MACPAC

Potential Recommendations on Coverage Grace Period and Rebate Cap

Medicaid and CHIP Payment and Access Commission

Chris Park

Session Overview

- Grace period rationale and implications
- Rebate cap rationale and implications
- Decisions on potential recommendations
  - Should the grace period be for 90 days or 180 days?
  - Should the grace period be paired with a requirement that states have a formal coverage policy in place at the end of the grace period?
  - Should the rebate cap should be completely removed or raised to 125 percent of AMP (or some other percentage)?

Medicaid Coverage Grace Period

Medicaid Coverage Requirements

- State Medicaid programs generally must cover all covered outpatient drugs upon approval by the Food and Drug Administration (FDA)
- State Pharmacy & Therapeutics (P&T) committee determines coverage guidelines and preferred drug list (PDL) placement for new drugs
  - Coverage guidelines may be based on drug's label, studies conducted for FDA, professional society guidelines
  - Generally look at safety, relative effectiveness, and cost
- P&T committee review can be time and resource intensive

State Process for Reviewing Drugs

- Review of scientific literature
  - Generally within 2-3 months
  - May vary if new class or novel treatment
- P&T committee review
  - Generally meet quarterly
  - May have public notice and comment periods
  - May require multiple meetings to finalize coverage policy
- While P&T committee review is underway, states generally place prior authorization on drug
  - May effectively be excluding coverage during this time

Coverage Requirements for Other Federal Payers

- Qualified Health Plans – review within 90 days, coverage decision within 180 days
- Medicare Part D Plans – review within 90 days, coverage decision within 180 days
  - 90 days for coverage decision for protected classes
  - New drugs in protected classes are placed on formulary if no decision after 90 days

Medicaid Drug Coverage Grace Period

- Amend Section 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug during grace period
- Allows states time to develop coverage criteria that helps ensure medications are prescribed appropriately for medically accepted indications
- Would codify a practice that is already taking place informally while providing clear guidance to states, beneficiaries, and manufacturers on what is permissible

Length of Grace Period

90 days

- Aligns with Medicare protected classes
- Most states can do clinical review in 90 days
- May have to change P&T review process

180 days

- Aligns with QHP and most of Medicare Part D
- Would allow most states to maintain their P&T review timelines

Coverage Requirement after Grace Period

- Requirement that state publish coverage criteria at end of grace period
- If coverage criteria has not been established and published at the end of the grace period, then state must cover as preferred drug (e.g., no prior authorization) until formal coverage criteria in place
- Would incentivize states to use the grace period to make informed coverage decisions and not simply delay access to the drug
- Could be done through regulatory or sub-regulatory guidance implementing grace period

Implications

- Federal spending
  - 90-day grace period – less than $25 million in savings over 10 years
  - 180-day grace period – less than $25 million in savings over 10 years
- States – would welcome flexibility; may object to mandatory PDL coverage after grace period
- Enrollees – may have some delays in access
- Manufacturers – would oppose but may be more accepting if paired with coverage requirement after grace period

Cap on Medicaid Rebates

Rebate Cap

- Section 1927(c)(2)(D) of the Social Security Act caps total rebates at 100 percent of a drug's average manufacturer price
  - In the 4th quarter of 2015, 18.5 percent of brand drugs (at NDC level) reached the rebate cap
- Generally applies to drugs that have a substantial inflationary rebates due to large price increases
- Can limit a manufacturer's incentive to moderate price increases once the cap is reached

Remove or Raise the Cap

- Amend Section 1927(c)(2)(D) of the Social Security Act to raise or remove the cap on rebates
- Will result in higher Medicaid rebates
- More downward pressure on price increases
- Does not address all high-cost drugs, only those with large price increases over time

Implications

- Federal spending
  - Remove cap: $15-20 billion in savings over 10 years
  - Raise cap to 125 percent of AMP: $5-10 billion over 10 years
- States – receive non-federal share of savings
- Enrollees – unlikely to have a measurable effect
- Manufacturers – would pay higher rebates; may raise launch prices or cost shift to other payers

Next Steps

- Finalize potential recommendations
  - Should the grace period be for 90 days or 180 days?
  - Should the grace period be paired with a requirement that states have a formal coverage policy in place at the end of the grace period?
  - Should the rebate cap should be completely removed or raised to 125 percent of AMP (or some other percentage)?
- Plan to vote at April meeting
- Chapter and recommendations in June report

Potential Recommendations

0- Amend Section 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug for 90 or 180 days after a new drug or new formulation of a drug has been approved by the FDA and entered the market

1- In guidance implementing the grace period, the Secretary of Health and Human Services should require that a drug is considered preferred if coverage criteria has not been published at the end of the grace period

2- Amend Section 1927(c)(2)(D) of the Social Security Act to raise or remove the cap on rebates

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