I have no conflicts to declare pertinent to this presentation

LEARNING OBJECTIVES: PARTICIPANTS WILL
1. Observe the history of federal policy pertaining to solid organ transplantation and immunosuppression
2. Understand how policy evolves in response to changes in clinical practice
3. Appreciate challenges facing policymakers and practitioners in the current climate
4. Realize potential for ongoing advocacy in policy pertinent to transplantation

Medicare payment for immunosuppressant drugs
1. Is available via Part A for eligible transplant recipients
2. Has been available for all eligible patients since ESRD Medicare in 1972
3. Is available to all eligible patients since Part D created in 2003
4. Is available via Part B for patients eligible for Medicare at the time of a solid organ transplant
LBJ signs Medicare Amendment to SSA
July 30, 1965
Transplantation and the US Congress

1972: Social Security amendment created ESRD Medicare
- Transplantation a covered service
- Loss of eligibility one year after transplantation
- No coverage for medications

1978: PL95-292
- Medicare coverage effective at the time of transplantation
- Extended ESRD Medicare eligibility after transplantation from 1 to 3 years
- Again, nothing about immunosuppressants

1984: PL98-507 National Organ Transplant Act (NOTA)
- Created OPTN
- Established organ recovery agencies
- Outlawed “valuable consideration”

1986: OBRA
Made immunosuppressant coverage a 1 year benefit under Part B
Transplantation and the US Congress

- 1972: Social Security amendments created ESRD Medicare
- 1978: PL95-292 made Medicare coverage effective at transplant
- 1984: National Organ Transplant Act (NOTA)
- 1986: OBRA - immunosuppressant coverage a 1 year benefit under Part B
- 1993: OBRA - staged extension of immunosuppressant coverage from 1 to 3 years, phased in through 1997

Impact of extending Medicare immunosuppressant coverage from 1 to 3 years

Institute of Medicine Committee on Medicare Coverage Extensions

- “Most sessions of Congress see proposals to expand Medicare coverage to some currently excluded services”
- Balanced Budget Act of 1997 (PL 105-33) called for HHS to ask NAS (via IOM) to analyze “short- and long-term benefits, and costs to Medicare”
  - Screening for skin cancer
  - Medically necessary dental services
  - Elimination of time restrictions on coverage for immunosuppressive drugs after transplants
IOM Report
Limits of evidence
“The committee is hardly the first to note the many complexities created by Medicare coverage distinctions for
• People with and without ESRD
• ESRD patients on dialysis versus those who receive kidney transplants
• Kidney versus other transplant candidates or recipients
• Medicare-covered transplant recipients versus other beneficiaries needing expensive outpatient drugs”


IOM Report
Limits of evidence
“Because Medicare now covers immunosuppressive(s) … for up to 3 years … and because government policy more generally promotes guardianship of organs before and after transplantation, it seems straightforward to argue for elimination of the 3-year limit.”

IOM Report
Limits of evidence

“Because Medicare now covers immunosuppressive(s) ... for up to 3 years ... and because government policy more generally promotes guardianship of organs before and after transplantation, it seems straightforward to argue for elimination of the 3-year limit.”

“Fairly quickly, however, the question arises about whether this is fair, given that the lives and well-being of many Medicare beneficiaries with other medical problems depend on expensive prescription drugs ... excluded from coverage”

IOM Report
Conclusions

“... elimination of the time limit ... Presents some delicate ethical and policy considerations.”

“... recipients of organ transplants who are eligible for Medicare by reason of age, disability, or ESRD already have a drug benefit that few other classes of beneficiaries have”

“ESRD-qualified Medicare beneficiaries are generally treated as a special group.”

“... termination of the drug benefit at the end of 3 years may result in

• More graft loss
• More expenses for treatment of graft rejection and return to dialysis, and
• Added demands for scarce organs for retransplantation”

IOM Report
Conclusions

• “Given this evidence and the existing Medicare policy of supporting organ transplants, the rationale for eliminating the current time limits for coverage of immunosuppressive drugs for all solid organ transplant recipients is strong.”

• 5 year net cost to Medicare
  • $778 million if limited to those eligible by age/disability
  • $1.06 billion if also applied to those eligible by ESRD

Transplantation and the US Congress

2001: Benefits Improvement and Protection Act of 2000 eliminated 3 year immunosuppressant limit
  • * Co-terminus with Medicare eligibility *
  • Impact
    • Long-term/lifetime coverage of immunosuppressants for those whose Medicare eligibility the result of age or disability (most recipients of extrarenal transplants)
    • None on those Medicare eligible by ESRD, where (since 1978) coverage terminates with loss of Medicare eligibility 3 years post-transplant

Implications of Current Medicare Immuno Coverage

• Loss of ESRD Medicare eligibility at 3 years
  • 1/3 with employer-sponsored coverage
  • 1/3 remain eligible due to age or non-ESRD disability
  • 1/3 without defined coverage for immunosuppression (ACA offers access to coverage for some)
• >70% of transplant centers
  – report patients have “very serious” cost issues related to drugs
  – report deaths or grafts lost in patients due to inability to obtain drugs
  – report not waitlisting patients for inability to define consistent drug payment source

AST and Immunosuppressant Coverage

• 1998: AST Immunosuppression Conference in Organ Transplantation, Philadelphia
  (Kasiske BL et al for the AST, JAMA 283: 2443, 2000)
• 2000: Comprehensive Immunosuppressive Drug Coverage for Kidney Patients Act
  • Introduced in 106th US Congress and subsequently
  • Sponsorship/Champions have included
    • Senate: Cochran (R-Miss), Durbin (D-IL), DeWine (R-OH), Schumer (D-NY)
    • House: Congressmen Camp (R-MI), Burgess (R-TX), Kind (D-WI)
  • 114th Congress: Burgess and Kind
Transplantation and the US Congress
Additional pertinent history
2003: Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) created a voluntary benefit for beneficiaries (Part D)
2009: Affordable Healthcare for Americans Act (ACA) as passed in House included immunosuppressant coverage
• In conference, funding to be derived from savings in dialysis via bundling
• Opposed by Kidney Care Partners and NKF
• Durbin amendment in Senate withdrawn
(Cohen and Murphy, CJASN 5: 746, 2010)

Transplantation and the US Congress
2004: Organ Donation and Recovery Improvement Act
– Assistance for living organ donation
– Public awareness
– Organ donation as a concern of PHS
2007: PL110-144 Charlie Norwood Living Organ Donation Act
– Criminal penalties do not apply to paired donation
2013: PL113-51 HIV Organ Policy Equity (HOPE) Act

AST, Public policy, and the 114th Congress
• Living Donor Protection Act of 2016
• NIH-HHS Annual Funding Legislation
• 21st Century CURES Act (passed 12/16)
• Preserving transplant immunosuppressants as protected class in Part D
• FDA policy for LDTs
• Organ Donor Clarification Act (Cartwright, D-PA)
Medicare payment for immunosuppressant drugs
1. Is no longer an issue since passage of ACA in 2010
2. Is lost at the time eligibility is lost for patients with ESRD Medicare
3. Is not an issue as most patients have other coverage for immunosuppressants
4. Is not an issue as effectiveness of tolerance protocols preclude long-term need

AST, Public policy, and the 115th Congress

Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2016 [Burgess (R-TX) and Kind (D-WI)]
- Introduced in 114th Congress
- 115th Congress
  - Ongoing support of transplant community and Congressional sponsors
  - Busy and challenging healthcare agenda