

Jack W. Campbell, IV
Executive Director

Mailing Address:
6015 Farrington Rd., Suite 201
Chapel Hill, NC 27517

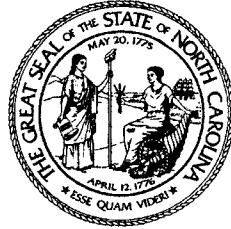
919-246-1050
FAX: 919-246-1056
www.ncbop.org

Clinton R. Pinyan
Brooks, Pierce, McLendon,
Humphrey & Leonard, LLP

Legal Counsel
336-373-8850

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June 16, 2010

VIA ELECTRONIC MAIL (loriwilson@carolina.rr.com) AND US MAIL

Lori Wilson, R.Ph.
Cleveland County Health Department
315 East Grover Street
Shelby, NC 28150

Dear Lori:

Thank you for appearing before the Board of Pharmacy yesterday to discuss substitution issues that may arise should the North Carolina Division of Medical Assistance adopt a pending Preferred Drug List ("PDL").

Specifically, you asked about two types of substitutions: (1) substitution of vial-packaged insulin products for cartridge, pen, or similarly packaged insulin products, with specific reference to page 14 of the proposed PDL (copy of that page attached); and (2) substitution of individual albuterol sulfate and ipratropium bromide nebulizer formulations for DuoNeb®, which is likewise a nebulizer formulation of albuterol sulfate and ipratropium bromide in combined form, with specific reference to page 21 of the proposed PDL (copy of that page attached).

North Carolina law defines an "equivalent drug product" as a "drug product which has the same established name, active ingredient, strength, quantity, and dosage form, and which is therapeutically equivalent to the drug product identified in the prescription." N.C.G.S. § 90-85.27(1). When a prescriber authorizes substitution, a pharmacist may select an "equivalent drug product" for dispensing.

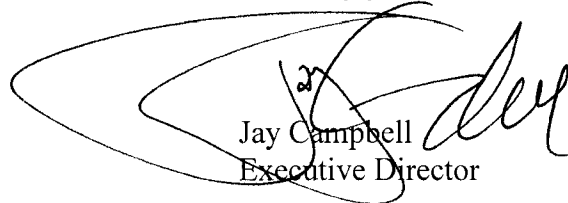
The Board members agree that, as described on page 14 of the proposed PDL, an insulin product packaged in a vial is an equivalent drug product to an identical insulin product packaged in a cartridge, pen, or similar. Accordingly, where substitution is authorized by the prescriber, the pharmacist would not have to obtain a new prescription to dispense the vial-packaged insulin rather than a cartridge- or pen-packaged insulin. Of course, as with all prescription drugs careful

counseling of the patient is paramount – this being especially so where injectable drugs are concerned. The Board members are cognizant, as well, that volumes of insulin product contained in vial-packaging versus cartridge- or pen-packaging may vary, and that pharmacists must be afforded some leeway in providing “days supply” or the like in light of those differences.

The Board members also agree that, as described on page 21 of the proposed PDL, on a prescription DuoNeb® for which substitution is authorized, the pharmacist may substitute equivalent strength individual nebulizer dosage forms of albuterol sulfate and ipratropium bromide. The pharmacist would not be required to obtain a new prescription in this circumstance. Again, patient counseling and education on appropriate usage would be paramount.

Not only did the Board members determine that these substitutions are allowable under North Carolina law, they emphasized that such substitutions serve the public health and safety by ensuring that North Carolina Medicaid patients do not encounter lengthy delays and frustration in obtaining these medications critical to treatment of typically chronic illness.

