

# IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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August 2, 2023

Susan L. Parker, R.Ph, Pharm.D.  
Pharmacy Director  
Iowa Medicaid  
1305 East Walnut  
Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 2, 2023. At this meeting, the DUR Commission members discussed new or updated PA criteria for Palivizumab (Synagis); IL-5 Antagonists; Select Anticonvulsants; Cyclosporine Ophthalmic Emulsion (Verkazia); Topical Acne and Rosacea Products; and removal of PA criteria and quantity limit for Naloxone Nasal Spray. In addition, the DUR Commission discussed ProDUR quantity limits for Verkazia and Winlevi. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a May 5, 2023 letter that was sent to them detailing the new or updated PA criteria for Palivizumab (Synagis); IL-5 Antagonists; Select Anticonvulsants; Cyclosporine Ophthalmic Emulsion (Verkazia); Topical Acne and Rosacea Products; removal of PA criteria and quantity limit for Naloxone Nasal Spray, as well as recommended ProDUR quantity limits for Verkazia and Winlevi.

## **Palivizumab (Synagis)**

### Current Clinical Prior Authorization Criteria

Respiratory Syncytial Virus (RSV) Season is defined by the centers for disease control and prevention of the United States department of health and human services and described in the RSV surveillance reports published annually in the Morbidity and Mortality Weekly Report (MMWR) and available at <http://www.cdc.gov/surveillance/nrevss/rsv/reports.html>.

1. Medicaid will use virology data provided by the Iowa department of public health (IDPH) to prospectively estimate the start of the RSV season and follow the virology data to the end of the season.
2. Medicaid will provide coverage of prescription drugs that protect against RSV consistent with the current American Academy of Pediatrics (AAP) Guidelines for Infants and Children at Risk for Severe Illness due to RSV Infection.

3. The start date will begin two weeks prior to the expected season start date for the state of Iowa. The start date will be adjusted to an earlier date by Medicaid if indicated by the virological data. The expected season start date shall be derived from the median start date of the past 5 seasons using Iowa virological data.

Prior authorization (PA) is required for therapy with palivizumab. PAs will be approved for administration during the RSV season for a maximum of five doses per patient. No allowances will be made for a sixth dose. Patients who experience a breakthrough RSV hospitalization should have their monthly prophylaxis discontinued, as there is an extremely low likelihood of a second RSV hospitalization in the same season. Payment for palivizumab will be considered for patients who meet one of the following criteria:

#### Chronic Lung Disease (CLD) of Prematurity

1. Patient is less than 12 months of age at start of therapy and has CLD of prematurity (defined as gestational age less than 32 weeks and required greater than 21% oxygen for at least the first 28 days after birth).
2. Requests for patients during their second year of life (12 months to < 24 months) will be considered for patients meeting the CLD of prematurity definition above and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.

#### Prematurity (without CLD of Prematurity or Congenital Heart Disease)

1. Patient is less than 12 months of age at start of therapy with a gestational age of less than 29 weeks.

#### Neuromuscular Disorders or Anatomic Pulmonary Abnormalities

1. Patient is 12 months of age or younger at the start of therapy and has either severe neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway due to an ineffective cough.

#### Hemodynamically Significant Congenital Heart Disease (CHD)

1. Patient is less than 12 months of age at start of therapy and has hemodynamically significant CHD further defined by any of the following: Acyanotic heart disease receiving medication to control congestive heart failure and will require cardiac surgical procedures, moderate to severe pulmonary hypertension, or cyanotic heart defects with documentation of consultation with a pediatric cardiologist that recommends palivizumab prophylaxis.

#### Immunocompromised Children

1. Patient is less than 24 months of age at start of therapy and is profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, receiving chemotherapy).

#### Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)

*Respiratory Syncytial Virus (RSV) surveillance is tracked* ~~Season is defined by the national respiratory and enteric virus surveillance system (NREVSS) on the centers for disease control and prevention of the United States department of health and human services website. and described in the RSV surveillance reports published annually in the Morbidity and Mortality Weekly Report (MMWR) and available at <http://www.cdc.gov/surveillance/nrevss/rsv/reports.html>.~~

1. Medicaid will use *Iowa* virology data *reported to the NREVSS, as documented under RSV state trends.* ~~provided by the Iowa department of public health (IDPH) to prospectively estimate the start of the RSV season and follow the virology data to the end of the season.~~
2. Medicaid will provide coverage of prescription drugs that protect against RSV consistent with the current American Academy of Pediatrics (AAP) Guidelines for Infants and Children at Risk for Severe Illness due to RSV Infection.

3. *The RSV season in Iowa is predefined as November 1<sup>st</sup> through March 31<sup>st</sup> of each RSV season. Prescribers and dispensing pharmacies should monitor state specific virology data and hold administration of palivizumab if data indicates RSV is not prevalent at the beginning of the predefined Iowa RSV season. Consideration of use of palivizumab during interseasonal spread of RSV may be considered by Medicaid with widespread RSV circulation. The start date will begin two weeks prior to the expected season start date for the state of Iowa. The start date will be adjusted to an earlier date by Medicaid if indicated by the virological data. The expected season start date shall be derived from the median start date of the past 5 seasons using Iowa virological data.*

Prior authorization (PA) is required for therapy with palivizumab. PAs will be approved for administration during the RSV season for a maximum of five doses per patient. No allowances will be made for a sixth dose. Patients who experience a breakthrough RSV hospitalization *in the prior 5 months* should have their monthly prophylaxis discontinued, as there is an extremely low likelihood of a second RSV hospitalization in the same season. Payment for palivizumab will be considered for patients who meet one of the following criteria:

#### Chronic Lung Disease (CLD) of Prematurity

1. Patient is less than 12 months of age at start of therapy and has CLD of prematurity (defined as gestational age less than 32 weeks and required greater than 21% oxygen for at least the first 28 days after birth).
2. Requests for patients during their second year of life (12 months to < 24 months) will be considered for patients meeting the CLD of prematurity definition above and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.

#### Prematurity (without CLD of Prematurity or Congenital Heart Disease)

1. Patient is less than 12 months of age at start of therapy with a gestational age of less than 29 weeks.

#### Neuromuscular Disorders or Anatomic Pulmonary Abnormalities

1. Patient is 12 months of age or younger at the start of therapy and has either severe neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway due to an ineffective cough.

#### Hemodynamically Significant Congenital Heart Disease (CHD)

1. Patient is less than 12 months of age at start of therapy and has hemodynamically significant CHD further defined by any of the following: Acyanotic heart disease receiving medication to control congestive heart failure and will require cardiac surgical procedures, moderate to severe pulmonary hypertension, or cyanotic heart defects with documentation of consultation with a pediatric cardiologist that recommends palivizumab prophylaxis.

#### Immunocompromised Children

1. Patient is less than 24 months of age at start of therapy and is profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, receiving chemotherapy).

## **IL-5 Antagonists**

### Current Clinical Prior Authorization Criteria

Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. Is requested for an FDA approved or compendia indicated diagnosis; and

