MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

June 12, 2014

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: MARTA E. STAGLIANO, CHIEF OF PROGRAM INTEGRITY

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to MSM Chapter 1200 are being proposed to reflect approved actions by the Drug Use Review (DUR) Board at the July 25, 2013 meeting.

The DUR Board is a requirement of the Social Security Act to identify and reduce fraud, abuse, overuse, and medically unnecessary care. The DUR Board also works to minimize drug interactions, drug-induced illness, and undesirable drug reactions in recipients.

Prior authorization criteria was approved by the DUR Board on July 25, 2013 for the following drugs. Prior authorization criteria will be added or criteria will be revised to MSM Chapter 1200 for Eliquis® (apixaban); Pradaxa® (dabigatran etexilate); Xarelto® (rivaroxaban); Ampyra® (dalfampridine); Cymbalta® (duloxetine); Suboxone® (buprenorphine/naloxone); Subutex® (buprenorphine); Genotropin® (somatropin); Humatrope® (somatropin); Norditropin® (somatropin) Nutropin® (somatropin); Omnitrope® (somatropin); Saizen® (somatropin); Tev-Tropin® (somatropin); Serostim® (somatropin); Zorbtive® (somatropin); Cinryze® (C1 esterase inhibitor); Berinert® (C1 esterase inhibitor); Kalbitor® (ecallantide); Firazyr® (icatibant); Leukine® (sargramostim); Neulasta® (pegfilgrastim); Neupogen® (filgrastim); Subsys® (fentanyl sublingual spray); Onsolis® (fentanyl citrate buccal film); Fentora® (fentanyl citrate buccal tablet); Lazanda® (fentanyl citrate nasal spray); Abstral® (fentanyl citrate sublingual tablet); Cesamet® (nabilone); Marinol® (dronabinol); and Actiq® (fentanyl citrate transmucosal lozenge).

The length of prioritization approval for Omontys® (peginesatide) will be changed from one year to one month.

Clarifying language was added under Injectable Immunomodulators, Crohn's Disease.

Bone pain was removed under Cox-2 Inhibitors.

These changes are effective July 1, 2014.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
MTL N/A MSM CHAPTER 1200 – PRESCRIBED DRUGS	CL 27787 MSM CHAPTER 1200 – PRESCRIBED DRUGS

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A	**Table of Contents**	Added the drugs with new criteria listed to the Table of Contents.
Appendix A	**B - Cox-2 Inhibitors**	Bone pain was removed, as this currently is not a FDA approved indication.
Appendix A	**D - Growth Hormone**	For children up to age 21, criteria was revised to remove idiopathic short stature as a qualifying diagnosis for growth hormone. All recipients must fail two growth hormone stimulation tests. The previous criteria required one failure. Criteria for Serostim® (somatropin) was added for recipients with weight loss associated with HIV. Criteria for Zorbtive® (somatropin) was added for recipients with weight loss from short bowel syndrome.
Appendix A	**G - Immediate Release Fentanyl Products**	Incorporated the previous criteria for Fentora®, and Actiq® into a new drug category called Immediate Release Fentanyl Products. The criteria now includes Subsys® (fentanyl sublingual spray); Onsolis® (fentanyl citrate buccal film); Fentora® (fentanyl citrate buccal tablet); Lazanda® (fentanyl citrate nasal spray); Abstral® (fentanyl citrate sublingual tablet); and Actiq® (fentanyl citrate transmucosal lozenge). The only revision to the original criteria was the removal of Non-Covered Indications.
Appendix A	**H - Hematopoietic / Hematinic Agents**	Under Coverage and Limitations, added a parenthesis after Epogen®.
Appendix A	**L - Injectable Immunomodulator Drugs**	Under Coverage and Limitations, Section (f.) added Cimzia®, Humira® to clarify the drugs included for the treatment of Crohn's disease.
Appendix A	**V - Sedative Hypnotics**	Deleted Quantity Limitations as they are documented in the Pharmacy Billing Manual.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A	**X - Antiemetics – Serotonin Receptor Antagonists (also known as 5-HT3 Antiemetics)**	Corrected typo under Therapeutic Class: Antiemetics.
Appendix A	**Z - Cymbalta® (duloxetine)**	Added language that Cymbalta® is subject to prior authorization and quantity limits as well as a reference to the Pharmacy Manual for specific quantity limit information. Added Chronic Musculoskeletal Pain, Generalized Anxiety Disorder, and Major Depressive Disorder to the list of qualifying diagnoses. Each diagnosis requires an inadequate response to other specified drugs before Cymbalta® will be approved. Also added language indicating that certain documentation must be included on the claim form as a qualifying criteria for payment.
Appendix A	**BB - Suboxone® (buprenorphone/ naloxone) and Subutex® (buprenorphone)**	Revision to original criteria where now formal substance counseling is encouraged rather than required and deleted language regarding parameters of previously required counseling. Added new criteria for Subutex® (buprenorphone) that all recipients must either be pregnant or breastfeeding an infant dependent on methadone or morphine.
Appendix A	**CC - Ampyra® (delfampridine)**	Remove ™ from Ampyra and add ®. The original criteria requiring a timed 25 foot walk and the criteria for renewal of the prior authorization has been removed. Clarifying language was added under Prior Authorization Guidelines.
Appendix A	**FF - Pradaxa® (dabigatran etexilate); Eliquis® (apixaban); Xarelto® (rivaroxaban)**	Added Eliquis® (apixaban) and Xarelto® (rivaroxaban) to the Pradaxa® (dabigatran etexilate) criteria. Added the disclaimer related to prior authorization and quantity limits as well as a reference to the Pharmacy Manual. Revised the criteria to allow for the submittal of a specified ICD-9 code on the prescription to bypass the requirement of a prior authorization. Revised the original criteria to focus on nonvalvular atrial fibrillation, pulmonary embolism and infarction, acute venous embolism and thrombosis of the deep vessels of the lower extremity. Added verbiage stating recipients must not have an active

