MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

October 25, 2018

TO: Custodians of Medicaid Services Manual

FROM: Lynne Foster, Chief of Division Compliance

SUBJECT: Medicaid Services Manual Changes
Chapter 1200 – Prescribed Drugs

BACKGROUND AND EXPLANATION

Revisions are being proposed to Medicaid Services Manual (MSM) Chapter 1200, Appendix A, Section P, Monoclonal Antibody Agents for a clarification and Section HHH, Orkambi® for an update.

These changes are effective November 5, 2018.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL 32241 Chapter 1200 – Prescribed Drugs	MTL N/A Chapter 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A. Section P, (1)(A)(2)(e)	**Monoclonal Antibody Agents Xolair®**	Remove (e) "The recipient must have had an inadequate response, adverse reaction or contraindication to inhaled, oral corticosteroids; and"
Appendix A. Section HHH (1)(b)	**Orkambi®**	Update (b) by removing the six and replacing with a two to read, "the recipient is two years of age or older; and"

P. Monoclonal Antibody Agents

Therapeutic Class: Respiratory Monoclonal Antibody Agents
Fasenra reviewed by DUR Board: April 26, 2018
~~Last Reviewed by the DUR Board: July 28, 2016~~
Xolair previously reviewed: October 19, 2017
Last Reviewed by the DUR Board: July 28, 2016

Xolair® (Omalizumab) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

A. Xolair® (Omalizumab)

1. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies.

2. All of the following criteria must be met and documented for a diagnosis of moderate to severe persistent asthma:

a. The recipient must be six years of age or older; and

b. The recipient must have a history of a positive skin test or Radioallergosorbent (RAST) test to a perennial aeroallergen; and

c. The prescriber must be either a pulmonologist or allergist/ immunologist; and

d. The recipient must have had an inadequate response, adverse reaction or contraindication to inhaled, oral corticosteroids; and

~~e. The recipient must have had an inadequate response, adverse reaction or contraindication to an oral second generation antihistamine; and~~

~~f.~~e. The recipient must have had an inadequate response, adverse reaction or contraindication to a leukotriene receptor antagonist; and

~~g.~~f. The recipient must have had a pretreatment serum total Immunoglobulin E (IgE) level between 30 IU/mL and 700 IU/mL; and

~~h.~~g. The recipient's current weight must be recorded; and

~~i.~~h. The requested dose is appropriate for the recipient’s pre-treatment serum IgE and body weight (see Table 1).

HHH. Orkambi® (lumacaftor/ivacaftor)

Therapeutic Class: Cystic Fibrosis Agent
Last Reviewed by the DUR Board: January 26, 2017
Previously reviewed November 5, 2015

Orkambi® (lumacaftor/ivacaftor) is subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

   Approval will be given if the following criteria are met and documented:

   a. The recipient has a diagnosis of cystic fibrosis; and

   b. The recipient is ~~six~~ two years of age or older; and

   c. The recipient is homozygous for the F508del mutation in the CFTR gene; and

   d. The requested dose is two tablets every 12 hours; or

   e. The requested dose is one tablet every 12 hours in the presence of severe hepatic impairment.

2. Prior Authorization Guidelines:

   a. Prior Authorization approvals will be for one year.

   b. Prior Authorizaition forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx