KERN HEALTH SYSTEMS

PROVIDER bulletin

March 15, 2019

Dear Provider:

"First" reconstituted suspensions: Are not FDA approved formulations. Medicaid funds may not be spent on these medications. Preparations would need to be compounded in their place if warranted due to the member not being able to swallow the solid oral product. Examples would include using IV vancomycin in place of "First-vancomycin," or using capsules for the "First-omeprazole."

Firvanq©, however, has been reviewed and approved from the FDA. This product requires prior authorization and may be approved if medically necessary.

NDC labeler code is a ten digit unique, three-segment number which serves as a product identifier for human drugs. The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1. First segment of NDC Labeler code identifies the establishment; FDA will assign this number and will be unique for each establishment (manufacturer, packer, labeler etc...). Second segment of NDC Labeler code identifies the drug (strength, dosage and formulation). Third segment of NDC Labeler code identifies the package size and package type. The second and third segments are assigned by the labeler. Assignment of NDC number does not denote FDA approval of the drug or manufacturer.

THE INCLUSION OF A FIRM OR ITS PRODUCTS IN THE NDC DIRECTORY DOES NOT DENOTE APPROVAL BY THE FDA OF THE FIRM OR ANY OF ITS MARKETED PRODUCTS, NOR IS IT A DETERMINATION THAT A PRODUCT IS A DRUG AS DEFINED BY THE ACT, NOR DOES IT DENOTE THAT A PRODUCT IS COVERED BY OR ELIGIBLE FOR REIMBURSEMENT BY MEDICARE, MEDICAID, OR OTHER PAYERS.

More information may be found at the FDA's website,
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829

Sincerely,

Bruce Wearda, R.Ph.
Director of Pharmacy