THERAPEUTIC APHERESIS

A Guide to Billing and Securing Appropriate Reimbursement

2019 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:

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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:

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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 2019 edition of the Reimbursement Guide:

- All Medicare payment rates for products and hospital and physician services have been updated to reflect the current 2019 rate schedules.

- Referenced Medicare regulations and other resources, including the bibliography for further reading, have been updated.

- Important information regarding pertinent documentation related to reimbursement has been included in Appendix 1.

Note also that the 2019 edition of the Reimbursement Guide reflects the following significant changes that were implemented effective 1/1/2018:

- CPT 36515 (Therapeutic apheresis; with extracorporeal Immunoadsorption and plasma reinfusion) has been deleted from the CPT code set.

- The description of CPT 36516 has been expanded to include extracorporeal Immunoadsorption, and now reads "Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption, or selective filtration and plasma reinfusion."

- Significant increases in relative value units (RVUs) and associated insurance payment rates for therapeutic plasma exchange and photopheresis procedures performed in the non-hospital (physician office or clinic) treatment setting became effective starting 1/1/2018. Physician work RVUs for therapeutic apheresis procedures were also modestly revised.

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 and members of the Malachite Management team for their work and 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, which can present a range of 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 insurance billing process for apheresis services can be subdivided on the basis of:

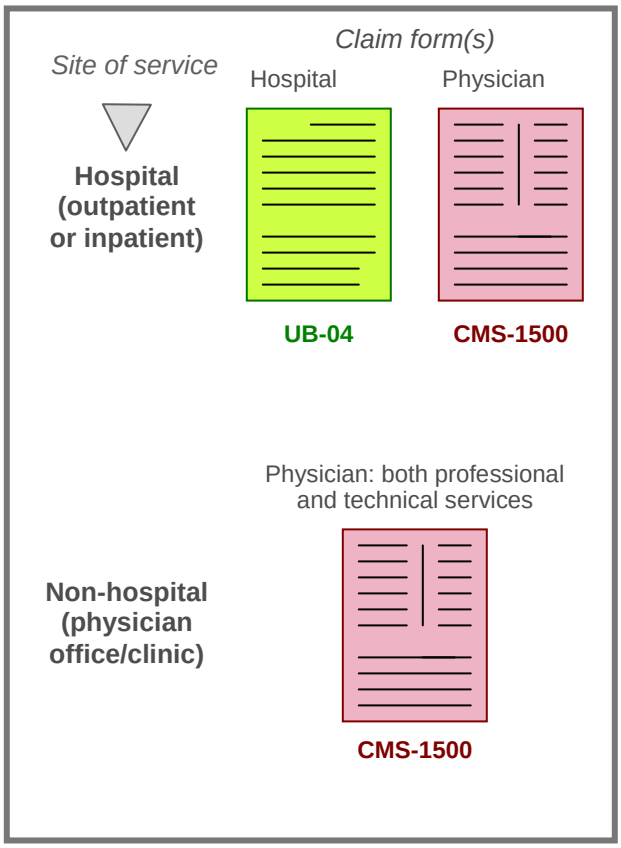
- **The treatment setting** in which the service is performed (hospital vs. physician office/physician-directed clinic);
- **The provider** that is submitting a service claim (**physician** or **hospital**).

When therapeutic apheresis services are provided in the **hospital inpatient or outpatient** setting generally involves separate submission of ***two*** claim forms:

- The ***CMS-1500*** by the **physician**, to facilitate payment for the physician's professional services associated with the procedure; and
- The ***UB-04*** by the **hospital**, to facilitate payment for the technical service itself (including non-physician procedure staff, disposable supplies, equipment costs, space costs, etc.).

When the procedure is performed in a **physician office or clinic**, only a ***single*** CMS-1500 claim form is required.

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

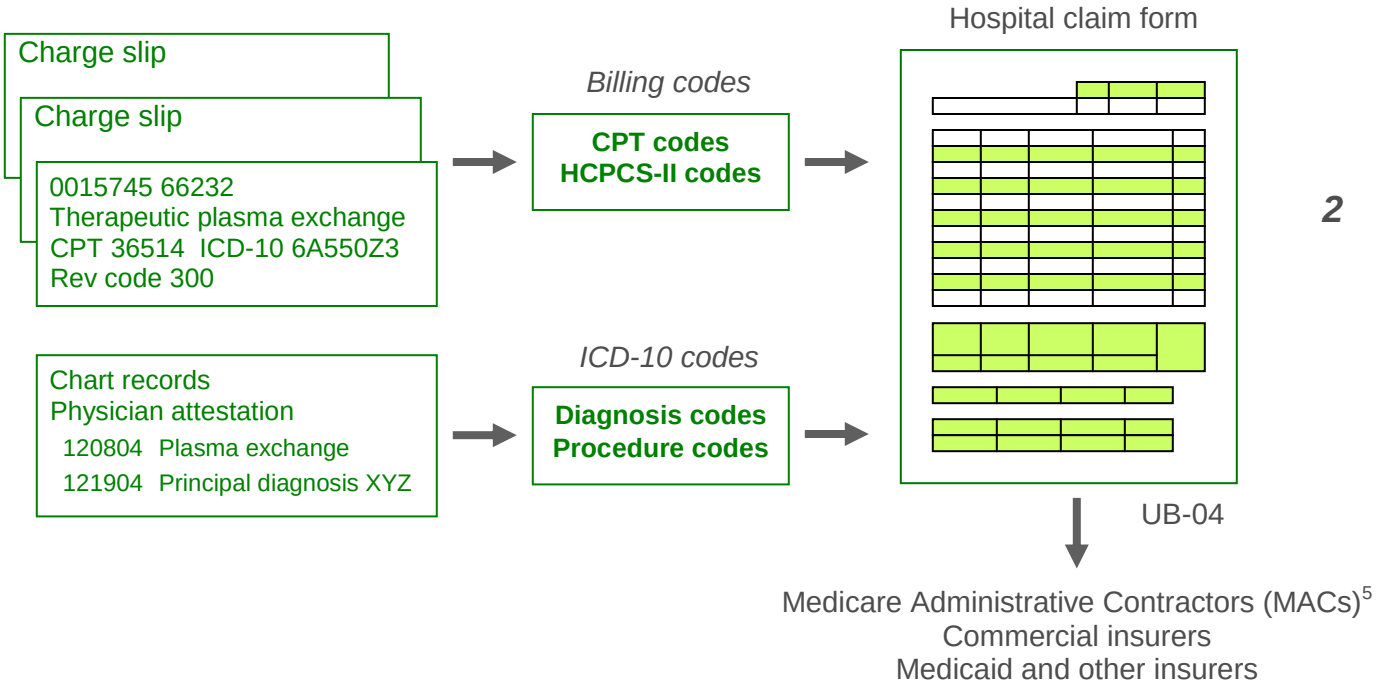
Hospital Billing on the UB-04 Claim Form

The hospital's "**charge master**" 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, a paper or electronic "**charge slip**" is generated and sent to the billing department to be added to the patient's 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© 2019. American Medical Association. All rights reserved.

