

THERAPEUTIC APHERESIS

A Guide to Billing and Securing
Appropriate Reimbursement

2016 Edition

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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.

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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 the **Therapeutic Apheresis: A Guide to Billing and Securing Appropriate Reimbursement** document. The latest edition of the Guide has been extensively updated, in part due to the transition to ICD-10-CM diagnosis and ICD-10-PCS procedure codes that were mandated by the federal government to occur in the fall of 2015. Below are listed the significant changes that appear in the 2016 Reimbursement Guide:

- All ICD-9-CM diagnosis and procedure codes have been replaced by ICD-10-CM diagnosis and ICD-10-PCS procedure codes.
- All discontinued Ambulatory Payment Classifications (APCs) have been replaced with new APCs effective in calendar 2016.
- All Medicare payment rates for products and hospital and physician services have been updated to reflect the current 2016 rate schedules.
- Referenced Medicare regulations and other resources, including the bibliography for further reading, have been updated and/or expanded.
- Text has been added to clarify that Medicare Administrative Contractors (MACs) have discretion in determining whether to cover therapeutic apheresis for clinical indications not identified in the National Coverage Determination (NCD).
- Medicare coverage policy with respect to autologous and allogeneic stem cell transplantation has been updated to reflect a National Coverage Determination (NCD) amended in early 2016.
- FDA approval of revised indications for LDL-C apheresis performed on the Liposorber System, reducing the lower threshold for baseline LDL-C level to ≥ 160 mg/dL, is now identified in that section.

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 of potential reimbursement issues that they have encountered as it 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 to the requirements of a particular insurer, or to alert that insurer to a contractual agreement.

1

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

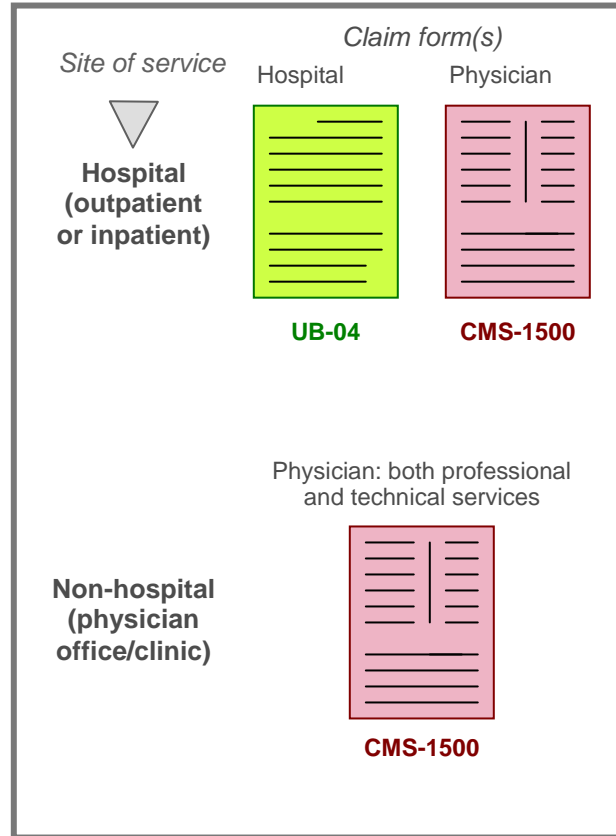
- **The treatment setting** in which the service is performed (hospital vs. physician office/physician-directed clinic);
- **The provider** that is submitting a service claim (**physician** or **hospital**).

