ACBSCT Update on Medicare Reimbursement Initiatives

September 2016

Reimbursement Recommendations

- **Recommendation 11 (2010)**
  ACBSCT recommends to the Secretary that Medicare reimburse for the acquisition of blood, marrow and cord blood products for hematopoietic transplantation on a cost basis similar to how reimbursement is made for graft acquisition in solid organ transplantation.

- **Recommendation 27 (2015)**
  The ACBSCT recommends that the Secretary encourage the Centers for Medicare & Medicaid Services (CMS) to reimburse for the acquisition of blood stem cells, bone marrow, or umbilical cord blood products for hematopoietic stem cell transplant on a cost basis, consistent with CMS guidelines for solid organ transplants

Payer Coverage Analysis Summary

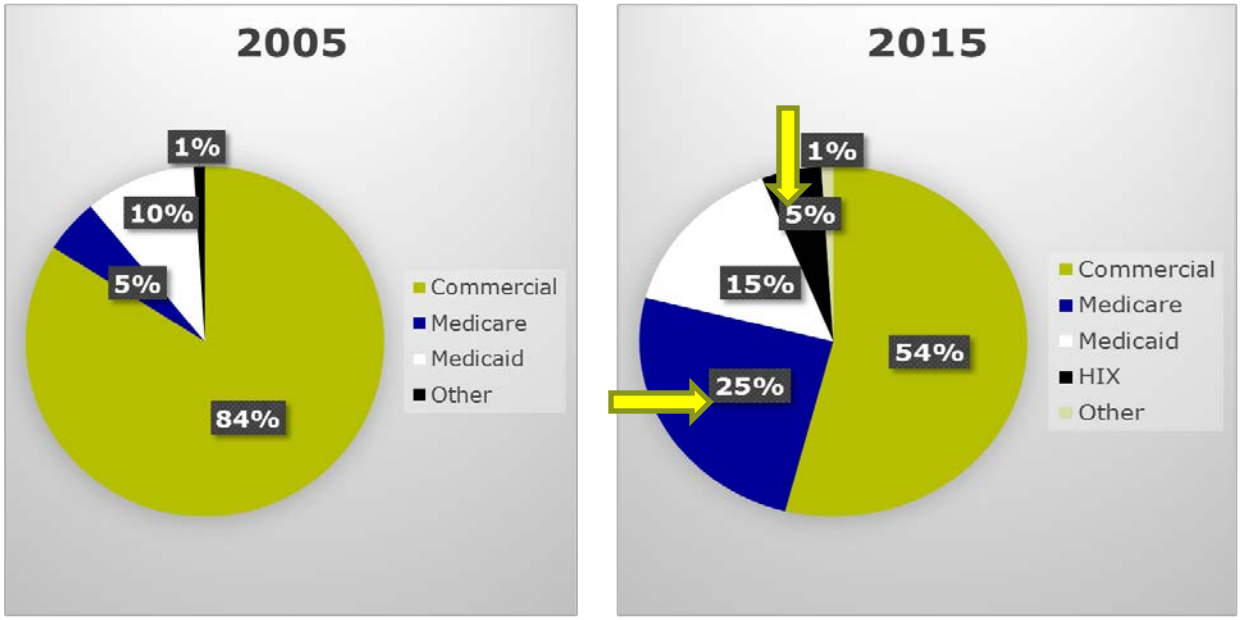
Medicare	Medicaid	Fully Insured	Self-Insured	Individual*
• Coverage info is public • Coverage limited, lags science • Inadequate reimbursement	• Coverage rules complex, not public • Each state is different • Inadequate reimbursement (in most states) • Search/donor not well covered • Often mimics Medicare coverage	• Most coverage info is public • Best end-to-end coverage • Most indications covered • Travel/Lodging benefits • Best reimbursement	• Coverage info not public • Consultants & TPA's drive plan design (not payers) • Limited coverage for search/travel • High out-of-pocket costs • Lots of regulatory pressures	• Public information limited, often wrong • Limited coverage for search/travel • High out-of-pocket costs • Often does not use FI TC network
3%* per year	35 % last year	7% last year	1 % last year	37% last year
	Projected	* Last year = Q1 2014-Q1 2015		On and off exchange

http://www.statista.com/statistics/245626/projected-average-annual-growth-in-medicare-enrollment/

