



September 28, 2016

Richard J. Stec Jr., Ph.D.
Vice President
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RE: Billing Units and Package Sizes of Alternative Products to:
Clindesse® (clindamycin phosphate) Vaginal Cream, 2%, NDC 45802-0042-01
Gynazole-1® (butoconazole nitrate) Vaginal Cream, NDC 45802-0396-01

Dear Dr. Stec:

This letter is in response to Perrigo's request to the NCPDP WG2 Product Review and Billing Unit Exception Task Group to review the billing units and package sizes associated with products which are alternatives in the marketplace to NDC 45802-0042-01 Clindesse 2% Vaginal Cream and NDC 45802-0396-01 Gynazole-1 Vaginal Cream.

Representatives from the data compendia reviewed the list of alternative products provided by Perrigo and performed the following actions:

1. Removed suppository and ovule products from the list because they are measured in a different way than creams.
2. Provided the billing units and package sizes for the alternate products from their files.
3. Obtained labels for the alternate products.
4. Confirmed there is consistency across all compendia for the billing units and package sizes for the alternate products.
5. Confirmed labels for the alternate products do not mention overfill on the package label.
6. Confirmed the billing units on file for alternate products are in line with section 5.3.1 of the Billing Unit Standard (BUS) (*Dosage form billed as grams for creams of 1 GM or greater*).

The enclosed spreadsheet outlines the results of their work.

Since the alternate products do not list an overfill amount on the package label, Section 5.3.1 of the NCPDP Billing Unit Standard is applied in determining the billing unit. For Clindesse and Gynazole-1, Section 7.34 is applied because the overfill amount is included on the package label.

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services

organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

For direct inquiries or questions related to this letter, please contact

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Sincerely,

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Enclosure

cc: NCPDP Board of Trustees
cc: WG2 C0-Chairs