2. Patient meets the FDA approved or compendia indicated age and dose for submitted diagnosis; and
3. Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and
  - a. Patient has a pretreatment blood eosinophil count of  $\geq 150$  cells/mcL within the previous 6 weeks or blood eosinophils  $\geq 300$  cells/ mcL within 12 months prior to initiation of therapy; and
  - b. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and
  - c. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and
  - d. A pretreatment forced expiratory volume in 1 second ( $FEV_1$ )  $< 80\%$  predicted in adults and  $< 90\%$  in adolescents; or
4. Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and
  - a. Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and
  - b. One of the following:
    - i. Eosinophil count  $> 1000$  cells/mcL; or
    - ii. Eosinophil count  $> 10\%$  of the total leukocyte count; and
5. Patient has a diagnosis of hypereosinophilic syndrome (HES); and
  - a. Patient has been diagnosed with HES for  $\geq 6$  months prior to starting treatment; and
  - b. Documentation that non-hematologic secondary causes of HES have been ruled out; and
  - c. Documentation patient does not have FIP1L1-PDGFR $\alpha$  kinase-positive HES; and
  - d. Documentation of  $\geq 2$  HES flares within the previous 12 months while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and
  - e. Patient has a blood eosinophil count  $\geq 1,000$  cells/mcL; and
  - f. Medication will be used in combination with stable doses of at least one other HES therapy; and
6. Prescribed by or in consultation with an allergist, hematologist, immunologist, pulmonologist, or rheumatologist.

If criteria for coverage are met, an initial authorization will be given for 3 months for a diagnosis of severe asthma with an eosinophilic phenotype and eosinophilic granulomatosis with polyangiitis or 6 months for a diagnosis of hypereosinophilic syndrome to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:

Severe Asthma with an Eosinophilic Phenotype:

1. Patient continues to receive therapy with an ICS, LABA and LTRA; and
2. Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or
3. Patient has experienced a decrease in administration of rescue medication (albuterol); or
4. Patient has experienced a decrease in exacerbation frequency; or
5. Patient has experienced an increase in predicted  $FEV_1$  from the pretreatment baseline.

Eosinophilic Granulomatosis with Polyangiitis

1. Patient has demonstrated a positive clinical response to therapy (increase in remission time).

Hypereosinophilic Syndrome:

1. Patient has demonstrated positive clinical response to therapy (improvement of symptoms and/or reduction in the number of flares); and
2. Medication continues to be used in combination with stable doses or at least one other HES therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)

Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered *when patient has an FDA approved or compendia indication for the requested drug* under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations* ~~is requested for an FDA approved or compendia indicated diagnosis; and~~
2. ~~Patient meets the FDA approved or compendia indicated age and dose for submitted diagnosis; and~~
3. Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and
  - a. Patient has a pretreatment blood eosinophil count of  $\geq 150$  cells/mcL within the previous 6 weeks or blood eosinophils  $\geq 300$  cells/ mcL within 12 months prior to initiation of therapy; and
  - b. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and
  - c. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and
  - d. A pretreatment forced expiratory volume in 1 second (FEV<sub>1</sub>)  $< 80\%$  predicted in adults and  $< 90\%$  in adolescents; or
4. Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and
  - a. Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and
  - b. One of the following:
    - i. Eosinophil count  $> 1000$  cells/mcL; or
    - ii. Eosinophil count  $> 10\%$  of the total leukocyte count; ~~and-or~~
5. Patient has a diagnosis of hypereosinophilic syndrome (HES); and
  - a. Patient has been diagnosed with HES for  $\geq 6$  months prior to starting treatment; and
  - b. Documentation that non-hematologic secondary causes of HES have been ruled out; and
  - c. Documentation patient does not have FIP1L1-PDGFR $\alpha$  kinase-positive HES; and
  - d. Documentation of  $\geq 2$  HES flares within the previous 12 months while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and
  - e. Patient has a blood eosinophil count  $\geq 1,000$  cells/mcL; and
  - f. Medication will be used in combination with stable doses of at least one other HES therapy; ~~and or~~

6. Patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP); and
  - a. Documentation mepolizumab will be used as an add-on maintenance treatment with a nasal corticosteroid spray; and
  - b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
    - i. Nasal corticosteroid spray; and
    - ii. Oral corticosteroid; and
7. Prescribed by or in consultation with an allergist, hematologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

If criteria for coverage are met, an initial authorization will be given for 3 months for a diagnosis of severe asthma with an eosinophilic phenotype and eosinophilic granulomatosis with polyangiitis or 6 months for a diagnosis of hypereosinophilic syndrome or CRSwNP to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:

Severe Asthma with an Eosinophilic Phenotype:

1. Patient continues to receive therapy with an ICS, LABA and LTRA; and
2. Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or
3. Patient has experienced a decrease in administration of rescue medication (albuterol); or
4. Patient has experienced a decrease in exacerbation frequency; or
5. Patient has experienced an increase in predicted FEV<sub>1</sub> from the pretreatment baseline.