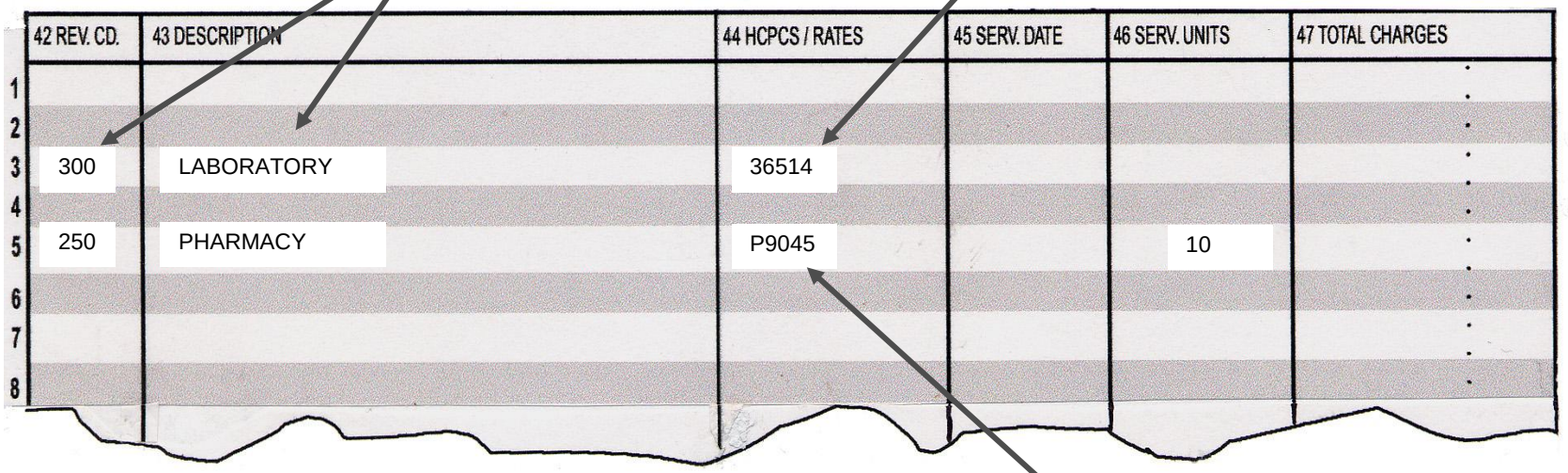
[2]Healthcare Common Procedure Coding System.

[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.

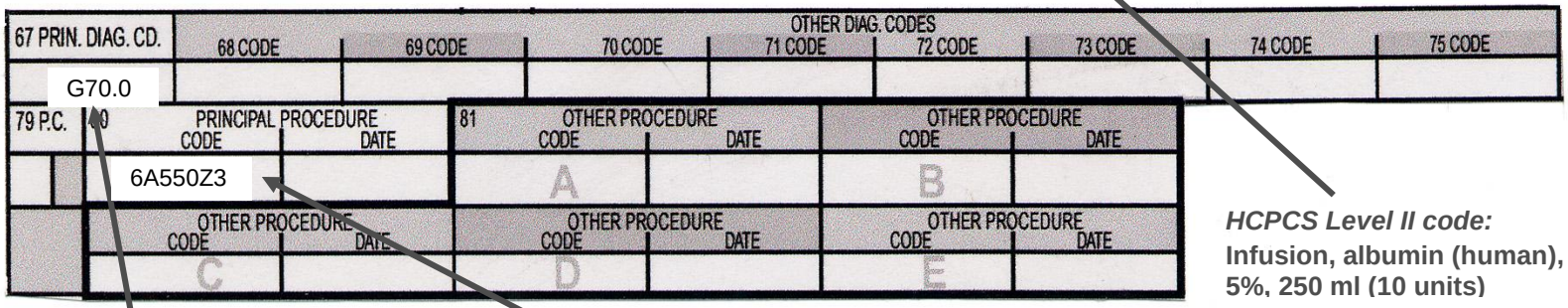
Sample Coding of a Hospital Therapeutic Apheresis Claim



Revenue codes
(cost centers)

CPT procedure code:
Therapeutic apheresis; for plasmapheresis

REQUIRED ONLY FOR HOSPITAL OUTPATIENTS



HCPCS Level II code:
Infusion, albumin (human), 5%, 250 ml (10 units)

REQUIRED ONLY FOR HOSPITAL OUTPATIENTS

ICD-10-CM diagnosis code:
Myasthenia gravis (principal diagnosis)

ICD-10-PCS procedure code(s)

REQUIRED ONLY FOR HOSPITAL INPATIENTS

Physician Billing on the CMS-1500 Claim Form

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

Enter

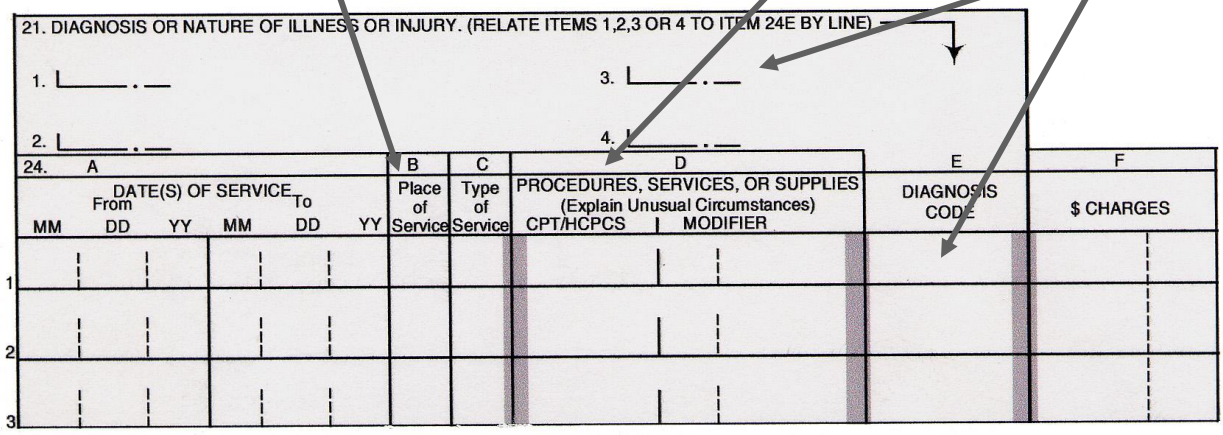
- **11 Physician's office or non-hospital MD-directed clinic setting**
- **22 Hospital outpatient setting**
- **21 Hospital inpatient setting**

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 physician supervision of the apheresis procedure*.[1]

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.

Effective 10/1/2015, ICD-10-CM codes replaced ICD-9-CM codes for diagnosis coding in all settings.

[1]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-CM procedure codes & nomenclature*[1]
36511 Therapeutic apheresis; for white blood cells	6A550Z1 Therapeutic leukapheresis (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[2]	6A55 Therapeutic apheresis, other
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]Effective since October 1, 2015, ICD-10-PCS procedure codes replaced ICD-9-CM procedure codes specifically in the hospital inpatient setting.

