MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

July 31, 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

The Division of Health Care Financing and Policy (DHCFP) proposes revisions to Medicaid Services Manual (MSM) Chapter 1200, Appendix A, based on recommendations approved at the April 26, 2018 Drug Use Review (DUR) Board meeting. The recommended changes include the addition of Fasenra® prior authorization criteria to the existing monoclonal antibody agent class, the removal of prior authorization criteria for Makena®, the revision of the existing prior authorization criteria for GnRH Analogs to include the diagnosis Gender Dysphoria formerly known as Gender Identity Disorder and the addition of new prior authorization criteria for High Dollar Claims. High Dollar Claims are defined as single point-of-sale claims that exceed $10,000.

These changes are effective August 6, 2018.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL 32030 MSM Ch 1200 – Prescribed Drugs	MTL N/A MSM Ch 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section P	**Monoclonal Antibody Agents**	Added Fasenra® review date of April 26, 2018. Added the drug Fasenra® to the existing section for Monoclonal Antibody Agents and new prior authorization criteria.
Appendix A Section GG	**Makena®**	Removal of entire prior authorization criteria for Makena®**.**
Appendix A Section YY	**GnRH Analogs**	Revised previously reviewed date to, "April 26, 2018."

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		Revised GnRH Analogs prior authorization criteria to include to diagnosis of Gender Dysphoria and added the new criteria for the diagnosis.
Appendix A Section UUU	**High Dollar Claim**	Added new prior authorization criteria for High Dollar Claims.

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

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

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

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

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

3. All the following criteria must be met and documented for diagnosis of chronic idiopathic urticaria (CIU); and

   a. The recipient is 12 years of age or older; and

   b. The recipient must have had an inadequate response, adverse reaction or contraindication to two different oral second generation antihistamines; and

   c. The recipient must have had an inadequate response, adverse reaction or contraindication to an oral second generation antihistamine in combination with a leukotriene receptor antagonist; and

   d. The prescriber must be either an allergist/immunologist, dermatologist or a rheumatologist or there is documentation in the recipient's medical record that a consultation was done by an allergist/immunologist, dermatologist or a rheumatologist regarding the diagnosis and treatment recommendations; and

   e. The requested dose is:

      1. Initial therapy: 150 mg every four weeks or 300 mg every four weeks and clinical rationale for starting therapy at 300 mg every four weeks has been provided.

      2. Continuation of therapy: 150 mg or 300 mg every four weeks.

B. Nucala® (mepolizumab), Cinqair® (reslizumab)

1. All the following criteria must be met and documented:

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

   b. The recipient must have a diagnosis of severe eosinophilic-phenotype asthma; and

   c. The recipient must be an appropriate age:

      1. Mepolizumab: 12 years of age or older

      2. Reslizumab: 18 years of age or older

d. And, the prescriber must be either a pulmonologist or allergist/ immunologist; and

e. The recipient must be uncontrolled on current therapy including high dose corticosteroid and/or on a secondary asthma inhaler; and

f. There is documentation of the recipient's vaccination status; and

g. The requested dose is appropriate:

1. Mepolizumab: 100 mg subcutaneously every four weeks.

2. Reslizumab: 3 mg/kg via intravenous infusion of 20 to 50 minutes every four weeks.

C. Fasenra® (benralizumab)

1. All the following criteria must be met and documented:

a. The recipient must be 12 years of age or older; and

b. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthamtic monoclonal antibodies; and

c. The recipient must have a diagnosis of severe asthma; and

d. Asthma is an eosinaophilic phenotype as defined by a baseline blood eosinophil level greater than or equal to 300 cells per microliter; and

e. One of the following:

1. Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months; or

2. Any prior intubation for an asthma exacerbation; or

3. Prior asthma-related hospitalization within the past 12 months.

f. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

1. Both a high-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and an additional asthma controller medication (e.g., leukotriene

receptor antagonist, long-acting beta-2 agonist (LABA), theophylline); or

2. One maximally-dosed combination ICS/LABA product (e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/ formoterol)).

g. Prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergy/Immunology specialist.

2. Recertification Request: Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

a. There is documentation of a positive clinical response (e.g., reduction in exacerbation).

b. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

1. Both an inhaled corticosteroid (ICS) (5,E) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline); or

2. A combination ICS/LABA product (e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)).

c. Prescribed by or in consultation with one of the following:

1. Pulmonologist; or

2. Allergy/Immunology specialist.

2. Prior Authorization Guidelines

A. Prior Authorization approval will be for 12 months.

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

GG. Makena™ (Criteria for Physician Administered Drug)

Therapeutic Class: Progestational Agents
Last Reviewed by the DUR Board: April 28, 2011

Makena™ 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

Authorization will be given if all of the following criteria are met and documented:

a. Treatment with Makena™ is ordered by or recommended by a physician specializing in Obstetrics/Gynecology, Perinatology or Maternal/Fetal Medicine; and

b. The recipient is female, 16 years of age or older and pregnant with a singleton pregnancy; and

c. The recipient's pregnancy is between 16 weeks, 0 days and 20 weeks, six days of gestation when therapy begins; and

d. The recipient has a history of singleton spontaneous preterm birth (prior to 37 weeks gestation); and

e. The recipient does not have other risk factors for preterm birth; and

f. There is no known major fetal anomaly or fetal demise; and

g. The recipient has not been treated with heparin therapy during the current pregnancy; and

h. The recipient has no history of thromboembolic disease; and

i. The recipient has no maternal/obstetrical complication (e.g. current or planned cerclage, hypertension requiring medication or seizure disorder).

