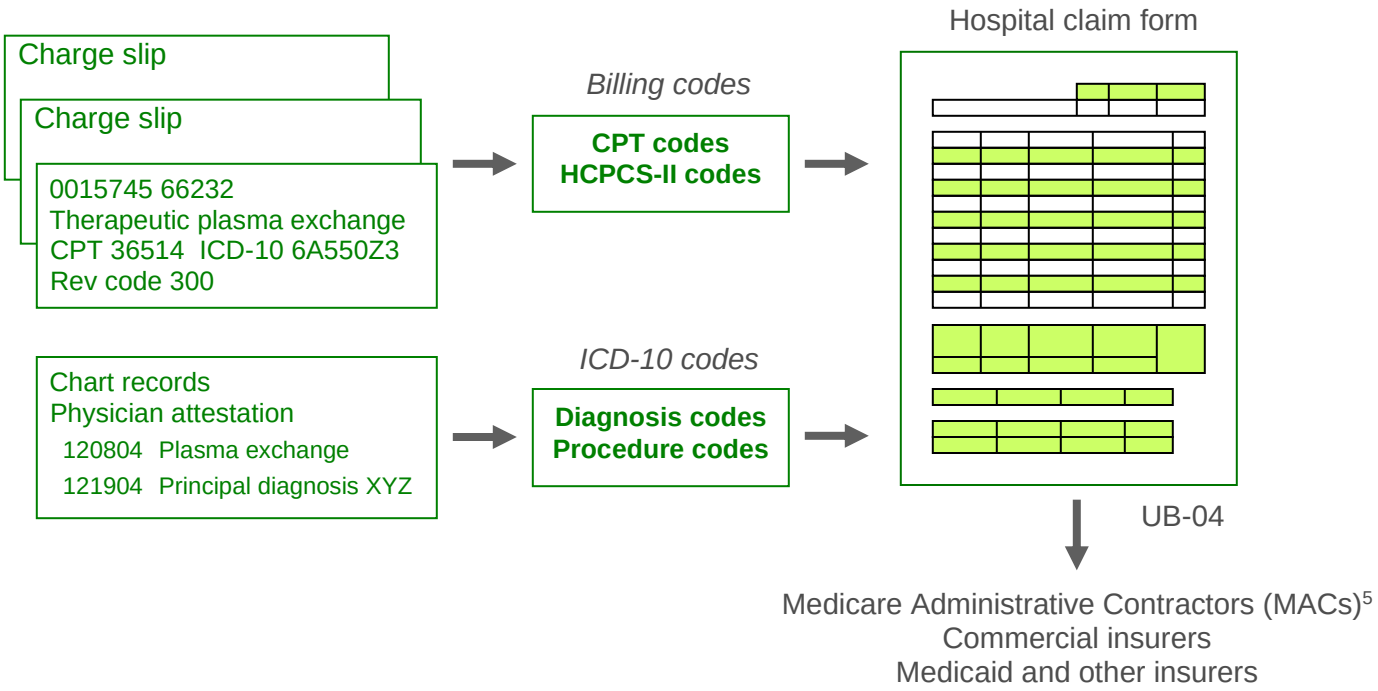
Hospital Billing on the UB-04 Claim Form

The hospital's "**chargemaster**" contains a database of thousands of services and items.

Each of these services and items is assigned not only a **charge** but an associated **CPT**[1] or **HCPCS**[2] **Level II billing code** to identify it for the insurer, and a three-digit **revenue code** which allows it to be grouped by type of service, or by a specific operating department in the hospital.

Every time a procedure is performed or an item is used for a hospital inpatient or outpatient, an electronic or paper "**charge slip**" is generated and sent to the billing department to be included with the patient's insurance claim.

Separately, both input from the attending physician and examination of patient chart notes enables billing staff to enter **ICD-10-CM**[3] **diagnosis codes** and **ICD-10-PCS**[4] **procedure codes**.



Key billing codes used with the UB-04 hospital claim form

CPT codes: identify outpatient procedures, physician services, and hospital laboratory services

HCPCS Level II codes: identify drugs, biologicals, blood products, durable medical equipment (DME), certain supplies, and selected procedures

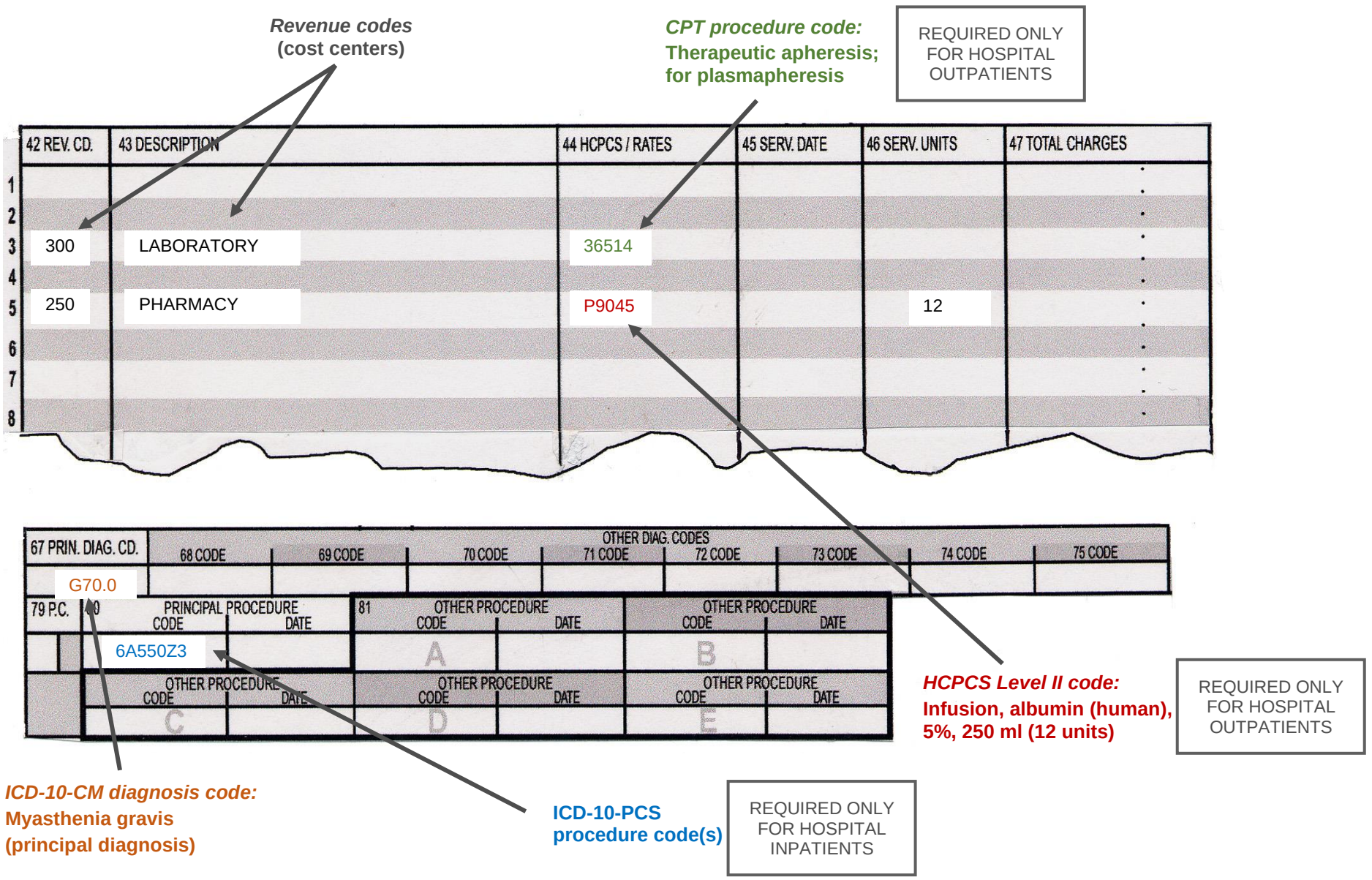
ICD-10-CM[3] diagnosis codes: identify diseases and injuries; code a 5th digit when applicable

ICD-10-PCS[4] procedure codes: identify procedures in the hospital inpatient setting

Revenue codes: group similar types of hospital services and items by type of service

[1]Current Procedural Terminology: CPT© 2024. American Medical Association. All rights reserved.
[2]Healthcare Common Procedure Coding System.
[3]International Classification of Diseases, 10th Revision, Clinical Modification.
[4]International Classification of Diseases, 10th Revision, Procedure Coding System.
[5]There are 12 A/B MAC jurisdictions.

Sample Coding of a Hospital Therapeutic Apheresis Claim



Physician Billing on the CMS-1500 Claim Form

For apheresis procedures, the **place of service code** (Field 24B) is *extremely important*

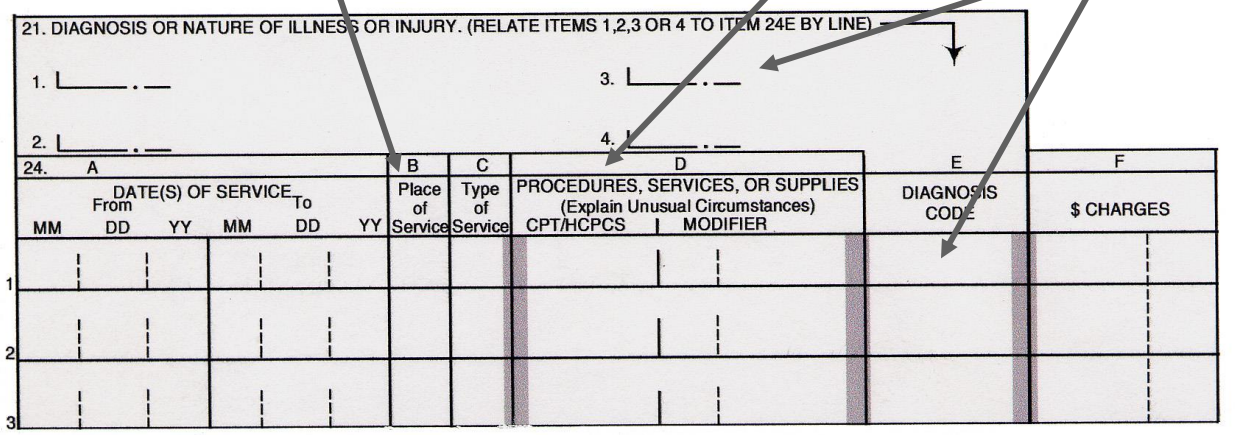
Enter

- **11** **Physician's office or non-hospital MD-directed clinic setting**
- **22** **Hospital outpatient setting**
- **21** **Hospital inpatient setting**

Treatment-related information required for insurers to process claims from physicians and physician-directed clinics prominently includes:

CPT coded procedures or services *and* **HCPCS Level II** coded blood products, biologicals, drugs, DME

ICD-10-CM diagnosis codes specifying the diagnosis that "relates" to each CPT-coded service or HCPCS-coded item



NOTE: The physician can separately bill an **Evaluation & Management (E/M) code** for a history and physical exam to determine the appropriateness of the therapeutic apheresis procedure, *as long as the E/M service is performed on a different day than supervision of the apheresis procedure*[*].