[2]LDL-C apheresis performed on two FDA-licensed apheresis systems is currently the only FDA-approved procedure for which CPT 36516 is applicable. (NOTE: 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 coverage determination (the "Focus" sections that follow address insurance coverage issues for specific apheresis procedures):

- The **scope of coverage** – all conditions determined to be medically necessary – **may vary by insurer**, depending on their methodology and rigor in establishing and updating their coverage policies.

  Some insurers use clinical consultants to help define or refine coverage policies, others adapt Medicare coverage policies, and still others contract the services of third party administrators (TPAs). Increasingly, formal **technology assessments** influence coverage policy-making (see below).

- 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 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 1 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 Determination (NCD) or a Local Coverage Determination (LCD), or may be determined on an individual consideration basis.

Examples of Treatment Guidelines and Technology Assessments That Can Influence Insurance Coverage Policies for Therapeutic Apheresis Services:

Padmanabhan A, Connelly-Smith L, Aqui N, 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 Eight Special Issue. *J Clin Apher* 2019;34:171-354. https://doi.org/10.1002/jca.21705

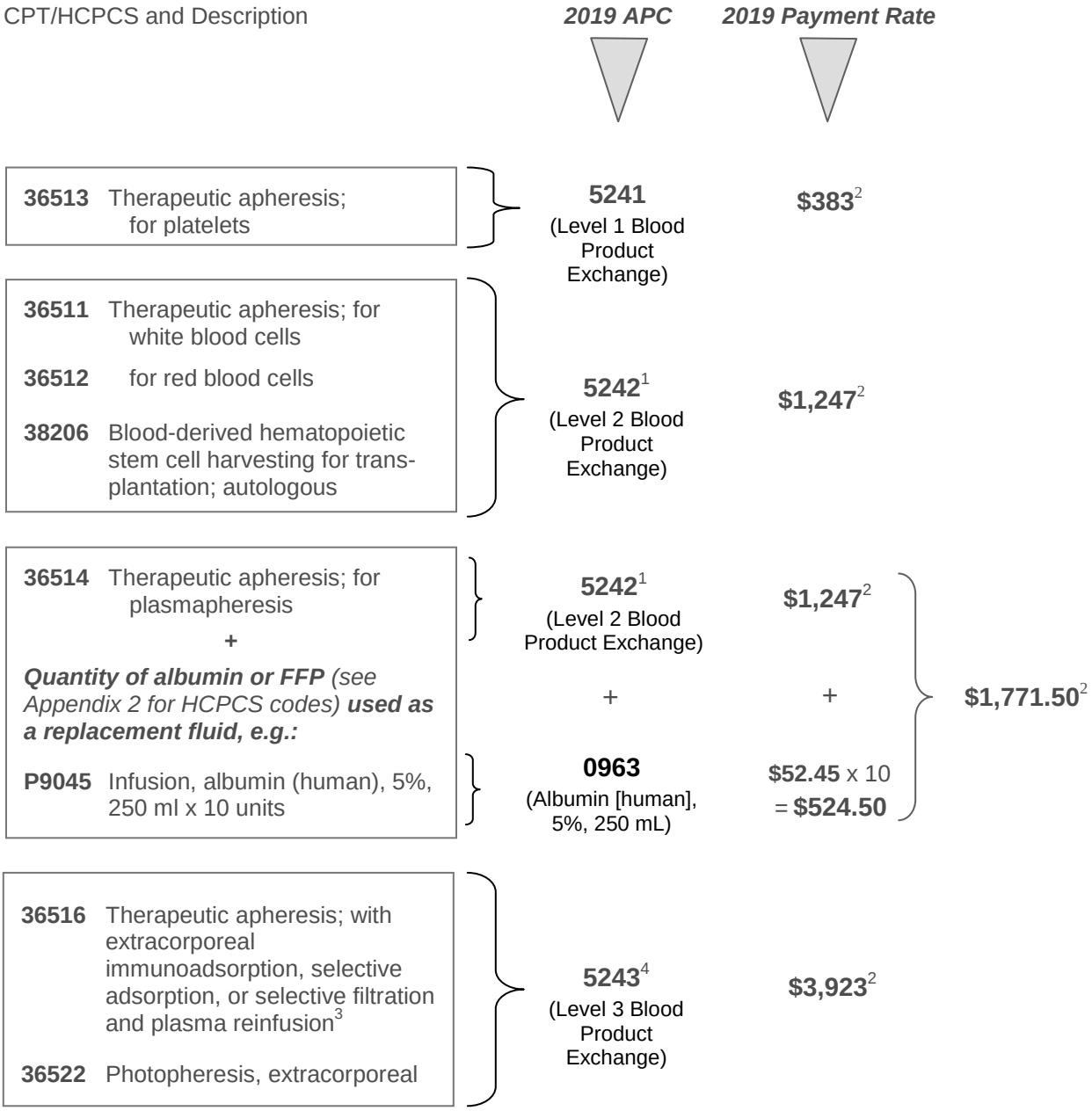
Ito MK, McGowan MP, Moriarty PM. Management of familial hypercholesterolemias in adult patients: Recommendations from the National Lipid Association Expert Panel on FH. *J Clin Lipidol* 2011;5:S38-S45.

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

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 actual payment rate for procedure-based APCs is adjusted for hospitals in each geographic locality by applying the "IPPS wage index" to the labor-related portion of the payment rate to reflect geographic wage variations. *Federal Register*, Vol. 83, No. 217, November 21, 2018, p. 58863.