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		pathological bleed.
Appendix A	**KK - Xarelto® (rivaroxaban)**	Deleted the criteria as this information has been incorporated into Appendix A, Section FF.
Appendix A	**KK - Hereditary Angiodema Agents**	New criteria for Cinryze® (C1 esterase inhibitor), Beromert® (C1 esterase inhibitor), Kalbitor® ecallantide) and Firazyr® (icatibant). In addition to the addition of the quantity limit disclaimer, new criteria requires recipients have a diagnosis of hereditary angioedema. Drugs must be prescribed by or in consultation with an immunologist or allergist. The recipient must have experienced an inadequate response to attenuated androgen agents. Prior Authorization Guidelines document an initial approval of six months with continuation of therapy for one year.
Appendix A	**RR - Cesamet® (nabilone) Marinol® (dronabinol)**	Added "all" to Coverage and Limitations regarding approval if all of the following criteria are met and documented. Under Cesamet® (nabilone) added "and" after criteria #1 and #2 for clarity. Under Marinol® (dronabinol) renumbered and added sub-criteria. Added "and" after criteria #1, (a.), (b.) and after criteria #2; added "or" after criteria #1(c.) for clarity.
Appendix A	**SS - Omontys® (peginesatide)**	Revised Prior Authorization (PA) Guidelines to indicate that PA approvals are for one month rather than one year.
Appendix A	**TT - Colony Stimulating Factors (Point of Sale Claims Only)**	New criteria for Leukine® (sargramostim), Neulasta® (pegfilgrastim) and Neupogen® (filgrastim). In addition to the addition of the quantity limit disclaimer, new criteria requires recipients to have a qualifying diagnosis such as non-myeloid malignancy, or must be undergoing bone marrow transplantation, or is at high risk for neutropenia, or has experienced a prior episode of febrile neutropenia. PA Guidelines document approval for one month.

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All drugs in Appendix A may be subject Quantity Limitations. Check the Nevada Medicaid and Nevada Check Up Pharmacy Manual for a listing of the exact Quantity Limitation.

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B. Cox-2 Inhibitors

Therapeutic Class: NSAIDs (nonsteriodal anti-inflammatory drugs)
Last Reviewed by the DUR Board: April 28, 2011

Cox-2 Inhibitors are subject to prior authorizations and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer for the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Indications:

A diagnosis of osteoarthritis, rheumatoid arthritis, alkylosing spondylitis, juvenile rheumatoid arthritis, primary dysmenorrheal, ~~bone pain~~ or acute pain in adults.

Upon documentation of a listed indication, authorization will be given if the patient meets one of the following criteria:

a. Patient is at high risk of NSAID induced adverse GI events as evidenced by any of the following:

1. Patient has a documented history or presence of peptic ulcer disease.

2. Patient has a history or presence of NSAID-related ulcer.

3. Patient has a history or presence of clinically significant GI bleeding.

b. Patient is greater than 65 years of age.

c. Patient is at risk for GI complications due to the presence of any of the following concomitant drug therapies:

1. Anticoagulants (e.g. warfarin, heparin or Low Molecular Weight (LMW) heparin).

2. Chronic use of oral corticosteroids.

d. Patient has a documented history of inability to tolerate therapy with at least two non-selective (traditional) NSAIDs.

e. The patient is not being treated daily with aspirin for cardioprophylaxis unless concurrent use of a proton pump inhibitor is documented.

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D. Growth Hormone

Therapeutic Class: Growth Hormone
Last Reviewed by the DUR Board: ~~January 24, 2008~~ July 25, 2013

~~Growth Hormone (GH) therapy is subject to prior authorization. A Food and Drug Administration (FDA)-approved indication for the diagnosis being treated is required.~~

~~1. Coverage and Limitations~~

~~a. Children (up to age 21)~~

~~The following apply to all requests for children:~~

~~1. An evaluation by a pediatric endocrinologist or pediatric nephrologist with a recommendation for therapy.~~

~~2. All other causes for short stature are ruled out.~~

~~3. Patient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonatropic hormones.~~

~~Therapy will be approved for any one of the following:~~

~~4. Diagnosis of Turner's Syndrome.~~

~~5. Diagnosis of Prader-Willi Syndrome.~~

~~6. Patient has chronic renal insufficiency (defined as Creatinine Clearance between five and 75/ml/min/1.73m2).~~

~~7. If the patient has evidence of hypothalamic-pituitary disease or structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation and meeting any one of the following:~~

~~a. Has failed at least one GH stimulation test (peak GH level <10 nanograms (ng/ml).~~

~~b. Had at least one documented low IGF-1 level (below normal range for patients age – refer to range on submitted lab document).~~

~~c. Has deficiencies in three or more pituitary axes (i.e. TSH, LH, FSH, ACTH, ADH).~~

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8. If the patient is a newborn infant and has evidence of hypoglycemia and either a low GH level (<20ng/ml) or a low for age IGF-1 or IGF Binding Protein #3 level (IGFPB#3) (no stimulation test required for infants).

9. Children with a history of intrauterine growth restriction (small for gestational age (SGA)) who at age two years have a height at least two Standard Deviations (SD) below the mean for the patient's age and gender.

10. For Idiopathic Short Stature all the following criteria must be met:

a. Bone age>2 SD below the mean for age, Epiphysis open. Height >2.25 SD below the mean for age or >2 SD below the mid-parenteral height percentile or growth velocity <25th percentile for bone age.

b. At least one provocative stimuli test to show failure to raise the grow hormone level above 10 ng/ml.

c. Exception to the requirement for stimuli testing: Patients meeting (10)(a) and (10)(b) above in addition to a documented low serum insulin-like growth factor 1 (IGF-1) and/or insulin-like growth factor binding protein #3 (IGFPB#3) will not be required to have stimuli testing.

b. Criteria for the continuation of growth hormone therapy for children includes all of the following:

Bone age >2 SD below the mean for age. Epiphysis open.

