| Reference number(s) |
| --- |
| 3072-A |

# Specialty Guideline Management Universal Criteria (MD Review)

## Program Summary

The Specialty Universal Criteria ensure appropriate utilization of specialty medications and confirm that selection elements established in the FDA-approved product labeling are followed. These universal criteria for approval apply to high-cost, new to market medications with no formulary alternatives that are not otherwise managed through product-specific Specialty Guideline Management (SGM) or Prior Authorization programs. The criteria may be applied in situations where specific criteria are pending development.

These universal criteria confirm the medication is prescribed for an FDA-approved indication and that the member has no contraindications to therapy as described in the FDA-approved product labeling.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review: Detailed chart notes supporting the diagnosis, including history of therapies previously tried.

## Coverage Criteria

Authorization of 3 months may be granted for a requested medication when all of the following criteria are met:

- The medication is prescribed for an FDA-approved indication.
- The member has no contraindications to therapy as described in the FDA-approved product labeling.