**09-J2000-54**

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# Subject: Mepolizumab (Nucala)

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|---|---|---|---|---|---|
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## DESCRIPTION:

Mepolizumab (Nucala), a humanized IL-5 antagonist monoclonal antibody, was approved by the U.S. Food and Drug Administration (FDA) in November 2015 for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. In December 2017, mepolizumab was approved for treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). In 2019, a single-dose, prefilled auto-injector and prefilled syringe became commercially available for self-administration.

The safety and effectiveness of mepolizumab was established in three multicenter, double-blind, randomized, placebo-controlled trials and two open-label extension studies of the initial trials in individuals with severe eosinophilic asthma confirmed by blood eosinophils ≥ 150 cells/microliter at initiation of treatment or blood eosinophils ≥ 300 cells/microliter in the past 12 months. Study data confirms the efficacy of mepolizumab in reducing exacerbations that require hospitalization and/or emergency department visits and improvement in asthma control (that is, a longer time to the first exacerbation) and quality of life measures.

DREAM, an international, multicenter, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging dose selection trial, evaluated the efficacy and safety of mepolizumab on rates of exacerbation in individuals with severe recurrent asthma exacerbations and evidence of eosinophilic inflammation (e.g., sputum eosinophils, peripheral blood eosinophilia, or elevated exhaled nitric oxide) (n=621). Participants were required to be on background maintenance therapy with a high-dose ICS for the prior 12 months (with or without oral corticosteroids) plus an additional controller (LABA, leukotriene inhibitor, or theophylline) medication. Subjects received either intravenous mepolizumab at 75 mg, 250 mg, or 750 mg or placebo at 4-week intervals to week 48 (13 infusions). The primary outcome, an annualized rate of clinically significant asthma exacerbations, was decreased in all mepolizumab groups compared with placebo with the greatest reduction in the 750 mg group (52%

reduction; 95% CI 36%-64%; p<0.0001). The effects of mepolizumab on symptoms and quality of life and pulmonary function (FEV1) did not differ significantly from those reported with placebo. The frequency of serious adverse events was similar across treatment groups. There were no reports of serious life-threatening anaphylactic reactions.

SIRIUS, a phase III multicenter, randomized, double-blind, placebo-controlled, parallel-group trial, evaluated 135 participants with severe asthma and peripheral blood eosinophilia (300 eosinophils/mcL during the 12 months prior to study entry or 150 eosinophils/mcL during the optimization phase) despite maintenance oral glucocorticoid treatment (5 mg to 35 mg of prednisone or its equivalent per day). Subjects received either mepolizumab 100 mg or placebo administered subcutaneously every 4 weeks for 20 weeks. The primary efficacy outcome was the percentage reduction in daily oral glucocorticoid dose during weeks 20-24 compared with baseline dose while maintaining control of asthma. The likelihood of a reduction in the glucocorticoid dose was 2.39 times greater in the mepolizumab group (95% CI, 1.25-4.56; p=0.008). The median percentage reduction from baseline in the daily oral glucocorticoid dose was 50% in the mepolizumab group compared with no reduction in the placebo group (p=0.007). Mepolizumab was associated with a decrease in the number of asthma exacerbations (annualized rates were 1.44 per year in the mepolizumab group vs. 2.12 per year in the placebo group; rate ratio, 0.68; 95% CI, 0.47 to 0.99; p=0.04) and improved control of asthma symptoms. The most frequently reported adverse events were headache and nasopharyngitis (both groups). Local injection-site reactions were increased in the mepolizumab 100-mg subcutaneous treatment group compared with placebo.

