Supporting New Antimicrobials in Clinical Use

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Talking Points

- Traditional market mechanics are failing to support innovation and encourage clinical application
- Current model is at odds with clinical application best practices
- Examples of current program in the U.S.
- What will an ideal future model accomplish?

Disclosures

- Consultant for DayZero Diagnostics, Inc.

- Research grants: Gilead, Inc. and Thermofisher, Inc.

Traditional market mechanics are failing to support innovation and encourage clinical application

- Antimicrobial resistance (AMR) rates are increasing but research/innovation incentives for new treatments are lacking
- Majority of treatment courses are for defined duration *AND* Antimicrobial stewardship (ASP) best practice is to “reserve” usage in select cases -> less doses/units used/sold
- Majority of usage in hospitalized patients -> limited reimbursement by relatively low DRG payment models
- Successful efforts on *push* incentives, but not the *pull* spectrum

Current model is at odds with clinical application best practices

- *Push* Incentives: supporting early R&D, regulatory review and approval, and reaching market entry stage (many success stories)

- *Pull* Incentives: supporting and rewarding market entry in a manner that is decoupled from the traditional fee-per-unit model (lacking)

- If successful at bringing a new treatment to market today -> restricted agent, reserved for low number of cases, and less units used/sold
  - Pressure to raise price per unit, but
  - Low reimbursement discourages usage

Example of Current Pull Incentives in the U.S.

- **New Technology Add-on Payment (NTAP)**:
  - Allows for additional reimbursement for certain treatments/technologies
  - Criteria: substantial clinical improvement over existing therapies
  - 65%-75% of the additional cost of the technology or the cost of the overall treatment exceeding the DRG payment, whichever is lower
  - Agent- and indication-specific
  - Lasts 2-3 years
  - Many administrative hurdles to capture these incentives

- **Bottom line**: incentive for some medicines, for some indications, some of the time, and for a limited time-period

Example of Current Pull Incentives in the U.S.

- **New Technology Add-on Payment (NTAP)**:
  - Pros:
    - Decoupling from bundled DRG payments for hospitals (i.e., DRG carve-out)
    - Reward for new treatments with substantial benefits (vs. me-too treatments)
  - Cons:
    - No clear impact on the overall uptake of new treatments
    - Administratively complex
    - Difficult to quantify incentive at the local level to support/encourage uptake
    - Limited in scope and in duration
    - Reliant on “per unit” volume

Ideal Pull Incentive Model

- Decouples reimbursement from per-unit volume
- Guarantees reward at market entry while meeting meaningful criteria
- Sustainable for at least several years upon market entry
- Application to all patients (CMS and private payors)
- Encourages clinical application without financial strains
- Supports best practices of ASP to reserve for appropriate cases
- Ensures/supports accountability measures

Future Pull Models/Proposals in the U.S.

- **DISARM**:
  - Additional payment for designated antimicrobial drug(s) by removing these agents from bundled DRG payments and allowing separate reimbursement

- **PASTEUR**:
  - Subscription contracts for critical-need antimicrobial drugs

Summary and Closing Points

- New payment model is urgently needed (i.e., pull incentive)
- Ideally will have multiple solutions to support clinical uptake and ASP best practices
- Antimicrobial market forces are unique and require unique solutions
- Public-private collaborations are critically important

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