1. Growth rate with treatment is at least two centimeters greater than the untreated rate. Copy of the growth chart must accompany forms.

2. Child has not reached the 25th percentile of normal height for gender.

3. No diagnosis of an expanding lesion or tumor formation.

4. Patient has not undergone renal transplant.

c. Reasons for Non-Coverage/Denial include, but are not limited to, the following:

1. Indications other than those specified in this policy;

2. Any condition(s) which is contraindicated and/or considered to be experimental;

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3. Patients with expanding lesions or tumor formation;

4. Patients who have received renal transplantation; or

5. Patients who do not meet criteria as set by this policy.

6. Also, growth rate that is less than 2.0 cm/yr of untreated rate; growth that has reached the 25% of normal height for gender; bone age that is over recommended age for gender; or if epiphysis is closed.

An evaluation by a pediatric endocrinologist or a pediatric nephrologist is mandatory for initiation of growth hormone therapy and close monitoring either by a pediatric endocrinologist, pediatric nephrologist or the recipient's primary care physician is required throughout therapy.

Prior authorization will be given for a six month time period for initiation of therapy, and six-12 months for continuation of therapy, dependent upon the response of growth by the recipient.

d. Adults (age 21 and older)

Indications for growth hormone therapy in adults are:

Adults who were growth hormone deficient as children or adolescents.

All of the following criteria must be met:

1. The patient is evaluated by an endocrinologist.

2. Patient has a growth hormone deficiency either alone or with multiple hormone deficiencies (hypopituitarism), as a result of either disease of the pituitary or hypothalamus, or injury to either the pituitary or hypothalamus from surgery radiation therapy or trauma.

3. Patient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormone. Patient has failed to respond to standard growth stimulation tests. Exception: Complete hypopituitarism.

4. Patient has failed a growth hormone stimulation test. Failure generally defined as a maximum peak of <5ng/ml.

e. Human Immune Deficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) Wasting or Cachexia.

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~~Agents selected for treatment must have an FDA approved indication for the diagnosis being treated as stated in the package insert.~~

~~The following criteria must be met for the treatment of HIV/AIDS wasting or cachexia:~~

~~1. Patient must be stable on antiretroviral therapy and compliant with therapy.~~

~~2. Documented involuntary weight loss greater than 10% pre illness baseline or a body mass index of <20KG/M2 (weight and diagnosis must be confirmed by faxed chart notes).~~

~~a. Patient has failed to adequately respond to dietary measures.~~

~~b. Patient has failed to respond or is intolerant to appetite-stimulating drugs, (e.g. Megace) and anabolic steroids.~~

~~c. Absence of a concurrent illness or medical condition other than HIV infection that would explain these findings.~~

~~3. No active malignancy other than Kaposi's Sarcoma.~~

~~Prior authorization will be given for 12 weeks.~~

~~If patient maintains or gains weight, is experiencing no adverse events, and is being monitored on a regular basis by the prescriber, approve the prior authorization for 12 additional weeks. Subsequent prior authorization approvals based on this criteria may be granted in 12 week increments.~~

~~f. Requests involving the following should be denied:~~

~~1. Indications other than those specified above.~~

~~2. Any condition that is considered contraindicated and/or considered to be experimental.~~

~~3. Patients who do not meet the criteria.~~

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

Growth Hormones are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

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1. Coverage and Limitations:

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

a. Genotropin® (somatropin); Humatrope® (somatropin); Norditropin® (somatropin); Nutropin® (somatropin); Omnitrope® (somatropin); Saizen® (somatropin); Tev-Tropin® (somatropin):

1. Children, (up to age 21, with open epiphyses and with remaining growth potential) must meet all of the following:

a. The recipient has had an evaluation by a pediatric endocrinologist or pediatric nephrologist with a recommendation for growth hormone therapy; and

b. The recipient has had an evaluation ruling out all other causes for short stature; and

c. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormones.

The recipient must then meet one of the following:

1. The recipient has a diagnosis of Noonan Syndrome, Prader-Willi Syndrome or Turner Syndrome and their height is as least two standard deviations below the mean or below the third percentile for the patient's age and gender; or

2. The recipient has a diagnosis of chronic renal insufficiency (<75 mL/minute, and their height is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or

3. The recipient has a diagnosis of being small for gestational age, the recipient is two years of age or older, and their height is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or

4. The recipient is a newborn infant with evidence of hypoglycemia, and has low growth hormone level (<20 ng/mL), low for age insulin like growth factor (IGF)-1 or IGF binding protein (BP) 3 (no stimulation test required for infants); or

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5. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma or cranial irradiation), and their height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender.

   And recipient must meet one of the following:

   a. The recipient has failed two growth hormone stimulation tests (<10 ng/mL); or

   b. The recipient has failed one growth hormone stimulation test (<10 ng/mL) and one IGF-1 or IGFBP-3 test; or

   c. The recipient has failed one growth hormone stimulation test (<10 ng/mL) or IGF-1 or IGFBP-3 test and they have deficiencies in three or more pituitary axes (e.g., thyroid stimulating hormone (TSH), luteinizing hormone (LH), follicle stimulating hormone (FSH), adrenocorticotropic hormone (ACTH) or antidiuretic hormone (ADH).

2. Adults, (age 21 years and older, with closed epiphyses, and no remaining growth potential) must meet all of the following:

   a. The recipient is being evaluated by an endocrinologist; and

   b. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids or gonadotropic hormones; and

   c. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation) and

   The recipient must then meet one of the following:

   1. The recipient has failed two growth hormone stimulation tests (<5 ng/mL); or

   2. The recipient has failed one growth hormone stimulation test (<5 ng/mL) and one IGF-1 or IGFBP-3 test; or

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3. The recipient has failed one growth hormone stimulation test (<5 ng/mL) or IGFBP-3 test and has deficiencies in three or more pituitary axes (i.e., TSH, LH, FSH, ACTH, ADH), and has severe clinical manifestations of growth hormone deficiency as evident by alterations in body composition (e.g., decreased lean body mass, increased body fat), cardiovascular function (e.g., reduced cardiac output, lipid abnormalities) or bone mineral density.