MENSA, a 32-week phase III, multicenter, randomized, double-blind, double-dummy, placebo-controlled, parallel-group trial, evaluated 576 individuals aged 12 years or older with severe asthma. Participants with severe asthma and markers of eosinophilic airway inflammation (peripheral blood eosinophil count 150/mcL at screening or 300/mcL at some point in the previous year) despite high-dose IHS (with or without systemic glucocorticoids) received either mepolizumab 75 mg intravenously, mepolizumab 100 mg subcutaneously, or placebo every 4 weeks for 32 weeks. Study participants were required to have a FEV1 of less than 80% of the predicted value (in the case of adults) or an FEV1 of less than 90% of the predicted value or a ratio of the FEV1 to the forced vital capacity (FVC) of less than 0.8 (in the case of adolescents under the age of 18 years). The primary outcome was the annualized frequency of clinically significant exacerbations, defined as worsening of asthma that required the treating physician to administer systemic glucocorticoids for at least 3 days, an emergency department visit, or hospitalization. The rate of asthma exacerbations was reduced by 47% (95% CI, 28 to 60) in the intravenous mepolizumab group compared with placebo and by 53% (95% CI, 36 to 65) in the subcutaneous mepolizumab group compared with placebo (p<0.001 for both comparisons). At week 32, the mean increase in FEV1 from baseline was reported as 100 mL greater with intravenous mepolizumab compared with placebo (p=0.02) and 98 mL greater with subcutaneous mepolizumab compared with placebo (p=0.03). Adverse events during treatment, including nasopharyngitis and headache, were similar across all groups.

Evidence-based practice guidelines or position statements from the American Academy of Allergy, Asthma and Immunology (AAAAI), European Respiratory Society/American Thoracic Society (ERS/ATS), Global Initiative for Chronic Obstructive Lung Disease (GOLD), and National Heart, Lung and Blood Institute (NHLBI) have not been updated to include recommendations surrounding the use of mepolizumab.

A total of 136 subjects with EGPA were evaluated in a randomized, placebo-controlled, multicenter, 52-week trial. Subjects were 18 years of age and older and had been diagnosed with EGPA for at least 6 months based on the history or presence of: asthma plus eosinophilia (>1.0x10^9/Liter and/or >10% of leucocytes) plus at least two of the following additional features of EGPA; a biopsy showing histopathological evidence of eosinophilic vasculitis, or perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation; neuropathy, mono or poly (motor deficit or nerve conduction abnormality); pulmonary infiltrates, non-fixed; sino-nasal abnormality; cardiomyopathy (established by echocardiography or Magnetic Resonance Imaging); glomerulonephritis (hematuria, red cell casts, proteinuria); alveolar hemorrhage (by bronchoalveolar lavage); palpable purpura; anti neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinease 3). Subjects also were required to have a history of relapsing or refractory disease.

Subjects received 300 mg of mepolizumab or placebo administered subcutaneously once every 4 weeks while continuing their stable oral corticosteroid therapy. Starting at Week 4, the oral corticosteroid was tapered during the treatment period at the discretion of the investigator. The co-primary endpoints were the total accrued duration of remission over the 52‑week treatment period, defined as Birmingham Vasculitis Activity Score (BVAS) = 0 (no active vasculitis) plus prednisolone or prednisone dose less than or equal to 4 mg/day, and the proportion of subjects in remission at both Week 36 and Week 48 of treatment. The BVAS is a clinician-completed tool to assess clinically active vasculitis that would likely require treatment, after exclusion of other causes. Mepolizumab compared with placebo significantly increased the proportion of patients achieving remission at both 36 and 48 weeks (32% vs 3%), and at 52 weeks (19% vs 1%)

## POSITION STATEMENT:

**Site of Care**: If mepolizumab (Nucala) is administered in a hospital-affiliated outpatient setting, additional requirements may apply depending on the member's benefit. Refer to 09-J3000-46: Site of Care Policy for Select Specialty Medications.

**Comparative Effectiveness**

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary. This statement applies to Nucala prefilled auto-injectors and syringes.