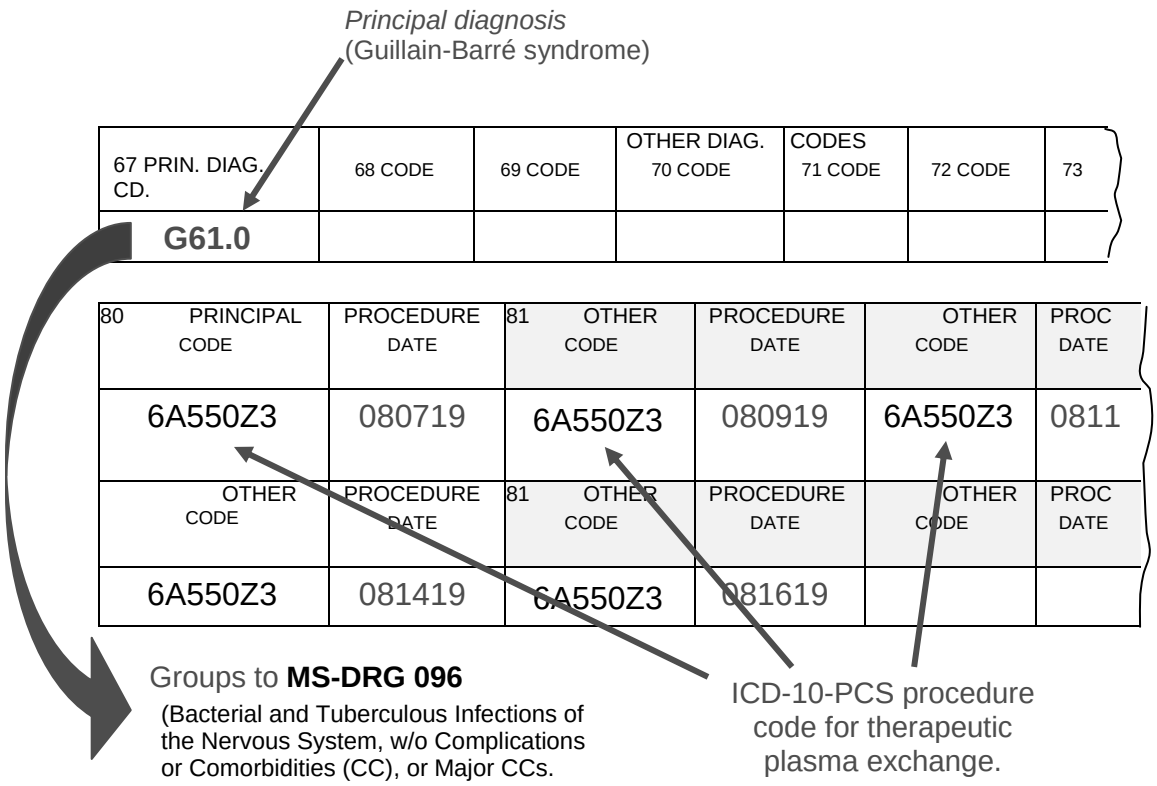
[3]Currently applies specifically to LDL-C apheresis (*Liposorber*® LA-15 System)

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

Medicare Payment in the Hospital Inpatient Setting

Medicare compensates hospitals for inpatient stays with prospectively fixed payments that correspond to more than 700 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 which involve therapeutic apheresis treatment(s) are usually driven instead 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 the 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 referred to as acute inflammatory demyelinating polyradiculoneuropathy (AIDP)

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	*ICD-10-CM*	*MS-DRG*	*2019 relative weight*
Guillain Barré syndrome (without CC)	G61.0	**096**	2.3809
Guillain Barré syndrome (with major CC)	G61.0	**094**	3.6779
Rapidly progressive nephritic syndrome with diffuse membranous glomerulonephritis (with major CC)	N01.2	**698**	1.6151
Thrombotic thrombocytopenic purpura (with major CC)	M31.1	**545**	2.4791
Cryoglobulinemia (with major CC)	D89.1	**823**	4.5246
Chronic inflammatory demyelinating polyneuropathy	G61.81	**074**	0.9739
Myasthenia gravis with exacerbation (acute)	G70.01	**057**	1.2089

CC = complications and comorbidities

A formula utilizing the "relative weight" for the assigned MS-DRG and a number of 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.

Two points concerning MS-DRGs and Medicare payment rates:

1. The MS-DRG-based payment rate for a hospitalization is **independent of whether therapeutic apheresis was provided, or the number of apheresis procedures provided** over the course of the stay; and

2. The MS-DRG, and thus the payment rate, is usually driven by the patient's **principal diagnosis**. It is not influenced by the use of apheresis, administration of drugs or biologicals like IVIG, or by other resources required over the course of the stay.

As MS-DRG assignments are based on coding and supporting documentation in the hospital chart, it is important that all medical records:

- Be comprehensive and complete
- Include all diagnoses, procedures, complications, and comorbidities
- Be legible

This attention to accuracy and detail facilitates proper coding, thereby maximizing the likelihood of appropriate MS-DRG assignment.

Medicare Payment for Office-Based Plasma Exchange, LDL-C Apheresis, and Photopheresis

When performed in the office-based treatment setting, Medicare covers and pays for both technical and professional service components of **therapeutic plasma exchange (CPT 36514)**, **selective therapeutic apheresis currently comprising lipoprotein apheresis (CPT 36516)** and **extracorporeal photopheresis (CPT 36522)**. Calendar year 2019 (CY 2019) 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.

In 2017, through efforts of ASFA and other stakeholder organizations, the AMA's Relative Value Update Committee (RUC) updated valuations of several PE inputs used to develop PE RVUs for these procedures, importantly including $100 and $740 increases in the recognized provider cost of TPE tubing sets and photopheresis procedure kits, respectively. Effective 1/1/2018 and thereafter, these and other new PE inputs significantly increase total non-facility RVUs for office-based CPT 36514 and CPT 36522 procedures.

Calendar 2019: Practice Expense Relative Value Units (RVUs) Now Defined for Therapeutic Apheresis Services in the Physician Office-Based Setting

CPT	Description	MD work RVUs	Non-facility PE[1] RVUs	Malpractice RVUs	Non-facility total
36514	Apheresis, plasma	1.81	**18.52**	0.17	**20.50**
36516	Apheresis, selective	1.56	**54.44**	0.27	**56.27**
36522	Photopheresis	1.75	**59.35**	0.12	**61.22**

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 2019 is **$36.0391**.[2]

Example: The U.S. average CY 2019 Medicare payment rate for an office-based TPE procedure (not including albumin) is $36.0391 x 20.50 RVUs = **$738.80.**

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. Current Medicare payment rates are accessible on the CMS website or from your local Medicare contractor. All other health insurers can similarly be billed for albumin using the same HCPCS codes and your submitted charges.

When a procedure is performed in the **hospital setting**, the physician bills only for his or her professional services. The Medicare payment rate will reflect the same physician work and malpractice expense RVUs, together with nominal **"facility practice expense RVUs"** (facility = hospital). These facility PE RVUs range from 0.63 to 0.97 RVUs, depending on the specific procedure. The total 2019 valuation for physician supervision of therapeutic apheresis procedures performed in the hospital setting range from **2.46 to 3.16 RVUs**.

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

[2]*Federal Register*, Vol. 83, No. 226, November 23, 2018, p. 60027.

Payment Policies by Commercial Insurers

Hospital:

Outpatient Setting:

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

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

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 condtions.

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, etc). "Outlier" provisions may provide additional reimbursement when overall costs exceed a certain threshold.

Physician:

Hospital Inpatient or Outpatient Setting:

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** (page 24): **Important Information Regarding Pertinent Documentation Related to Reimbursement**.

Physician Office or Physician-Directed Clinic Setting:

As noted earlier, Medicare identifies **relative value units** (RVUs) for "nonfacility practice expenses" applicable to **TPE** (CPT 36514), **immunoadsorption, selective adsorption, or selective filtration with plasma reinfusion** (CPT 36516), and **extracorporeal photopheresis** (CPT 36522).

Many commercial insurers may elect to base their payment rates on these new RVUs. Others will set payment rates on the basis of submitted charges or some other basis. Until these apheresis services become commonplace, some physicians can expect a back-and-forth process of rate negotiation with commercial insurers that agree to cover therapeutic apheresis procedures for their patients in the physician office or clinic setting.

Focus on Therapeutic Plasma Exchange (TPE)

Diagnosis Coding and Coverage:

Therapeutic plasma exchange (TPE) (CPT 36514) has been shown to be effective either as primary, adjunctive, or supportive therapy for a number of disorders, including but not limited to hematological, neurological, renal, and autoimmune disorders.