Key billing codes used for the CMS-1500 physician claim form

CPT codes: identify billable procedures and services

HCPCS Level II codes: identify drugs, biologicals, blood products, durable medical equipment (DME), certain supplies, and selected procedures

ICD-10-CM diagnosis codes: identify diseases and injuries; comprise 3 to 7 digits

Place of Service codes: informs insurer where the apheresis procedure was performed; dictates payment for global service or professional component only.

[*]A physician may bill an E/M code on the same date as supervision of an apheresis procedure only when: (1) the E/M code is for a separately identifiable service that involves more than the E/M portion of the apheresis procedure, *and* (2) the E/M service involves a different diagnosis than the diagnosis for which the apheresis procedure is being performed. Add a "-25" modifier to the E/M code.

Codes Used to Identify and Bill Apheresis Services

Procedure codes:

CPT procedure codes		*ICD-10-PCS procedure codes*	
36511	Therapeutic apheresis; for white blood cells	6A550Z1	Therapeutic leukopheresis (therapeutic leukocytapheresis)
36512	for red blood cells	6A550Z0	Therapeutic erythrocytapheresis (therapeutic erythropheresis)
36513	for platelets	6A550Z2	Therapeutic plateletpheresis
36514	for plasmapheresis	6A550Z3	Therapeutic plasmapheresis
36516	with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion[1]	6A55	Therapeutic apheresis, other[2]
36522	Photopheresis, extracorporeal	6A650ZZ	Therapeutic photopheresis
38205	Blood-derived hematopoietic stem cell harvesting for transplantation, per collection; allogeneic	6A550ZV	Apheresis (harvest) of stem cells
38206	autologous	6A550ZV	Apheresis (harvest) of stem cells

[1] Lipoprotein apheresis (LDL-C apheresis and lipoprotein[a] apheresis) is currently the only FDA-approved procedure for which CPT 36516 is applicable. These lipoprotein apheresis procedures are performed on a single FDA-licensed apheresis system (LIPOSORBER® system; Kaneka Medical Products).

[2] No specific ICD-10-PCS code has been defined for LDL-C apheresis or lipoprotein[a] apheresis.

Common revenue codes used by hospitals on UB-04 claim form:

Revenue code	*Descriptor*
300 (309)	Laboratory – General Classification (Other Laboratory)
510 (519)	Clinic – General Classification (Other Clinic)
20X	Intensive Care (200 – General; 202 – Medical; 209 – Other)
390 (399)	Blood Storage and Processing – General Classification (Other BSP)
280 (289)	Oncology – General Classification (Other Oncology)
940 (949)	Other Therapeutic Services – General Classification (Other Therap. Services)

Diagnosis codes: See "Focus" sections for specific therapeutic apheresis procedures.

Insurance Coverage for Therapeutic Apheresis Services

Below are general principles which broadly apply to apheresis coverage determination: ("Focus" sections that follow address insurance coverage issues for specific procedures):

- The **scope of coverage** – all disorders determined to be medically necessary – **may vary by insurer**, depending on their coverage process and the sources upon which they rely to make coverage determinations.

  In addition to referencing the published clinical literature, insurers may reference **published guidelines** or employ physician experts to define coverage policies for specific disorders or to make individual case coverage decisions where no formal coverage policy is in place.

- Therapeutic apheresis services are often covered by insurers *only* if the patient meets certain additional **laboratory, diagnostic and/or clinical criteria**.

  Example 1: ABC Health Plan covers TPE for exacerbations of relapsing forms of multiple sclerosis that are resistant to high-dose corticosteroids.

  Example 2: XYZ Care covers plateletpheresis for essential thrombocythemia when platelet count exceeds 1,000,000 per mm^3.

- **Preauthorization** (physician) or **precertification** (hospital) is commonly required by commercial insurers (HMOs, PPOs, indemnity plans, point-of-service plans) and Medicaid programs *prior* to performing outpatient therapeutic apheresis procedures.

  The insurer may specify documentation required for review by a case manager or medical director. This typically includes a detailed patient history, examination, treatment and/or laboratory records. Appendix 2 provides a guideline for preparing what is commonly referred to as a "Letter of Necessity" (LON) or "Statement of Medical Necessity" (SOMN) to accompany supportive medical and lab records.

- In some instances, coverage may be determined on an **individual consideration basis**, particularly where published clinical evidence is suggestive (e.g., successful case reports or small patient studies) but inconclusive or controversial.

- Medicare claims contractors do not require prior authorization. Depending on the procedure and clinical indication, coverage may variously be based on a Medicare National Coverage Determinations (NCD) or a Local Coverage Determination (LCD), or may be determined on an individual consideration basis.

Examples of Practice Guidelines That Can Influence Insurance Coverage Policies for Therapeutic Apheresis Services

Connelly-Smith L, Alquist CR, Aqui NA, et al. Guidelines on the Use of Therapeutic Apheresis in Clinical Practice – Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Ninth Special Issue. *J Clin Apher.* 2023;38(2):77-278.

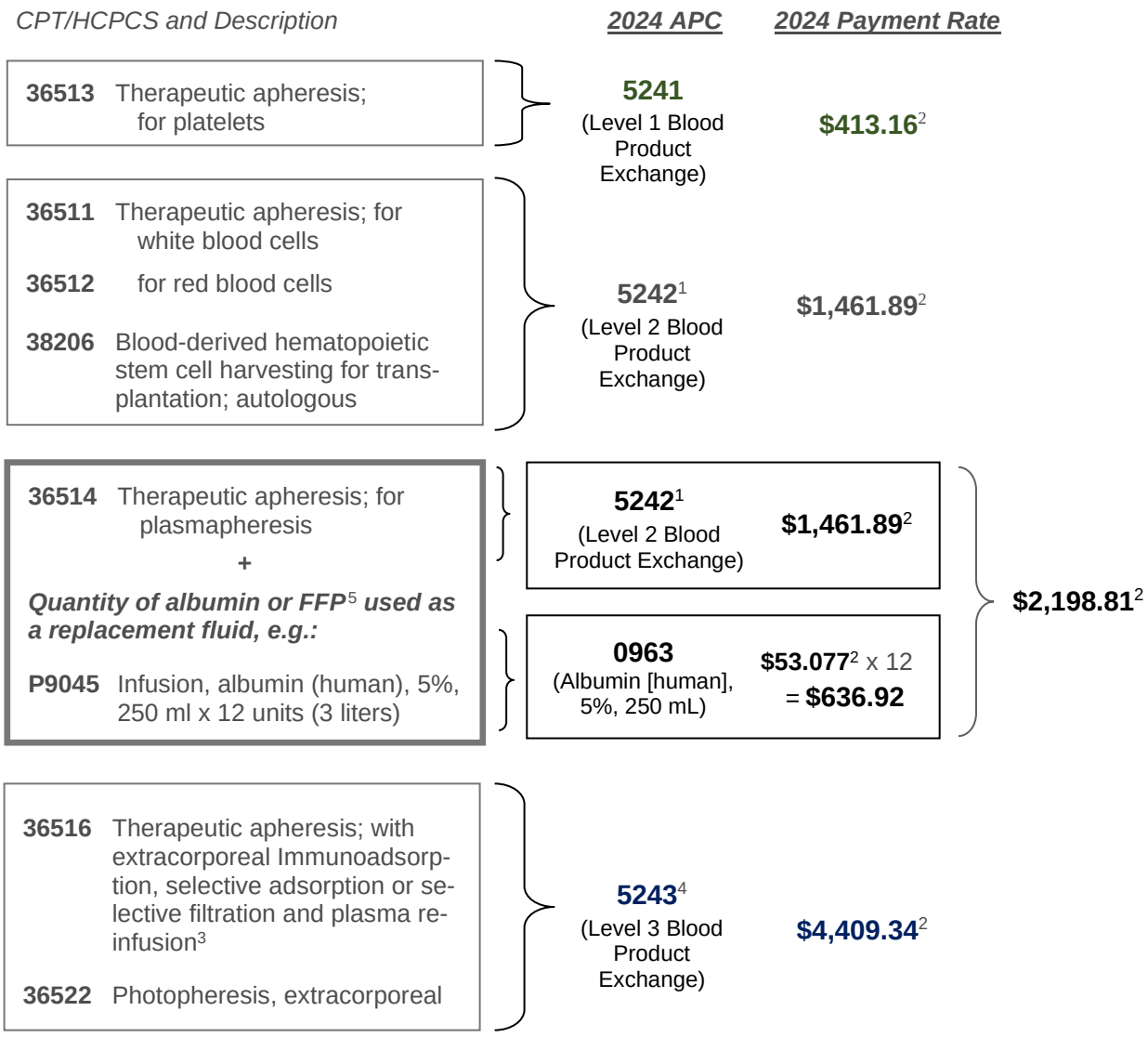
Cortese I, Chaudhry V, So TY, et al. Evidence-based guideline update: Plasmapheresis in neurologic disorders. *Neurology* 2011;76:294-300.