Shift in Transplant Center Payer Mix

Adult HCT Programs, NMDP data

Medicare growth due to increased ability to transplant older patients



Observations on The Landscape

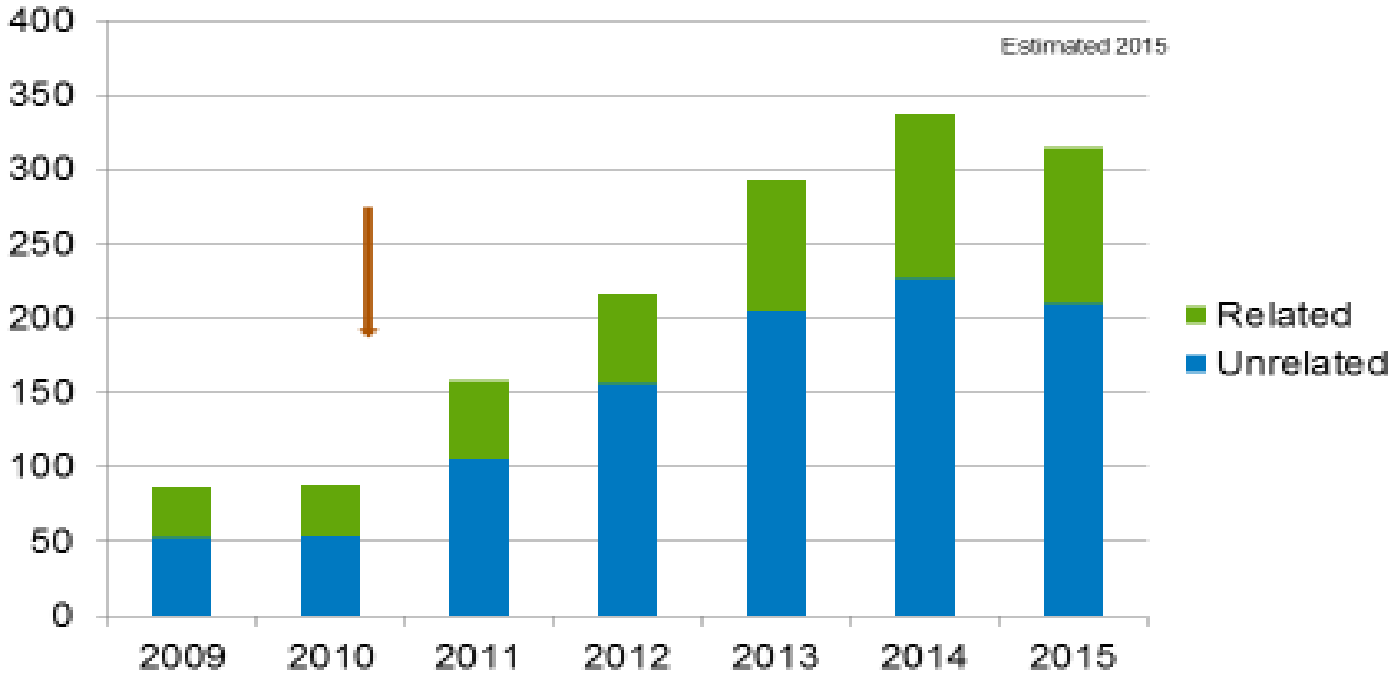
- Commercial payers
  - Reimbursement based on negotiated case rate basis
  - Presence of contracting networks standardizes coverage and reimbursement, e.g. Optum, Alliance
  - Ancillary costs are responsibility of transplant center within the case rate
  - Reinsurance and third party administrators further scrutinizes coverage and reimbursement in many cases

- Government payers
  - DRG or APC based reimbursement for Medicare
  - Case rate or deep discount to fee for service for Medicaid
  - No ability to pass on ancillary costs

MDS CED Expands Access

What if you remove insurance barriers?

