

# Medication Policy

## New Drug Exclusion Formulary Policy

**Policy Number:** 1097

### Policy History

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|------------------------|------------------------------------|-----------------|------------|
| Approve Date:          | 02/06/2019                         | Effective Date: | 04/01/2019 |
| Revised/Reviewed Date: | 02/01/2020, 12/04/2020, 04/28/2021 |                 |            |

### Policy

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| 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 will be excluded from coverage for 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. Clinical pharmacy staff will review for coverage new FDA approved drugs and dosage forms within 12 months of approval using available clinical and safety evidence and drug cost information to make recommendations for formulary coverage including utilization management requirements.
- V. Some clients may have custom formulary requirements that will override the Archimedes coverage rules.