Ito MK, McGowan MP, Moriarty PM. Management of familial hypercholesterolemias in adult patients: Recommendations from the National Lipid Association Expert Panel on FH. *J Clin Lipidol.* 2011;5:S38-S45.

Medicare Payment in the Hospital Outpatient Setting

Medicare groups hospital outpatient procedures involving similar types and resources into **ambulatory payment classifications (APCs)** for purposes of payment.

With the special exception of plasmapheresis (CPT 36514) where two APCs are assigned, single APCs apply for all therapeutic apheresis and stem cell collection procedures:



[1]Four other procedures also assign to **APC 5242**: CPT 38230, CPT 38241, CPT 38242 and CPT 38243.

[2]The payment rate for procedure-based APCs is adjusted for hospitals in each geographic locality by applying the FY 2024 Outpatient Prospective Payment System (OPPS) wage index to the labor-related portion of the payment rate to reflect geographic wage variations. OPPS Payment by HCPCS Code for CY 2024; Addendum A, July, 2024: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates.

[3]Currently applies specifically to lipoprotein apheresis (CPT 36516)

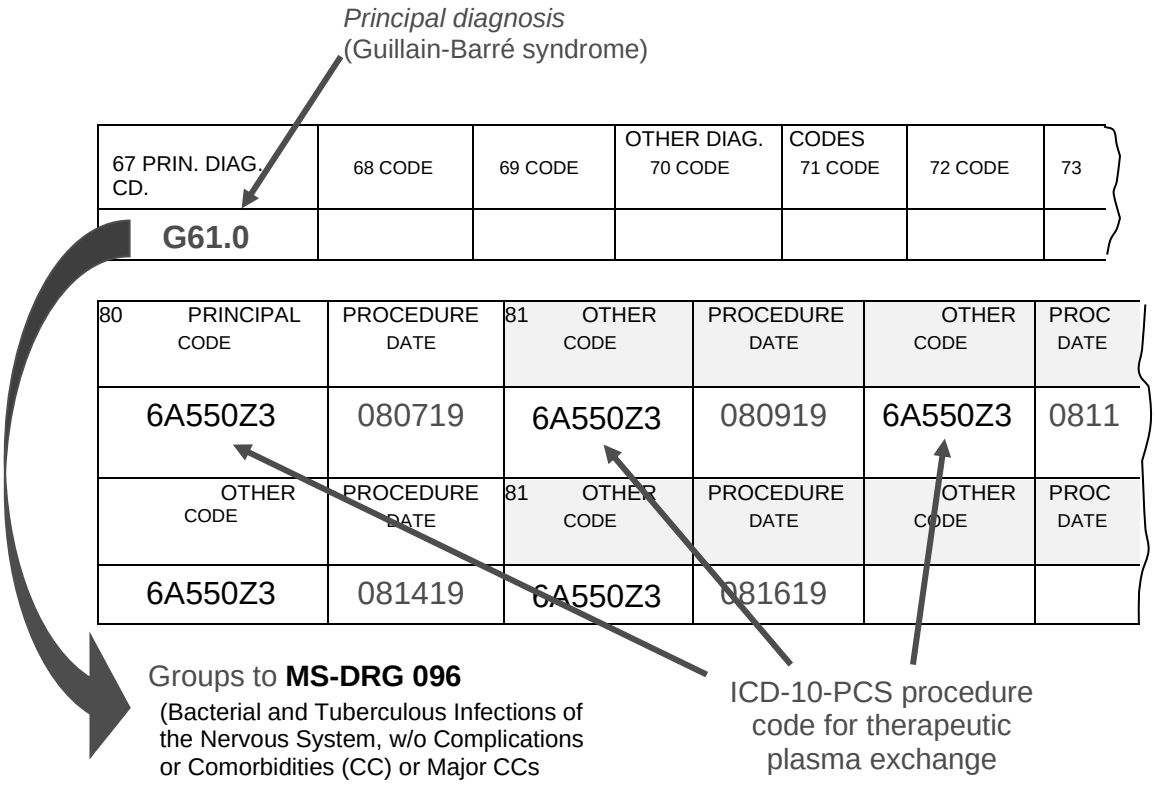
[4]One other procedure also assigns to APC 5243: CPT 38232 (Bone marrow harvest, autologous).

[5]See Appendix 3 for HCPCS codes corresponding to albumin and Fresh Frozen Plasma (FFP) products.

Medicare Payment in the Hospital Inpatient Setting

Medicare compensates hospitals for inpatient stays with prospectively fixed payments that correspond to 766 unique Medicare Severity **Diagnosis-Related Groups (MS-DRGs)**. While some MS-DRGs are assigned on the basis of a major operating room procedure, the MS-DRGs for inpatient stays that involve therapeutic apheresis are generally driven by the **principal diagnosis** – the diagnosis that accounted for the patient's hospitalization.

Below is an example of a claim submitted to the hospital's local Medicare claims contractor, which illustrates how an MS-DRG is assigned in accordance with submitted codes. This patient diagnosed with an uncomplicated case of Guillain-Barré syndrome[1] received a total of five therapeutic plasma exchange (TPE) procedures over her hospital stay.



MS-DRG 096 and its associated payment rate also applies for Medicare hospitalizations for nearly 50 other principal diagnoses, including various meningitis and encephalitis conditions. Your hospital's payment rate is based primarily on the "relative weight" assigned to MS-DRG 096. Had this patient experienced complications and/or comorbidities (CCs) or major CCs, payment would reflect higher-paying MS-DRG 095 or 094, respectively.

An admission for the closely related disorder chronic inflammatory demyelinating polyradiculoneuropathy (CIDP; ICD-10-CM G61.81), without presence of major CCs, groups to MS-DRG 074 (Cranial and Peripheral Nerve Disorders Without Major CCs). The Medicare payment rate for this hospitalization is less than one-half that for a Guillain-Barré case, reflecting the typically shorter hospital stay and less intensive treatment demands of this disorder.

[1]Also identified as acute inflammatory demyelinating polyradiculoneuropathy (AIDP) or acute infective polyneuritis.

Medicare Payment in the Hospital Inpatient Setting – continued

Below are examples of MS-DRGs commonly assigned for Medicare hospital inpatient stays in which therapeutic plasma exchange is commonly used to treat the principal diagnosis.

Principal Diagnosis (CC = complications and comorbidities)	*ICD-10-CM*	*MS-DRG*	*2024 relative weight*[1]
Guillain Barré syndrome (without CC)	G61.0	**096**	2.1797
Guillain Barré syndrome (with major CC)	G61.0	**094**	3.6227
Rapidly progressive nephritic syndrome with diffuse membranous glomerulonephritis (with major CC)	N01.2	**698**	1.6544
Thrombotic thrombocytopenic purpura (with major CC)	M31.1	**545**	2.4932
Cryoglobulinemia (with major CC)	D89.1	**823**	4.5019
Chronic inflammatory demyelinating polyneuropathy	G61.81	**074**	1.0262
Myasthenia gravis with exacerbation (acute)	G70.01	**057**	1.3632

[1]2024 MS-DRG relative wts: "FY 2024 Proposed Rule Tables; Table 5: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-proposed-rule-home-page#Data

A formula applying the "relative weight" for the assigned MS-DRG as well as several other variables, including local wage rates, uncompensated care burden and graduate medical education activity, is used to calculate each hospital's payment rate for that MS-DRG.

The assigned MS-DRG and the associated payment rate for a given hospitalization are independent of whether therapeutic apheresis procedures were or were not performed during the stay.

Medicare Payment for Physician Supervision of Apheresis Provided in Hospital Inpatient or Outpatient Settings

Physician supervision of apheresis procedures provided in the hospital inpatient or outpatient "facility" setting is billed on the CMS-1500 claim form as described on page 9. Calendar year 2024 Medicare payment rates for these services are determined by multiplying the assigned RVUs by the 2024 conversion factor (CF) ($33.2875 per RVU from 3/9/24 through 12/31/24[1]):

CPT	Description	MD work RVUs	Facility PE RVUs	Malpractice RVUs	Total RVUs	**2024 rates**[2]
36511	Apheresis, white blood cell	2.00	1.15	0.13	3.28	**$109.18**
36512	Apheresis, red blood cell	2.00	1.00	0.12	3.12	**$103.86**
36513	Apheresis, platelets	2.00	0.94	0.19	3.13	**$104.19**
36514	Apheresis, plasma	1.81	0.79	0.15	2.75	**$91.54**
36516	Apheresis, selective	1.56	0.67	0.31	2.54	**$84.55**
36522	Photopheresis	1.75	0.95	0.12	2.82	**$93.87**
38205	Harvest allogeneic stem cell	1.50	0.89	0.10	2.49	**$82.89**
38206	Harvest autologous stem cell	1.50	0.84	0.10	2.44	**$81.22**

[1]From 1/1-3/8/24, the CF is $32.7442. [2]U.S. average 2024 Medicare payment rate; actual payment rate will vary per locality.

Medicare Payment for Office-Based Therapeutic Plasma Exchange, Photopheresis, and Lipoprotein Apheresis

When performed in the office-based treatment setting, Medicare covers and pays for both technical and professional service components of **plasma exchange (CPT 36514)**, **low-density lipoprotein (LDL-C) apheresis (CPT 36516)** and **extracorporeal photopheresis (CPT 36522)**. Calendar year 2024 (CY 2024) Medicare payment rates in this setting reflect relative value units (RVUs) for (1) physician work, (2) practice expense (PE) and (3) a small allocation for malpractice insurance.

The same diagnosis-driven coverage policies apply for procedures performed in physician-directed offices/clinics as hospital outpatient departments and infusion centers.

Effective 1/1/2024, through the advocacy, work, and support of several organizations[1], CMS has agreed to increase the practice expense valuation of TPE by just over three RVUs – from 14.91 to 17.98 RVUs – to fully reflect the costs of disposable supplies used to perform the procedure; 16.2% increase in average 2024 CMS payment for office-based TPE procedures.