HCT in US for MDS over age 65 and CMS coverage



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CMS Covering More Indications with CED

- Expansion of national coverage for allogeneic HCT for patients within context of a CED
  - Multiple myeloma
  - Myelofibrosis
  - Sickle Cell Disease

- Other allogeneic indications covered by Medicare
  - Leukemia, leukemia in remission or aplastic anemia
  - Severe combined immunodeficiency disease (SCID) and Wiskott-Aldrich syndrome
  - Myelodysplastic Syndromes (MDS) under a CED

Medicare: Inadequate Reimbursement

Inpatient (IPPS) Payment Base, FY17:

- MS-DRG 014: Allogeneic: $64,217*
- MS-DRG 016: Auto w/ MCC/CC: $33,679
- MS-DRG 017: Auto w/o MCC/CC: $22,453

Outpatient (OPPS):

- C-APC 5244, CY17 (**proposed**): $15,267*

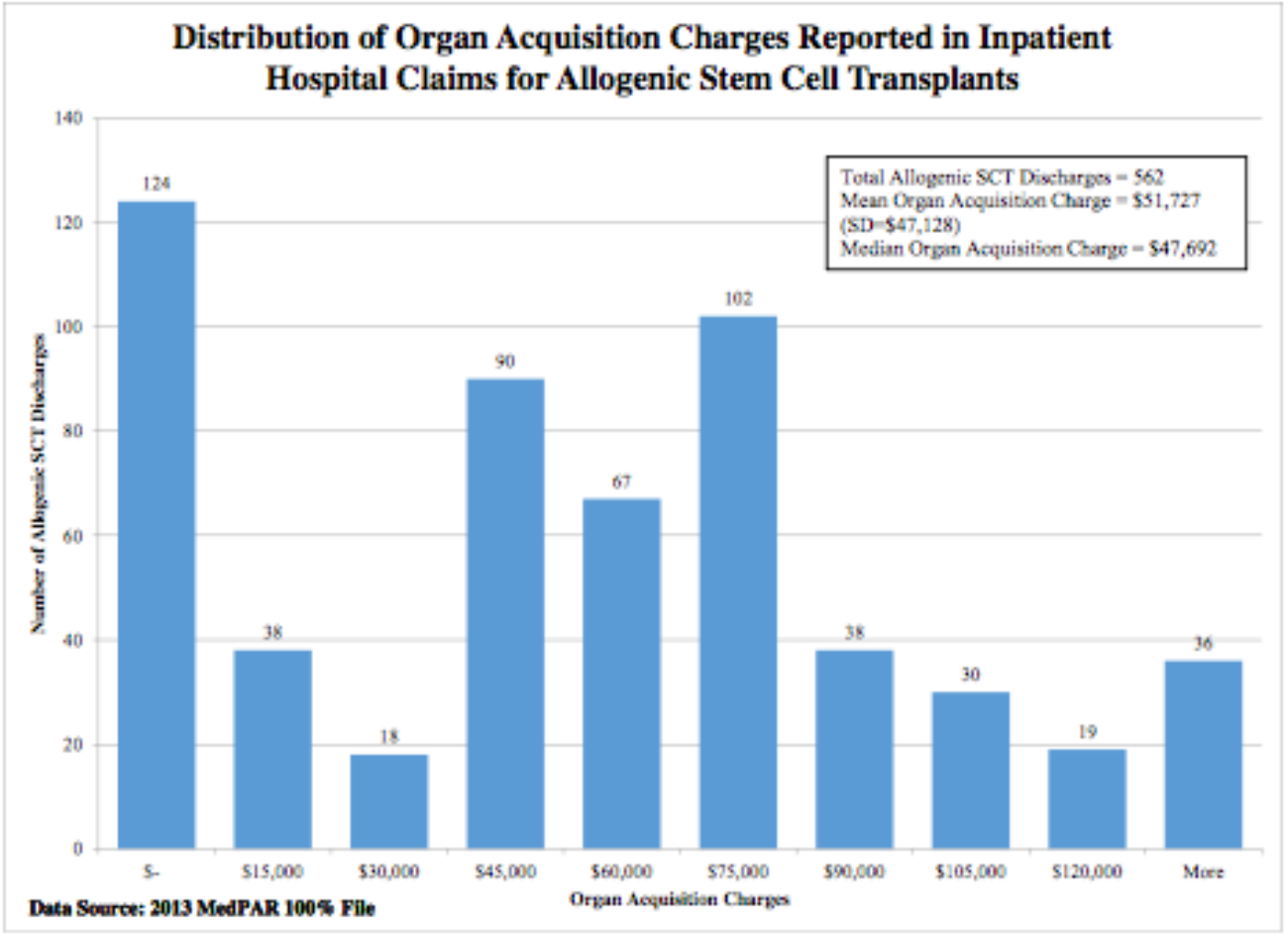
*Considered to be *inclusive* of donor search and acquisition costs.