3. Continued authorization will be given for recipients (up to age 21, with remaining growth potential) who meet all of the following:

a. The recipient has a diagnosis of chronic renal insufficiency, growth hormone deficiency, hypothalamic pituitary disease, newborn infant with evidence of hypoglycemia, Noonan Syndrome, Prader-Willi Syndrome, small for gestational age or Turner Syndrome; and

b. The recipient's epiphyses are open; and

c. The recipient's growth rate on treatment is at least 2.5 cm/year; and

d. The recipient does not have evidence of an expanding lesion or tumor formation; and

e. The recipient has not undergone a renal transplant.

4. Continued authorization will be given for recipients (age 21 years and older, with closed epiphyses and no remaining growth potential) who meet all of the following:

a. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease; and

b. There is documentation of improvement in clinical manifestations associated with growth hormone deficiency.

b. Serostim® (somatropin)

Recipients must meet all of the following:

1. The recipient has a diagnosis of Human Immune Deficiency Virus (HIV) with wasting or cachexia; and

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2. The medication is indicated to increase lean body mass, body weight and physical endurance; and

3. The recipient is receiving and is compliant with antiretroviral therapy; and

4. The recipient has experienced an involuntary weight loss of >10% pre-illness baseline or they have a body mass index of <20 kg/m²; and

5. The recipient has experienced an adverse event, allergy or inadequate response to megestrol acetate, or the recipient has a contraindication to treatment with this agent; and

6. The recipient has experienced an adverse event, allergy or inadequate response to an anabolic steroid (e.g., testosterone, oxandrolone, nandrolone), or the recipient has a contraindication to treatment with these agents.

c. Zorbtive® (somatropin)

Recipients must meet all of the following:

1. The recipient has a diagnosis of short bowel syndrome; and

2. The recipient is age 18 years or older; and

3. The medication is being prescribed by or following a consultation with a gastroenterologist; and

4. The recipient is receiving specialized nutritional support (e.g., high carbohydrate, low-fat diets via enteral or parenteral nutrition).

2. Prior Authorization Guidelines:

a. Prior Authorization approval will be 12 weeks for Serostim® (somatropin).

b. Prior Authorization approval will be six months for initial authorization (for all somatropin products except for Serostim®).

c. Prior Authorization approval will be one year for continuing treatment (for all somatropin products except Serostim®).

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

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G. ~~Fentora® and Actiq® (Fentanyl Citrate Buccal Tablet and Lozenge)~~Immediate-Release Fentanyl Products

Therapeutic Class: Analgesics, Narcotic
Last Reviewed by the DUR Board: July ~~30, 2009~~ 25, 2013

~~1. Coverage and Limitations~~

~~Fentanyl Citrate and Buccal Tablets and Lozenges~~ Immediate-Release Fentanyl Products are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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. Recipient must be age 18 years or older to receive fentanyl citrate buccal tablets;~~

~~b. Recipient must be age 16 years or older to receive fentanyl citrate lozenges; and~~

~~c. Recipient must have pain due to a malignancy; and~~

~~d. Recipient is already receiving and is tolerant to opioid therapy; and~~

~~e. Recipient is intolerant of two other immediate-release opioids including morphine, hydrocodone, oxycodone, or hydromorphone.~~

~~2. Non-Covered Indications~~

~~a. Recipient with non-malignant pain including but not limited to fibromyalgia, migraines, headaches, peripheral neuropathy, chronic pain syndrome.~~

~~b. Recipient is not opioid tolerant.~~

~~c. Recipient diagnosis is for acute pain or chronic pain due to surgery or injury.~~

~~d. Recipient diagnosis is for migraine/headache pain relief or prevention.~~

~~e. Recipients not taking chronic opiates.~~

a. Subsys® (fentanyl sublingual spray), Onsolis® (fentanyl citrate buccal film), Fentora® (fentanyl citrate buccal tablet), Lazanda® (fentanyl citrate nasal spray), Abstral® (fentanyl citrate sublingual tablet) and Actiq® (fentanyl citrate transmucosal lozenge):

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The recipient must meet all of the following:

1. The recipient is ≥ 18 years of age or ≥ 16 years of age if requesting fentanyl citrate transmucosal lozenge (Actiq®); and

2. The recipient has pain resulting from a malignancy; and

3. The recipient is already receiving and is tolerant to opioid therapy; and

4. The recipient is intolerant of at least two of the following immediate-release opioids: hydrocodone, hydromorphone, morphine or oxycodone.

~~3~~2. Prior Authorization Guidelines

a. ~~Initial p~~Prior ~~a~~Authorization approval will be for six months.

~~Continued coverage will require documentation of continued pain from the malignancy and the recipient is unable to use other oral dosage forms.~~

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

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H. Hematopoietic/Hematinic Agents

Therapeutic Class: Erythropoiesis Stimulating Agents (ESAs)
Last Reviewed by the DUR Board: January 24, 2008

This policy applies in all settings with the exception of inpatient facilities. Hematopoietics and Hematinics are subject to prior authorizations and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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

Recipients must meet one of the following criteria for coverage:

a. Achieve and maintain hemoglobin levels within the range of 10 to 12 gm/dl in one of the following conditions:

1. Treatment of anemia secondary to myelosuppressive anticancer chemotherapy.

2. Treatment of anemia related to zidovudine therapy in HIV-infected patients.

3. Treatment of anemia secondary to End Stage Renal Disease (ESRD).

b. Epoetin alfa (Epogen®) is indicated to reduce the need for allogenic transfusions in surgery patients when a significant blood loss is anticipated. It may be used to achieve and maintain hemoglobin levels within the range of 10 to 13 gm/dl. Darbepoetin Alfa (Aranesp®) does not have this indication.

