INCENTIVIZING MEDTECH REIMBURSEMENT

A PLAN TO REDUCE HEALTHCARE COSTS AND EXPEDITE COMMERCIALIZATION OF NEW THERAPIES

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PROBLEMS

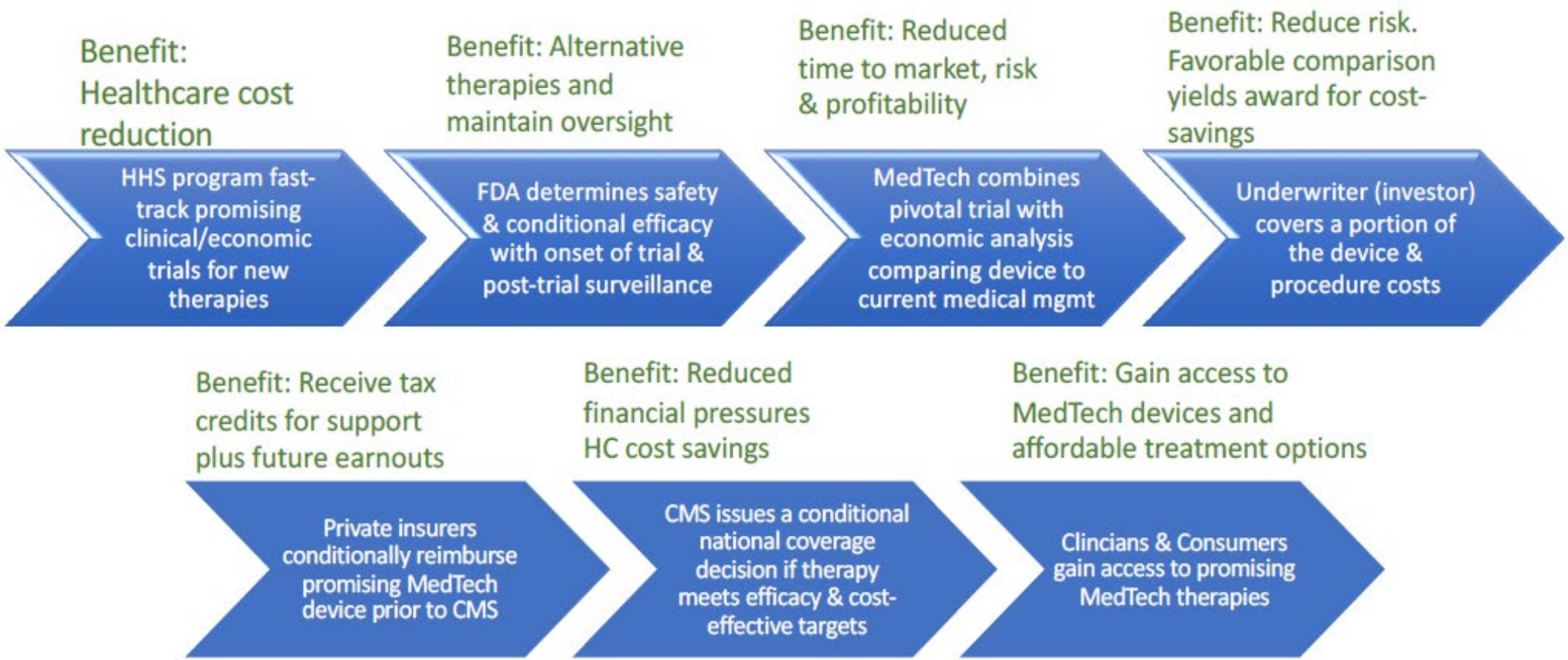
- New MedTech therapies hold great promise but can be costly to develop
- CMS does not cover all the new MedTech devices and therapies approved by the FDA
- Private insurers have little incentive to cover new therapies not already covered by CMS
- MedTech startups have difficulty attracting investment because of possible lack of reimbursement
- New devices in the U.S. often must undergo two stages of approvals with FDA and CMS
- Pharmaceutical therapies generally offer lower up-front costs to payers, reducing availability of new devices
- Clinical trials for new implanted devices are extremely costly, on the order of $50MM-$100MM

SOLUTION: INCENTIVIZED REIMBURSEMENT

- New HHS program to combine FDA & CMS staff to fast-track sponsored clinical/economic trials of new therapies
- Draws on concept of pay-for-performance introduced in 2003 MMA and 2010 ACA
- Private insurers are incentivized with grants, tax credits, and future earnouts to reimburse promising new MedTech therapies before CMS approval
- Combined pivotal trial/economic analysis compares device therapy to current medical management over three- to five-year time horizon
- FDA certifies device safety and likely efficacy before onset of trial and oversees post-trial surveillance
- CMS certifies eventual national coverage decision if therapy meets efficacy and cost effectiveness targets
- Insurer covers a portion of device and procedure cost previously borne entirely by vendor
- If new therapy compares favorably to existing therapy for identifiable patient population after completion of trial, insurer receives award portion of cost saving to CMS/VA over first 10-year period
- Tax on opioids helps fund upfront and administrative costs of program

BENEFITS

- Significantly reduces time to profitability for startup device firms
- Allows CMS to cover more new medical devices and therapies
- Encourages private-sector participation in healthcare cost-reduction
- Puts device therapies on a more level playing field with drugs by emphasizing long-term costs and benefits
- Reduces financial risk to investors in MedTech startups
- Enables FDA to prioritize device safety while engaging payers in evaluation of relative efficacy
- Neutralizes advantage of European device trials and ensures equal access to U.S.-funded research by U.S. patients
- Potentially appeals to bipartisan legislative base interested in cost savings and expanding access to more patients


Benefit: Healthcare cost reduction
HHS program fast-track promising clinical/economic trials for new therapies
Benefit: Alternative therapies and maintain oversight
FDA determines safety & conditional efficacy with onset of trial & post-trial surveillance
Benefit: Reduced time to market, risk & profitability
MedTech combines pivotal trial with economic analysis comparing device to current medical mgmt
Benefit: Reduce risk. Favorable comparison yields award for cost-savings
Underwriter (investor) covers a portion of the device & procedure costs
Benefit: Receive tax credits for support plus future earnouts
Private insurers conditionally reimburse promising MedTech device prior to CMS
Benefit: Reduced financial pressures HC cost savings
CMS issues a conditional national coverage decision if therapy meets efficacy & cost-effective targets
Benefit: Gain access to MedTech devices and affordable treatment options
Clincians & Consumers gain access to promising MedTech therapies