Calendar Year (CY) 2024: Practice Expense Relative Value Units (RVUs) Assigned for Therapeutic Apheresis Services in the Physician Office-Based Setting

CPT	Description	MD work RVUs	Non-facility PE[2] RVUs	Malpractice RVUs	Non-facility total
36514	Apheresis, plasma	1.81	**17.98**	0.15	**19.94**
36516	Apheresis, selective	1.56	**51.39**	0.31	**53.26**
36522	Photopheresis	1.75	**38.04**	0.12	**39.91**

The Medicare payment rate in a specific locality is based on the conversion factor (CF) and local geographic practice cost indices (GPCIs). The CF for CY 2024 is **$33.2875**.[3]

The U.S. average CY 2024 Medicare payment rate for an office-based TPE procedure (not including replacement albumin or plasma) is $33.2875 x 19.94 RVUs = **$663.75**.

Payment for albumin replacement solution. On a quarterly basis Medicare publishes its "payment allowance limits" for 5% 250 ml human albumin (**P9045**) as well as human albumin products supplied in other concentrations and volumes. All other health insurers can similarly be billed for albumin using the same HCPCS codes and your submitted charges.

For procedures provided in the **hospital ("facility") setting**, the physician bills only the professional supervision fee. The Medicare payment rate will reflect the same work and malpractice expense RVUs, plus nominal **"facility practice expense RVUs (PE RVUs)."** For RVUs and payment rates, see "**Medicare Payment for Supervision of Apheresis Procedures Provided in the Hospital Inpatient or Outpatient Settings**" on page 14.

[1]Health Research Associates; Terumo BCT; other organizations.

[2]Non-facility PE = Physician office or clinic (non-hospital) practice expense.

[3]The CF for 1/1/2024 through 3/8/2024 is $32.7442 (*Federal Register*, Vol. 88, No. 220, November 16, 2023, p. 79467. An update to the CY 2024 CF enacted on 3/9/2024 adjusts the CF to $33.2875, effective from 3/9/2024 through 12/31/2024 (https://www.cms.gov/medicare/payment/fee-schedules/physician).

Payment Policies by Commercial Insurers

Hospital:

Outpatient Setting:

Most claims for hospital outpatient services are paid on the basis of:

- **A percentage of the hospital's submitted charges** *or*
- **A set rate schedule** for CPT- and HCPCS-coded services/products

In both scenarios, each apheresis service is directly reimbursed by the payer, on the basis of pre-negotiated terms between insurer and hospital.

Inpatient Setting:

Per diems (fixed payment per hospitalization day) represent the predominant payment mechanism for hospital stays required to manage medical conditions.

Therapeutic apheresis services do not directly affect the per diem rate; this is true also when other costly resources are used (e.g., IVIG, lab tests). "Outlier" provisions may provide additional reimbursement when overall costs exceed a certain threshold.

Physician:

Hospital Inpatient or Outpatient Setting[1]

Without regard to whether an apheresis procedure was performed on a hospital outpatient or inpatient, the physician's separately billed professional fee is paid in accordance with the insurer's **allowable amount** (or "allowed charge").

Some commercial insurers set their physician reimbursement based on actual charges in the locality they serve. Others may pay the lesser of the physician charge or a rate schedule amount based on RVUs specified in the Medicare Physician Fee Schedule.

Important: For additional information regarding physician (and non-physician) documentation, please refer to Appendix 1 on page 29 (**Important Information Regarding Pertinent Documentation Related to Reimbursement**).

Physician Office or Physician-Directed Clinic Setting[2]

As noted earlier, **relative value units** (RVUs) are assigned for "non-facility practice expenses" applicable to **therapeutic plasma exchange** (CPT 36514), **immunoadsorption, selective adsorption or selective filtration with plasma reinfusion** (CPT 36516), and **extracorporeal photopheresis** (CPT 36522).

Most commercial insurers base their payment rates on these assigned non-facility RVUs. Others will set payment rates on the basis of submitted charges.

Nomenclature: 1) facility PE RVUs = hospital (facility) practice expense relative value units. 2) non-facility PE RVUs = physician office-based, non-hospital, practice expense relative value units.

Focus on Therapeutic Plasma Exchange (TPE)

Insurance Coverage and Diagnosis Coding:

- To define their Therapeutic Apheresis coverage policies and to make individual case coverage decisions, insurers attempt to rely upon high quality medical literature, including randomized controlled trials (RCTs) and well-designed clinical studies (cohort, case-control, and case series) which have evaluated the efficacy and safety of apheresis treatment in a wide range of neurologic, hematologic, rheumatologic, renal, transplant, and autoimmune disorders. Many insurers reference ASFA's Guidelines on the Use of Therapeutic Apheresis in Clinical Practice[1] for disorders under consideration.
- Medicare Administrative Contractors (MACs)[2] and most other payers do not reference a far-outdated Medicare coverage policy titled "Apheresis [Therapeutic Pheresis] (NCD 110.14)," which was published in 1992 and not revised in over 30 years.
- As coverage policies may be inconsistent from one insurer to the next, it is important to secure preauthorization for outpatient TPE therapy when required.

Below are examples of **ICD-10-coded diagnoses for which TPE is commonly covered**:

Diagnosis	*ICD-10-CM*	*Diagnosis*	*ICD-10-CM*
Guillain-Barré syndrome	G61.0	CIDP	G61.81
Myasthenia gravis/in crisis	G70.00/01	Sydenham's chorea, severe	I02.0
Macroglobulinemia (incl. Waldenstrom's)	C88.0	Thrombotic thrombocytopenic purpura (TTP)	M31.1
Glomerulonephritis w/anti-glomerular BM antibodies	M31.0	Other paraproteinemias (e.g. cryoglobulinemia)	D89.1
Rapidly progressive glomerulonephritis (unspecified)	N01.9	Systemic lupus erythematosus, severe	M32.14

Below are examples of diagnoses for which **cytapheresis procedures** are covered:

Procedure	*Commonly treated diagnoses*	*ICD-10-CM*
Leukocytapheresis (CPT 36511)	Leukocytosis	**D72.829**
Erythrocytapheresis (CPT 36512)	Sickle-cell disease Polycythemia; erythrocytosis	**D57.0*** **D75.1**
Thrombocytapheresis (CPT 36513)	Thrombocytosis, essential	**D69.3**

* Predominantly sickle-cell crisis (D57.00) or sickle cell crisis with acute chest syndrome (D57.01) or sickle cell crisis with splenic sequestration (D57.02)

[1]Connelly-Smith L, Alquist CR, Aqui NA, et al. Guidelines on the Use of Therapeutic Apheresis in Clinical Practice – Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Ninth Special Issue. *J Clin Apher.* 2023;38(2):77-278.

[2]Personal written communication: Richard Whitten, MD, MPH (Contractor Medical Director, Noridian Healthcare Solutions, Inc.) to K. Berman, MPH, MBA and J. Hofmann, MD. September 16, 2020.

Focus on Therapeutic Plasma Exchange – continued

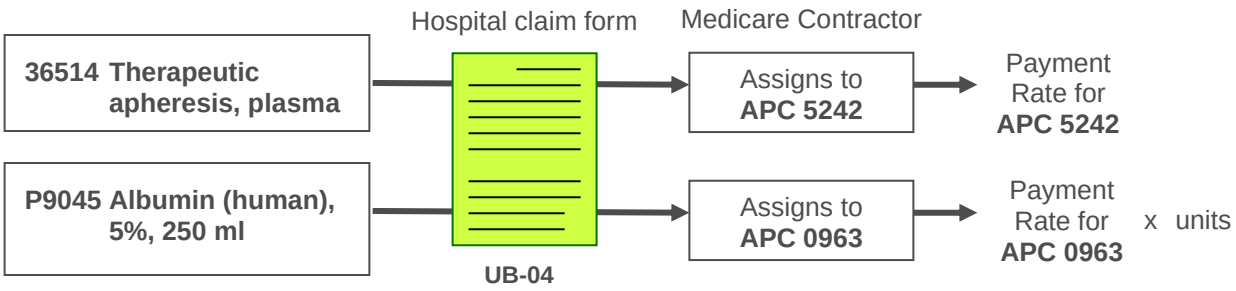
Hospital Outpatient Payment:

***Commercial insurers*.** Payment to the hospital for the technical component of a TPE procedure is generally based on a **fixed percentage of the hospital's submitted charge** negotiated between the hospital and insurer.

It is important to fully capture all supply items, drugs and IV fluids (exclusive of replacement albumin or plasma) *required to perform each TPE procedure in the chargemaster for TPE (CPT 36514)*.

Payment for the **physician's professional services** associated with hospital-based procedures is usually based on the insurer's allowable rate, which in turn is often tied to the 1.81 physician work relative value units (RVUs) defined for this service in 2024.

***Medicare*.** The hospital Outpatient Prospective Payment System (OPPS) assigns APC 5242 (Blood Product Exchange) for outpatient TPE claims (coded with CPT 36514):



See page 12 for an example of 2024 U.S. average Medicare outpatient payment rates for TPE procedure requiring 12 units (250 ml each) of 5% human albumin.*

Other replacement fluids, including 25% albumin, cryo-reduced plasma, and fresh frozen plasma (FFP) assign to their own unique APCs, for which multiple "units" can be billed and paid:

Product	*HCPCS-II*	*APC*
Albumin, 25%, 50 ml	P9047	**0965**
Cryo-reduced plasma	P9044	**9523**
FFP, frozen ≤8 hours	P9017	**9508**

See **Appendix 3** for a list of 2024 HCPCS codes for billing albumin, FFP, and blood components.

The same separate payment policy also applies for RBCs transfused as part of outpatient **red cell exchange**:

P9016 RBCs, leukoreduced

↓

APC 9512

↓

Payment rate x # of units

* The 2024 Medicare payment rate per individual 250 mL unit of 5% human albumin (APC 0963) is $53.077.

Focus on Therapeutic Plasma Exchange – continued

Hospital Inpatient Payment:

***Commercial insurers*.** The costs of TPE are usually subsumed under a flat **per diem** payment rate negotiated between the hospital and the insurer; there is no separate payment for TPE in this circumstance. Less frequently, TPE may be subsumed under a fixed, prospectively determined payment rate for the entire hospital stay. Uncommonly, hospitals are paid for TPE on the basis of a negotiated percentage of charges.