The benefits of TPE for many other proposed applications remain uncertain or unproven. These include ASFA's Category III disorders for which "the optimum role of apheresis therapy is not established." (*J Clin Apher* 2019;34:178).

Coverage of some diagnoses can be inconsistent from one insurer to the next, which is why it is important to secure preauthorization for TPE therapy when required.

Below are selected diagnoses for which TPE is commonly covered, variously as first-line therapy, adjunctive therapy, or as "last resort" or salvage therapy:

Diagnosis	*ICD-10-CM**	*Diagnosis*	*ICD-10-CM**
Guillain-Barré syndrome	G61.0	CIDP	G61.81
Lambert-Eaton myasthenic syndrome	G70.80	Thrombocytopenia, exchange transfusion	G61.0
Myasthenia gravis/in crisis	G70.00/01	Sydenham's chorea	I02.0
Macroglobulinemia (incl. Waldenstrom's)	C88.0	Thrombotic thrombocyto-penic purpura (TTP)	M31.1
Glomerulonephritis w/anti-glomerular BM antibodies	M31.0	Other paraproteinemias (e.g. cryoglobulinemia)	D89.1
Rapidly progressive glo-merulonephritis (unspeci-fied)	N01.9	Systemic lupus erythematosus	M32.14

*Replaced ICD-9-CM diagnosis codes effective October 1, 2015

Therapeutic Cytapheresis:
Examples of Generally Covered Clinical Diagnoses

Procedure	*Commonly treated diagnoses*	*ICD-10-CM**
Leukocytapheresis (CPT 36511)	Leukocytosis	**D72.829**
Erythrocytapheresis[1] (CPT 36512)	Sickle-cell disease Polycythemia; erythrocytosis	**D57.1**[2] **D75.1**
Plateletpheresis (CPT 36513)	Thrombocytosis, essential	**D69.3**

[1]with red cell exchange for sickle-cell anemia
[2]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).

Medicare's Coverage Policy for Therapeutic Plasma Exchange

Medicare Contractors reference the policy below to make coverage determinations for claims which include outpatient TPE. Coverage of other disorders is at the Contractor's discretion.

Commercial insurers may or may not reference this coverage policy in making their own coverage determinations. Current ASFA clinical guidelines are detailed in the "Guidelines on the Use of Therapeutic Apheresis in Clinical Practice" (*J Clin Apher* 2019;34:171-354).

Publication Number: 100-3
Medicare Coverage Manual Sect. 110.14 (Coverage Issues Manual §35-60)
Effective Date: 7/30/1992

Benefit Category:
Incident to a physician's professional Service
Outpatient Hospital Services Incident to a Physician's Service
Physicians' Services

Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, platelets, or cells) from whole blood. The remainder is retransfused into the person from whom the blood was taken.

For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date).

Indications and Limitations of Coverage. Apheresis is covered for the following indications:

- Plasma exchange for acquired myasthenia gravis;
- Leukapheresis in the treatment of leukemia;
- Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);
- Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;
- Plasmapheresis or plasma exchange as a last resort treatment of thromobotic thrombocytopenic purpura (TTP);
- Plasmapheresis or TPE in the last resort treatment of life threatening rheumatoid vasculitis;
- Plasma perfusion of charcoal filters for treatment of pruritis of cholestatic liver disease;
- Plasma exchange in the treatment of Goodpasture's Syndrome;
- Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;
- Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;
- Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy;
- Treatment of Guillain-Barré Syndrome; and
- Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.

Settings. Apheresis is covered only when performed in a hospital setting (inpatient or outpatient) or in a nonhospital setting, e.g., a physician directed clinic when the following conditions are met:

- A physician (or a number of physicians) is present to perform medical services and to respond to medical emergencies at all times during patient care hours;
- Each patient is under the care of a physician; and
- All nonphysician services are furnished under the direct, personal supervision of a physician.

Focus on Therapeutic Plasma Exchange – continued:

Payment: Hospital Outpatient

***Commercial insurers*.** Payment for the technical component of a TPE procedure is most commonly based either on a **fixed percentage of the hospital's submitted charge** or the insurer's **fee schedule amount**.

It is important to consistently itemize – or "capture" – all drugs, IV fluids, and supply items used in each TPE procedure, so they are all captured as charges on the claim.

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 1.74 physician work RVUs defined for this service in 2019.

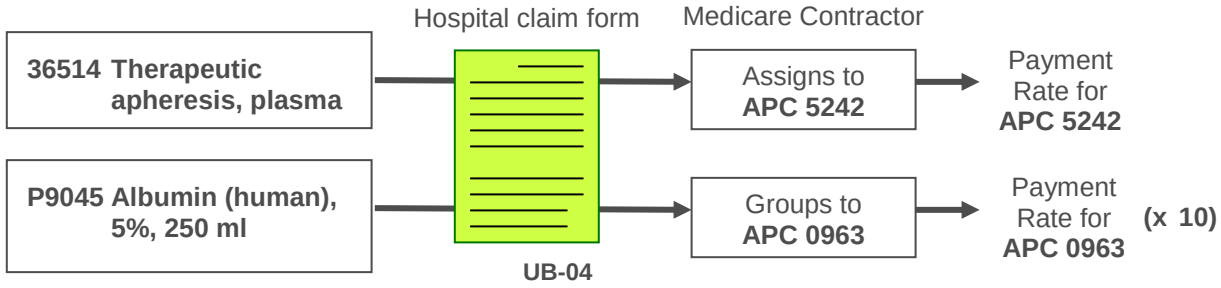
***Medicare*.** The hospital Outpatient Prospective Payment System (OPPS) assigns:

APC **5242** (Blood Product Exchange) for outpatient TPE claims coded with **CPT 36514**

+

An APC corresponding to **the blood or plasma product** replacing autologous plasma

Earlier (see "Medicare Payment in the Hospital Outpatient Setting") we reviewed a case example involving TPE (**CPT 36514**) with infusion of 10 units (250 mL) of 5% human albumin: the HCPCS Level II code for 5% 250 ml albumin (**P9045**) corresponds to **APC 0963**, whose 2019 payment rate is $52.45 per unit:



Other delivery forms of albumin (or plasma protein fraction) and fresh frozen plasma (FFP) may be administered or transfused as part of a TPE procedure; each groups to an APC, for which multiple "units" can be 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 2019 HCPCS codes for billing albumin, FFP, and blood components.

The same dual payment methodology applies for outpatient **red cell exchange**:

P9016 RBCs, leukoreduced

↓

APC 9512

↓

Payment rate x Units

Focus on Therapeutic Plasma Exchange – continued:

Payment: Hospital Outpatient (continued)

Below again are the three APCs to which the seven therapeutic apheresis and autologous stem cell harvesting procedures assign in 2019. Note that these three APC descriptors are very general and potentially misleading. It is best to refer to them solely by their numbers.