Initiation of mepolizumab (Nucala) **meets the definition of medical necessity** for members diagnosed with either of the following conditions when ALL associated criteria are met:

1. Severe eosinophilic asthma
    a. Member's diagnosis has been confirmed by **ONE** of the following – laboratory documentation must be provided:

i. Member has a baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids

ii. Member has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids

iii. Member has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids

b. Member has a history of uncontrolled asthma while on asthma control therapy as demonstrated by **ONE** of the following:

i. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months

ii. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months

iii. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered

iv. The member has baseline (prior to therapy with mepolizumab) Forced Expiratory Volume (FEV1) that is less than 80% of predicted

c. **ONE** of the following:

i. The member is **NOT** currently being treated with mepolizumab **AND** is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **AND** has been adherent for 90 days within the past 120 days

ii. The member is currently being treated with the mepolizumab **AND ONE** of the following:

- The member is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **AND** has been adherent for 90 days within the past 120 days
- The member is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **AND** has been adherent for 90 days within the past 120 days

iii. The member has an intolerance or hypersensitivity to inhaled corticosteroid therapy

iv. The member has an FDA labeled contraindication to **ALL** inhaled corticosteroids

d. **ONE** of the following:

i. The member is currently being treated for at least 3 months **AND** has been adherent for 90 days within the past 120 days with **ONE** of the following:

- A long-acting beta-2 agonist (LABA)
- A leukotriene receptor antagonist (LTRA)
- Long-acting muscarinic antagonist (LAMA)
- Theophylline

ii. The member has an intolerance or hypersensitivity to therapy with LABA, LTRA, LAMA, or theophylline

iii. The patient has an FDA labeled contraindication to **ALL** LABA, LTRA, LAMA, **AND** theophylline therapies

e. Member will continue asthma control therapy in combination with mepolizumab

f. Mepolizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), omalizumab (Xolair), or reslizumab (Cinqair)

g. Mepolizumab is prescribed by a board certified (or board eligible) allergist, immunologist, or pulmonologist

h. Dose does not exceed 100 mg every 4 weeks

i. Member is 6 years of age or older

2. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

a. There is information indicating the member's diagnosis was confirmed by **ONE** of the following:

i. Anterior rhinoscopy or endoscopy

ii. Computed tomography (CT) of the sinuses

b. The member has at least **TWO** of the following symptoms consistent with chronic rhinosinusitis (CRS):

i. Nasal discharge (rhinorrhea or post-nasal drainage)

ii. Nasal obstruction or congestion

iii. Loss or decreased sense of smell (hyposmia)

iv. Facial pressure or pain

c. The member has had symptoms consistent with CRS for at least 12 consecutive weeks

d. **ONE** of the following:

i. The member has tried and had an inadequate response to **ONE** intranasal corticosteroid (e.g., fluticasone, Sinuva) after at least a 4-week duration of therapy

ii. The member has an intolerance or hypersensitivity to **ONE** intranasal corticosteroid (e.g., fluticasone, Sinuva)

iii. The member has an FDA labeled contraindication to **ALL** intranasal corticosteroids

e. **BOTH** of the following:

i. The member is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids)

ii. The member will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with mepolizumab

f. Mepolizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), omalizumab (Xolair), or reslizumab (Cinqair)

g. Mepolizumab is prescribed by a board certified (or board eligible) allergist, immunologist, otolaryngologist (ear, nose, and throat specialist), or pulmonologist

h. Dose does not exceed 100 mg every 4 weeks

i. Member is 18 years of age or older

3. Eosinophilic granulomatosis with polyangiitis (EGPA)
    a. Member has relapsing or refractory disease
    b. Member's diagnosis is confirmed by the presence of **ALL** of the following:
        i. Asthma
        ii. Eosinophilia (defined as eosinophils greater than 1,500/mm3 OR greater than 10% of leucocytes) – laboratory documentation must be provided
        iii. Two of the following – documentation from the medical record must be provided:
            - Biopsy showing histopathological evidence of eosinophilic vasculitis, or perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
            - Mononeuropathy or polyneuropathy
            - Nonfixed pulmonary infiltrates
            - Abnormalities of paranasal sinuses
    c. Member's symptoms remain uncontrolled or inadequately controlled despite treatment with oral corticosteroids
    d. Mepolizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), omalizumab (Xolair), or reslizumab (Cinqair)
    e. Mepolizumab is prescribed by a board certified (or board eligible) allergist, immunologist, pulmonologist, or rheumatologist
    f. Dose does not exceed 300 mg every 4 weeks
    g. Member is 18 years of age or older
4. Hypereosinophilic Syndrome (HES)
    a. Member's diagnosis has been confirmed by **ONE** of the following – laboratory documentation must be provided
        a. Member has a peripheral blood eosinophil count greater than 1500 cells/microliter
        b. Member has a percentage of eosinophils in bone marrow section exceeding 20% of all nucleated cells
    b. Member has a history of two or more HES flares within the past 12 months – documentation from the medical record must be provided