Hospitals Often Do Not Include Transplant Costs on Cost Reports

Data Year	2007	2012	2013	2014	2015
Total Allogeneic Transplants (MS-DRG 014)	329	752	957	801	**924**
% reporting 0819	38%	75%	72.8%	76%	**79%**
Median 0819 charges reported (w/o $0 claims)	$8,000	$50,349	$56,380	$62,019	**$56,177**
% reporting Donor codes	N/A	75%	73.1%	76%	**71%**

Despite improved reporting,
discount in the CCR edit based on blood remains problematic

Current Reimbursement Rates Fall Short



Despite mean acquisition $51,727, current IPPS rate is only $62,245

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State-Specific Acquisition Costs Compared to IPPS Rate

State	Bone Marrow / PBSC	Remaining DRG Amount for Stay (BM)	Cord Blood	Remaining DRG Amount for Stay (CB)
CA	$67,246	($5,001)	$45,863	$16,382
CO	$46,659	$15,586	$70,364	($8,119)
GA	$43,572	$18,673	$72,899	($10,654)
NC	$43, 211	$19,034	$63,794	($1,549)
IL	$43,743	$18,502	$59,353	$2,892
OH	$48,150	$14,095	$67,906	($5,661)
MD	$41,545	$20,700	$59,503	$2,742
RI	$41,164	$21,081	$83,785	($21,540)

Hospitals are deciding not to provide access to HCT to Medicare patients

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Treat BM/PBSC Donors Same as Kidney Donors in IPPS

- Living donor regulatory policy
  - Kidney acquisition (living donors) treated apart from the DRG and compensate the hospital for reasonable expenses (42 CFR § 412.100)
  - HCT acquisition accounted for within the DRG (*Claims Processing Manual 90.3.3)*
- Similar services
  - Tissue typing, donor evaluation, excising organ, operating room/ancillary services, preservation costs, registry costs, transportation, lab services

Current IPPS Authority Would Permit Adopting Parallel Living Donor Policies

- Adapt the living kidney donor policy for HCT
  - Allow transplant centers to develop a standard reflecting the *average* cost associated with source
  - Acquisition costs billed from collecting entity
  - Transplant center keeps an itemized statements identifying the services furnished
  - Deduct acquisition charges for processing through the Pricer and pay on reasonable cost basis

- Need to maintain underlying DRG to support other hospital costs

Historic HOPPS Reimbursement Provided Was Deterrent To Outpatient Use

- Transplants in Outpatient Setting
  - Not as common as Inpatient Setting
  - Allows some cancer patients to return home during treatment rather than face a lengthy hospital stay

- OPPS rate woefully underfunds transplant
  - APC 5281 payment is $3,045.31 for all services
  - Mean cell acquisition costs of $51,727
  - Loss on each transplant is substantial
  - Incentivizes the most expensive setting rather than the most efficient and effective

Solution: Reimburse cells separately under the HOPPS as well

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Proposed HOPPS Rule for 2017

- Outpatient HCT (CPT 38240) will be moved into a new Comprehensive Ambulatory Payment Classification (C-APC).
  - all of the costs submitted on an outpatient HCT claim to remain together and be averaged with other outpatient HCT claims, versus being diluted by other lower cost services in a broader, non-comprehensive APC.

- New payment for C-APC is proposed to be $15,267.
  - Previous rate of $3,015.

- Not a complete solution
  - Does not reflect the total acquisition costs
  - Or other costs of the procedure,
  - New C-APC methodology will allow for upward adjustment based on cost reporting practices.