Eosinophilic Granulomatosis with Polyangiitis

1. Patient has demonstrated a positive clinical response to therapy (increase in remission time).

Hypereosinophilic Syndrome:

1. Patient has demonstrated positive clinical response to therapy (improvement of symptoms and/or reduction in the number of flares); and
2. Medication continues to be used in combination with stable doses or at least one other HES therapy.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

1. Patient has demonstrated positive clinical response to therapy (improvement in symptoms.); and
2. Continues to receive medication as add-on maintenance therapy with a nasal corticosteroid spray.

## Select Anticonvulsants

### Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for select anticonvulsants. Payment will be considered under the following conditions:

1. Patient meets the FDA approved age for submitted diagnosis and drug; and
2. Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, with documentation of an adequate trial and inadequate response with at least two preferred concomitant antiepileptic drugs (AEDs), if available; and
3. Is prescribed by or in consultation with a neurologist; and
4. Patient's current weight is provided; and

5. Follows FDA approved dosing for indication and drug. The total daily dose does not exceed the following:
  - a. Cannabidiol
    - i. Lennox-Gastaut syndrome or Dravet syndrome: 20 mg/kg/day; or
    - ii. Tuberous sclerosis complex: 25 mg/kg/day; or
  - b. Fenfluramine
    - i. With concomitant stiripentol (plus clobazam): 0.4 mg/kg/day with a maximum of 17 mg per day; or
    - ii. Without concomitant stiripentol: 0.7 mg/kg/day with a maximum of 26 mg per day; or
  - c. Stiripentol
    - i. Prescribed concomitantly with clobazam; and
    - ii. 50 mg/kg/day with a maximum of 3,000 mg/day.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized/stricken)

Prior authorization (PA) is required for select anticonvulsants. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; Patient meets the FDA approved age for submitted diagnosis and drug; and*
2. Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, ~~or~~ tuberous sclerosis complex, *or cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder* with documentation of an adequate trial and inadequate response with at least two preferred concomitant antiepileptic drugs (AEDs), if available; and
3. Is prescribed by or in consultation with a neurologist; and
4. Patient's current weight is provided; and
5. ~~Follows FDA approved dosing for indication and drug.~~ The total daily dose does not exceed the following:
  - a. Cannabidiol
    - i. Lennox-Gastaut syndrome or Dravet syndrome: 20 mg/kg/day; or
    - ii. Tuberous sclerosis complex: 25 mg/kg/day; or
  - b. Fenfluramine
    - i. With concomitant stiripentol (plus clobazam): 0.4 mg/kg/day with a maximum of 17 mg per day; or
    - ii. Without concomitant stiripentol: 0.7 mg/kg/day with a maximum of 26 mg per day; or
  - c. Stiripentol
    - i. Prescribed concomitantly with clobazam; and
    - ii. 50 mg/kg/day with a maximum of 3,000 mg/day; *or*
  - d. *Ganaxolone*
    - i. *Weight ≤ 28 kg: 63 mg/kg/day; or*
    - ii. *Weight > 28 kg: 1800 mg/day.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

## **Cyclosporine Ophthalmic Emulsion 0.1% (Verkazia)**

### Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for cyclosporine 0.1% ophthalmic emulsion (Verkazia). Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of moderate to severe vernal keratoconjunctivitis (VKC); and
3. Documentation of an adequate trial (2 to 3 weeks) and therapy failure with a preferred topical dual-acting mast cell stabilizer/topical antihistamine (e.g., olopatadine, azelastine); and
4. Documentation of an adequate trial (2 to 3 weeks) and therapy failure with a preferred topical ophthalmic corticosteroid (e.g., dexamethasone, prednisolone, fluorometholone, loteprednol); and
5. Is prescribed by or in consultation with an ophthalmologist or optometrist; and
6. Is not prescribed in combination with other ophthalmic cyclosporine products.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Initial requests will be approved for 6 months. Additional authorizations will be considered upon documentation of clinical response to therapy.

