



## Medicare Reimbursement For Allogeneic And Autologous Stem Cell Transplants

The Centers for Medicare and Medicaid Services (CMS) has defined stem cell transplantation as “a process in which stem cells are harvested from either a patient’s or donor’s bone marrow or peripheral blood for IV infusion.” CMS has clarified that transplantation is more than the transplant of stem cells; it is the entire process of mobilization, harvest, and transplant of stem cells along with the administration of high-dose chemotherapy or radiotherapy prior to the actual transplant.

There are two types of stem cell transplantation: allogeneic and autologous. Allogeneic stem cell transplantation is a procedure in which stem cells or bone marrow are acquired from a healthy donor. Autologous stem cell transplantation is a procedure where stem cells are restored using the patient’s own previously harvested cells.

CMS defines covered and non-covered conditions for both allogeneic and autologous stem cell transplantation. These conditions are listed in the Medicare Claims Processing Manual, Chapter 3. For conditions not included on these lists, coverage decisions are made at the local level.

Stem cell transplantation is paid under the Medicare Hospital Inpatient Prospective Payment System. The procedure is assigned to diagnosis-related group (DRG) 481 (Bone Marrow Transplant) and covers all services related to the transplantation process for recipient and donor (in the case of allogeneic stem cell transplantation).

### Allogeneic Reimbursement

All medically necessary expenses incurred by the donor are covered under the recipient’s Medicare benefit but are not paid separately (except physician services).

The services provided to the donor are bundled into the DRG payment for the actual transplant procedure. Hospitals identify stem cell acquisition charges separately using the revenue code 0819 on the UB-92/CMS-1450.

If the hospital submits an interim bill, the acquisition charges will appear on the billing form for the period during which the transplant took place. The hospital submits an adjusted bill if an interim bill has been processed.

The hospital uses revenue code 0362 for the actual transplant procedure but can choose its own cost center.

### Autologous Reimbursement

Acquisition charges are not applicable to autologous stem cell acquisitions because the stem cells are coming from the beneficiary. On the transplant bill, the hospital reports the charges for the stay in which the stem cells were obtained in the usual manner, and these charges are covered under DRG 481.

Similar to allogeneic billing, the hospital shows charges for the transplant procedure using revenue center code 0362 but can select its own cost center. Otherwise, stem cell transplantations are billed the same as any other inpatient procedure.

Claims are reviewed by the local Medicare fiscal intermediary (FI). The FI checks the transplant procedure codes against diagnosis codes to determine which cases meet the coverage criteria. Cases that have a diagnosis code for a covered condition will pass through the review as covered. All other cases are reviewed to ensure proper coverage decisions. Claims using the generic procedure code 41.00 (Bone marrow transplant, not otherwise specified) are classified as non-covered and returned to the hospital for a more specific procedure code.

### Did you know... that CMS is replacing the UB-92?

In February of 2005, the National Universal Billing Committee (NUBC) approved the UB-04 to replace the UB-92. The UB-04 was developed to meet several criteria including to accommodate ICD-10-CM codes, to include the National Provider Identifier (NPI), and to meet the National Committee on Vital and Health Statistics (NCVHS) request to align the paper UB with the HIPAA electronic 837i standard.

The UB-04 will be used starting March 1, 2007. A transition period will occur until May 22, 2007, where both the UB-92 and UB-04 will be accepted by CMS. After May 22, 2007, all institutional paper claims must be made with the UB-04.



## Medicare Policy and FDA Regulations for Cord Blood Stem Cells

Umbilical cord blood has become an increasingly popular source of stem cells for transplantation. Currently, CMS does not have a national coverage decision specifically dealing with cord blood stem cell transplantation. Section 110.8.1 of the National Coverage Determination Manual describes CMS policy for general stem cell transplantation. Stem cell transplantations using stem cells harvested from bone marrow or peripheral blood are covered under Medicare for indicated conditions. Although this policy does not mention using cord blood specifically, the source of the stem cells is not limited to bone marrow. Cord blood stem cell transplants should be covered under Medicare for these indicated conditions.

A cord blood stem cell transplantation procedure is billed in the same manner as transplantations with stem cells from bone marrow or peripheral blood. However, different CPT codes are used to identify the source of the stem cells. For the cord blood stem cell transplantation, the hospital uses either CPT code 38205 (Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic) or 38206 (Blood-derived

hematopoietic progenitor cell harvesting for transplantation, per collection; autologous). Similar to stem cell transplantation using bone marrow or peripheral blood, all necessary steps, including testing and donor matching, are included in coverage when the transplantation is covered.

In May 2005, the Food and Drug Administration (FDA) set out a full body of regulations outlining the particular procedural methods that cord blood banks and laboratories must follow. Regulation of cord blood falls under the Code of Federal Regulations (CFR) 21 CFR Part 1271 Subparts A-D as Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps).