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

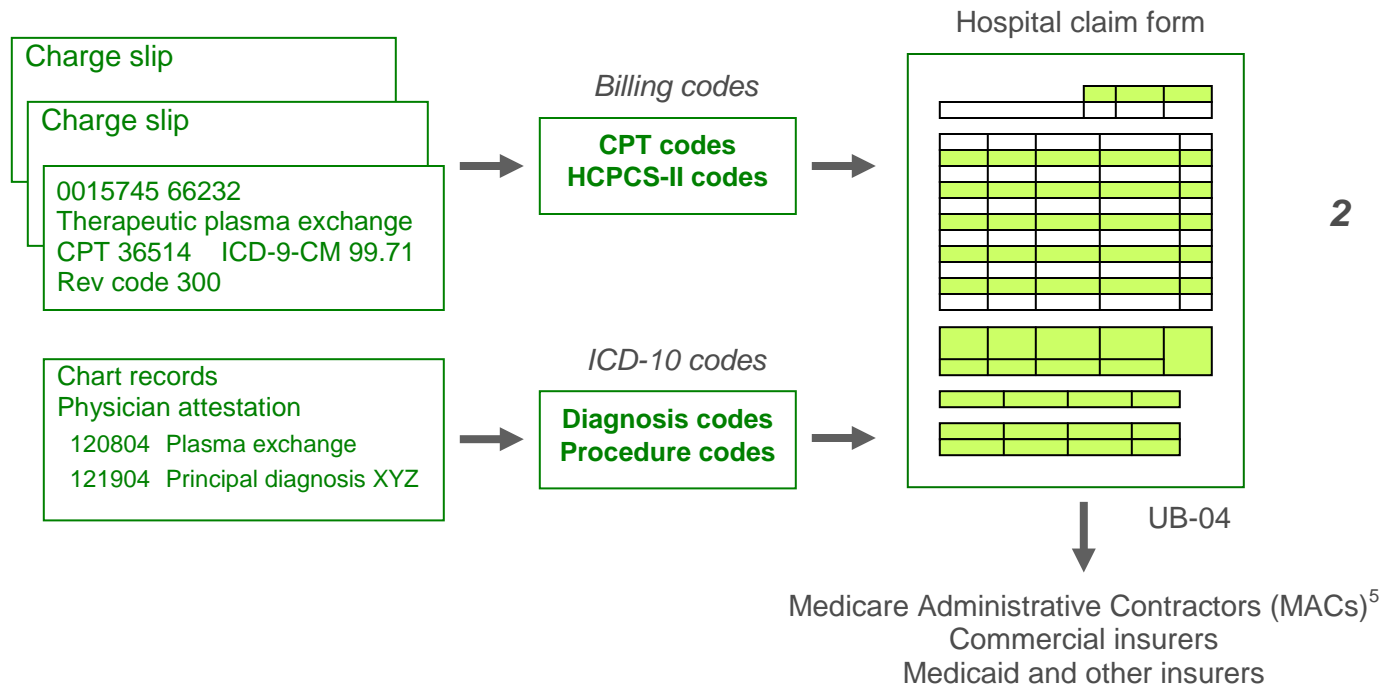
Hospital Billing on the UB-04 Claim Form

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 **CPT¹** or **HCPCS² 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-CM³ diagnosis codes** and **ICD-10-PCS⁴ 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-CM³ diagnosis codes:** identify diseases and injuries; code a 5th digit when applicable
- ICD-10-PCS⁴ procedure codes:** identify procedures in the hospital inpatient setting
- Revenue codes:** group similar types of hospital services and items by type of service

¹Current Procedural Terminology: CPT® 2016. American Medical Association. All rights reserved.

²Healthcare Common Procedure Coding System.

³International Classification of Diseases, 10th Revision, Clinical Modification.

⁴International Classification of Diseases, 10th Revision, Procedure Coding System.

⁵There are currently 12 A/B MACs, which will be consolidated eventually into 10 MACs.

Sample Coding of a Hospital Therapeutic Apheresis Claim

Revenue codes (cost centers)

CPT procedure code: Therapeutic apheresis; for plasmapheresis

REQUIRED ONLY FOR HOSPITAL OUTPATIENTS

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATES	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES
1					.
2					.
3	300 LABORATORY	36514			.
4					.
5	250 PHARMACY	P9045		10	.
6					.
7					.
8					.

67 PRIN. DIAG. CD.	68 CODE	69 CODE	70 CODE	OTHER DIAG. CODES			74 CODE	75 CODE
79 P.C.	80	81 OTHER PROCEDURE		OTHER PROCEDURE		OTHER PROCEDURE		
CODE	DATE	CODE	DATE	CODE	DATE	CODE	DATE	
G70.0		A		B				
		C		D		E		

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

ICD-10-PCS procedure code(s): REQUIRED ONLY FOR HOSPITAL INPATIENTS

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

REQUIRED ONLY FOR HOSPITAL OUTPATIENTS

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

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. (RELATE ITEMS 1,2,3 OR 4 TO ITEM 24E BY LINE)

1. _____ 3. _____

2. _____ 4. _____

24.	A					B	C	D		E	F
	DATE(S) OF SERVICE							Place of Service	Type of Service		
	From	To								CPT/HCPCS	MODIFIER
	MM	DD	YY	MM	DD	YY					
1											
2											
3											

4

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, *provided that the E/M service is not performed on the same day that an apheresis procedure is performed and charged for by the physician.*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.

¹A 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

<i>CPT procedure codes</i>	<i>ICD-10-CM procedure codes & nomenclature*</i>
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 selective adsorption or selective filtration and plasma reinfusion (LDL-C apheresis)	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

*Effective October 1, 2015, ICD-10-PCS procedure codes replaced ICD-9-CM procedure codes specifically in the hospital inpatient setting.

**No specific ICD-10-PCS code has been defined for this procedure

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

<i>Revenue code</i>	<i>Descriptor</i>
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 mm³.

- **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.

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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 Determinations (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

Schwartz J, Padmanabhan A, 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 seventh special issue. *J Clin Apher* 2016 June; 31(3):145-338.