Sincerely yours,



Jay Campbell
Executive Director

Attachments

cc: Lisa Weeks, Chief, Pharmacy and Ancillary Services, North Carolina Department of Health and Human Services (via email, Lisa.Weeks@ncmail.net)
Troy Trygstad, Director of Network Pharmacist Program, Community Care of North Carolina (via email, troy@t2email.com)

**North Carolina Division of Medical Assistance
Preferred Drug List (PDL)**

ENDOCRINOLOGY
INJECTABLE HYPOGLYCEMICS

Rapid Acting Insulin

Pens and Cartridges: Patients under 21 years old are exempt from prior authorization

Preferred		Non-Preferred
Humalog vial® Novolog vial®		Apidra cartridge® Aprida Solostar® Aprida vial® Humalog cartridge® Humalog Kwikpen® Humalog pen® Novolog cartridge® Novolog Flexpen®

Short Acting Insulin

Pens and Cartridges: Patients under 21 years old are exempt from prior authorization

Preferred		Non-Preferred
Humulin R vial® Novolin R vial®		

Intermediate Acting Insulin

Pens and Cartridges: Patients under 21 years old are exempt from prior authorization

Preferred		Non-Preferred
Humulin N vial® Novolin N vial®		Humulin N pen®

Long Acting Insulin

Pens and Cartridges: Patients under 21 years old are exempt from prior authorization

Preferred		Non-Preferred
Lantus vial® Levemir vial®		Lantus cartridge® Lantus solostar® Levemir FlexPen®

Premixed Combination Insulin

Pens and Cartridges: Patients under 21 years old are exempt from prior authorization

Preferred		Non-Preferred
Humalog Mix 75/25 vial® Humalog Mix 50/50 vial® Novolog Mix 70/30 vial®		Humalog Mix 50/50 Kwikpen® Humalog Mix 75/25 Kwikpen® Humalog Mix 50/50 pen® Humalog Mix 75/25 pen® Novolog Mix 70/30 Flexpen®

Premixed 70/30Combination Insulin

Pens and Cartridges: Patients under 21 years old are exempt from prior authorization

Preferred		Non-Preferred
Humulin 70/30 vial® Novolin 70/30 vial®		Humulin 70/30 pen®

Amylin Analogs

Requires trial and failure or insufficient response to metformin unless contraindication or adverse event even when using a preferred product

Preferred		Non-Preferred
Symlin® Symlin pen®		

GLP-1 Receptor Agonists

Requires trial and failure or insufficient response to metformin unless contraindication or adverse event even when using a preferred product

Preferred		Non-Preferred
Byetta® Victoza®		

**North Carolina Division of Medical Assistance
Preferred Drug List (PDL)**

RESPIRATORY

BETA ADRENERGIC HANDHELD, LONG ACTING

Preferred	Non-Preferred
Serevent Diskus® Foradil®	

BETA ADRENERGICS HANDHELD, SHORT ACTING

Preferred	Non-Preferred
Proventil HFA® Ventolin HFA®	Maxair Autohaler® Proair HFA® Relion Ventolin HFA® Xopenex HFA®

BETA-ADRENERGIC NEBULIZER, SHORT ACTING

Preferred	Non-Preferred
albuterol sulfate	Exemption for use of Accuneb/generic Accuneb in patients < 2 years old Accuneb® albuterol (generic of Accuneb®)
	levalbuterol solution (generic of Xopenex®) Xopenex®

BETA-ADRENERGIC NEBULIZER, LONG ACTING

Preferred	Non-Preferred
Brovana® Perforomist®	

COPD ANTICHOLINERGICS

Preferred	Non-Preferred
Atrovent HFA® Combivent® Spiriva® ipratropium bromide solution	Duoneb® ipratropium-albuterol (generic for Duoneb®)

CORTICOSTEROIDS

Preferred	Non-Preferred
budesonide suspension QVAR®	Clinical criteria apply Aerobid® Aerobid M® Alvesco® Pulmicort Flexhaler® Pulmicort Respules®
	Asmanex® Azmacort® Flovent Diskus® Flovent HFA®

CORTICOSTEROID COMBINATION

Preferred	Non-Preferred
Advair Diskus® Advair HFA® Symbicort®	Clinical criteria apply