Three final rules regarding HCT/Ps are contained in 21 CFR Part 1271:

- **Registration:** On January 19, 2001, FDA issued regulations to create a new unified system for registering HCT/P establishments and for listing their HCT/Ps. [66 FR 5447]

- **Donor Eligibility:** On May 25, 2004, FDA promulgated regulations requiring most cell and tissue donors to be tested and screened for relevant communicable diseases. [69 FR 29786]

- **Current Good Tissue Practices (CGTPs):** On November 18, 2004, FDA issued regulations that require establishments that manufacture HCT/Ps to comply with CGTP, which would include, among other things, proper handling, processing, labeling, and record-keeping procedures. The regulations require each establishment to maintain a quality program to ensure compliance with CGTP. [69 FR 68612]

Draft guidance for licensure of minimally manipulated unrelated allogeneic cord blood for homologous use is currently under development.

**Table 1: APC Payments for Blood and Blood Products**

HCPCS/CPT Code	Short Descriptor	Final 2006 APC Payment	Final 2007 APC Payment	Change	Percent Change
36430	Blood transfusion service	\$216.73	\$212.58	(\$4.15)	-2%
P9010	Whole blood for transfusion	\$118.04	\$131.98	\$13.94	12%
P9011	Blood split unit	\$82.59	\$137.22	\$54.63	66%
P9012	Cryoprecipitate each unit	\$47.15	\$48.59	\$1.44	3%
P9016	RBC leukocytes reduced	\$163.33	\$175.74	\$12.41	8%
P9017	Plasma 1 donor frz w/in 8 hr	\$70.47	\$70.21	(\$0.26)	0%
P9019	Platelets, each unit	\$51.55	\$58.95	\$7.40	14%
P9021	Red blood cells unit	\$121.61	\$129.53	\$7.92	7%
P9022	Washed red blood cells unit	\$189.42	\$211.03	\$21.61	11%
P9031	Platelets leukocytes reduced	\$98.41	\$95.08	(\$3.33)	-3%
P9032	Platelets, irradiated	\$86.64	\$129.57	\$42.93	50%
P9033	Platelets leukoreduced irradiated	\$150.74	\$125.33	(\$25.41)	-17%
P9034	Platelets, pheresis	\$434.48	\$452.93	\$18.45	4%
P9035	Platelet pheres leukoreduced	\$493.66	\$488.74	(\$4.92)	-1%
P9036	Platelet pheresis irradiated	\$326.22	\$418.52	\$92.30	28%
P9037	Plate pheres leukoredu irradiated	\$581.64	\$617.40	\$35.76	6%
P9038	RBC irradiated	\$147.63	\$197.00	\$49.37	33%
P9040	RBC leukoreduced irradiated	\$218.27	\$217.56	(\$0.71)	0%
P9041	Albumin (human), 5%, 50ml	\$29.68	\$29.68	\$0.00	0%
P9044	Cryoprecipitate reduced plasma	\$74.60	\$82.39	\$7.79	10%
P9045	Albumin (human), 5%, 250 ml	\$76.81	\$76.81	\$0.00	0%
P9046	Albumin (human), 25%, 20 ml	\$28.80	\$28.80	\$0.00	0%
P9047	Albumin (human), 25%, 50ml	\$65.26	\$65.26	\$0.00	0%
P9051	Blood, l/r, cmv-neg	\$207.95	\$156.70	(\$51.25)	-25%
P9052	Platelets, hla-m, l/r, unit	\$610.14	\$671.62	\$61.48	10%
P9055	Plt, aph/pher, l/r, cmv-neg	\$526.57	\$396.81	(\$129.76)	-25%
P9056	Blood, l/r, irradiated	\$178.56	\$144.28	(\$34.28)	-19%
P9058	RBC, l/r, cmv-neg, irradiated	\$267.18	\$262.18	(\$5.00)	-2%
P9059	Plasma, frz between 8-24hour	\$74.78	\$76.77	\$1.99	3%

## 2007 Final Medicare Hospital Outpatient Payment Rates Published

On November 1, 2006, CMS released the fiscal year (FY) 2007 Medicare Hospital Outpatient Prospective Payment System (OPPS) final rule. The rule finalizes Medicare payment policy updates effective for blood-related services furnished to hospital outpatients beginning on January 1, 2007.

The table at left lists the final APC payments for blood-related services for the 2006 and the 2007 fiscal years. The changes in payment rates for 2007 result in an average increase of 6% for blood and blood product APCs.

Overall, hospital outpatient departments will receive a 3.4 percent market-basket update to Medicare payment rates for outpatient services in 2007.