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), single APCs apply for all therapeutic apheresis and stem cell collection procedures:

CPT/HCPCS and Description	2016 APC	2016 Payment Rate
36511 Therapeutic apheresis; for white blood cells 36512 for red blood cells 36513 for platelets 38206 Blood-derived hematopoietic stem cell harvesting for transplantation; autologous	 5271³	 \$1,048¹
36514 Therapeutic apheresis; for plasmapheresis + Quantity of albumin or FFP used as a replacement fluid, e.g.: P9045 Infusion, albumin (human), 5%, 250 ml <i>[ex: patient requires 10 units]</i>	5271³ + 0963	\$1,048¹ + $\$54.54 \times 10 = \545
36516 Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion ² 36522 Photopheresis, extracorporeal	5281⁴	\$3,015¹
		\$1,593¹

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¹The actual payment rate is adjusted for each locality by applying the “IPPS wage index” to the labor-related portion of the payment rate to reflect geographic wage variations. *Federal Register*, Vol. 80, No. 219, November 13, 2015, p. 70357.

²Currently applies to LDL-C apheresis (*Liposorber*[®] and *Plasmat Futura/Plasmat Secura H.E.L.P.*[®] Systems).

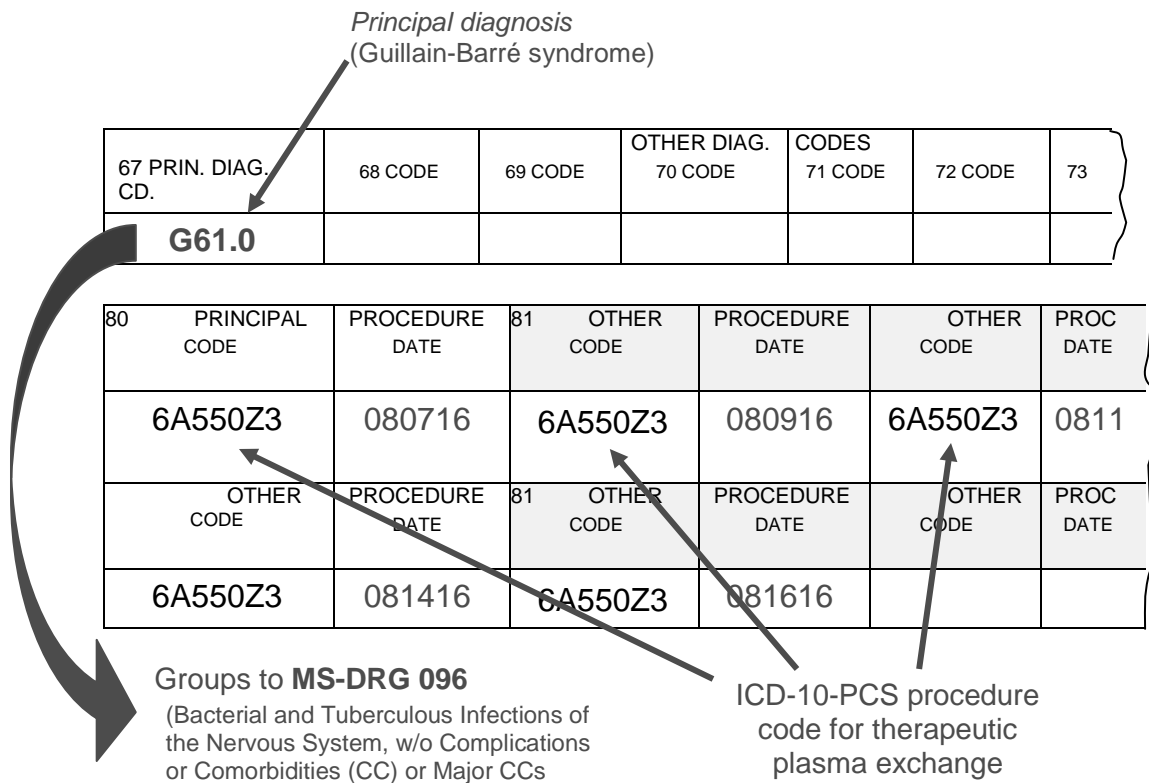
³Seven other procedures also assign to APC 5271 (formerly 0111): CPT 38210-38215 and 38242-38243.

⁴Five other procedures also assign to APC 5281 (formerly 0112): CPT 36515, 38230-38232 and 38240-38241.

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 a therapeutic apheresis 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 syndrome¹ received a total of five therapeutic plasma exchange (TPE) procedures over her hospital stay.



MS-DRG 096 and its associated payment rate also apply 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,

¹Also referred to as acute inflammatory demyelinating polyradiculoneuropathy (AIDP) or acute infective polyneuritis.

Medicare Payment in the Hospital Inpatient Setting – continued:

reflecting the typically shorter hospital stay and less intensive treatment demands of this disorder.

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.