***Medicare*.** Refer to **"Medicare Payment in the Hospital Inpatient Setting"** (pages 13-14), which provides an example of a Guillain-Barré patient treated with plasma exchange.

Physician Reimbursement for TPE Supervision:

Refer to the Guide section titled **"Medicare Payment for Physician Supervision of Apheresis Procedures Provided in Hospital Inpatient or Outpatient Settings"** (page 14).

Reimbursement for Physician Offices or Physician-Directed Clinics:

Refer to the Guide section titled **"Medicare Payment for Office-Based Therapeutic Plasma Exchange, Photopheresis, and Lipoprotein Apheresis"** (page 15).

Focus on Extracorporeal Photopheresis (ECP)

Diagnosis Coding:

Extracorporeal photopheresis (ECP) is indicated by the FDA for treatment of **cutaneous T cell lymphoma (CTCL)**, which is a general term for two closely related malignancies:

Mycosis fungoides	**C84.0**
Sézary disease	**C84.1**

Other non-indicated clinical applications for which ECP is utilized include:

Chronic graft-versus-host disease	**D89.813**
Complications of bone marrow transplant	**T86.00**
Complications of stem cell transplant	**T86.5**
Heart transplant rejection	**T86.21**
Lung transplant rejection	**T86.810**

CTCL: 5th Digit Subclassifications

To more accurately specify the diagnosis, the physician can add a 5th digit to add to mycosis fungoides (C84.0) or Sézary disease (C84.1):

- **0** unspecified or extranodal/solid organ sites
- **1** lymph nodes of head, face, and neck
- **2** intrathoracic lymph nodes
- **3** intra-abdominal lymph nodes
- **4** lymph nodes of axilla upper limb
- **5** lymph nodes of inguinal region/lower limb
- **6** intrapelvic lymph nodes
- **7** spleen
- **8** lymph nodes of multiple sites
- **9** Extranodal and solid organ sites

Example: **C84.17** represents Sézary disease with splenic involvement

Procedure coding:

CPT 36522	Physicians – CMS-1500 Hospitals (Outpatient) – UB-04
ICD-10-PCS 6A65	Hospitals (Inpatient) – UB-04

Medicare covers ECP solely for:

- **Palliative treatment of skin manifestations of CTCL** in patients who have failed to adequately respond to conventional therapy;
- **Chronic graft-versus-host disease (cGVHD)** that is refractory to standard immuno-suppressive drug therapy;
- **Rejection of a cardiac allograft** that is refractory to standard immunosuppressive drug therapy.
- **Bronchiolitis obliterans syndrome (BOS) following lung allograft transplantation**, when provided by participating sites in an approved clinical study under Coverage with Evidence Development (CED)*. *ECP is not covered by Medicare for BOS when provided in any hospital or clinic that is not a participating site for this CMS-approved study*.

  *For information about this clinical study, visit https://clinicaltrials.gov/ct2/show/NCT02181257.

Most **commercial insurers** cover ECP for CTCL and for cGVHD that is refractory to standard drug therapy. Other diagnoses (see table above) may be covered on an individual consideration basis. Preauthorization or precertification for a planned series of treatments should always be secured from the primary and, as applicable, secondary insurer.

Focus on Extracorporeal Photopheresis – continued

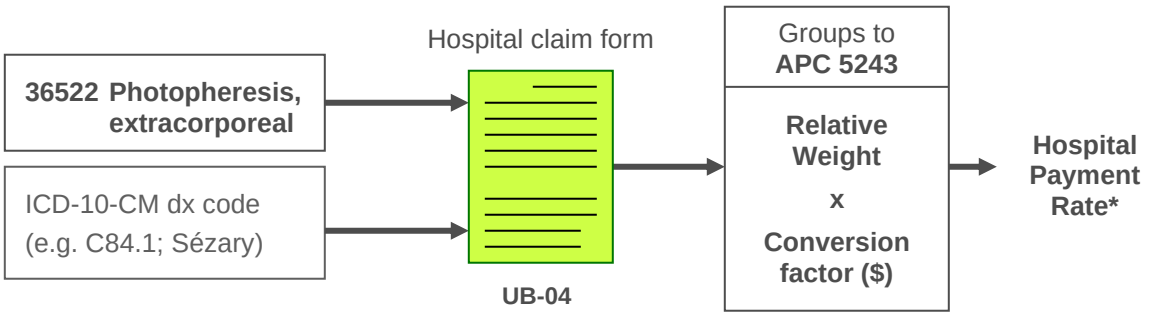
Hospital Outpatient Payment:

***Commercial insurers*.** Payment for the technical component of an ECP procedure is most commonly based on a **fixed percentage of the hospital's submitted charge** or the insurer's **fee schedule amount**. Periodically there may be a **negotiation** between the institution and the insurer to arrive at a mutually acceptable payment rate.

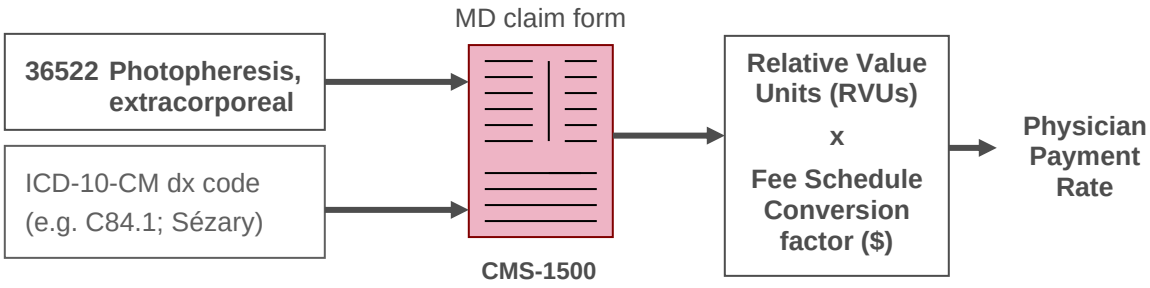
For bone marrow or stem cell transplant patients, many insurers negotiate a **global case rate** which includes all hospital (and often physician) services provided over the first 6-12 weeks of outpatient treatment. Thus, unless stipulated otherwise, ECP services to treat GVHD during that global period would be included in that global case rate. Subsequent to the global period, ECP procedures preauthorized up to a designated number or time frame are separately paid.

Payment for the **physician's professional services** associated with hospital-based procedures is usually based on the insurer's allowable rate schedule amount. The physician may separately bill **one Evaluation & Management (E&M) service** for a history/physical exam to determine the appropriateness of the **first day's procedure**.

***Medicare*.** The Medicare Hospital Outpatient Prospective Payment System (HOPPS) assigns APC **5243** (Level 3 Blood Product Exchange and Related Procedures) to outpatient photopheresis claims coded with CPT 36522:



The **physician's professional services** are paid by submitting a claim (CMS-1500) to the local Medicare Administrative Contractor (MAC):



*Adjusted to reflect geographic wage variations using the local wage index. *If a different procedure is also performed on the same day, payment for the ECP procedure under APC 5243 is not discounted.*

Focus on Extracorporeal Photopheresis – continued

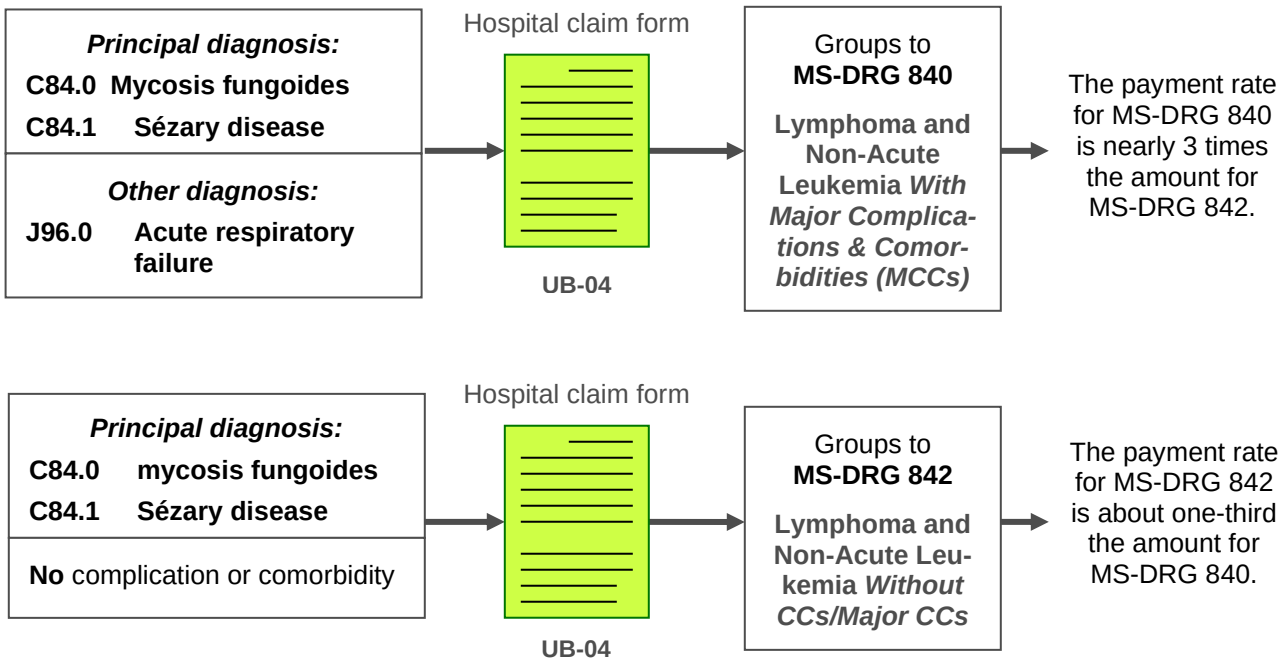
Hospital Inpatient Payment:

While most patients are treated with ECP on an outpatient basis, some may have already been hospitalized to acutely manage their illness. In selected instances, some physicians prefer to hospitalize the patient for his or her ECP therapy.