2. Non-Covered Indications

a. Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis.

b. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers.

c. Anemia of cancer not related to cancer treatment.

d. Any anemia associated only with radiotherapy.

e. Prophylactic use to prevent chemotherapy-induced anemia.

f. Prophylactic use to reduce tumor hypoxia.

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L. Injectable Immunomodulator Drugs

Therapeutic Class: Immunomodulators, Injectable
Last Reviewed by the DUR Board: June 3, 2010

Actemra® (tocilizumab)	Cimzia® (certolizumab pegol)
Amevive® (alefacept)	Kineret® (ankinra)
Enbrel® (etanercept)	Orencia® (abatacept)
Humira® (adalimumab)	Remicade® (infliximab)
Simponi™ (golimumab)	Stelara™ (ustekinumab)

Injectable immunomodulator drugs are subject to prior authorization.

1. Coverage and Limitations

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

a. Rheumatoid Arthritis (Enbrel®, Humira®, Remicade®, Orencia®, Kineret®, Cimzia®, Simponi™, Actemra®):

1. Diagnosis of rheumatoid arthritis; and

2. Rheumatology consult with date of visit; and

3. Negative tuberculin test (Remicade®, Humira®, Orencia®, Cimzia®, Enbrel®, Simponi™, Actemra®) or if positive, therapy with isoniazid was initiated at least one month prior to request;

4. Patient does not have an active infection or a history of recurring infections;

5. Patient has had RA for ≤ six months (early RA) and has high disease activity;

Patient has had RA for ≥ six months (intermediate or long-term disease duration) and has moderate disease activity and has an inadequate response to a Disease Modifying Antirheumatic Drug (DMARD) (methotrexate, hydroxychloroquine, leflunomide, minocycline or sulfasalazine); or

6. Patient has had RA for ≥ six months (intermediate or long-term disease duration) and has high disease activity.

b. Psoriatic Arthritis (Enbrel®, Humira®, Remicade®, Simponi™):

1. Diagnosis of moderate or severe psoriatic arthritis; and

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2. Rheumatology consult with date of visit or Dermatology consult with date of visit;

3. Inadequate response to any one NSAID or contraindication to treatment with an NSAID or to any one of the following DMARD (methotrexate, leflunomide, cyclosporine or sulfasalazine) as documented by a physician;

4. Negative tuberculin test (Enbrel®, Humira®, Remicade®, Simponi™) or if positive, therapy with isoniazid was initiated at least one month prior to request; and

5. Patient does not have active infection or a history of recurring infections.

c. Ankylosing Spondylitis (Enbrel®, Remicade®, Humira®, Simponi™):

1. Diagnosis of ankylosing spondylitis; and

2. Inadequate response to NSAIDs and to any one of the DMARDs (methotrexate, hydroxychloroquine, sulfasalzine, leflunomide, minocycline);

3. Negative tuberculin test (Enbrel®, Humira®, Remicade®, Simponi™) or if positive, isoniazid was initiated at least one month prior to request; and

4. Patient does not have an active infection or a history of recurring infections.

d. Juvenile Rheumatoid Arthritis/Juvenile Idiopathic Arthritis (Enbrel®, Humira®, Orencia®, Actemra®):

1. Diagnosis of moderately or severely active juvenile rheumatoid arthritis; and

2. Patient is at least two years of age; and

3. At least five swollen joints; and

4. Three or more joints with limitation of motion and pain, tenderness or both; and

5. Inadequate response to one DMARD;

6. Negative tuberculin test (Enbrel®, Humira®, Orencia®), or if positive, isoniazid was initiated at least one month prior to request; and

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7. Patient does not have an active infection or a history of recurring infections.

e. Plaque Psoriasis (Amevive®, Enbrel®, Humira®, Remicade®, Stelara™):

1. Diagnosis of chronic, moderate to severe plaque psoriasis; and

2. Prescribed by a dermatologist; and

3. Failed to adequately respond to a topical agent; and

4. Failed to adequately respond to at least one oral treatment;

5. Negative tuberculin test (Amevive®, Humira®, Enbrel®, Remicade®, Stelara™) or if positive, therapy with isoniazid was initiated at least one month prior to request; and

6. Patient does not have an active infection or a history of recurring infections.

f. Crohn's Disease (Cimzia®, Humira®, Remicade®):

1. Diagnosis of moderate to severe Crohn's Disease; and

2. Failed to adequately respond to conventional therapy (e.g. sulfasalzine, mesalamine, antibiotics, corticosteroids, azathioprine, 6-mercaptopurine, parenteral methotrexate) or those with fistulizing Crohn's disease, and;

3. Negative tuberculin test, or if positive, isoniazid therapy was initiated at least one month prior to request (Cimzia®, Humira®, Remicade®); and

4. Patient does not have an active infection or a history of recurring infections.

g. Ulcerative Colitis (Remicade®):

1. Diagnosis of moderate to severe ulcerative colitis; and

2. Failed to adequately respond to one or more of the following standard therapies:

a. Corticosteroids;

b. 5-aminosalicylic acid agents;

c. Immunosuppresants; and/or

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V. Sedative Hypnotics

Therapeutic Class:
Last Reviewed by the DUR Board:

Sedatives Hypnotics are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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~~

~~Quantity limit of 30 tablets per month of only one strength.~~

DRAFT

X. Antiemetics – Serotonin Receptor Antagonists (also known as 5-HT3 Antiemetics)

Therapeutic Class: Antiemetics, Antivertigo Agents
Last Reviewed by the DUR Board: October 28, 2010

1. Coverage and Limitations

5-HT3 Antiemetics are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

An approved prior authorization is required for any prescription exceeding the quantity limits. Approval for additional medication beyond these limits will be considered only under the following circumstances:

a. The recipient has failed on chemotherapy-related antiemetic therapy at lower doses; or

b. The recipient is receiving chemotherapy treatments more often than once a week; or

c. The recipient has a diagnosis of AIDS associated nausea and vomiting; or

d. The recipient has a diagnosis of hyperemesis gravidarum and has failed at least one other antiemetic therapy or all other available therapies are medically contraindicated.