<i>Principal Diagnosis</i>	<i>ICD-10-CM</i>	<i>MS-DRG</i>	<i>2016 relative weight</i>
Guillain Barré syndrome (without CC)	G61.0	096	2.1855
Guillain Barré syndrome (with major CC)	G61.0	094	3.4429
Rapidly progressive nephritic syndrome with diffuse membranous glomerulonephritis (with major CC)	N01.2	698	1.5524
Thrombotic thrombocytopenic purpura (with major CC)	M31.1	545	2.4409
Cryoglobulinemia (with major CC)	D89.1	823	4.4536
Chronic inflammatory demyelinating polyneuropathy (CIDP)	G61.81	074	0.9063
Myasthenia gravis with exacerbation (acute)	G70.01	057	1.0716

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, Immunoadsorption, LDL-C Apheresis and Photopheresis

Medicare covers and pays for the technical and professional service components of **therapeutic plasma exchange (TPE)** (CPT 36514), **immunoadsorption with plasma reinfusion**¹ (CPT 36515) and **selective adsorption or filtration with plasma reinfusion (LDL-C apheresis)** (CPT 36516) procedures in the office-based setting. Calendar year 2016 Medicare payment rates in this treatment setting incorporate (1) physician work, (2) procedural overhead including all practice expenses and (3) a small allocation for malpractice insurance.

Medicare similarly pays for practice expense, physician work and malpractice costs assigned to **photopheresis** (CPT 36522) when performed in the office-based setting.

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

Calendar 2016: 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 ³ RVUs	Malpractice RVUs	Non-facility total
36514	Apheresis, plasma	1.74	13.35	0.17	15.26
36516	Apheresis, selective	1.22	57.47	0.30	58.99
36522	Photopheresis	1.67	37.94	0.12	39.73

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The Medicare office-based payment rate in a specific locality is based on the conversion factor (CF) and local geographic practice cost indices (GPCIs). The CF for calendar year 2016 is **\$35.8279**.

Example: The U.S. average calendar 2016 Medicare payment rate for an office-based TPE procedure (not including albumin) is $\$35.8279 \times 15.26 \text{ RVUs} = \mathbf{\$546.73}$.

Payment for albumin replacement solution. On a quarterly basis Medicare publishes its “payment allowance limits” for 5% 250 ml human albumin (**P9045**) and plasma protein fraction (**P9048**) products, as well as these products in other concentrations and volumes. Current payment rates are accessible on the CMS website or from your local Medicare contractor. Commercial insurers should be billed using the same HCPCS code and your submitted charge.

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 0.49 to 1.14 RVUs, depending on the specific procedure. Total 2016 physician supervision RVUs for procedures performed in the hospital setting range from **2.01 to 2.93**.²

¹The *Prosorba*[®] immunoadsorption column technology, which codes to CPT 36515, is no longer commercially available in the U.S. No other apheresis procedures currently code to CPT 36515.

²*Federal Register*, Vol. 80, No. 220, November 16, 2015.

³Non-facility PE = non-hospital (physician office or clinic) practice expense.

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 therapeutic apheresis service is directly reimbursed by the payer, on the basis of pre-negotiated terms between the insurer and the 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

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: In the procedure note, it is highly recommended that the physician 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 the Use of Therapeutic Apheresis in Clinical Practice. *J Clin Apher* 2016 June; 31[3]:145-338)¹.

Physician Office or Physician-Directed Clinic Setting

As noted earlier, Medicare now identifies **relative value units** (RVUs) for "nonfacility practice expenses" applicable to **TPE** (CPT 36514), **immunoabsorption with plasma reinfusion** (CPT 36515), **selective adsorption or filtration with plasma reinfusion** (CPT 36516) and/or **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.

¹Given that TA procedures are increasingly being done in a diversity of settings, along with the advent of telemedicine and its potential applicability to the management of patients receiving TA, the documentation recommendation of "seeing and evaluating the patient" may evolve to reflect advances in other medical specialty areas using electronic monitoring in clinical care and patient management.

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* 2016 June; 31[3]:151).

Coverage of some diagnoses can be inconsistent from one insurer to the next, which is thus 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:

<i>Diagnosis</i>	<i>ICD-10-CM</i>	<i>Diagnosis</i>	<i>ICD-10-CM*</i>
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 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	M32.14

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

Therapeutic Cytapheresis: Examples of Generally Covered Clinical Diagnoses

<i>Procedure</i>	<i>Commonly treated diagnoses</i>	<i>ICD-10-CM³</i>
Leukocytapheresis (CPT 36511)	Leukocytosis	D72.829
Erythrocytapheresis ¹ (CPT 36512)	Sickle-cell disease Polycythemia; erythrocytosis	D57.1² D75.1
Plateletpheresis (CPT 36513)	Thrombocytosis, essential	D69.3

¹with red cell exchange for sickle-cell anemia

²predominantly 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. Other disorders may be covered 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 for the Use of Therapeutic Apheresis in Clinical Practice (*J Clin Apher* 2016; 31[3]:145-338).

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 thrombotic thrombocytopenic purpura (TTP);
- Plasmapheresis or PE 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.

