Perrigo
Pharmaceuticals

April 19, 2016

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 Sir/Madam:

Perrigo wishes to inform the National Council for Prescription Drug Programs of the proper billing unit for the drug products Clindesse® Vaginal Cream, 2% (NDC 45802-0042-01 and NDC 64011-124-08) and Gynazole-1® Vaginal Cream USP, 2% (NDC 45802-396-01 and NDC 64011-246-01). Both products are packaged in a prefilled applicator containing a net weight of 5.8g prominently displayed on the FDA approved outer carton product labeling. The Dosage and Administration section of the Physicians Labeling or Package Insert identifies a recommended dose of 5g of the cream. It has been brought to our attention that the 5g product dose has been inappropriately assigned in the re-imbursement data banks as the net weight and billing unit for Clindesse® and Gynazole-1® drug products. We have confirmed with Lieutenant Emeka Egwin, PharmD, RPh., Centers for Medicare and Medicaid Services that the correct Clindesse® Vaginal Cream, 2% and Gynazole-1® Vaginal Cream USP, 2% billing unit for assignment of the AMP is 5.8g (communication appended).

Perrigo respectfully requests that National Council for Prescription Drug Programs urgently update the data bank to reflect the correct 5.8g billing unit for Clindesse® Vaginal Cream, 2% (NDC 45802-0042-01 and NDC 64011-124-08) and Gynazole-1® Vaginal Cream USP, 2% (NDC 45802-396-01 and NDC 64011-246-01).

Perrigo is aware of instances where patients have been denied coverage by their insurance plans resulting from this discrepancy. Your urgent attention to this matter is greatly appreciated.

Regards,

PERRIGO COMPANY, PLC

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From: Saddler, Kwan P. (CMS/CMCS) [mailto:Kwan.Saddler@cms.hhs.gov]
Sent: Friday, February 19, 2016 4:30 PM
To: Nick O'Brien; Egwim, Emeka S. (CMS/CMCS)
Cc: Saddler, Kwan P. (CMS/CMCS)
Subject: 45802 - UPPS question

Hello Nick,

Thanks for calling our attention to this issue and taking the time to chat with us today about it. Specifically, you inquired about the proper reporting for one of your products (NDC 45802-0042-01). This product is sold in a prefilled applicator which contains 5.8 GM of the product but only delivers 5 GM to when administered to the patient. You stated that you have based your pricing calculations off the quantity in the applicator. However, Medispan and First Databank, based on an NCPDP decision, have listed this product with a billing unit of 5 GM because that is the approximate dosage that results from using this product.

In our review of this case in light of the requirements of the Medicaid Drug Rebate Program, we believe that:

The Unit type should be (GM)
The Units Per Package Size should be (5.8 GM)
The AMP should be based on 5.8 GM

We note that for some drugs products the quantity dispensed versus quantity delivered/administered can be two different values things.
Furthermore, we have no control over the recommendations of the compendia which occasionally do not align with the requirements of the MDRP.

Given the discrepancies between these values and the listings in the compendia, we suggest that you communicate with the states on the proper billing/reimbursement conversion factors for the NDC. This will ensure that states reimburse pharmacies for all 5.8 GMS of the drug and that the state is properly rebated on the full 5.8 GM quantity.

Regards,

LT Emeka Egwim, PharmD, RPh.
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