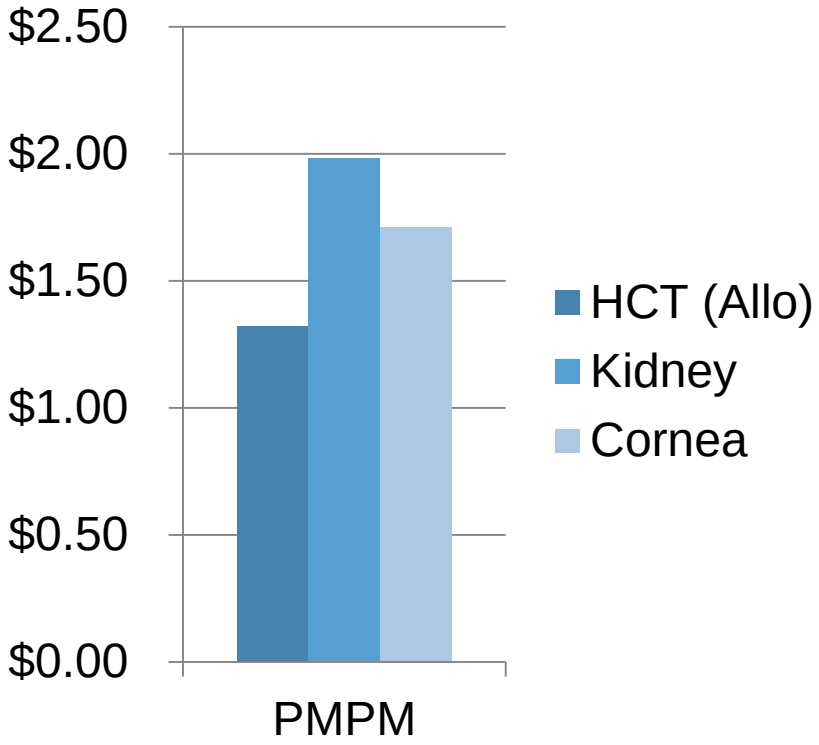
Proposed HOPPS Rule for 2017

- New revenue code for tracking donor procurement and related charges is proposed – 112.50, “Allogeneic Stem Cell Acquisition”.
  - Would replace a more general revenue code
  - Takes it out of blood products Cost to Charge Ratio (CCR) edit
  - Will provide clearer understanding of these costs and better adjust rates in the future.
  - Apply only to allogeneic HCT.

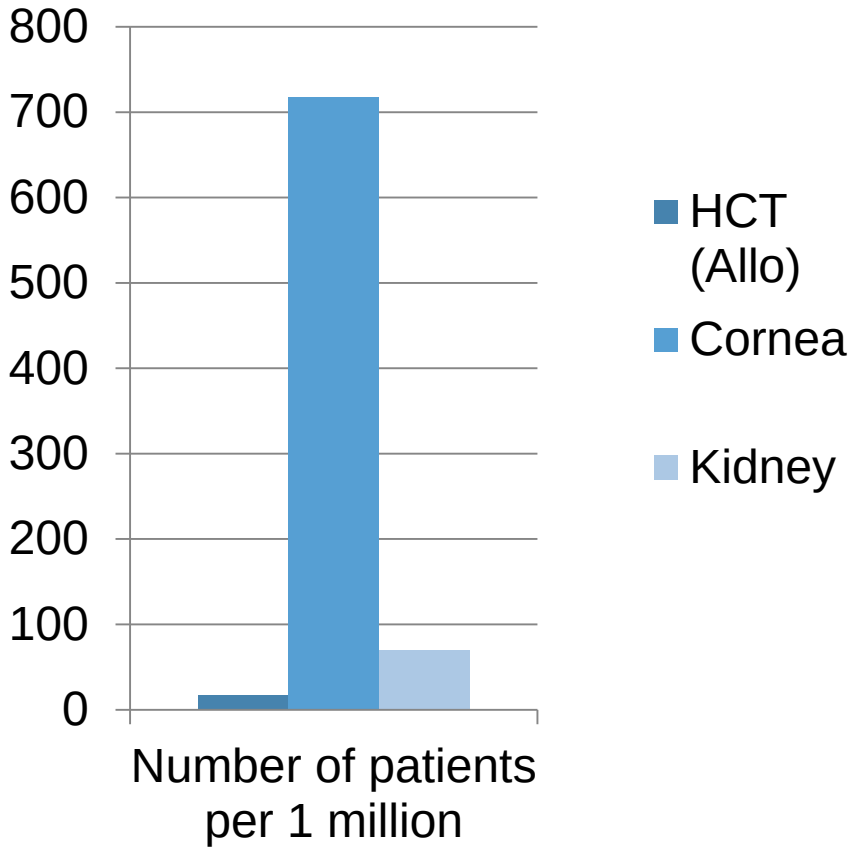
- Requires that acquisition charges to be reported in Field 42 on CMS Form 1450 (UB-04)
  - Allows CMS to assess the charges and gauge how well the C-APC payment reflects the costs of providing these services.
  - including NMDP fees, HLA typing, donor evaluation, collection of cells and other costs

Impact on Patients Is Enormous; Impact on Medicare Will Be Small

PMPM Cost of Transplants for Patients 65+



Estimated Number of Patients 65+ Accessing Transplants



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Source: Milliman, "2014 U.S. organ and tissue transplant cost estimates and discussion"