

| Market Applicability | | | | | | | | | | | | | | | |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | NA |

*FHK- Florida Healthy Kids

Cresemba (isavuconazonium)

| Override(s) | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization Quantity Limit | 1 year |

| Medications | Quantity Limit |
|--------------------------------------|--------------------|
| Cresemba (isavuconazonium) 186mg | 2 capsules per day |
| Cresemba 372 mg powder for injection | 1 vial per day |

Loading dose for invasive aspergillosis and mucormycosis: May approve up to an additional 10 capsules (186 mg) and 5 vials (372 mg) in the first 48 hours of treatment.

Requests for a greater quantity will be reviewed on a case-by-case basis.

APPROVAL CRITERIA

Requests for Cresemba (isavuconazonium) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older;

AND

- II. One of the following:
 - a. Individual initiated treatment in an inpatient setting and requires continued treatment of invasive aspergillosis or mucormycosis in an outpatient setting;

OR

- b. Individual has a diagnosis of invasive aspergillosis; **AND**
- c. Individual has had an inadequate response to, is intolerant of, or has a contraindication to voriconazole or liposomal amphotericin B (ATS 2011, IDSA 2008);

OR

- d. Individual has a diagnosis of invasive mucormycosis; **AND**
- e. Individual has had an inadequate response to is intolerant of, or has a contraindication to amphotericin B (ATS 2001).

Cresemba (isavuconazonium) may **not** be approved for the following:

| Market Applicability | | | | | | | | | | | | | | | |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | NA |

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- I. Individual has a diagnosis or history of familial short QT syndrome; **OR**
- II. Use in combination with strong CYP3A4 inhibitors (such as but not limited to, ketoconazole); **OR**
- III. Use in combination with strong CYP3A4 inducers (such as but not limited to, rifampin).

Note: Fungal cultures and other relevant laboratory studies to identify causative organisms should be obtained prior to initiating empiric antifungal therapy. Once results are available, therapy should be adjusted accordingly.

| State Specific Mandates | | |
|-------------------------|-----|-----|
| N/A | N/A | N/A |

Key References:

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Cresemba [Package insert]. Northbrook, IL. Astellas Pharma US, Inc.; 2015. Available from: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207500s001,207501s001lbl.pdf. Accessed on: June 21, 2015.

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Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc.; 2015. Updated periodically.

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Limper AH, Knox KS, Sarosi GA, et al. An Official American Thoracic Society Statement: Treatment of Fungal Infections in Adult Pulmonary and Critical Care Patients. *Am J Respir Crit Care Med*. 2011; 183:96–128. Available from: <http://www.thoracic.org/statements/resources/mtpi/treatment-of-fungal-infections-in-adult-pulmonary-critical-care-and-sleep-medicine.pdf>. Accessed on: June 21, 2015.

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