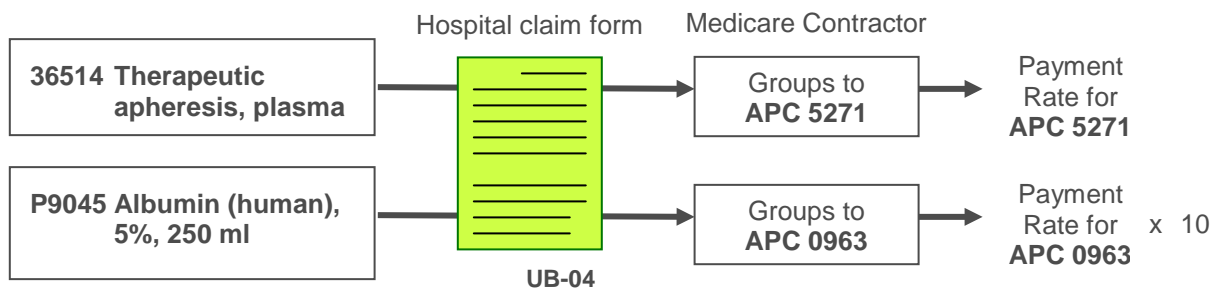
Payment for the **physician’s professional services** associated with hospital-based procedures is usually based on the insurer’s allowable rate, which in turn is often tied to the 1.74 physician work RVUs defined for this service in 2016.

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

APC **5271** (Blood Product Exchange) for outpatient TPE claims coded with **CPT 36514**
 +
 An APC corresponding to **the blood or plasma product** replacing autologous plasma

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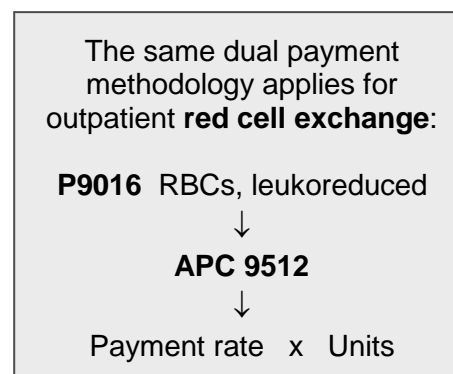
Earlier (see “Medicare Payment in the Hospital Outpatient Setting”) we reviewed a case example involving TPE (**CPT 36514**) with infusion of 10 units (250 mL) of 5% human albumin: the HCPCS Level II code for 5% 250 ml albumin (**P9045**) corresponds to **APC 0963**, whose 2016 payment rate is \$54.54 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
PPF, 5%, 250 ml	P9048	9519
Cryo-reduced plasma	P9044	9523
FFP, frozen ≤8 hours	P9017	9508

See **Appendix 2** for a list of 2016 HCPCS codes for billing albumin, FFP and blood components



Focus on Therapeutic Plasma Exchange – continued

Payment: Hospital Outpatient (continued)

Below again are the two APCs which correspond to the eight therapeutic apheresis and autologous stem cell harvesting procedures. Note that the descriptors for these APCs are confusing and potentially misleading. It is best to refer to them solely by their numbers.

<i>CPT and Description</i>	
36511	Therapeutic apheresis; for white blood cells
36512	for red blood cells
36513	for platelets
36514	for plasmapheresis
38206	Blood-derived hematopoietic stem cell harvesting for transplantation; autologous
APC 5271* Blood product exchange	
36515	Therapeutic apheresis; with extracorporeal immunoadsorption and plasma reinfusion
36516	Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion
36522	Photopheresis, extracorporeal
APC 5281** Apheresis and Stem Cell Procedures	

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* CPT 38210-38215, 38242 and 38243 also assign to APC 5271

** CPT 38230, 38232, 38240 and 38241 also assign to APC 5281

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. Please refer “**Medicare Payment in the Hospital Inpatient Setting**” (pp. 8-9), which offers an example of a Guillain-Barré patient treated with plasma exchange.

Payment: Physician Office or Physician-Directed Clinic

Please refer to the guide section titled “**Medicare Payment for Office-Based Plasma Exchange, Immunoadsorption, 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 immunosuppressive 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 as a participating site in an approved clinical study under Coverage with Evidence Development (CED).*

*For information about this registry 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

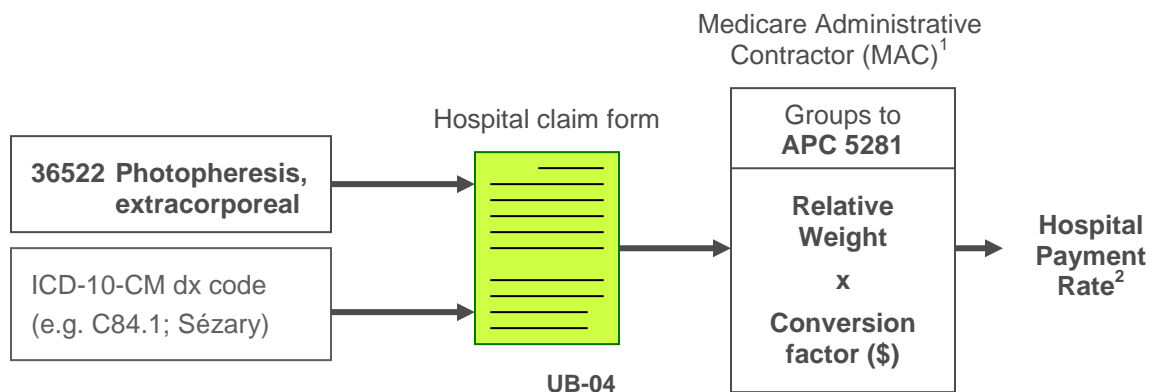
Commercial insurers. Payment for the technical component of an ECP procedure is most commonly based on a **fixed percentage of the hospital's submitted charge** or the insurer's **fee schedule amount**. Periodically there may be a **negotiation** between the institution and the insurer to arrive at a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