## **Topical Acne and Rosacea Products**

### Current Prior Authorization Criteria

Prior authorization (PA) is not required for preferred topical acne agents (topical antibiotics and topical retinoids) for members under 21 years of age. PA is required for preferred topical acne agents for members 21 years or older, non-preferred topical acne agents and all topical rosacea agents. Payment will be considered under the following conditions:

1. Documentation of diagnosis; and
2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid; and
3. Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid); and
4. Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent; and
5. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products; and
6. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis; and



7. Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

#### Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized/stricken)

Prior authorization (PA) is not required for preferred topical acne agents (topical antibiotics and topical retinoids) for members under 21 years of age. PA is required for preferred topical acne agents for members 21 years or older, non-preferred topical acne agents and all topical rosacea agents. Payment will be considered *when member has an FDA approved or compendia indication for the requested drug, except for any drug or indication excluded from coverage, as defined in Section 1927 (2)(d) of the Social Security Act, Iowa's CMS approved State Plan, and the Iowa Administrative Code (IAC) when* under the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Documentation of diagnosis; and
3. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid; and
4. Payment for non-preferred topical *antibiotic or topical retinoid* acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid); and
5. *Payment for non-preferred topical acne products outside of the antibiotic or retinoid class (e.g., Winlevi) will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred topical retinoid and at least two other topical acne agents. If criteria for coverage are met, initial requests will be approved for six months; and*
6. Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent; and
7. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products; and
8. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis; and
9. Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

#### **Naloxone Nasal Spray**

Naloxone nasal spray PA criteria and the number of naloxone doses allowed per year was reviewed by the DUR Commission due to provider confusion regarding coverage and requirements. After discussion, in order to remove barriers to access of naloxone, the DUR Commission made a recommendation to remove current PA criteria and current quantity limits and monitor for appropriate utilization post-payment.

Current Clinical Prior Authorization (recommendation to remove PA criteria)

Prior authorization (PA) is required for a patient requiring more than 2 doses of naloxone nasal spray per 365 days. Requests for quantities greater than 2 doses per 365 days will be considered under the following conditions:

1. Documentation is provided indicating why patient needs additional doses of naloxone nasal spray (accidental overdose, intentional overdose, other reason); and
2. Naloxone nasal spray is to be used solely for the patient it is prescribed for; and
3. The patient is receiving an opioid as verified in pharmacy claims; and
4. Patient has been reeducated on opioid overdose prevention; and
5. Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and
6. A treatment plan is included documenting a plan to lower the opioid dose.

**Proposed ProDUR Quantity Limits**

<b>Drug Product</b>	<b>Quantity</b>	<b>Days Supply</b>
Verkazia (cyclosporine ophthalmic emulsion 0.1%)	1 box (120 single-dose vials)	30
Winlevi (clascoterone cream 1%)	60 gm (1 tube)	30

Thank you in advance for the Department’s consideration of accepting the DUR Commission’s recommendations for Palivizumab (Synagis); IL-5 Antagonists; Select Anticonvulsants; Cyclosporine Ophthalmic Emulsion (Verkazia); Topical Acne and Rosacea Products; removal of PA criteria and quantity limit for Naloxone Nasal Spray, as well as recommended ProDUR quantity limits for Verkazia and Winlevi.

Sincerely,



Pamela Smith, R.Ph.  
Drug Utilization Review Project Coordinator  
Iowa Medicaid

Cc: Erin Halverson, R.Ph, Iowa Medicaid  
Gina Kuebler, R.Ph, Iowa Medicaid