Defining Specialty Drugs: An Environmental Scan and Comparison of Specialty Drug Lists

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Background
There is little consensus about the definition of specialty drugs. They have been defined based on higher price, special instructions in product handling or administration, indication for treatment of chronic and debilitating diseases, requirement of treatment by a specialist, and non-oral administration. In order to better understand how to manage and track specialty drugs, a draft operational definition of specialty drugs was developed in a collaborative effort among Medicaid pharmacy directors. This study compares that operational definition with specialty drug lists from the six largest pharmacy benefit managers (PBM).

Objective
To compare drugs classified as specialty drugs by the six largest PBMs, and to help understand the definition(s) of specialty drugs used by the PBMs using 2012 fee-for-service Mississippi (MS) Medicaid pharmacy claims data.

Methods
Websites of six PBMs were searched to compile a list of specialty drugs and were compared to assess commonalities. In order to understand the definitions used, the 2012 MS Medicaid data were utilized to identify drugs that met one of five definitions of specialty drugs – cost greater than $600 per prescription claim, dispensed from pharmacies that have a median reimbursement of greater than $600 for all prescriptions filled, provider administered drugs, orphan drugs, and biologics.

Results
341 unique drugs were identified from the PBMs considered. Only 84 of these were defined as specialty drugs by all PBMs. Most of the drugs were antineoplastics (103), antivirals (46), and immunosuppressants (27). Frequencies of these therapeutic categories were consistently high for all PBMs. Upon cross-tabulating with the five definitions, cost of the drug being greater than $600 was seen to be the major determinant of classification as a specialty drug for all PBMs; on average, 89% of drugs met this criterion. Some of the other definitions varied across PBMs: a higher percentage of drugs were filled from pharmacies with a median cost of prescription fill of greater than $600 in two PBMs (about 65% for both, and between 44-50% in others), and 63% of drugs were provider administered in one PBM while it was 30-50% in others. If all the five definitions was used to classify specialty drugs, almost 99% of drugs in each PBM list were captured.

Conclusion
Ample variability was observed in the definition of specialty drugs across the PBMs considered. In order to define specialty drugs appropriately, a multifaceted definition, accounting for all the five definitions used here, is necessary.