April 26, 2016

Richard J. Stec Jr., Ph.D.
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RE: Clindesse® (clindamycin phosphate) Vaginal Cream, 2%
NDC 45802-042-01 and NDC 64011-124-08
Gynazole-1® (butoconazole nitrate) Vaginal Cream USP, 2%
NDC 45802-396-01 and NDC 64011-246-01

Dear Dr. Stec:

The National Council for Prescription Drug Programs (NCPDP) thanks you for your letter of April 19, 2016 providing information on the referenced products. NCPDP is a not-for-profit American National Standards Institute (ANSI)-accredited Standards Development Organization (SDO) consisting of nearly 1600 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, industry professional societies, service organizations, government agencies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry.

The NCPDP Billing Unit Standard (BUS), first published as Version 1.0 in 1993, was developed to address the critical need within the industry to provide a "common billing unit language" in the submission of prescription claims. The BUS is maintained by NCPDP Work Group 2 Product Identification. NCPDP encourages manufacturers to contact NCPDP during the initial phase of packaging development (i.e. at the point when packaging and labeling begins, continuing to the market entry date) and whenever changes occur (packaging) on their product(s) to assist in the determination of billing units. Additionally, as units are reported to CMS for rebate purposes, it is recommended that the billing units be confirmed with NCPDP for appropriateness.

It is important to note the NCPDP Telecommunication Standard Implementation Guide Version D.0 was named in the HIPAA final rule of January 16, 2009 as the Retail Pharmacy transaction to be used for health claims and equivalent encounter information. The most current version of the NCPDP BUS is incorporated into the rule by reference within the Telecommunication Standard Implementation Guide Version D.0.

In June 2015, NCPDP was asked to review and confirm the billing unit for the new launch of NDC 45802004201 CLINDESSE 2% VAGINAL CREAM. Prior to making a determination, a review of all Clindesse and Gynazole listings was made. Our review noted the following:

Obsolete Dates	NDC	Name
	*64011024601	GYNAZOLE 1 2% CREAM
6/30/2008	54868483800	GYNAZOLE-1 CREAM
10/16/2012	64011000108	GYNAZOLE-1 CREAM
7/1/2008	54569545200	GYNAZOLE-1 CREAM
	*45802004201	CLINDESSE 2% VAGINAL CREAM
1/24/2011	21695085805	CLINDESSE 2% VAGINAL CREAM
7/1/2015	64011012408	CLINDESSE 2% VAGINAL CREAM

While the application of the BUS indicates the billing unit should be 5 grams, there were concerns regarding impact to the industry in changing the billing unit of existing products. Even though a review of claim data showed some but not significant usage, it was determined to apply the standard of 5 grams only to the active NDCs 64011024601 (Gynazole) and 45802004201 (Clindesse) and any new products released in the future per Section 7.34 of the BUS. To minimize disruption in the market place, the older products for Clindesse (NDCs 21695085805 and 64011012408) and Gynazole (NDCs 54868483800, 64011000108 and 54569545200) with obsolete dates would not change billing units and would remain with a billing unit of 5.8 grams. Section 7.34 of the BUS states:

7.34 HOW DO I BILL PRODUCTS THAT HAVE AN OVERFILL?

For non-injectable products, the package size will be based on the total amount of the product delivered (amount that can be extracted from the container; i.e. dispensed). Any overfill will not be considered as part of the reported quantity. Example: Tamiflu for Oral Solution contains approximately 33 mL, after reconstitution. Each bottle delivers 25mL of suspension. The reported quantity for dispensing should be 25mL.

For non-injectable products where the deliverable volume is expressed as a range, the reported quantity for dispensing will be the lower volume of the range. Example: CellCept 200mg/mL oral suspension lists the net content after reconstitution as 175 mL and the deliverable volume after constitution as 160-165 mL. The reported quantity for dispensing should be 160mL.

This billing unit decision was made by a consensus vote of the members at the NCPDP Work Group 2 Product Identification meeting of August 2015. At that meeting it was also determined the compendia would coordinate to reflect this change within their systems effective August 20, 2015.

In order for products to be properly billed, reimbursed and rebated correctly, the billing unit should reflect the amount dispensed. Including the overfill amount in the billable quantity could lead to incorrect payment on the claim by the payer and incorrect utilization reported to the manufacturer. We respect the decision from CMS; however, there are occurrences such as this one where NCPDP does not agree with the CMS Medicaid Drug Rebate Program. However, CMS is aware of the conversion table to be used to map between the CMS rebateable and NCPDP billable quantities.

Should you wish to discuss further, please contact Patsy McElroy (pmcelroy@ncpdp.org) and she will arrange a call with the Work Group 2 Co-chairs.

Sincerely,

Lee Ann C. Stember
President

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