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
- Coverage info is public
- Coverage limited, lags science
- Inadequate reimbursement

Medicaid
- Coverage rules complex, not public
- Each state is different
- Inadequate reimbursement (in most states)
- Search/donor not well covered
- Often mimics Medicare coverage

Fully Insured
- Most coverage info is public
- Best end-to-end coverage
- Most indications covered
- Travel/Lodging benefits
- Best reimbursement

Self-Insured
- 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

Individual*
- Public information limited, often wrong
- Limited coverage for search/travel
- High out-of-pocket costs
- Often does not use FI TC network

* Last year = Q1 2014-Q1 2015

Projected

On and off exchange

Shift in Transplant Center Payer Mix
Adult HCT Programs, NMDP data

Medicare growth due to increased ability to transplant older patients

2005
- 84% Other
- 10% Commercial
- 1% Medicare
- 5% Medicaid

2015
- 54% Commercial
- 15% Medicare
- 25% Medicaid
- 1% Other
- 1% HIX
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

- Green bars: Related
- Blue bars: Unrelated

<table>
<thead>
<tr>
<th>Year</th>
<th>Related</th>
<th>Unrelated</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>50</td>
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</tr>
<tr>
<td>2010</td>
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<td>2011</td>
<td>150</td>
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<td>2012</td>
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<td>2013</td>
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<td>2014</td>
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<td></td>
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<tr>
<td>2015</td>
<td>350</td>
<td></td>
</tr>
</tbody>
</table>

Estimated 2015
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

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

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
## State-Specific Acquisition Costs Compared to IPPS Rate

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

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

<table>
<thead>
<tr>
<th>Cost (PMPM)</th>
<th>HCT (Allo)</th>
<th>Kidney</th>
<th>Cornea</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0.00</td>
<td>$0.50</td>
<td>$1.00</td>
<td>$1.50</td>
</tr>
<tr>
<td>$1.00</td>
<td>$1.50</td>
<td>$2.00</td>
<td>$2.50</td>
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</tbody>
</table>

Estimated Number of Patients 65+ Accessing Transplants

<table>
<thead>
<tr>
<th>Organ</th>
<th>Number of Patients per 1 million</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCT (Allo)</td>
<td>700</td>
</tr>
<tr>
<td>Cornea</td>
<td>100</td>
</tr>
<tr>
<td>Kidney</td>
<td>200</td>
</tr>
</tbody>
</table>

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