c. Secondary (reactive, non-hematologic) causes of eosinophilia have been excluded (e.g., infection, allergy/atopy, medications, collagen vascular disease, metabolic [e.g., adrenal insufficiency], solid tumor/lymphoma)

d. Member has evidence of hypereosinophilia-related organ damage (e.g., fibrosis of lung, heart, digestive tract, skin, etc.; thrombosis with or without thromboembolism; cutaneous erythema, edema/angioedema, ulceration, pruritis, or eczema; peripheral or central neuropathy with chronic or recurrent neurologic deficit; other organ system involvement such as liver, pancreas, kidney) – documentation from the medical record must be provided

e. Member does **NOT** have FIP1L1-PDGFRA-positive disease

f. Member is currently treated with a maximally tolerated oral corticosteroid or has an intolerance, hypersensitivity, or FDA labeled contraindication to oral corticosteroid therapy

g. Member is currently treated with hydroxyura, interferon-a, or another immunosuppressive agent (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** has an intolerance, hypersensitivity, or FDA labeled contraindication to hydroxyurea, interferon-a, and all other immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus)

h. Mepolizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), omalizumab (Xolair), or reslizumab (Cinqair)

i. Mepolizumab is prescribed by a board certified (or board eligible) allergist, hematologist, immunologist, pulmonologist, or rheumatologist

j. Dose does not exceed 300 mg every 4 weeks

k. Member is 12 years of age or older

**Approval duration**: 6 months

Continuation of mepolizumab (Nucala) **meets the definition of medical necessity** for members meeting the following criteria:

1. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years for severe eosinophilic asthma, CRSwNP, EGPA, or HES, OR the member has previously met all indication-specific initiation criteria
2. **ONE** of the following:
    a. Member is currently treated and is compliant with asthma control therapy [e.g, inhaled corticosteroids, ICS/long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline **AND** has a beneficial response to treatment with mepolizumab for severe eosinophilic asthma as demonstrated by at least **ONE** of the following and supported by documentation from the medical record:
        i. The member has had an increase in percent predicted Forced Expiratory Volume (FEV1)

ii. The member has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma

iii. The member has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma

iv. The member has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma

b. Member has a clinical benefit in CRSwNP as evidenced by a reduction in disease severity (e.g., reduction in nasal congestion, nasal polyp size, anterior or posterior rhinorrhea, sinonasal inflammation, facial pressure/pain; improved sese of smell; or reduction in corticosteroid use) – documentation from the medical record must be provided

c. Member achieves remission of EGPA

d. Member has a 50% reduction in HES flares

3. Mepolizumab is prescribed by or in consultation with a board certified (or board eligible) allergist, hematologist, immunologist, otolaryngologist (ear, nose, and throat specialist, pulmonologist, or rheumatologist

4. Mepolizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), omalizumab (Xolair), or reslizumab (Cinqair)

5. Dose does not exceed:

a. Severe eosinophilic asthma: 100 mg every 4 weeks

b. CRSwNP: 100 mg every 4 weeks

c. EGPA: 300 mg every 4 weeks

d. HES: 300 mg every 4 weeks

**Approval duration**: 12 months

## DOSAGE/ADMINISTRATION:

**THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.**

**FDA-approved**

- Asthma:
  - 12 years of age and older: 100 mg administered subcutaneously once every 4 weeks
  - 6 to 11 years of age: 40 mg administered subcutaneously once every 4 weeks
- Chronic Rhinosinusitis with Nasal Polyps
  - 100 mg administered subcutaneously once every 4 weeks
- EGPA: 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks

- HES: 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks

**Dose Adjustments**

- None

**Drug Availability**

- 100 mg of lyophilized powder in a single-dose vial for reconstitution
- 100 mg/mL, single-dose, prefilled autoinjector or single-dose prefilled syringe

## PRECAUTIONS:

**Boxed Warning**

- None

**Contraindications**

- History of hypersensitivity to mepolizumab or excipients in the formulation

**Precautions/Warnings**

- Hypersensitivity reactions (e.g., angioedema, bronchospasm, hypotension, urticaria, rash) have occurred after administration
- Herpes zoster infections have occurred
- Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy
- Treat patients with pre-existing helminth infections before therapy

## BILLING/CODING INFORMATION:

The following codes may be used to describe:

### HCPCS Coding

| | |
|---|---|
| J2182 | Injection, mepolizumab, 1 mg |

### ICD-10 Diagnosis Codes That Support Medical Necessity

| | |
|---|---|
| D72.1 | Eosinophilia |
| J33.0 – J33.9 | Nasal polyp |
| J82 | Pulmonary eosinophilia, not elsewhere classified |
| M30.1 | Polyarteritis with lung involvement [Churg-Strauss] |

## REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Part D:** Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

**Medicare Advantage:** No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date. The Site of Care Policy for Select Specialty Medications does not apply to Medicare Advantage members.

## DEFINITIONS:

**FEV1:**

- Forced expiratory volume in 1 second.

**FVC:**

- Forced vital capacity.

**PEF:**

- Peak expiratory flow.

**Mild Intermittent Asthma:**

- Symptoms < or = to 2 times a week
- Asymptomatic and normal PEF between exacerbations
- Exacerbations brief (from a few hours to a few days); intensity may vary
- Nighttime symptoms < or = to 2 times a month
- FEV1 or PEF > or = to 80% predicted
- PEF variability < 20%.

**Mild Persistent Asthma:**

- Symptoms > 2 times a week but < 1 time a day
- Exacerbations may affect activity
- Nighttime symptoms > 2 times a month
- FEV1 or PEF > or = to 80% predicted
- PEF variability 20 to 30 %.

**Moderate Persistent Asthma:**

- Daily symptoms
- Nighttime symptoms > one time a week

- Daily use of inhaled short-acting beta2-agonist
- Exacerbations may affect activity
- Exacerbations > or = to 2 times a week; may last days
- FEV1 or PEF > 60% but less than 80% predicted
- PEF variability > 30%.

**Severe Persistent Asthma:**

- Continual symptoms (i.e., coughing, dyspnea, wheezing)
- Limited physical activity
- Frequent exacerbations
- Frequent nighttime symptoms
- FEV1 or PEF < or = 60% predicted
- PEF variability > 30%.

## RELATED GUIDELINES:

**Benralizumab (Fasenra), 09-J2000-92**

**Omalizumab (Xolair®), 09-J0000-44**

**Reslizumab (Cinqair®) IV infusion, 09-J2000-63**

## OTHER:

### Table 1 - Low, medium and high ICS doses: adults/adolescents (GINA 2020, Box 3-6A)

| Inhaled Corticosteroid | Total daily ICS dose (mcg) | | |
|---|---|---|---|
| | Low | Medium | High |
| Beclomethasone dipropionate (pMDI, standard particle, HFA) | 200-500 | >500-1000 | >1000 |
| Beclomethasone dipropionate (pMDI, extrafine particle, HFA) | 100-200 | >200-400 | >400 |
| Budesonide (DPI) | 200-400 | >400-800 | >800 |
| Ciclesonide (pMDI, extrafine particle, HFA) | 80-160 | >160-320 | >320 |
| Fluticasone furoate (DPI) | 100 | 100 | 200 |
| Fluticasone propionate (DPI) | 100-250 | >250-500 | >500 |
| Fluticasone propionate (pMDI, standard particle, HFA) | 100-250 | >250-500 | >500 |
| Mometasone furoate (DPI) | 200 | 200 | 400 |
| Mometasone furoate (pMDI, standard particle, HFA) | 200-400 | 200-400 | >400 |
| DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler (non-CFC) | | | |