2. Prior Authorization Guidelines

A prior authorization to override the quantity limits to allow for a 30 day fill for these drugs may be effective for up to six months.

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Z. Cymbalta® (duloxetine)

Therapeutic Class: Sertonin-Norepinephrine Reuptake Inhibitor (SNRI)
Last Reviewed by the DUR Board: ~~Not Available~~July 25, 2013

Cymbalta® ~~(duloxetine)~~ is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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. Recipients must meet at least one diagnosis listed below:

~~1.~~a. Diabetic Peripheral Neuropathy (DPN):

~~a.~~1. If an ICD-9 code of 250.6 Diabetes with Neurological Manifestations is documented on the prescription and transmitted on the claim; or

~~b.~~2. Completion of a prior authorization documenting a diagnosis of Diabetes with Neurological Manifestations.

b. ~~2.~~ Fibromyalgia:

1. ~~a.~~ If an ICD-9 code 729.1 Myalgia and Myositis unspecified is documented on the prescription and transmitted on the claim; or

2. ~~b.~~ Completion of a prior authorization documenting a diagnosis of Fibromyalgia and/or Myalgia and Myositis, unspecified.

c. Chronic Musculoskeletal Pain:

The recipient must meet one of the following:

1. The recipient has experienced an inadequate response or adverse event to at least two oral or topical non-steroidal anti-inflammatory drug (NSAIDS); or

2. The recipient has an allergy or contraindication to two NSAIDS.

d. Generalized Anxiety Disorder:

The recipient must meet the following:

1. The recipient has experienced an inadequate response or adverse event to at least two antidepressants from any of the following classes: selective serotonin reuptake inhibitors, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors or buspirone.

e. Major Depressive Disorder:

The recipient must meet the following:

1. The recipient has experienced an inadequate response, and/or adverse event and/or an allergy and/or contraindication to at least two antidepressants.

2. Prior Authorization Guidelines

a. Prior Authorization approval will be for one year.

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

DRAFT

BB. Buprenorphine/Naloxone (Suboxone®) ~~(buprenorphine/naloxone)~~ and Buprenorphine (Subutex®) ~~(buprenorphine)~~

Therapeutic Class: Narcotic Withdrawal Therapy Agents
Last Reviewed by the DUR Board: ~~June 3, 2010~~ July 25, 2013

Buprenorphine/Naloxone (Brand Suboxone®) and Buprenorphine (Brand Subutex®) ~~is~~ are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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

Nevada Medicaid encourages recipients to participate in formal substance abuse counseling and treatment.

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

~~a. Diagnosis of Opioid Dependence;~~

~~b. Patient is 16 years of age or older;~~

~~c. Medication is prescribed by a physician with a Drug Addiction Treatment Act (DATA) of 2000 waiver:~~

~~1. Authorizes a physician to treat narcotic-dependent patients using Schedule III-V substances without obtaining a separate Drug Enforcement Agency (DEA) registration as a narcotic treatment program.~~

~~2. A Unique Identification Number (UIN), in addition to the DEA number, is required on the prescription, and is the same as the DEA number except an "X" replaces the first alpha character of the DEA number.~~

~~d. Formal substance abuse counseling/treatment must be in place or, if the prescriber is a psychiatrist or certified addiction specialist, they may confirm that they personally render the counseling;~~

~~e. Document the name of the specific substance abuse program or the name of the psychiatrist or certified addiction specialist that will provide the counseling services. The program license number and/or the treating psychiatrist's or certified addiction specialist's license number may be requested and documented; and~~

~~f. Confirm that the patient has honored all of their office visits and counseling sessions in a compliant manner.~~

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a. Buprenorphine/Naloxone (Suboxone®)

The recipient must meet all of the following:

1. The recipient has a diagnosis of opioid dependence; and

2. The recipient is 16 years of age or older; and

3. There is documentation that the recipient has honored all of their office visits; and

4. The medication is being prescribed by a physician with a Drug Addiction Treatment Act (DATA) of 2000 waiver who has a unique "X" DEA number.

b. Buprenorphine (Subutex®) (for female recipients):

The recipient must meet all of the following:

1. There is documentation that the recipient is pregnant or there is documentation the recipient is breastfeeding an infant who is dependent on methadone or morphine; and

2. The recipient has a diagnosis of opioid dependence; and

3. The recipient is 16 years of age or older; and

4. There is documentation that the recipient has honored all of their office visits; and

5. The medication is being prescribed by a physician with a Drug Addiction Treatment Act (DATA) of 2000 waiver who has a unique "X" DEA number.

2. Prior Authorization Guidelines

a. Prior Authorization approval will be for one year.