CPT and Description		
36513 Therapeutic apheresis; for platelets	**APC 5241**	Level 1 Blood Product Exchange and Related Procedures
36511 Therapeutic apheresis; for white blood cells **36512** for red blood cells **36514** **for plasmapheresis** **38206** Blood-derived hematopoietic stem cell harvesting for trans-plantation; autologous	**APC 5242**[1]	Level 2 Blood Product Exchange and Related Procedures
36516 Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption, or selective filtration and plasma reinfusion. **36522** Photopheresis, extracorporeal	**APC 5243**[2]	Level 3 Blood Product Exchange and Related Procedures

[1]CPT 38230, CPT 38241, CPT 38242, and CPT 38243 also assign to APC 5242.

[2]CPT 38232 also assigns to APC 5243.

Payment: Hospital Inpatient

***Commercial insurers*.** The costs of TPE may be 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, or paid on the basis of a negotiated percentage of charges.

***Medicare*.** Refer to **"Medicare Payment in the Hospital Inpatient Setting"** (pp. 8-9), which provides an example of a Guillain-Barré patient treated with plasma exchange.

Payment: Physician Office or Physician-Directed Clinic

Refer to the Guide section titled **"Medicare Payment for Office-Based Plasma Exchange, LDL-C Apheresis, and Photopheresis"** (page 10).

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. Additionally, they may formally cover drug-refractory cardiac allograft rejection and certain other diagnoses, or may cover these uses 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:

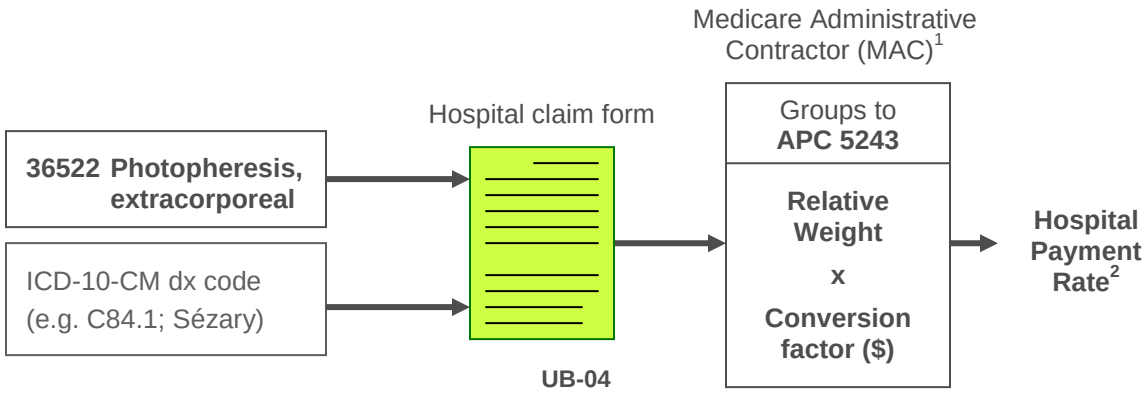
Payment: *Hospital Outpatient*

***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.

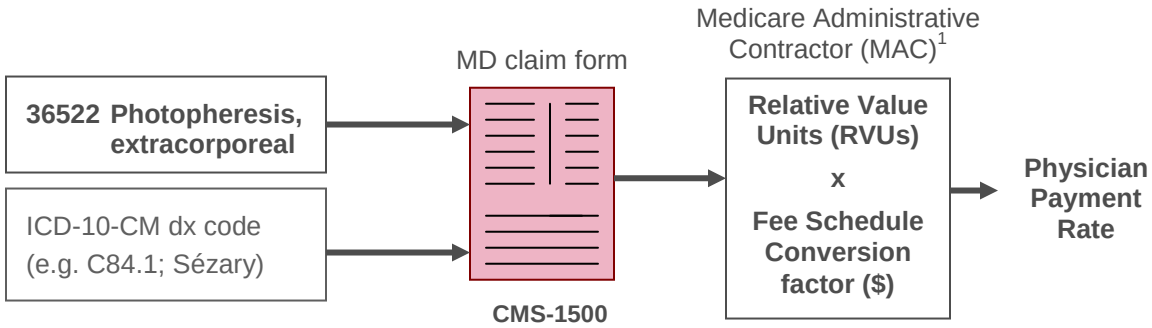
For bone marrow or stem cell transplant patients, many insurers negotiate a **global case rate** which includes all hospital (and often physician) services provided over the first 6-12 weeks of outpatient treatment. Thus, unless stipulated otherwise, ECP services to treat GVHD during that global period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

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 MAC:



[1]Medicare Carriers and Intermediaries have been replaced by Medicare Administrative Contractors (MACs), which provide both hospital and physician claims processing services.

[2]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:

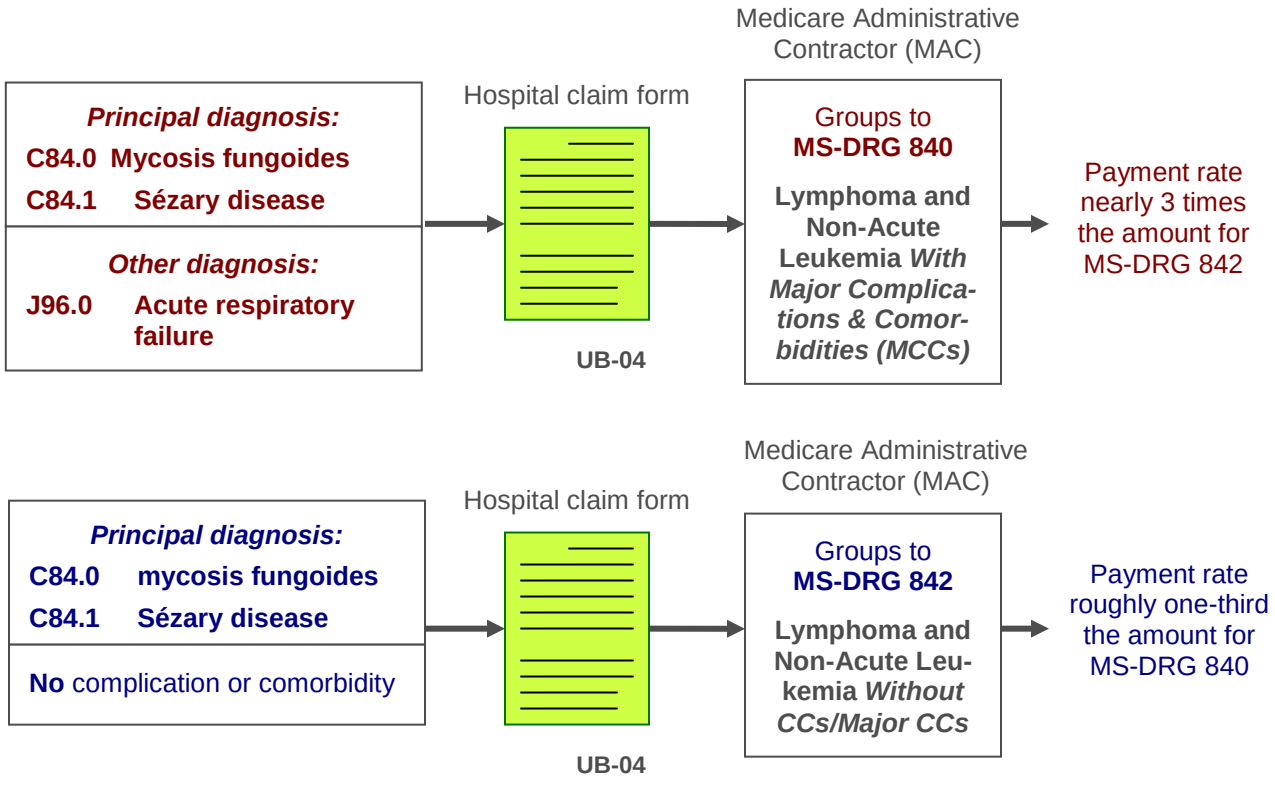
Payment: Hospital Inpatient

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, listed 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**:



