



*North Carolina*  
**State Health Plan**  
FOR TEACHERS AND STATE EMPLOYEES



## 2013 Pharmacy Benefit Language Revisions

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*A Division of the Department of State Treasurer*

# 2013 Pharmacy Benefit Language Revisions

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- ✓ Re-name Prescription Benefit Tiers (*Traditional Pharmacy Benefit*)
- ✓ Specialty Pharmacy Benefit Language
- ✓ Benefit Exclusion for all Medical Foods

# Current and Proposed Pharmacy Benefit Tiers

Tiers	Current	Proposed
Tier 1	Generics	Lower-cost medications, which would include mostly generic drugs.
Tier 2	Preferred Brand	Preferred brand medications, including some high cost generic drugs and compound drugs.
Tier 3	Non-Preferred Brand	All other non-preferred brand drugs for which alternatives are available in lower tiers.
Brand name drug with a generic equivalent	Generic copay + the difference between the Plan's cost of the brand name drug and the Plan's cost of the generic drug not to exceed \$100 per a 30-day supply of the brand medication.	Tier 1 copay + the difference between the Plan's cost of the brand name drug and the Plan's cost of the generic drug not to exceed \$100 per a 30-day supply of the brand medication.
Tier 4	All Specialty Medications	Preferred Specialty medications which may include some Biosimilar specialty medications.
Tier 5	n/a	Non-preferred Specialty medications which may include some Biosimilar specialty medications.

# Rationale for Benefit Tier Changes

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- Many generics are introduced to the market now with marketing exclusivity for 6 months for one manufacturer which usually results in a costly generic when first released.
- Allows the Plan to place high cost generic medications in a higher copay tier when other less costly, higher value generic medications are available.
- Provides cost differential in generic tiers to incentivize medications with higher therapeutic value.
- Allows the Plan to have multiple specialty pharmacy copay tiers to differentiate member cost share for preferred and non-preferred specialty medications when Biosimilars become available.
- *The Plan, with guidance from the Plan's Pharmacy and Therapeutics committee, will classify drugs into the appropriate tiers based on safety, therapeutic value, clinical effectiveness, and cost-effectiveness of the medication.*

# Current and Proposed Specialty Definition

Current Specialty Definition	Proposed Specialty Definition
<p>Specialty medications are covered biotech medications and other medications designated and classified by the Plan as specialty medications that are significantly more expensive than alternative drugs or therapies.</p>	<p>Specialty and <b>biosimilar</b> medications are covered biotech medications and other medications designated and classified by the Plan as specialty medications that are significantly more expensive than alternative drugs or therapies.</p>
<p>Medications classified by the State Health Plan as specialty medications meet all of the following conditions:</p> <ul style="list-style-type: none"> <li>• Have unique uses for the treatment of complex diseases</li> <li>• Require special dosing or administration</li> <li>• Require special handling</li> <li>• Are typically prescribed by a specialist provider</li> <li>• Exceed \$400 cost to the Plan per prescription</li> </ul>	<p>Medications classified by the Plan as specialty or <b>biosimilar</b> medications shall meet the following guidelines:</p> <ul style="list-style-type: none"> <li>• Have unique uses for the treatment of complex diseases</li> <li>• Require special dosing or administration.</li> <li>• Require special handling.</li> <li>• Are typically prescribed by a specialist provider.</li> <li>• Exceed four hundred dollars (\$400.00) cost to the Plan per prescription.</li> </ul>
<p>The current copay is 25% up to \$100 for a 30 day supply.</p>	<p>When <b>biosimilars</b> become available the Plan may impose a higher specialty copay for non-preferred specialty medications. The maximum copay for the non-preferred specialty medications could be set higher than the preferred per 30-day supply.</p>

# What is a Biosimilar?

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- Biologic definition- a drug produced from proteins, living organisms or complex large molecule drugs.
- Biosimilar definition- generic or follow on product to a biologic that produces the same clinical results and no clinically meaningful differences to the reference product.
- Biosimilars are still specialty medications and will remain extremely expensive. They should be placed in the Plan's specialty copay tier; however, they may be more cost effective and may need to be incentivized with a lower member cost share.
- The first Biosimilars are expected on the market in 2014.

# What are Medical Foods?

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- Medical foods are a diverse and expanding group of products that are intended for the specific dietary management of a disease or condition for which distinct nutritional requirements have been established.
- Medical foods were regulated as drugs until 1972 when they were reclassified as foods. These “foods” may be used as part of the treatment of a condition that requires ongoing medical supervision.
- A product that is marketed as a medical food does not require any FDA review or approval prior to marketing. The FDA does not have existing regulation nor clear guidance on what products should be considered medical foods or on the requirements needed to ensure that these foods do what they suggest they do and are safe for their intended use.
- Most of these formulas are available on an over-the-counter (OTC) basis. However, other products in this category have come onto the market as prescription products due to the inclusion of a prescription product with unproven labeled uses.

# Current Coverage of Medical Foods

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- The Plan currently covers prescription federal legend medical foods based on our benefit language that states that all federal legend drugs are covered except if specifically excluded.
- This creates confusion as to why some medical foods are covered and others are not.
- All over-the-counter medical foods are excluded from coverage.



# Current and Proposed Medical Foods Benefit Language

Current Benefit Booklet Language	Proposed Benefit Booklet Language
<p>What is not covered: For over-the-counter and non-federal legend vitamins and medical foods.</p> <p>For food supplements or replacements, nutritional or dietary supplements, formulas, or special foods of any kind.</p>	<p>What is not covered: For over-the-counter and non-federal legend vitamins.</p> <p>For food supplements or replacements, nutritional or dietary supplements, formulas, special foods, or <b>medical foods</b> of any kind.</p>

- With the lack of regulatory requirements for prescription medical foods, and the lack of FDA oversight it is expected that there will be strong growth in the medical foods market.
- Clarification of the current inconsistent benefit language now with the Plan covering some FDA legend prescription medical foods but not covering other non-federal legend medical foods.