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

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CC. Ampyra™® (dalfampridine)

Therapeutic Class: Agents for the treatment of Neuromuscular Transmission Disorder
Last Reviewed by the DUR Board: ~~July 22, 2010~~ July 25, 2013

Ampyra™® (dalfampridine) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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 for Ampyra™® (dalfampridine) will be given if all of the following criteria are met and documented:

~~a. Prescriber is a neurologist;~~

~~b. The patient has a diagnosis of Multiple Sclerosis (ICD-9 code of 340);~~

~~c. The use is for the FDA Approved Indication: to improve walking;~~

~~d. The patient is ambulatory and has an EDSS score between 2.5 and 6.5;~~

~~e. The patient has undergone a timed 25 foot walk to establish baseline walking speed and baseline walking speed is documented to be between eight and 45 seconds;~~

~~f. The patient does not have moderate to severe renal dysfunction (CrCL > 50ml/min);~~

~~g. The patient does not have a history of seizures; and~~

~~h. The patient is not pregnant.~~

a. Ampyra® (dalfampridine)

The recipient must meet all of the following:

1. The recipient must have a diagnosis of Multiple Sclerosis (ICD-9 code of 340); and

2. The medication is being used to improve the recipient's walking speed; and

3. The medication is being prescribed by or in consultation with a neurologist; and

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4. The recipient is ambulatory and has an EDSS score between 2.5 and 6.5; and

5. The recipient does not have moderate to severe renal dysfunction (CrCL >50 ml/min); and

6. The recipient does not have a history of seizures; and

7. The recipient is not currently pregnant or attempting to conceive.

2. Prior Authorization Guidelines

~~The prior authorization initial approval duration is 12 weeks. At 12 weeks of treatment, the prescriber may request continuation of the prior authorization.~~

a. Initial Prior Authorization approval will be for three months.

b. Requests for continuation of therapy will be approved for one year.

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

~~3. Criteria for renewal of the prior authorization~~

~~Approval for continuation of Ampyra™ (dalfampridine) will be given if all of the following criteria are met and documented:~~

~~a. Patient still meets all initial criteria;~~

~~b. Patient has demonstrated an improvement in timed walking speed of at least 20% on Ampyra™; and~~

~~c. The patient is not pregnant.~~

~~4. Renewal Prior Authorization Guidelines~~

~~The duration of renewal of the prior authorization is one year.~~

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

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FF. Pradaxa® (dabigatran etexilate); Eliquis® (apixaban); Xarelto® (rivaroxaban)

Therapeutic Class: Thrombin Inhibitors
Last Reviewed by the DUR Board: ~~Not Available~~ July 25, 2013

Pradaxa® (dabigatran etexilate), Eliquis® (apixaban) and Xarelto® (rivaroxaban) ~~is~~ are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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. ~~Recipient has a diagnosis of non-valvular (no prosthetic valve) atrial fibrillation; and~~Pradaxa® (dabigatran etexilate)

1. An ICD-9 code of 427.31 (Atrial Fibrillation) documented on the prescription and transmitted on the claim; or

2. An approved Prior Authorization documenting the recipient having all of the following and:

a. The recipient has a diagnosis of nonvalvular Atrial Fibrillation; and

b. The recipient does not have an active pathological bleed; and

c. The recipient does not have a mechanical prosthetic heart valve.

~~b. Recipient has at least one of the following documented risk factors for stroke:~~

~~1. History of stroke, TIA, or systemic embolism; or~~

~~2. Age ≥75 years; or~~

~~3. Diabetes Mellitus; or~~

~~4. History of left ventricular dysfunction or heart failure; or~~

~~5. Age ≥65 years with the presence of one of the following:~~

~~1. Diabetes mellitus; or~~

~~2. Coronary artery disease (CAD); or~~

~~3. Hypertension; and~~

~~c. Recipient has failed warfarin therapy or has a contraindication to warfarin therapy. Failure consists of an adequate trial of at least three months where the goal INR (2.0-3.0) has not been achieved (most recent two INR values outside of the therapeutic range). If recipient is being transitioned from warfarin to dabigatran etexilate, current INR is <2.0; and~~

~~d. Recipient is >18 years of age; and~~

~~e. Recipient does not have a history of any of the following:~~

~~1. Gastrointestinal bleeding.~~

~~2. Pathological bleeding.~~

~~3. Rheumatic heart disease.~~

~~4. Mechanical valve prosthesis.~~

~~5. Mitral valve disease.~~

~~6. Severe renal impairment (estimated creatitine clearance <15 mL/minute) or on dialysis.~~

~~7. Inability to take capsules whole (capsules must not be broken, chewed or opened).~~

~~8. Recipient is not receiving traditional (non-selective) nonsteroidal anti-inflammatory drugs (NSAIDs).~~

~~2. Length of approval: up to one year.~~

b. Eliquis® (apixaban)

1. An ICD-9 code of 427.31 (Atrial Fibrillation) documented on the prescription and transmitted on the claim; or

2. An approved Prior Authorization documenting the recipient having all of the following:

a. The recipient has a diagnosis of nonvalvular Atrial Fibrilation; and

b. The recipient does not have an active pathological bleed.

c. Xarelto® (rivaroxaban)

1. An ICD-9 code of 427.31 (Atrial Fibrillation) or an ICD-9 code beginning with 415.1 (Pulmonary Embolism and Infarction) or an ICD-9 code

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beginning with 453.4 (Acute Venous Embolism and Thrombosis of Deep Vessels of Lower Extremity) documented on the prescription and transmitted on the claim; or

2. An approved Prior Authorization documenting the recipient meeting all of the following:

a. The recipient has a diagnosis of nonvalvular Atrial Fibrillation, or Deep Vein Thrombosis (DVT), or Pulmonary Embolism (PE), or treatment is needed for the reduction in the risk of recurrence of the DVT or PE; and

b. The recipient does not have an active pathological bleed.

2. Prior Authorization Guidelines

a. Prior Authorization approval will be for up to one year.

