

Reimbursement – An Issue on Two Levels

Side -- FDA “Charging Regulation”

R 312.8

Q&A

<https://www.fda.gov/downloads/drugs/guidance/ucm351264.pdf>

Side
care
caid

Commercial Insurance



BEFORE AFTER

What Are the Potential Sources of Reimbursement?

Part B

Expanded Access Treatment “Reasonable and Necessary”

What if a drug was billed using a “miscellaneous code”

Note: Free product can’t be billed – there would have to be a charge

Part D

Expanded Access Treatments “Covered Outpatient Drug

definition not

an addition to the existing statutory definition needed?

Partial Reimbursement (cont.)

Expanded Access Treatments “Covered Outpatient Drug”
likely not, but state by state permission could be sought
federal approval to states through “Dear Medicaid Director” letters
increase use

Special Coverage

Expanded Access Treatments “Investigational” or
“Experimental” or are they a last line of “treatment”?
need for collection of examples