



July 23, 2014

Copaxone® 20 mg. Billing Unit Changes Effective Q4 2014

A new package configuration for Copaxone® 20mg NDC 68546-0317-30, which no longer contains alcohol swabs or any other prepping supplies, was introduced in Q1 2014. A new National Drug Code (NDC) was not required by the FDA; however per section 5.2.2 of the NCPDP Billing Unit Standard, the billing unit will be changed from 1 EA kit to 1 ML per syringe (package size of 30). Due to the significance of this change on the pharmacy industry, the drug compendia will make the changes within the September/October 2014 timeframe.

The following examples highlight changes to dispensed quantity and unit of measure that will be apparent as a result of the billing unit change:

Examples (assuming unbroken packages):

Claim Billing Field	Prior to change:			Post change:		
Quantity Dispensed (442-E7)	1.000	2.000	3.000	30.000	60.000	90.000
Days Supply (405-D5)	30	60	90	30	60	90
Unit of Measure (600-28)	EA	EA	EA	ML	ML	ML

In order to avoid point of service rejections, drug utilization review (DUR) issues, and incorrect pricing, the payer and pharmacy must leverage the same billing unit values to ensure accurate point of service adjudication results. The following recommendations provide two possible options for plan/payers and pharmacies to mitigate risks and maintain patient safety.

Recommendations:

Option 1: Validate Unit of Measure to Determine Billing Unit

- If plan/payer currently does not require the Unit of Measure, and elects to begin requiring this field, updated payer sheets must be provided in a timely manner to the pharmacy network.
- Leverage the Unit of Measure (600-28) and Quantity Dispensed (442-E7) to determine if billed quantity is based on:
 - Total number of ML dispensed (new billing unit)
 Or,
 - Total number of kits / EA (old billing unit)

Option 2: Infer Unit of Measure to Determine Billing Unit

If Unit of Measure (600-28) is not available, leverage alternate fields on the claim to infer what the unit of measure may be and determine the billing unit. Alternate fields may include (but are not limited to):

- Quantity Dispensed (442-E7)

- Days Supply (405-D5)
 - Ingredient Cost Submitted (409-D9)
- As outlined in the below chart of examples, the combination of the Quantity Dispensed (442-E7), Days Supply (405-D5) and Ingredient Cost Submitted (409-D9) can be used to determine if billed quantity is based on:
 - Total number of ML dispensed (new billing unit)
 Or,
 - Total number of kits / EA (old billing unit)

Details are shown in readable text versus the actual transmission format.

<i>The dollar amounts are examples only</i>	Example 1 Valid	Example 2 Valid	Example 3 Invalid	Example 4 Valid	Example 5 Valid	Example 6 Valid	Example 7 Invalid
Quantity Dispensed (442-E7)	1.000	1.000	1.000	0.500	30.000	60.000	3.000
Unit of Measure (600-28) *							
Days Supply (405-D5)	30	1	1	15	30	60	90
Ingredient Cost Submitted (409-D9)	\$5000	\$166	\$5000	\$2500	\$5000	\$10000	\$498
<i>Dispensing Assumption:</i>	Old packaging (1 kit of 30 syringes)	Broken pack, 1 mL syringe from a new package	Old packaging (1 kit of 30 syringes each)	Broken pack with 15 syringes from an old kit	New packaging (1 30-syringe box)	New packaging (2 30-syringe boxes)	Old packaging (3 kits of 30 syringes each)
<i>Unit of Measure Assumption:</i>	EA	ML	EA	EA	ML	ML	EA
<i>Ingredient Cost Validation:</i>	Passes	Passes	Fails: Quantity/Days Supply imply 1 syringe (\$166) but Ingredient Cost Submitted implies 30 MLs (\$5000)	Passes	Passes	Passes	Fails: Quantity/Days Supply imply 3 EA Kits (\$15000) but Ingredient Cost Submitted implies 3 MLs (\$498)

<i>Assume Price Based On:</i>	Old kit rules	New per-ML rules	Old kit rules	Old kit rules	New per-ML rules	New per-ML rules	Old kit rules
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* In these examples Unit of Measure is not sent. Days Supply and Ingredient Cost Submitted are used as validation.

Additional notes for plans/payers:

- Discussion with your Compendium regarding conversion of price per kit versus price per milliliter. The plan/payer may need to determine whether to interpret the quantity on kit versus milliliter, based on the dispensed date in conjunction with the pricing effective date change from each to milliliter.
- Plan/payers should communicate to their network pharmacies the date (e.g. October 1, 2014) in which the billing unit of EA (kit) will no longer be recognized, and adjudication will be based on the new billing unit of ML.

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