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

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KK. ~~Xarelto® (rivaroxaban)~~Hereditary Angioedema Agents

~~Therapeutic Class: Direct Factor XO Inhibitors~~
~~Last Reviewed by the DUR Board: July 26, 2012~~

~~Xarelto® (rivaroxaban) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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 the following criteria are met and documented:~~

~~a. The recipient has a diagnosis of nonvalvular atrial fibrillation;~~

~~b. The recipient does not have an active pathological bleed; and~~

~~c. The recipient has failed to consistently achieve and maintain an INR of 2.0 to 3.0 on warfarin therapy despite an adequate trial that included patient education and dose titration; or~~

~~d. The recipient experienced an adverse event with warfarin therapy; or~~

~~e. The recipient has an allergy or contraindication to warfarin therapy; or~~

~~f. The recipient has a barrier of access to care.~~

~~2. Prior Authorization Guidelines:~~

~~a. Prior authorization will be for one year.~~

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

~~c. Xarelto® 10 mg tablets are available without prior authorization and are indicated for the prophylaxis of deep vein thrombosis in patients undergoing knee or hip replacement surgery.~~

Therapeutic Class: Hereditary Angioedema Agents
Last Reviewed By DUR Board: July 25, 2013

Hereditary angioedema agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

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1. Coverage and Limitations

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

a. Cinryze® (C1 esterase inhibitor)

The recipient must meet all of the following:

1. The recipient has a diagnosis of hereditary angioedema; and

2. The medication is being prescribed by or in consultation with an allergist or immunologist; and

3. The medication is being used as prophylaxis for hereditary angioedema attacks; and

4. The recipient has experienced an inadequate response or adverse event with an attenuated androgen (e.g. danazol, stanozolol) or antifibrinolytic (e.g. tranexamic acid, aminocaproic acid) agent or has a contraindication to all agents in these classes; and

5. The recipient routinely experiences more than one hereditary angioedema attack per month, or the recipient has a history of laryngeal attacks.

b. Berinert® (C1 esterase inhibitor), Kalbitor® (ecallantide) and Firazyr® (icatibant)

The recipient must meet all of the following:

1. The recipient has a diagnosis of hereditary angioedema; and

2. The medication is being prescribed by or in consultation with an allergist or immunologist; and

3. The medication is being used to treat acute hereditary angioedema attacks.

2. Prior Authorization Guidelines

a. Initial Prior Authorization approval will be for six months.

b. Prior Authorization requests for continuation therapy will be approved for one year.

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

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RR. Cesamet® (Nabilone) and Marinol® (Dronabinol)

Therapeutic Class: Antiemetic
Last Reviewed by DUR Board: October 25, 2012

Cesamet® (Nabilone) and Marinol® (Dronabinol) are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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 all the following criteria are met and documented:

a. Cesamet® (Nabilone)

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

2. The recipient has experienced an inadequate response, adverse event, or has a contraindication to at least one serotonin receptor antagonist; and

3. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

4. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

b. Marinol® (Dronabinol)

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

a. ~~2.~~ The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and

b. ~~3.~~ The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

c. ~~4.~~ The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient; or

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~~5~~2. The recipient has been diagnosed with Acquired Immune Deficiency Syndrome (AIDS) and has anorexia associated with weight loss; and

a. ~~6.~~ The recipient has experienced an inadequate response, adverse event or has a contraindication to megestrol (Megace®); and

b. ~~7.~~ The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

2. Prior Authorization Guidelines

a. Prior Authorization approval will be for one year.

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

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SS. Omontys® (Peginesatide)

Therapeutic Class: Erythropoiesis Stimulating Agent (ESA)
Last Reviewed by DUR Board: October 25, 2012

Omontys® (Peginesatide) is subject to prior authorization based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board.

1. Coverage and Limitations

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

a. The recipient has a diagnosis of anemia secondary to chronic kidney disease, and

b. The recipient must be over 18 years of age;

c. The recipient is receiving dialysis;

d. Other causes for anemia have been evaluated and ruled out (e.g., iron, vitamin B12 or folate deficiencies);

e. The recipient's hemoglobin level is <10 g/dL, (laboratory values from the previous 14 days must accompany the request); and

f. The target hemoglobin level will not exceed 11 g/dL.

2. Prior Authorization Guidelines

a. Prior Authorization approval will be for one ~~year~~month.

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

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TT. Colony Stimulating Factors (Point of Sale Claims Only)

Therapeutic Class: Colony Stimulating Factors
Last Reviewed by the DUR Board: July 25, 2013

Colony Stimulating Factors are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act 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. Leukine® (sargramostim)

The recipient must meet one of the following:

1. The requested medication is being used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; or

2. The recipient has a diagnosis of acute myeloid leukemia, and has received induction chemotherapy; or

3. The recipient has a diagnosis of non-Hodgkin's lymphoma, acute lymphoblastic leukemia or Hodgkin's disease and is undergoing autologous bone marrow transplantation; or

4. The recipient is undergoing allogeneic bone marrow transplantation from human leukocyte antigen-matched related donors; or

5. The recipient has undergone allogeneic or autologous bone marrow transplantation and is experiencing engraftment failure or delay.

b. Neulasta® (pegfilgrastim)

The recipient must meet the following criteria:

1. The recipient has a diagnosis of nonmyeloid malignancy and

a. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile neutropenia risk of ≥ 20%; or

b. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age >65, absolute

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neutrophil count (ANC) <100 cells/µL, or the expected duration of neutropenia is > 10 days); or

c. The recipient has experienced a prior episode of febrile neutropenia and the requested drug will be used as secondary prophylaxis.

c. Neupogen® (filgrastim)

The recipient must meet one of the following (1 to 5):

1. The recipient has a diagnosis of nonmyeloid malignancy; and

a. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile neutropenia risk of ≥20%; or

b. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age >65, ANC <100 cells/µL or the expected duration of neutropenia is >10 days); or

c. The recipient has experienced a prior episode of febrile neutropenia and the requested drug will be used as a secondary prophylaxis; or

2. The recipient has a diagnosis of acute myeloid leukemia and has received induction or consolidation chemotherapy; or

3. The recipient has a diagnosis of nonmyeloid malignancy and is undergoing myeloablative chemotherapy followed by marrow transplantation; or

4. The recipient has a diagnosis of symptomatic congenital neutropenia, cyclic neutropenia or idiopathic neutropenia; or

5. The requested medication is being used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

2. Prior Authorization Guidelines

a. Prior Authorization approval will be for one month.

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

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