In the event that this procedure is provided in the inpatient setting, below are payment policies which most commonly apply.

***Commercial insurers*.** The costs of ECP may be subsumed under a flat **per diem** payment rate negotiated between the hospital and the insurer; there is no separate payment for ECP in this circumstance. Less frequently, ECP may be subsumed under a fixed, prospectively determined payment rate for the entire hospital stay, or paid on the basis of a negotiated percentage of charges.

***Medicare*.** Unlike Medicare outpatients, for whom payment is driven by the CPT 36522 procedure code, the two major MS-DRGs which apply for inpatients treated for CTCL are driven by **ICD-10-CM diagnosis codes**:



Physician Office/Clinic Payment:

Refer to the Guide section titled **"Medicare Payment for Office-Based Therapeutic Plasma Exchange, Photopheresis, and Lipoprotein Apheresis"** on page 15.

Focus on Lipoprotein Apheresis

Diagnosis Coding:

At present, lipoprotein apheresis represents the only approved and available procedure that can be coded to **CPT 36516**. Other investigational procedures that selectively adsorb or filter out undesirable proteins or other plasma elements may also fall under CPT 36516 if approved in the future for clinical use.

Below are the current FDA-approved indications for the sole available lipoprotein apheresis enabling technology (Liposorber LA-15 System; Kaneka Medical America) in high-risk patient populations for whom diet has been ineffective and maximum drug therapy has either been ineffective or not tolerated:

1) Group A: Clinically diagnosed FH[1] homozygotes with LDL-C >500 mg/dL.
2) Group B: Clinically diagnosed FH heterozygotes with LDL-C ≥300 mg/dL.
3) Group C: Clinically diagnosed FH heterozygotes with LDL-C ≥100 mg/dL and either documented coronary artery disease (CAD) or peripheral artery disease (PAD).
4) Group D: Clinically diagnosed FH heterozygotes with LDL-C ≥100 mg/dL and lipoprotein(a) [Lp(a)] ≥60 mg/dL, and either documented CAD or PAD.
5) Adult and pediatric patients with nephrotic syndrome associated with primary focal segmental glomerulosclerosis (FSGS)[2], as Humanitarian Use Device.

Diagnosis	*ICD-10-CM*
Pure hypercholesterolemia, unspecified	**E78.00**
Familial hypercholesterolemia	**E78.01**
Mixed hyperlipidemia*	**E78.2**
Primary focal segmental glomerulosclerosis	**N04.1**

*Some insurers do not cover claims coded with ICD-10 E78.2

Procedure code:

CPT 36516*	Physicians – CMS-1500 Hospitals (Outpatient) – UB-04

***S2120** may be required by some Blue Cross Blue Shield plans

Coverage:

CMS' Apheresis (Therapeutic Pheresis) National Coverage Determination (NCD 110.14) allows Medicare Administrative Contractor (MAC) coverage discretion in the use of lipoprotein apheresis for the treatment of refractory familial hypercholesterolemia. Two MACs[3] have active coverage articles that have not been updated for more than a decade, and

---

[1]FH = Familial Hypercholesterolemia

[2]The Liposorber LA-15 System (Kaneka Medical America) is indicated for use in adult and pediatric patients with nephrotic syndrome associated with primary FSGS when standard treatment options, including corticosteroid and/or calcineurin inhibitor treatments, are unsuccessful or not well tolerated, and the patient has a GFR ≥60 mL/min/1.73 m^2, or the patient is post-renal transplantation. [LA-15 System Operator's Manual, Special HDE Supplement for H120005 and H170002, Attachment 3, S205H-9, 07/2022, Kaneka Medical America LLC].

[3]CGS Administrators (Local Coverage Article [LCA] A56289) (KY, OH); Noridian Healthcare Solutions (LCA 54543/54545) (AK, AZ, CA, ID, HI, MT, ND, NV, SD, UT, WY, Guam, American Samoa).

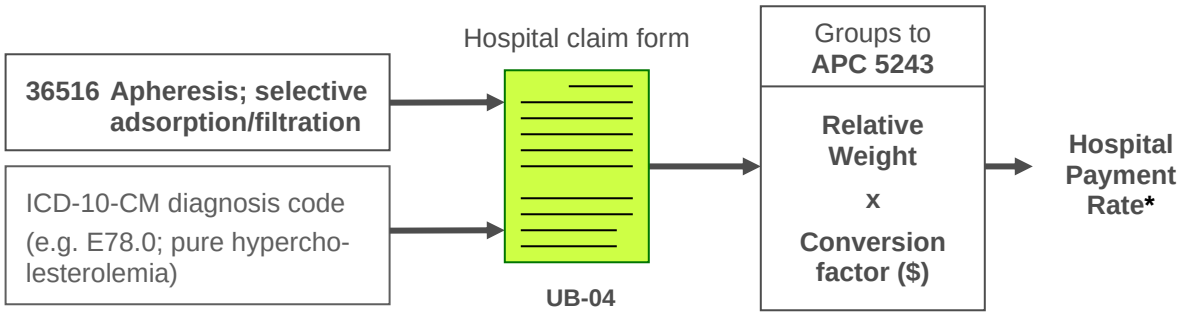
therefore fail to reflect important revisions and additions to the approved FDA indications for the Liposorber LA-15 System. Many commercial insurers have similarly not updated their coverage policies for lipoprotein apheresis (CPT 36516) for many years; few reflect the current FDA-approved indications for the Liposorber LA-15 System.

Hospital Outpatient Payment:

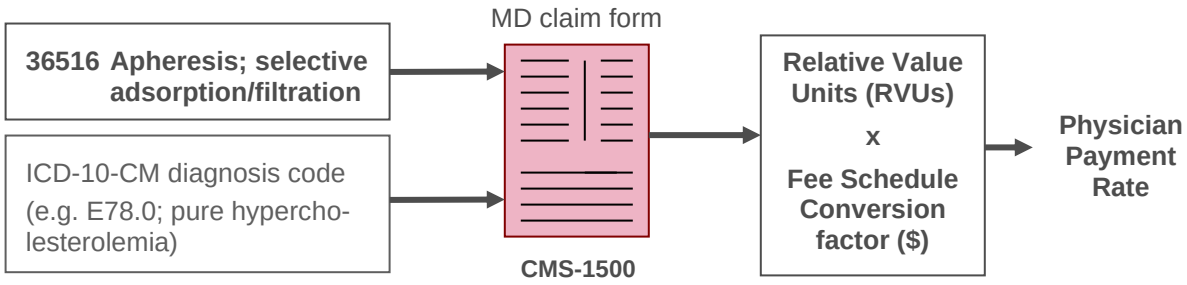
***Commercial insurers*.** Payment for the technical component of a lipoprotein apheresis procedure is usually based on a **fixed percentage of the hospital's submitted charge** or, less commonly, a negotiated **fee schedule amount**.

Payment of the **physician fee** associated with hospital-based LDL-C apheresis procedures is usually based on local physician charges or a fee schedule negotiated with the insurer.

***Medicare*.** The Medicare hospital Outpatient Prospective Payment System (OPPS) assigns Ambulatory Payment Classification (APC) **5243** (Level 3 Blood Product Exchange and Related Procedures) to outpatient LDL-C apheresis claims coded with CPT 36516:



The **physician's professional services** are paid by submitting a claim (CMS-1500) to the local Medicare Administrative Contractor:



Physician-Directed Clinic Payment:

Refer to the guide section titled **"Medicare Payment for Office-Based Therapeutic Plasma Exchange, Photopheresis, and Lipoprotein Apheresis"** (page 15).

Hospital Inpatient Payment:

Lipoprotein apheresis generally is not provided on a hospital inpatient basis. Should such an instance occur, payment policies will conform to the same principles described in earlier sections covering CPT 36514 and CPT 36522.

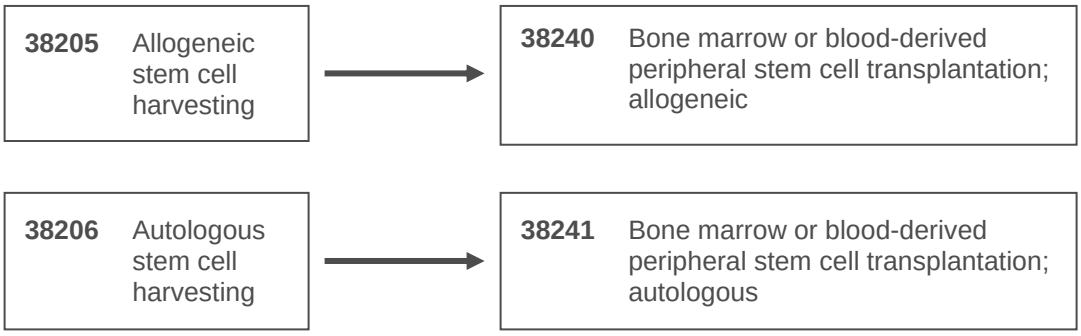
*Adjusted to reflect geographic wage variations. If one or more other procedures are also performed on the same day, Medicare payment for APC 5243 assigned for LDL-C apheresis is *not* discounted.

Focus on Blood-Derived Stem Cell Harvesting

Two CPT procedure codes are respectively used to identify and bill apheresis-based collection of peripheral hematopoietic stem cells from allogeneic and autologous donors:

38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous

Allogeneic (**CPT 38205**) or autologous (**CPT 38206**) stem cells acquired from one or more donor procedures are later transplanted into the intended recipient in a separately coded procedure on a separate claim form (and may be performed by a different entity):



Diagnosis Coding:

In the same manner as diagnosis coding for therapeutic apheresis procedures, insurers review claims for stem cell harvesting to confirm the presence of a diagnosis for which both the harvesting and transplantation procedures are “reasonable and necessary.”

A claim for the outpatient stem cell harvesting procedure should identify the diagnosis (e.g., the specific leukemia, lymphoma, aplastic anemia, or other ICD-10-CM coded disorder) **for which the transplantation procedure is intended**.

This applies also for the healthy matched allogeneic donor whose stem cells are being harvested for transplantation into a specified recipient: the ICD-10-CM diagnosis code corresponding to the recipient’s condition requiring the transplantation procedure should be entered on the claim for the donor stem cell harvesting procedure.

