

Update on Medicaid Hepatitis C Virus Drug Coverage

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September 2016

Medicaid Drug Rebate (MDRP) Program

- Prescription drugs are an optional benefit in Medicaid programs
- More than 600 drug manufacturers participate in the MDR program
- Manufacturers must sign an agreement with the Secretary of HHS in order for their drugs to be covered by Medicaid, with the exception of certain drugs cited in the rebate statute.
- Manufacturers are required to pay statutory rebates to states on a quarterly basis as a condition of Medicaid reimbursement for their drugs dispensed to Medicaid fee-for-service (FFS) and MCO beneficiaries, and for physician administered drugs.
- Managed care organizations (MCOs) may negotiate their own rebates, but states also collect statutory rebates on MCO drugs.

Controlling Costs and Promoting Quality

Key Points

- Medicaid controls drug costs primarily through the Federal Medicaid Drug Rebate (MDR) Program and supplemental rebates negotiated by states.
- States manage appropriate drug use and leverage better manufacturer rebates through Prior Authorization (PA), Preferred Drug List (PDL), and Drug Utilization Review (DUR).
- Medicaid sets broad parameters for state Medicaid pharmacy reimbursement.

Rebates for Drugs Dispensed Through Managed Care Organizations (MCOs)

- The Affordable Care Act required and the final rule implements (at **447.509(b)**) the requirement that manufacturers participating in the MDR program pay rebates for covered outpatient drugs (CODs) dispensed to beneficiaries enrolled in Medicaid MCOs if the MCO is responsible for covering such drugs.
- Manufacturers are exempt from the requirement if such drugs are:
 - Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act; and
 - Discounted under section 340B of the Public Health Service Act.

Rebate Amount

The rebate amount due for each unit of a drug is based on statutory formulas:

- **Innovator Drugs** – the greater of 23.1 % of the AMP or difference between AMP and best price and adjusted by the Consumer Price Index-Urban (CPI-U). Prior to the Affordable Care Act, the percentage was 15.1%.
- **Blood Clotting Factors and Drugs Approved by FDA Exclusively for Pediatric Indications** – the greater of 17.1 % of AMP or difference between AMP and best price and adjusted by CPI-U. Prior to the Affordable Care Act, the percentage was 15.1%.
- **Non-innovator Drugs** – 13 % of the AMP. Prior to the Affordable Care Act, the percentage was 11%.

Supplemental Rebates

- With CMS' approval via their State Plan Amendment, states may enter into single-state and multi-state supplemental drug rebate pools that generate rebates that are at least as large as the rebates as set forth in the national rebate agreement with drug manufacturers.
- States use Prior Authorizations (PA) and Preferred Drug Lists (PDL) to leverage further “supplemental” rebates from drug manufacturers, further lowering their costs.
- Some states extend these supplemental rebates to MCO claims.

Framework for Medicaid MCO Prescription Drug Coverage

In accordance with sections 1902 and 1903 of the Social Security Act (the Act):

- Prescription drug coverage under Medicaid MCOs should demonstrate coverage consistent with the amount, duration, and scope as described by Medicaid Fee-For-Service (FFS).
- MCOs can not have medically necessary criteria for prescription drugs that are more stringent than Medicaid FFS.

Drug Utilization Review (DUR) Program

States use a DUR program to ensure that:

- Drugs are appropriate,
- Medically necessary, and
- Not likely to result in adverse medical results.

DUR is a two-phase process that is conducted by the Medicaid state agencies

- First phase (prospective DUR), state Medicaid agency's electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy and clinical misuse or abuse.
- Second phase (retrospective DUR) involves ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care and implements corrective action when needed.

Purpose of HCV Drug Guidance

- Advise States on Current Medicaid Drug Coverage Requirements and Permissible Restrictions
- Recognize Significant Cost of the Drugs and the Role of Manufacturers in Affordability
- Encourage sound clinical judgment and use of DUR Board and P+T Committees to develop coverage policies
- Indicate Availability of Treatment Guidelines
- Restate Rules Regarding MCO Drug Coverage

Purpose of HCV Drug Guidance

- CMS guidance to states and manufacturers on HCV drug coverage – November 5, 2015
 - *“...some states restricting access to HCV drugs contrary to statutory requirements...by imposing conditions that may unreasonable restrict access...”*
 - *“...states should examine their drug benefits to ensure that limitations do not unreasonable restrict coverage...”*
 - *“...services covered under managed care must be furnished in an amount, duration and scope that is no less than....FFS Medicaid.”*
 - *“...no more restrictive than coverage under FFS...”*