Payment: Physician Office or Physician-Directed Clinic

Refer to the Guide section titled **"Medicare Payment for Office-Based Plasma Exchange, LDL-C Apheresis, and Photopheresis"** on page 10.

Focus on LDL-C Apheresis

Diagnosis Coding:

At present, two FDA-approved LDL-C apheresis technologies (Liposorber and H.E.L.P. System) represent the only procedures which 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.

LDL-C apheresis is indicated for use in a narrowly defined patient population with **familial hypercholesterolemia (FH)** which requires chronic lowering of the plasma LDL cholesterol (LDL-C) level.

Diagnosis	*ICD-10-CM*
Pure hypercholesterolemia	**E78.0**
Mixed hyperlipidemia*	**E78.2**

*Some insurers may not cover claims coded E78.2

Procedure coding:

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

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

Coverage:

Most commercial insurers and two Medicare MACs[1] have a formal coverage policy for LDL-C apheresis, loosely modeled on FDA indications established in the mid-1990s for the two licensed LDL-C apheresis technologies. LDL-C apheresis is generally covered for patients who have completed, at minimum, a 6-month trial of an American Heart Association Step II diet (or equivalent) and maximum tolerated combination drug therapy designed to reduce LDL-C, and at their baseline examination meet one (or more) of following additional criteria:

1. Homozygous FH with LDL cholesterol (LDL-C) >500 mg/dl;
2. Heterozygous FH with LDL-C ≥300 mg/dl;
3. Heterozygous FH with LDL-C ≥200 mg/dl and documented coronary heart disease (CHD);

Some coverage policies specify types of lipid-lowering drugs that must have been evaluated.

In 2011, the National Lipid Association (NLA) published a clinical practice guideline (Ito MK et al. *J Clin Lipidol* 2011;5:S38-S45) considerably expanding the LDL-C apheresis-eligible patient population. Some insurers may consider coverage for FH patients whose baseline LDL-C level falls below the labeled indication and within the NLA guideline range.

In March 2019, FDA approved a revision to the Group C indication for use of the Liposorber LA-15 LDL-C apheresis system, reducing the minimum LDL-C threshold to ≥100 mg/dL for functional heterozygotes with documented CHD or peripheral artery disease (PAD):

1. Group A: Functional hypercholesterolemic homozygotes with LDL-C >500 mg/dl;
2. Group B: Functional hypercholesterolemic heterozygotes with LDL-C ≥300 mg/dl;
3. **Group C: Functional hypercholesterolemic heterozygotes with LDL-C ≥100 mg/dl and either documented CHD or PAD**.

[1]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).

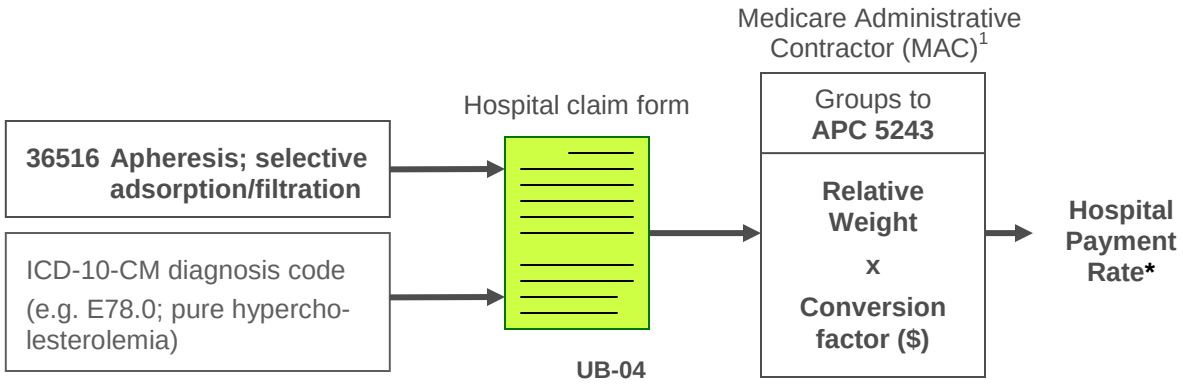
Focus on LDL-C Apheresis – continued:

Payment: *Hospital Outpatient*

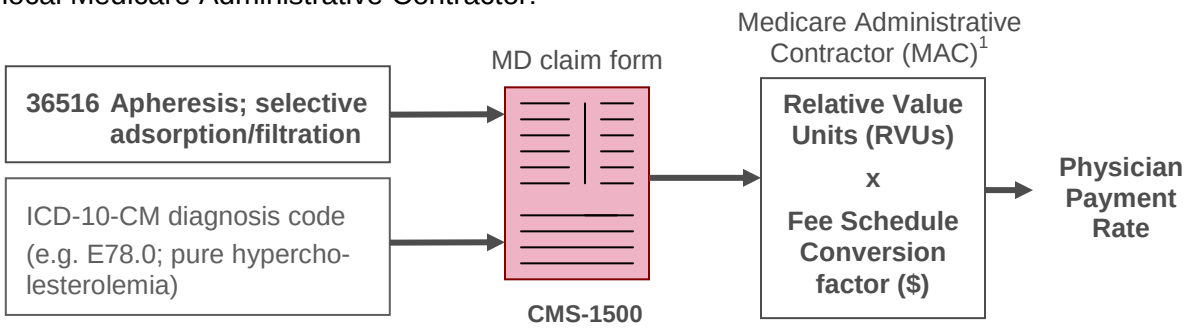
***Commercial insurers*.** Payment for the technical component of an LDL-C apheresis procedure is most commonly based on a **fixed percentage of the hospital's submitted charge** or a negotiated **fee schedule amount**. There may be **negotiation** between the institution and the insurer to arrive at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

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:



Payment: *Physician-Directed Clinic*

Please refer to the guide section titled **"Medicare Payment for Office-Based Plasma Exchange, LDL-C Apheresis, and Photopheresis"** on page 10.

Payment: *Hospital Inpatient*

LDL-C 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.