Focus on Blood-Derived Stem Cell Harvesting – continued

Coverage:

Medicare. Effective 1/27/2016, Medicare revised its National Coverage Determination (NCD) for Stem Cell Transplantation,* which identifies covered and non-covered diagnoses for allogeneic and autologous hematopoietic stem cell transplantation (HSCT). Coverage for allogeneic HSCT is also specified for several disorders pursuant to an approved prospective clinical study.

The Medicare Stem Cell Transplantation NCD (NCD 110.23; formerly NCD 110.8.1), which identifies all covered and non-covered diagnoses for allogeneic (CPT 38205; 38240) and autologous (CPT 38206; 38241) hematopoietic stem cell transplantation (updated as of 10-12-2023) can be accessed at https://www.cms.gov (see below).*

Commercial insurers. Coverage policies for allogeneic and autologous hematopoietic stem cell transplantation vary by individual commercial insurer. Prior insurance authorization for the transplantation procedure should always be confirmed before performing the donor stem cell harvesting procedure.

Hospital Outpatient Payment:

***Medicare*. Autologous stem cell harvesting (CPT 38206)** is paid under **APC 5242** (Level 2 Blood Product Exchange and Related Procedures). Multiple procedures performed on different days are separately payable. Allogeneic stem cell harvesting (CPT 38205) is not separately payable under the Medicare hospital outpatient prospective payment system.

***Commercial insurers*.** Payment for the large majority of stem cell harvesting procedures falls under a **negotiated global case rate** for all transplantation-related services. A UB-04 claim form is still completed and submitted, but payment will be a fixed amount agreed to by the hospital and insurer.

Otherwise, payment for the technical component of a stem cell harvesting procedure (CPT 38205 or 38206) is usually based on a **negotiated percentage of the hospital's submitted charge**, or less commonly on the insurer's **rate schedule**. If multiple harvesting procedures are required, they would be individually paid.

Physician Payment:

When not subsumed under a global payment rate agreement, payment for the **physician's professional services** associated with allogeneic or autologous hospital-based stem cell harvesting is based on the insurer's allowable rate schedule amount, which in general is dictated by the assigned physician work, practice expense, and malpractice RVUs (2.49 RVUs for CPT 38205 and 2.44 RVUs for CPT 38206 in 2024; see page 14).

* Medicare National Coverage Determinations Manual, Section 110.23 (Rev. 12299, 10-12-23). Accessed at: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=366&ncdver=1&chapter=all&sortBy=title&bc=18.

Focus on Intravascular Access Device (IVAD) Maintenance

Declotting the implanted vascular access device (IVAD) used for venous access in some therapeutic apheresis patients engenders significant nurse technician labor, thrombolytic drug, and supply costs.

It is important both to fully account for these costs and have robust standard procedures and chart documentation in place to assure that entries or charge slips are generated for your billing department to include in the insurance claim.

Coding:

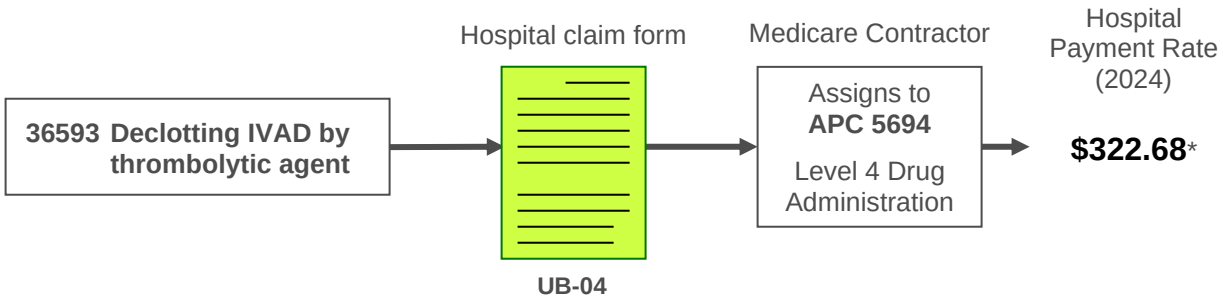
As applicable, the following codes should be identified in the claim:

CPT / HCPCS-II	*Procedure or item description**
36593	Declotting by thrombolytic agent of implanted vascular access device or catheter
J2997	Injection, alteplase recombinant, 1 mg *(use for Activase, Cathflo)*
J3101	Injection, tenecteplase, 1 mg

*Bill multiple units when multiple units are used (e.g. bill 3 units of J2997 for 3 mg alteplase).

Medicare Payment in the Hospital Outpatient Setting:

For **Medicare beneficiaries** whose catheter occlusions are treated in the **hospital outpatient department**, CPT **36593** assigns to an Ambulatory Payment Classification (APC):



Medicare has assigned a “T” status indicator to CPT 36593, which means that, if more than one APC is assigned on the same date of service, the one with the highest payment rate will be paid on a 100% basis, while this and all other procedures with the “T” status indicator will be paid at 50% of the normal payment rate.

All outpatient therapeutic apheresis procedures assign to APCs with an “S” status indicator, and are never discounted. In the circumstance where this declotting procedure is performed in conjunction with an apheresis procedure, it will be paid at 50% of the payment amount that applies for APC 5694.

*Adjusted using the current IPPS wage index for each hospital to reflect geographic wage variations.

Focus on Autologous T-Cell Collections for Chimeric Antigen Receptor (CAR) T-Cell Therapy

CAR T-cell therapy is a cell-based gene therapy wherein the patient's blood-derived T lymphocytes (T-cells) are harvested by apheresis, genetically modified to express a chimeric antigen receptor (CAR) that binds to a specific protein on the patient's cancerous (or other dysfunctional) cells, and administered to the patient to attack those specific cells.

The CPT procedure code for the T-cell harvesting procedure is as follows:

CPT	*CPT Description*
0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day

Inpatient CAR T-cell therapy. When CAR T-cell therapy is provided on an **inpatient** basis, the provider bills the applicable ICD-10-PCS procedure code for that therapy and route of delivery (*e.g., axicabtagene ciloleucel [Yescarta] via a peripheral vein is coded with ICD-10-PCS XW033H7, and via a central vein is coded with ICD-10-PCS XW043H7*).

- **The apheresis-based T-cell harvesting procedure (HCPCS 0537T) is subsumed under MS-DRG 018** (CAR T-Cell and Other Immunotherapy) **and is not separately payable**; however, HCPCS 0537T should be identified on the hospital's insurance claim under **revenue code 0871**.

Outpatient CAR T-cell therapy. When CAR T-cell therapy is provided on an **outpatient** basis, the provider bills the applicable HCPCS Level II procedure code for that therapy (*e.g., ciltacabtagene autoleucel [Carvykti] via peripheral vein is coded with HCPCS Q2056*).

- **Again, for outpatient CAR T-cell therapy, the apheresis-based T-cell harvesting procedure (HCPCS 0537T) is not separately payable**. **T-cell collection is packaged under the APC to which each HCPCS-coded therapy assigns**. The hospital is reimbursed at a single payment rate that subsumes T-cell collection, T-cell processing and storage by the manufacturer, storage and processing of modified T-cells following receipt from the manufacturer, and infusion of the modified T-cells.

  For all CAR T-cell therapies currently covered by Medicare in CY 2024, below are HCPCS and APC codes to which they assign and national average payment rates:

HCPCS	*Procedure*	*APC*	*Rate*
Q2041	Axicabtagene ciloleucel (Yescarta)	9035	$449,342
Q2042	Tisagenlecleucel (Kymriah)	9194	$484,623
Q2053	Brexucabtagene Autoleucel (Tecartus)	9391	$449,440
Q2054	Lisocabtagene maraleucel (Breyanzi)	9413	$473,458
Q2055	Idecabtagene vicleucel (Abecma)	9422	$483,454
Q2056	Ciltacabtagene autoleucel (Carvykti)	9498	$497,025

Appendix 1

Important Information Regarding Pertinent Documentation Related to Reimbursement

No statutory generating entity, regulatory agency, or accreditation agency has defined the required type, extent, or format needed for physician documentation in the patient's medical record for clinical oversight of the patient's apheresis procedure. In response to ASFA membership requests, an internal ASFA committee deliberated and in 2005 created the following document: Guidelines for Documentation of Therapeutic Apheresis Procedures in the Medical Record by Apheresis Physicians. As ASFA is a professional society, the recommendations are not binding or prescriptive. This guideline was initially based upon opinion as to a reasonable approach regarding adequate documentation to secure Medicare part B billing. These discussions and their subsequent articulation were predicated on the practice environment and available technologies at the time and have been referenced and adopted by many non-ASFA parties.

From these deliberations in 2005, it was recommended that in the apheresis procedure note the physician should document that he/she: **(1)** reviewed and evaluated pertinent clinical and lab data, **(2)** made the decision to perform the treatment that day, **(3)** saw and evaluated the patient for the procedure, and **(4)** remained available to respond in person (or now, if appropriate, by telemedicine) to emergencies or other situations requiring his/her intervention throughout the procedure (Guidelines For Documentation of Therapeutic Apheresis Procedures in the Medical Record by Apheresis Physicians. *J Clin Apher*. 2007;22(3):183).

Since the publication of this guideline, medicine and the technologies supporting medical care have markedly evolved. Specifically, the expansion of telemedicine/telehealth post-COVID-19 pandemic to include Apheresis Medicine evaluation and procedural oversight has brought a renewed focus on best practices in apheresis documentation and billing. Furthermore, there is increasing interest in leveraging the expertise of Apheresis Medicine specialists nationally to bring the highest quality of care to patients with a myriad of challenging diseases, through remotely guiding their physicians and providing point-of-care evidence-based recommendations. There are a variety of pathways for providing expert remote apheresis consultation[1], compensation models for such services, and templates for minimizing medical liability through appropriate disclaimers when providing physician peer-to-peer consultation. The ASFA Public Affairs and Advocacy Committee will continuously monitor developments in these areas and periodically publish summary updates.