2. Length of approval:

Makena™ will be approved for use until the recipient's pregnancy is 36 weeks, six days of gestation or delivery, whichever occurs first.

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

YY. GnRH Analogs

Therapeutic Class: GnRH Analogs
Last Reviewed by the DUR Board: ~~July 28, 2016~~April 26, 2018

GnRH Analogs are subject to prior authorization and quantity limits 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. This prior authorization criteria only applies to recipients who are under 18 years of age. Approval of Lupron® (leuprolide) will be given if all the following criteria, per individual diagnosis, are met and documented:

1. The recipient has a diagnosis of idiopathic or neurogenic central precocious puberty (CPP), and

a. The requested dose and frequency is based on FDA-approved guidelines; and

b. The medication is being prescribed by or in consultation with a pediatric endocrinologist; and

c. There is an onset of secondary sex characteristics before age eight years (females) or nine years (males); and

d. The recipient is currently less than 11 years of age (females) or 12 years of age (males).

2. The recipient has a diagnosis of gender dysphoria, formerly known as gender identity disorder; and

a. The medication is being prescribed for suppression of puberty; and

b. The provider indicates a demonstrable knowledge what gonadotropins medically can and cannot do and their social benefits and risks; and

c. One of the following:

1. A documented real-life experience (living as the other gender) for at least three months prior to the administration of gonadotropin; or

2. A period of psychotherapy for a duration specified by the mental health professional after the initial evaluation (usually a minimum of three months).

d. The member must meet the definition of gender identity disorder (see definition below):

1. Gender Identity Disorder:

a. A strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex).

b. Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.

c. The disturbance is not concurrent with a physical intersex condition.

d. The disturbance causes clinically significant distress or impairment in social, occupational or other important areas of functioning.

e. The transsexual identity has been present persistently for at least two years.

f. The disorder is not a symptom of another mental disorder or a chromosomal abnormality.

~~2.~~3. The recipient has a diagnosis of ~~of~~ endometriosis, and

1. The requested dose and frequency is based on FDA-approved guidelines; and

2. The recipient has had an inadequate response, adverse reaction or contraindication to an NSAID; and

3. The recipient has had an inadequate response, adverse reaction or contraindication to a hormonal contraceptive.

~~3.~~4. The recipient has a diagnosis of uterine leiomyomata (fibroids), and

a. The requested dose and frequency is based on FDA-approved guidelines; and

b. The recipient is symptomatic; and

c. Documentation has been submitted of the anticipated surgery date (or notation that surgery is planned once the fibroids shrink) or clinical rational why surgical intervention is not required.

~~4.~~5. The recipient has a diagnosis of prostate cancer, and
a. The requested dose and frequency is based on FDA-approved guidelines.

2. Prior Authorization Guidelines

a. Prior authorization approval will be given for an appropriate length of therapy based on the diagnosis, unless the prescriber indicates a shorter duration of approval.

1. CPP: One year, or until the member reaches the age of 11 years (female) or 12 years (male).

2. Endometriosis: One year.

3. Uterine Leiomyomata (fibroids): One month or until the time of the documented surgery (maximum of three months).

4. Prostate Cancer: One year.

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

UUU. High Dollar Claim

Last Reviewed by the DUR Board: April 26, 2018

A High Dollar Claim is defined as a single point-of-sale claim that exceeds $10,000. A High Dollar Claim 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. If other prior authorization criteria exists, it will supersede this criteria.

1. Coverage and Limitations

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

a. One of the following:

1. The medication is being prescribed for a Food and Drug Administration (FDA) approved indication; or

2. One of the following:

a. Diagnosis is supported as a use of American Society of Health-System Pharmacists Drug Information (AHFS DI); or

b. Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation and carries a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section); or

3. Both of the following:

a. Diagnosis is listed in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation and carries a Strength of Recommendation rating of III or Class Indeterminant (see DRUGDEX Strength of Recommendation table in Background section); and

b. Efficacy is rated as “Effective” or “Evidence Favors Efficacy” (see DRUGDEX Efficacy Rating and Prior Authorization Approval Status table in Background section); or

4. Diagnosis is supported in any other section in DRUGDEX; or

5. The use is supported by clinical research in two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and

convincing contradictory evidence presented in a major peer-reviewed medical journal.

b. And one of the following:

1. The dosage/quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice; or

2. The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

a. American Hospital Formulary Service (AHFS) Compendium.

b. Thomson Reuters (Healthcare) Micromedex/DRUGDEX (not Drug Points) Compendium.

c. Elsevier Gold Standard Clinical Pharmacology Compendium.

d. National Comprehensive Cancer Network Drugs and Biologics Compendium.

c. Excluded:

1. Hemostatic coagulation factors used for the treatment of hemophilia are excluded from this criteria.

d. Prior Authorization Guidelines:

1. Prior Authorization approval will be for 12 months.

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