RATIONALE FOR EXTENDING MEDICAID ELIGIBILITY TO UNINSURED PERSONS WITH CHRONIC HEPATITIS B INFECTION

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Primary Objective

Examine the feasibility of extending Medicaid eligibility for chronic hepatitis B (CHB) care to uninsured persons with CHB

Secondary Objective

Evaluate effect of coverage model on morbidity and mortality



Chronic Hepatitis B

- Viral infection of the liver
- Leading cause of liver cancer, cirrhosis, disability and premature death, esp. among API men age 40-50 years
- Transmission from mother-to-child at birth, sexually and contaminated needles
- Risk of ESLD (final stage of total liver failure) increases significantly with increasing amount of virus in the blood (viral load)
- Effective suppression of HBV viral load is key to slowing the progression of the disease^{*}
- Care and treatment for CHB is expensive, between \$3000-\$8000/yr
- Recent advancements in treatment for HBV have created an opportunity to effectively alter the natural history of the disease
- Treatment can modify disease, help prevent or slow progression to ESLD, improve morbidity and mortality, and save costs usually covered by Emergency Medicaid

* Chen G., Lin W., et al. (2006). American Journal of Gastroenterology 101, 1797-1805.



Burden of Chronic Hepatitis B

- Between 1.25 2 million persons have CHB in the US*
 - < 30% have been diagnosed
 - < 5% are receiving treatment
 - 400 receive <u>liver transplants</u>/year
 - 5000 <u>die</u> from HBV each year
 - Although immunization has effectively reduced the number of new cases occurring in the U.S., the actual number of cases of CHB have <u>increased</u> due to immigration of persons from areas where HBV is endemic
- Disparity among API
 - Prevalence of CHB in API Americans is ~10% (approx. 1,000,000); 30x higher than the general American population
 - In NYC >150,000 cases of CHB: ~80% are API
 - ~35% of API <200% FPL are uninsured^{3**}

- * Data from CDC, Department of Viral Hepatitis
- ** Hoffman et al. The Kaiser Commission on Medicaid and the Uninsured, Washington D.C., November 2005.



Medicaid Beneficiary Groups

Mandatory Populations

- Children below federal minimum income levels
- Adults in families with children, below FPL
- Pregnant women <133%
 FPL
- Disabled SSI beneficiaries
- Certain working disabled
- Elderly SSI beneficiaries
- Medicare buy-in groups

Optional Populations

- Children above federal minimum income levels
- Adults in families with children above FPL limits
- Pregnant women >133% FPL
- Disabled (above SSI levels)
- Disabled (under HCBS waiver)
- Certain working disabled (>SSI levels)
- Elderly (>SSI; SSP-only recipients)
- Elderly nursing home residents (>SSI levels)
- Medically needy

Medicaid 1115 Waiver Mechanism

<u>Problem</u>: Medicaid does not offer broad access to care for a majority of uninsured individuals with CHB.

Current Medicaid policy pays for failure - ESLD, liver transplantation

Potential Solution: Improve access to care for CHB by selective expansion of Medicaid eligibility via 1115 Waiver

- Section 1115 of Social Security Act
- Allows states to test new ideas of policy merit to demonstrate and evaluate a policy or approach that has not been demonstrated on a widespread basis
- 1115 Waiver mechanism would allow for expansion of standard eligibility requirements, on a state-by-state basis

Major Condition for Waiver

- Must prove budget neutrality in 5 years
 - Coverage Costs Business As Usual Costs ≤ 0



Business as Usual vs. Coverage Model



Markov Model

- <u>Model design</u>
 - Feasibility of policy scenarios assessed with Markov models, random walk Monte Carlo simulation
 - 2 state transition models; 5-15 year horizon; cycle length of 1 year
- Baseline cohort
 - Derived from screening population
 - All tx-naïve
 - Static no new entries
- <u>Transition rates</u>
 - Represent annual probability of moving from one state to another
 - Taken from literature
- <u>Costs</u>
 - Coverage Model
 - Costs are for clinical management at all stages of disease; Includes Medicaid reimbursement rates for clinic visits, laboratory tests, drugs, and other surgical procedures (incl. liver transplantation) required for management of CHB infection
 - Business as Usual (BAU)
 - Costs for those who are disabled and for those uninsured who qualify for Emergency Medicaid when they present to hospitals with ESLD or HCC; includes Medicaid reimbursements for hospitalization, drugs, liver transplantations, liver resection, & post-liver transplantation care



Results Reduction in Morbidity & Mortality



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HCC Cases Prevented



Results Cost of Coverage vs. BAU (Per patient cost over 5 years)

Coverage Model

\$7,278

Business As Usual \$3,805

Model most sensitive to

Cost of Treatment Entry Criteria

Does not result in budget neutrality within the allotted 5 years

Coverage Model - BAU >0



Sensitivity Analysis

Modify Medication Costs

- Average cost of \$5000/yr could decrease
 - By increased volume
 - By use of generic drugs when patents expire
 - By better Medicaid price negotiation

Modify Entry Criteria

- <u>VL > 10⁴</u>
 - ~50% of CHB; associated with greatly increased risk of developing ESLD or HCC
 - Still no budget neutrality within 5 years
- <u>Cirrhosis</u>
 - ~10% of CHB; most asymptomatic initially highest likelihood of progression to ESLD or HCC in 5 years
 - Diagnosing cirrhosis is costly (biopsy); most uninsured would not already be diagnosed
 - Newer methods of diagnosing (Fibroscan) may make this feasible^{*}
 - Overall impact low

Ogawa E, Furus yo N, et al. (2007). *Hepatology Research* 37 (12), 1002-1010.



Sensitivity Cost Analysis

Entry Criteria	4 Years		5 Years		9 Years		10 Years		11 Years		15 Years		
	Coverage	BAU	Coverage	BAU	Coverage	BAU	Coverage	BAU	Coverage	BAU	Coverage	BAU	
All Persons with CHB													
Rx \$1000/year	\$4,681	\$2,876	\$5,727	\$3,805			\$9,623	\$9,188	\$9,917	\$11,994	\$12,400	\$17,169	
Rx \$3000/year	\$6,119	\$2,876	\$7,278	\$3,805			\$12,632	\$9,188	\$11,931	\$11,994	\$16,160	\$17,169	
Rx \$5000/year	\$7,073	\$2,876	\$9,347	\$3,805			\$15,102	\$9,188	\$15,529	\$11,994	\$20,539	\$17,169	
CHB, VL > 10^4													
Rx \$1000/year	\$6,351	\$3,541	\$9,260	\$5,636	\$12,675	\$13,213	\$13,460	\$15,701	\$13,902	\$17,934	\$16,168	\$27,378	
Rx \$3000/year	\$10,998	\$3,541	\$12,459	\$5,636	\$17,205	\$13,213	\$18,795	\$15,701	\$19,255	\$17,934	\$24,553	\$27,378	
Rx \$5000/year	\$14,379	\$3,541	\$15,891	\$5,636	\$21,043	\$13,213	\$22,889	\$15,701	\$24,288	\$17,934	\$30,551	\$27,378	
Compensated Cirrhosis													
Rx \$1000/year	\$11,659	\$21,319	\$16,921	\$28,693			\$23,549	\$21,742			\$30,236	\$89,507	
Rx \$3000/year	\$16,360	\$21,319	\$18,550	\$28,693			\$37,499	\$21,742			\$47,734	\$89,507	
Rx \$5000/year	\$21,928	\$21,319	\$25,405	\$28,693			\$39,739	\$21,742			\$47,404	\$89,507	
Dollar figures indicated re	Pollar figures indicated represent the cumulative cost per person at the corresponding year of the program and at the indicated drug co												

Variations in drug cost and entry criteria have the greatest impact on when budget neutrality is achieved



Conclusions

- Providing medical care to uninsured persons with CHB has tremendous positive impact on CHB-related morbidity and mortality and reduce the disparity of CHB among API
- The 1115 waiver could be a way to provide coverage to the uninsured, but the requirement for budget neutrality over 5 years may be difficult to achieve and may place constraints on the program that would severely limit its impact



Discussion

- This is a preliminary analysis. The model assumptions are based on best estimates from published data and expert opinion.
 - Next step is to apply actual costs dispensed by Medicaid for CHB to this model
- Advances in technology for diagnosing early cirrhosis or changes in the cost of medication can effect the model significantly
- Extending the Medicaid waiver analysis to include persons with HCV might bring cost calculations closer to budget neutrality in 5 years
- Alternate mechanisms for expanding access to care outside of a 1115 waiver
 - Will require greater political pressure
 - Will allow for QOL, loss of income, and impact on other federal/state programs to enter into the cost analysis
- Legislation similar to the Breast Cancer Prevention and Treatment Act of 2000 may provide benefits to persons with CHB who have been diagnosed by federal programs, in particular, pregnant women



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