

PROVIDER BULLETIN

PROVIDER INFORMATION



December 10, 2015

Prior Authorization Requirements for a New Drug, Orkambi (lumacaftor/ivacaftor)

Blue Cross and Blue Shield of Minnesota (Blue Cross) will require prior authorization (PA) for a new drug, Orkambi (lumacaftor/ivacaftor). This PA requirement will become effective February 1, 2016, pending the release of FDA-approved indications for this drug.

Orkambi (lumacaftor/ivacaftor) is a drug anticipated to be approved for the treatment of cystic fibrosis in people ages 12 and older who have two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

As stewards of healthcare expenditures for our subscribers, we are charged with ensuring the highest quality, evidence based care for our members. One method for doing so is through the prior authorization process. The primary purpose is to ensure that evidence based care is provided to our members, driving quality, safety, and affordability.

The intent of this prior authorization is to ensure appropriate selection of patients for treatment according to FDA approved product labeling. The Orkambi (lumacaftor/ivacaftor) PA defines appropriate use as use in patients who have an FDA approved indication, who are receiving the FDA labeled dose, and who do not have any FDA labeled contraindications. Requests will be reviewed when patient-specific documentation has been provided.

Products impacted

This PA program applies to commercial lines of business **and** the following Minnesota Health Care Programs:

- Blue Advantage Prepaid Medical Assistance Program (PMAP)
- Minnesota Senior Care Plus (MSC+)
- MinnesotaCare

Drug-specific PA criteria will be developed and posted after FDA-approved indications are released, and can be accessed using the Blue Cross provider link.

- Access providers.bluecrossmn.com
- Under Tools And Resources, select Medical policy, then acknowledge the Acceptance statement
- Select Utilization Management
- Select Pharmacy Utilization Management

Questions?

If you have questions, please contact provider services at **(651) 662-5200** or **1-800-262-0820**.