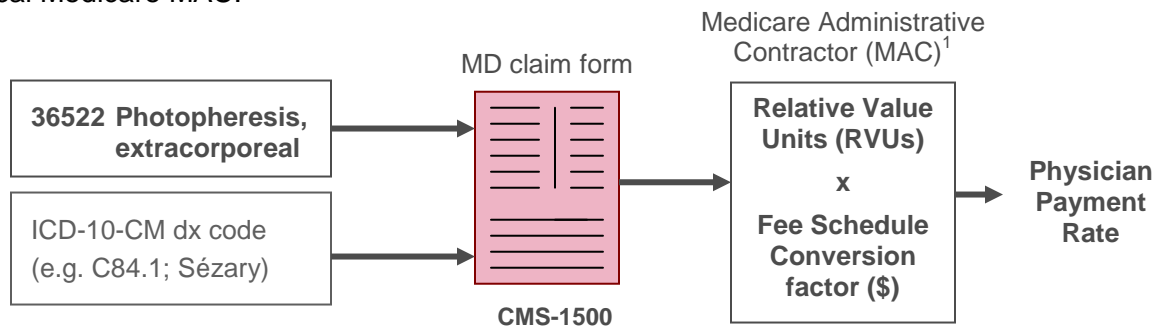
Payment for the **physician's professional services** associated with hospital-based procedures is usually based on the insurer's allowable rate schedule amount. The physician may separately bill **one Evaluation & Management (E/M) service** for a history/physical exam to determine the appropriateness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

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Medicare. The Medicare Hospital Outpatient Prospective Payment System (HOPPS) assigns Ambulatory Payment Classification (APC) **0112** (Apheresis, Photopheresis and Plasmapheresis) 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:



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

²Adjusted to reflect geographic wage variations using the local wage index. If a different procedure is also performed on the same day, the APC 5281 for the ECP procedure is *not* discounted.

