

QUANTITY LIMIT EXCEPTION CRITERIA FOR APPROVAL

1. The patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent
AND
2. ONE of the following:
 - A. The requested quantity (dose) does NOT exceed the program quantity limit
OR
 - B. ALL of the following:
 - i. The requested quantity (dose) is greater than the program quantity limit
AND
 - ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
AND
 - iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
OR
 - C. ALL of the following:
 - i. The requested quantity (dose) is greater than the program quantity limit
AND
 - ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
AND
 - iii. The prescriber has submitted provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months