

## 1 . Criteria

Product Name: Less than or equal to the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*	
Approval Length	12 Months (except for titration of loading-dose purposes)
Guideline Type	Administrative

**Approval Criteria**

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

**OR**

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

**AND**

2 - One of the following:

2.1 For titration or loading-dose purposes (one time authorization)

**OR**

2.2 Requested strength/dose is commercially unavailable

**OR**

2.3 Patient is on a dose alternating schedule

**OR**

<b>2.4</b> For topical applications, patient requires a larger quantity to cover a larger surface area	
Notes	Not to exceed maximum dose as specified in the product prescribing information or compendia for off-label uses. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. *This guideline only applies in the absence of a drug-specific quantity limit override guideline

Product Name: Greater than the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*	
Approval Length	12 month(s)
Guideline Type	Administrative
<p><b>Approval Criteria</b></p> <p><b>1</b> - One of the following:</p> <p><b>1.1</b> Quantity limit override requests must involve an FDA-approved indication</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Quantity limit override requests involving off-label indications must meet off-label guideline requirements</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - One of the following:</p> <p><b>2.1</b> The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition</p>	

**AND**

**3** - One of the following:\*\*

**3.1** Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

**OR**

**3.2** Higher dose or quantity is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Notes

\*This guideline only applies in the absence of a drug-specific quantity limit override guideline. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. \*\*NOTE: Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.