Focus on Extracorporeal Photopheresis – continued

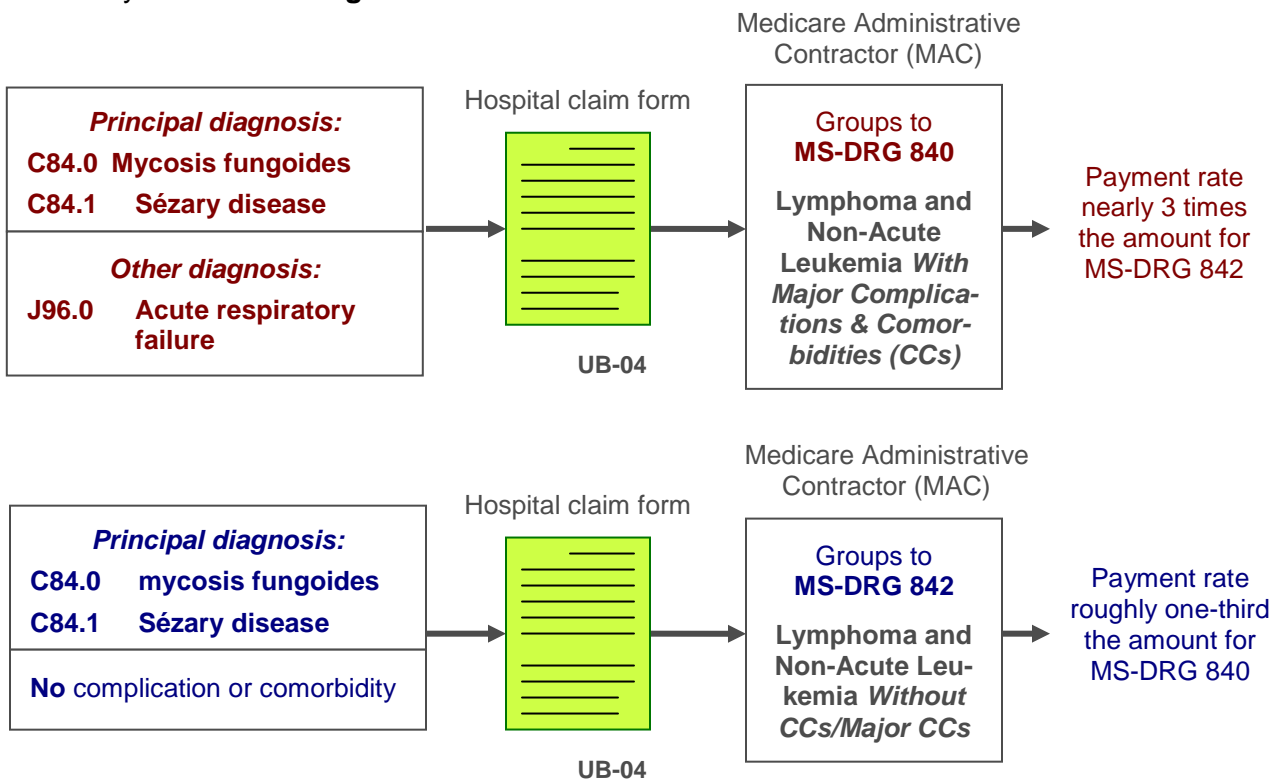
Payment: Hospital Inpatient

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, 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

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

Focus on Selective Adsorption/Filtration (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 licensed 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
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*S2120 is used by many Blue Cross and Blue Shield plans

19 Coverage

Private insurers and two Medicare Contractors (MACs) 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 the following additional criteria:

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

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 (see page 6: Ito MK et al. *J Clin Lipidol* 2011) 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 July 2015, the FDA modified the indications for use of the Liposorber LDL-C apheresis system as follows:

1. Group A: Functional hypercholesterolemic homozygotes with LDL-C $>$ \geq 500 mg/dl;
2. Group B: Functional hypercholesterolemic homozygotes with LDL-C $>$ \geq 300 mg/dl;
3. Group C: Functional hypercholesterolemic homozygotes with **LDL-C $>$ \geq 160 mg/dl and documented coronary heart disease (CHD).**

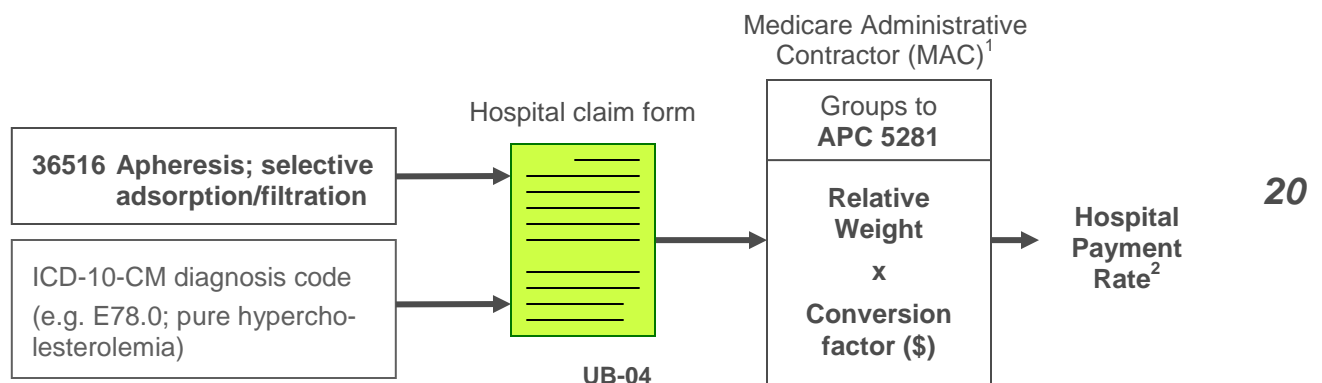
Focus on Selective Adsorption/Filtration (LDL-C Apheresis) - continued

Payment: Hospital Outpatient

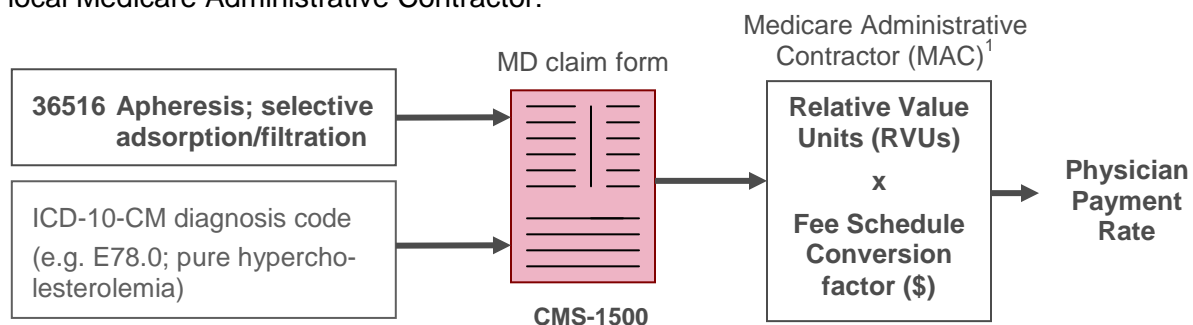
Commercial insurers. Payment for the technical component of an LDL-C apheresis procedure is most commonly based on a **fixed percentage of the hospital's submitted charge** or a negotiated **fee schedule amount**. There may be **negotiation** between the institution and the insurer to arrive at a mutually 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) **5281** (Apheresis, Photopheresis and Plasmapheresis) 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 **“Expanded Medicare Payment for Office-Based Plasma Exchange, Immunoadsorption, 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 for CPT 36514, CPT 36515 and CPT 36522.