[1]Wachter RM et al. JAMA 2019;Jun27.doi:10.1001/jama.2019.6607

Appendix 2

Useful Documentation to Include in a "Statement of Medical Necessity" for Insurance Preauthorization

[Date] [Medical Director name] [Insurance entity and address]

Patient name: **Name in bold**
Insurance plan number: **Number in bold**

- Document **patient age**, **diagnostic work-up**, and related **clinical history**. As appropriate, attach and reference test findings, disease scoring worksheets, etc. to more fully portray the patient's clinical course and status.

- If applicable, include **detailed review of conventional therapy and documentation of the disappointing nature of the patient's response**.

- Briefly overview **how the procedure works**, and **its advantages in relation to other treatment alternatives**.

- Describe your treatment plan: initial frequency and continuing frequency and length of therapy scenarios based on alternative response patterns.

- Educate the insurance plan's Medical and/or Associate Medical Director about the clinical rationale for therapeutic apheresis in this particular patient:

  → **Cite *and enclose* copies of authoritative studies or reviews** which document the therapeutic benefit of the procedure in similar patients. *Cite literature which provides supportive evidence and conclusions*.

  → **Cite formal technology assessments which support the medical necessity of therapeutic apheresis as primary, adjunctive or salvage therapy for your patient**, as applicable.

  → **Ask for preauthorization of a specified number of treatments** likely to be required, again accompanied by either a major review or several citations in the literature which corroborate the use of a series of treatments.

  Insurers want and need a proposed treatment algorithm which (1) is reasonably consistent with the body of evidence in the published literature, and (2) allows a case manager to monitor progress and assure that futile or minimally effective therapy is *not* provided and billed.

- **Point out the urgency of a prompt response**, to enable your patient to begin receiving treatment as soon as possible. Note (as appropriate) that **earlier initiation of therapy generally yields better outcomes**, and again cite one or more supportive references; if available, enclose them in your letter.

- Offer to provide any **additional information** that might be needed concerning this patient, and include your direct telephone number. Use **a courteous and professional tone** throughout the letter.

Appendix 3

HCPCS Codes for Billing Albumin, FFP, and Red Blood Cells

HCPCS-II Code	Albumin Products
P9041	Infusion, albumin (human), 5%, 50 ml
P9045	Infusion, albumin (human), 5%, 250 ml
P9046	Infusion, albumin (human), 25%, 20 ml
P9047	Infusion, albumin (human), 25%, 50 ml

HCPCS-II Code	FFP and Red Blood Cell Products
P9010	Blood (whole), for transfusion, per unit
P9011	Blood (split unit), specify amount
P9012	Cryoprecipitate, each unit
P9016	Red blood cells, leukocytes reduced, each unit
P9017	Fresh frozen plasma (single donor), frozen within 8 hours of collection, each unit
P9021	Red blood cells, each unit
P9022	Red blood cells, washed, each unit
P9038	Red blood cells, irradiated, each unit
P9039	Red blood cells, deglycerolized, each unit
P9040	Red blood cells, leukocytes reduced, irradiated, each unit
P9044	Plasma, cryoprecipitate reduced, each unit
P9051	Whole blood or red blood cells, leukoreduced, CMV-negative, each unit
P9054	Blood, leukoreduced, frozen, deglycerolized, washed, each unit
P9056	Whole blood, leukoreduced, irradiated, each unit
P9057	Red blood cells, frozen/deglycerolized/washed, leukocyte-reduced, irradiated, each unit
P9058	Red blood cells, leukocyte-reduced, CMV negative, irradiated, each unit
P9059	Fresh frozen plasma between 8-24 hours of collection, each unit
P9060	Fresh frozen plasma, donor retested, each unit

Appendix 4

Glossary of Selected Insurance Terms

Allowable amount. The maximum amount an insurer will "allow" the provider for a service or supply, representing the total of the insurer's payment and the patient's balance payment.

Ambulatory Payment Classification (APC). A four-digit designation to which related outpatient hospital procedures which use similar resources are assigned; each APC is assigned a payment rate.

Beneficiary. A person eligible to receive benefits under an insurance policy.

Carrier. An insurance company that "carries" insurance; the preferable term is "insurer." A Medicare Carrier contracts with Medicare to process claims from physicians and freestanding non-hospital facilities paid under Medicare's Part B benefits (Note: all Medicare Carriers and Fiscal Intermediaries have been merged into Medicare Administrative Contractors [MACs]).

Claim. The demand for benefits as provided by an insurance policy.

CMS. The Centers for Medicare and Medicaid Services; formerly the Health Care Financing Administration (HCFA). The federal government agency that administers Medicare, Medicaid and Child Health Insurance Programs.

CMS-1500 claim form. The standard claim form required by Medicare and other health insurers for billing physician services.

Coinsurance. The percentage of the cost of care for which the patient is responsible; this often applies after a specific deductible is met.

Current Procedural Terminology (CPT). A listing of descriptive terms and codes for reporting medical services and procedures performed by physicians, which is maintained by the American Medical Association.

Deductible. The initial amount the patient is responsible for paying in a calendar year for particular covered services before insurance coverage begins.

Explanation of benefits (EOB). Documentation which accompanies payment of a claim, explaining (1) what was covered and not covered and why, (2) the payment rates or allowable amounts for billed services and products, (3) the amounts paid by the insurer, and (4) the amounts, if any, which are the patient's responsibility.

Fiscal Intermediary. An entity that contracts with Medicare to process hospital claims paid under Medicare's Part A benefits. Fiscal Intermediaries have been replaced by Medicare Administrative Contractors (MACs).

Global period. Services which follow and are directly related to the initial procedure over a defined "global period" are considered part of the initial procedure and are subsumed under its payment rate (i.e., not separately payable).

Glossary of Selected Insurance Terms – continued

Global payment rate. A single payment rate for both hospital and physician services.

Hospital Outpatient Prospective Payment System. The Medicare program's system for classification and payment of outpatient services.

ICD-10-CM. The diagnosis classification system now in use in all health care treatment settings.

ICD-10-PCS. The procedure classification system for use in inpatient hospital settings only.

Local Coverage Determination (LCD). A coverage policy established by a local Medicare Contractor, which addresses a medical service or procedure not addressed under an NCD.

Medically necessary services. A covered service that is required for the diagnosis or treatment of an illness or injury, or preserve the health status of an eligible person in accordance with local standards of medical practice.

Medicare Administrative Contractor (MAC). A single contract entity replacing Intermediaries and Carriers, with responsibility for payment of both Part A and Part B Medicare claims.

Medicare Part A and Part B. Hospital and medical insurance, respectively, under Medicare.

Modifier. Appended to a CPT code to further specify the nature of the service (e.g., the modifier "-TC" indicates only the technical component of the service).

MS-DRG (Medicare Severity-Adjusted Diagnosis-Related Group). A method used by Medicare and some other insurers to group inpatient hospital stays by principal and other diagnoses, procedures, age, gender and discharge status. MS-DRGs are assigned predetermined fixed payments per episode of care, independent of resource usage.

National Coverage Determination. A CMS coverage policy for a procedure.

Preauthorization (also precertification and prior authorization). A method to monitor and control utilization of a medical service by requiring a determination of whether it is both medical necessary and covered under the insurance plan prior to that service.

Relative value unit (RVU). A standard for measuring the value of a medical service provided by physicians relative to other medical services provided by physicians. Each service RVU has three components: physician work, overhead (reflecting all categories of practice expenses) and malpractice expense.

Revenue codes. A 3-digit coding system categorizing hospital services for billing purposes.

UB-04 claim form. The standard claim form required by Medicare and other insurers for billing hospital services.

Usual, Customary and Reasonable (UCR). A physician charge deemed reasonable for a service, which does not exceed his or her usual charges or the amount customarily charged by other physicians in the area for the service. Often defined as a specific percentile of all charges for services in the community.

Appendix 5: Bibliography For Further Reading

Centers for Medicare and Medicaid Services (CMS). Medicare Program: CY 2024 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Final rule. *Federal Register*, Vol. 88, No. 220, November 16, 2023. Accessed at: https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f.

Centers for Medicare and Medicaid Services (CMS). Medicare Program: Changes to Hospital Outpatient Prospective Payment; Final Rule. *Federal Register*, Vol. 88, No. 224, November 22, 2023. Accessed at: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc.

Centers for Medicare and Medicaid Services (CMS). FY 2024 IPPS Final Rule Home Page. Table 5: MS-DRGs, Relative Weighting Factors and Geometric and Arithmetic Mean Length of Stay. Accessed at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page#Tables.

Connelly-Smith L, Alquist CR, Aqui NA, et al. Guidelines on the Use of Therapeutic Apheresis in Clinical Practice – Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Ninth Special Issue. *J Clin Apher.* 2023;38(2):77-278.

Andrzejewski Jr C, Linz W, Hofmann J et al. ASFA white paper: considerations for medical staff apheresis medicine physician credentialing and privileging. *J Clin Apher.* 2012;27(6):330-335.

ICD-10 Resources. Centers for Medicare and Medicaid Services (CMS). Accessed at: https://www.cms.gov/Medicare/Coding/ICD10/ICD-10Resources.

Chimeric Antigen Receptor (CAR) T-cell Therapy: National Coverage Determination (NCD) 110.24. Centers for Medicare and Medicaid Services (CMS). Accessed at: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374.

National Coverage Determination 110.24: Chimeric Antigen Receptor T-cell Therapy. MLN Matters (MM12928); revised 12/30/2022. Centers for Medicare and Medicaid Services (CMS). Accessed at: https://www.cms.gov/files/document/mm12928-national-coverage-determination-11024-chimeric-antigen-receptor-t-cell-therapy.pdf.

Chimeric Antigen Receptor (CAR) T-cell Therapy Revenue Code and HCPCS Setup Revisions. MLN Matters (SE19009). Centers for Medicare and Medicaid Services (CMS). Accessed at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf.

ASFA
American Society for Apheresis

570 West 7th Avenue, Suite 402
Vancouver, BC, Canada V5Z 1B3
Phone: 604-484-2851
Fax: 604-874-4378
e-mail: asfa@apheresis.org
www.apheresis.org