

# Medication Policy

## New Drug Exclusion Formulary Policy

**Policy Number:** 1097

### Policy History

Approve Date:	02/06/2019	Effective Date:	04/01/2019
Reviewed/Revised Date:	02/01/2020, 12/04/2020		

### Preauthorization

All Plans	<p>Archimedes clinical pharmacist staff monitor FDA new drug approval alerts. New drug entities and formulations may be excluded for a period not to exceed twelve months from the date of the release of the drug after FDA approval.</p> <p>Archimedes clinical pharmacist staff will review the available clinical effectiveness, safety and cost information and will make formulary coverage decisions including tier placement and utilization management requirements (step-therapy, prior authorization, quantity limits).</p>
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### Section I—Approval Criteria

- I. Archimedes clinical pharmacist staff identifies new FDA-drug approvals through the daily FDA-alert email system.
- II. Any New FDA approved drugs and dosage forms may be excluded from coverage for up to a 12-month period.
- III. New FDA-drug exclusions will be identified on the weekly Medi-Span NDC file and provided to the Archimedes Data and Analytics team for routine updates with claims processing system.
- IV. Archimedes clinical pharmacist staff will review for coverage new FDA-approved drugs and dosage forms within 12-months of using available clinical and safety evidence and drug cost information to make recommendations for formulary coverage including utilization management requirements.
- V. New FDA-approved drug formulary coverage decisions will be communicated to the Archimedes Data and Analytics team for updating with the claims processing system.
- VI. Some clients may have custom formulary requirements that will override the Archimedes coverage rules.