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

²Adjusted to reflect geographic wage variations using the local wage index. If a different procedure is also performed on the same day, the APC 5281 for the LDL-C apheresis procedure is *not* discounted.

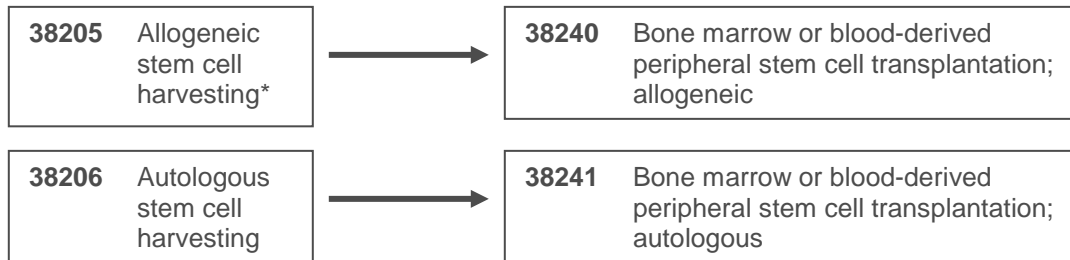
Focus on Blood-Derived Stem Cell Harvesting

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):

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Diagnosis Coding

In the same vein 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

Medicare recently revised its National Coverage Determination (NCD) for stem cell transplantation,* which identifies covered and non-covered diagnoses for which allogeneic or autologous hematopoietic stem cell transplantation (HSCT). Coverage for allogeneic is also specified for several disorders when performed under a Medicare-approved prospective clinical study.

* Medicare National Coverage Determinations Manual, Section 110.23 (Rev. 191), effective 01/27/2016.

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)
- Myelofibrosis (MF)
- Durie-Salmon Stage II or III multiple myeloma
- 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

22

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. Outpatient claims coded with **CPT 38206** (autologous stem cell harvesting) are paid under APC **5271** (Blood Product Exchange). Multiple procedures performed on different days are separately payable. **CPT 30205** (allogeneic stem cell harvesting) 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 2016) 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

The following codes should be identified in the claim as appropriate:

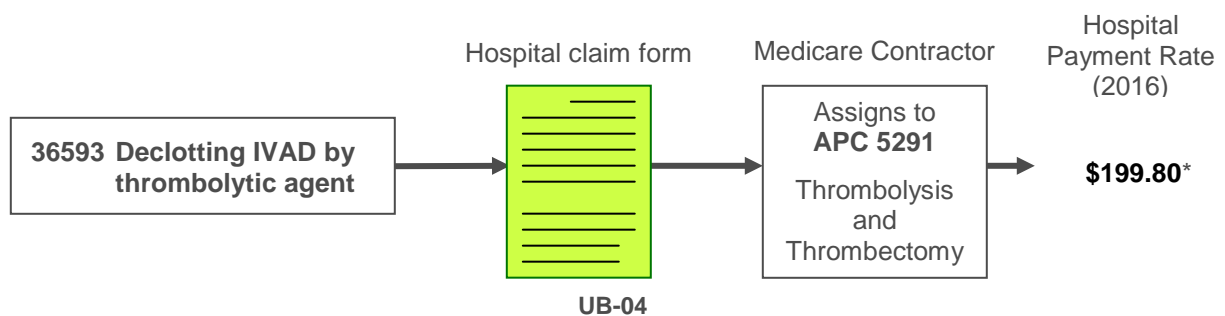
*CPT / HCPCS-II Procedure or item description**

36593	Declotting by thrombolytic agent of implanted vascular access device or catheter
J2997	Injection, alteplase recombinant, 1 mg (<i>use for Activase, Cathflo</i>)
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 this particular APC has a “T” status indicator, which means that, if more than one APC with this same “T” status indicator is assigned on the same date of service, the one with the highest payment rate will be paid on a 100% basis, while all other procedures with the “T” designation will be paid at 50% of the normal payment rate.

All outpatient therapeutic apheresis procedures group to APCs *without* “T” status indicator, and are never discounted. In the likely circumstance that the declotting procedure is the only other CPT-coded service that groups to an APC, it will also be fully paid.

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

Appendix 1

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 2

HCPCS Codes for Billing Albumin, FFP and Red Blood Cells

**HCPCS-II
Code**

Albumin Products

P9041	Infusion, albumin (human), 5%, 50 ml
P9043	Infusion, plasma protein fraction (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
P9048	Infusion, plasma protein fraction (human), 5%, 250 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 3

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.

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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 4

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