### Table 2 - Low, medium and high ICS doses: children 6-11 years (GINA 2020, Box 3-6B)

| Inhaled Corticosteroid | Total daily ICS dose (mcg) | | |
|---|---|---|---|
| | Low | Medium | High |

| | | | |
|---|---|---|---|
| Beclomethasone dipropionate (pMDI, standard particle, HFA) | 100-200 | >200-400 | >400 |
| Beclomethasone dipropionate (pMDI, extrafine particle, HFA) | 50-100 | >100-200 | >200 |
| Budesonide (DPI) | 100-200 | >200-400 | >400 |
| Budesonide (nebules) | 250-500 | >500-1000 | >1000 |
| Ciclesonide (pMDI, extrafine particle, HFA) | 80 | >80-160 | >160 |
| Fluticasone furoate (DPI) | 50 | 50 | N/A |
| Fluticasone propionate (DPI) | 50-100 | >100-200 | >200 |
| Fluticasone propionate (pMDI, standard particle, HFA) | 50-100 | >100-200 | >200 |
| Mometasone furoate (pMDI, standard particle, HFA) | 100 | 100 | 200 |
| DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler (non-CFC) | | | |

### Table 3 - Low, medium and high ICS doses: children 5 years and younger (GINA 2020, Box 3-6B)

| Inhaled Corticosteroid | Total daily ICS dose (mcg) | | |
|---|---|---|---|
| | Low | Medium | High |
| Beclomethasone dipropionate (pMDI, standard particle, HFA) | 100-200 | >200-400 | >400 |
| Beclomethasone dipropionate (pMDI, extrafine particle, HFA) | 50-100 | >100-200 | >200 |
| Budesonide (nebules) | 250-500 | >500-1000 | >1000 |
| Ciclesonide (pMDI, extrafine particle, HFA) | N/A | N/A | N/A |
| Fluticasone furoate (DPI) | N/A | N/A | N/A |
| Fluticasone propionate (pMDI, standard particle, HFA) | 100-200 | >200-500 | >500 |
| Mometasone furoate (pMDI, standard particle, HFA) | 100 | 100 | 200 |
| DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler (non-CFC) | | | |

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## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 01/08/25.

## GUIDELINE UPDATE INFORMATION:

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| 03/15/16 | New Medical Coverage Guideline. |
| 04/01/16 | Revision to guideline consisting of adding code C9473. |
| 07/15/16 | Revision to guideline consisting of changes to Position Statement. |
| 01/01/17 | Revision: Added HCPCS code J2182. |
| 02/15/17 | Review and revision to guideline; update references. |
| 02/15/18 | Revision to guideline; consisting of position statement, coding, references. |
| 07/15/18 | Revision to guideline; consisting of position statement. |
| 02/15/19 | Review and revision to guideline; update references. |
| 9/15/19 | Revision to guideline; consisting of description, dosing, references |
| 11/11/19 | Revision to guideline consisting of adding a reference to the Site of Care Policy for Select Specialty Medications and updating the Program Exceptions. |

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| 02/15/20 | Review and revision to guideline; updated position statement, dosing, references. |
| 12/15/20 | Updated Position Statement with new FDA approved indication |
| 02/15/21 | Review and revision to guideline; update references. |
| 02/15/22 | Review and revision to guideline; update position statement, coding, references. |
| 02/15/23 | Review and revision to guideline; update position statement and references. |
| 02/15/24 | Review and revision to guideline; update position statement and references. |
| 02/15/25 | Review and revision to guideline; update position statement and references. |