

Utilization Management Policy Name: Request for Waiver of Brand Drug Additional Fees

Additional fees may be waived for a brand name medication when a generic is available if all the following are met:

1. The prescriber has indicated on the prescription “Dispense As Written (DAW)”; **AND**
2. The patient has tried an AB-rated generic equivalent to a brand name medication; **AND**
3. The patient had a documented allergic reaction to an excipient (inactive ingredient) that is present in the generic formulation, but is absent in the brand name equivalent; **AND/OR**
4. The patient had a documented life-threatening side effect that required medical intervention to a generic medication that did not occur with the brand; **AND**
5. The prescriber completed and submitted an FDA MedWatch Adverse Event Reporting Form [the prescriber must provide a copy of the completed MedWatch form; authorization will not be considered unless the form is completed and submitted to the FDA].

Duration of Approval: 365 days (1 year)

References: all information referenced is from FDA package insert unless otherwise noted below.

Information regarding MedWatch, the FDA Safety Information and Adverse Event Reporting Program can be found at:
<http://www.fda.gov/Safety/MedWatch>

The MedWatch form for healthcare professionals can be found at:
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q4 annually.

March 2024: Reformatted criteria. Updated duration of approval to 1 year.

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