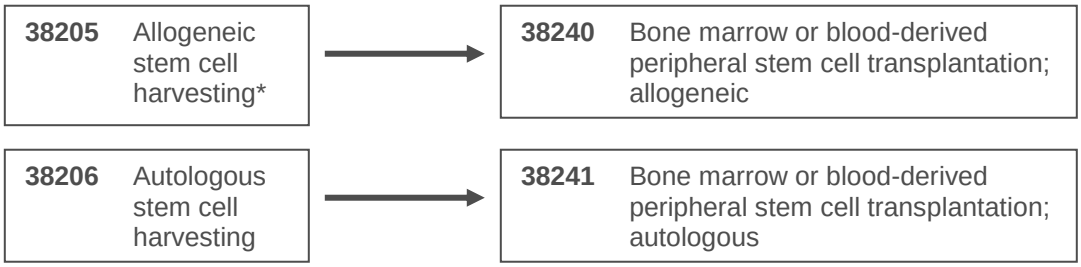
*Adjusted to reflect geographic wage variations. If one or more other procedures are also performed on the same day, Medicare payment for APC 5243 assigned for LDL-C apheresis is *not* discounted.

Focus on Blood-Derived Stem Cell Harvesting

Two CPT procedure codes are respectively used to identify and bill apheresis-based collection of peripheral blood 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 leukemia, lymphoma, aplastic anemia, or other ICD-10-CM coded condition) **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 transplant should be entered on the claim for the donor stem cell harvesting procedure.

Coverage:

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; these include defined subsets of patients with myelodysplastic syndromes (MDS), multiple myeloma, myelofibrosis (MF) and sickle cell disease (SCD).

[*] Medicare National Coverage Determinations Manual, Section 110.23 (Rev. 193, 07-01-16), effective 01-27-16. Accessed at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf.

Focus on Blood-Derived Stem Cell Harvesting – continued:

Below is a summary of indications for HSCT (and associated stem cell harvesting procedures) covered by Medicare, when reasonable and necessary:

Allogeneic Stem Cell Transplantation **(CPT 38205, 38240)**

The following uses are **covered** under Medicare:

- Leukemia, leukemia in remission, or aplastic anemia when reasonable and necessary
- Severe combined immunodeficiency disease (SCID) and Wiskott-Aldrich syndrome

Covered with evidence development (CED) under an approved prospective clinical study:

- Myelodysplastic syndrome (MDS)
- Durie-Salmon Stage II or III multiple myeloma
- Myelofibrosis (MF)
- Sickle cell disease (SCD)

Autologous Stem Cell Transplantation **(CPT 38206, 38241)**

The following uses are **covered** under Medicare, when reasonable and necessary:

- Acute leukemia in remission with a high probability of relapse and no human leucocyte antigens (HLA)-matched.
- Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response.
- Recurrent or refractory neuroblastoma
- Advanced Hodgkin's disease patients who have failed conventional therapy and have no HLA-matched donor.
- Durie-Salmon Stage II or III patients that fit specified requirements; includes multiple myeloma and primary amyloidosis.

Payment: Hospital Outpatient

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 is most commonly based either on a **fixed percentage of the hospital's submitted charge** or the insurer's **rate schedule** for CPT 38205 and 38206. If multiple harvesting procedures are required, they would be individually paid.

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.

Payment: Physician

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 turn, is usually tied to the physician work RVUs (1.5 RVUs in 2019) for the procedure.

Focus on Intravascular Access Device (IVAD) Maintenance

Defining and Documenting Costs of Catheter Declotting:

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 in place to assure that entries or charge slips are generated for your billing department to include in the insurance claim.

Coding Opportunities:

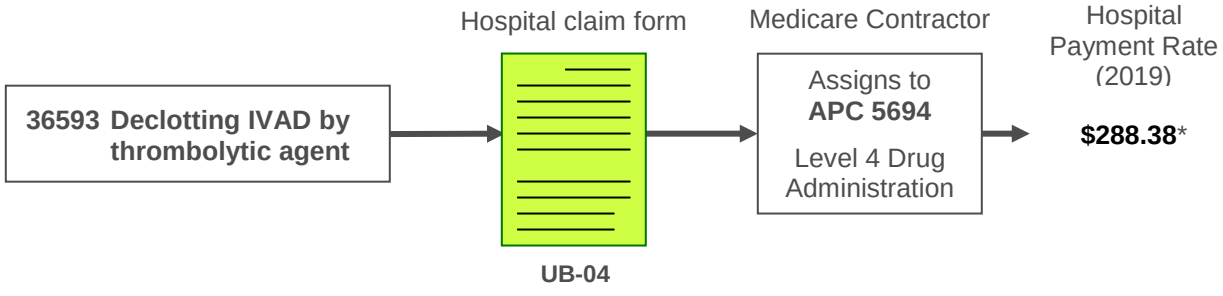
As appropriate, the following codes should be identified in the claim:

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)*
J3364	Injection, urokinase, 5000 IU vial

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

Coding for Medicare Payment in the Hospital Outpatient Setting:

For **Medicare beneficiaries** whose catheter occlusions are treated in the **hospital outpatient department**, the CPT procedure code **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.

Appendix 1

Important Information Regarding Pertinent Documentation Related to Reimbursement

No statutory generating entity, regulatory agency, or accreditation agency has definitively promulgated the required type, extent, and format needed for physician documentation in the patient's medical record for apheresis service. Due to inquiries from ASFA membership as to how this should best be accomplished, 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 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 subsequently.

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 to emergencies or other situations requiring his/her presence throughout the procedure (Guidelines For Documentation of Therapeutic Apheresis Procedures in the Medical Record by Apheresis Physicians. Available at: http://www.apheresis.org/?page=Guidelines).

Since the publication of this guideline, medicine and the technologies supporting medical care have markedly evolved. The workforce has contracted, mid-level provider participation is widely adopted, electronic medical records documentation has been de facto institutionalized, remote patient monitoring is feasible, and telemedicine/telehealth is now recognized as legitimate practice. It is anticipated that due to these innovations, new guidance will be forthcoming from pertinent entities regarding acceptable documentation and billing options for such 21st century activities by medical practitioners, including Apheresis Medicine specialists. To this end, there is increasing interest in leveraging the expertise of transfusion and apheresis medicine specialists around the country to bring higher quality of care to patients with challenging autoimmune diseases through remotely guiding their physicians and providing point-of-care evidence-based recommendations. There appear to be a variety of pathways for providing expert remote "virtual" apheresis consultation[1], models for being compensated 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 is monitoring developments in these areas, especially as they pertain to the development of billing codes and payment models related to the provision of telemedicine/telehealth services that Apheresis Medicine specialists may utilize in their management of patients receiving apheresis therapies.

[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 (Short Descriptors*)
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

* The short descriptors for HCPCS codes are listed in Addendum B of the hospital outpatient prospective payment rule, which is updated quarterly. The most recent update from July 2019 is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html.

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

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The short descriptors for HCPCS codes (Appendix III, page 26) are listed in Addendum B of the hospital outpatient prospective payment rule, which is updated quarterly. The most recent update from July 2019 is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html.

The long descriptors are also available on the CMS website: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html?DLSort=0&DLEntries=10&DLPage=1&DLSortDir=descending.

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