CLINICAL MEDICAL POLICY	
Policy Name:	Interleukin-5 Inhibitors
Policy Number:	MP-025-MD-PA
Approved By:	Medical Management
Provider Notice Date:	11/1/2016
Original Effective Date:	12/1/2016
Annual Approval Date:	8/7/2017
Revision Date:	NA
Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 6

Disclaimer

Gateway Health℠'s (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

http://gatewayhealthplan.com/MedicalPolicies

POLICY STATEMENT:

Gateway Health℠ provides coverage under the medical benefits of the Company's Medicaid products for medically necessary Interleukin-5 Inhibitors.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrants individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS:

Prior Authorization Review Panel – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

FEV1 – Forced expiratory volume in 1 second.

FVC – Forced vital capacity.

PEF – Peak expiratory flow.

Mild Intermittent Asthma – defined as:

- Symptoms ≤ 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 ≤ 2 times a month
- FEV1 or PEF ≥ 80% predicted
- PEF variability < 20%

Mild Persistent Asthma – defined as:

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

Moderate Persistent Asthma – defined as:

- Daily symptoms
- Nighttime symptoms > 1 time a week
- Daily use of inhaled short-acting beta2-agonist
- Exacerbations may affect activity
- Exacerbations ≥ 2 times a week; may last days
- FEV1 or PEF > 60% but less than 80% predicted
- PEF variability > 30%

Severe Persistent Asthma – defined as:

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

PROCEDURES:

This medical policy addresses two specific medications: Nucala® (mepolizumab) and CINQAIR® (reslizumab).

1. Coverage will be provided for Interleukin-5 Inhibitor drugs when the following medical necessity criteria listed are met:
   a. The patient is at least 12 years of age for Nucala® OR the patient is at least 18 years of age for CINQAIR®; AND
   b. The medication is being prescribed by, or in consultation with, a pulmonologist, allergist or immunologist; AND
   c. The patient has a confirmed diagnosis of asthma consistent with all of the following:

1) The medical history and physical exam findings are consistent with a diagnosis of asthma per the most recent Global Initiative for Asthma (GINA) or the National Heart, Lung, and Blood Institute (NHLBI) guidelines for the diagnosis and management of asthma; AND
2) Spirometry shows obstruction; AND
3) Evidence of reversibility demonstrated by either an increase in the FEV1 of ≥ 12% from baseline or by an increase of ≥ 10% of predicted FEV1 after inhalation of a short-acting bronchodilator;

AND

d. The patient's asthma is classified as severe and is confirmed by one or more of the following components of severity:
   1) Asthma symptoms such as cough, wheezing or dyspnea that occur throughout the day;
   2) Nighttime awakenings occurring seven times a week;
   3) Use of a rescue inhaler such as a long-acting beta2-agonist several times per day;
   4) FEV1 < 60% of predicted;
   5) FEV1/FVC reduced by 5%

AND

e. The patient has an eosinophilic phenotype consistent with one of the following:
   1) For Nucala®:
      a) Blood eosinophil levels are ≥ 150 cells/mm3 at initiation; OR
      b) Blood eosinophil levels have been ≥ 300 cells/mm3 in the past 12 months

OR

   2) For CINQAIR®
      a) Blood eosinophil levels are ≥ 400 cells/mm3 within the previous 4 weeks (prior treatment with CINQAIR®)

AND

f. Other causes of eosinophilia have been ruled out; AND
g. Symptoms have been uncontrolled AND the patient has been adherent to controller medications, which include an inhaled corticosteroid plus another agent, for ≥ 3 months; OR
h. The patient has experienced ≥ 2 asthma exacerbations in the previous 12 months that required a higher level of care despite adherence to controller medications, which include an inhaled corticosteroid plus another agent: AND
i. Pharmacy claims data must demonstrate consistent fills of at least medium-dosed inhaled corticosteroids (approximately ≥ 440 mcg fluticasone propionate-equivalent [refer to Attachment D]) for the past 3 months; AND
j. The requested medication will be used in conjunction with traditional controller medications (inhaled corticosteroids, long-acting inhaled beta agonists, mast cell stabilizers, leukotriene modifiers); AND
k. The requested medication will not be used in combination with other anti-asthma monoclonal antibodies including Xolair®; AND
l. The patient does not have a current parasitic (helminth) infection; AND
m. Any other criteria relating to the specific agent requested, as follows:
   1) Reslizumab (CINQAIR®)
      a) The dose does not exceed 3 mg/kg intravenously every 4 weeks
   2) Mepolizumab (Nucala®)
      a) The dose does not exceed 100 mg subcutaneously every 4 weeks
      b) Consider administration of varicella vaccination if clinically appropriate due to risk of Herpes Zoster infection

Note: In order to receive continued coverage for these medications, the following information must be documented in the patient's medical record:

a. There is documentation of an up-to-date office visit (e.g., within last 3 months)
b. There is documentation of **one or more** of the following:
    1) Decrease in asthma exacerbations
    2) Decrease in asthma-related hospitalization
    3) Decrease in asthma-related emergency room visits
    4) Decreased requirement for oral and/or inhaled corticosteroid therapy evidenced by chart documentation or pharmacy claims (if appropriate)
    5) A reduction in reported asthma-related symptoms
    6) Documentation of improvement in FEV1 from pretreatment baseline

2. Contraindications
   The safety and efficacy in pediatric individuals younger than 12 years of age have not been established.

3. When Nucala® and CINQAIR® services are not covered
   All other conditions not listed above are considered experimental/investigational. Scientific evidence has not been established to support the use of Interleuken-5 Inhibitors for any other indication.

   When the above criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override the criteria when, in their professional judgement, the requested medication is medically necessary.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for administration of Nucala® or CINQAIR® is outpatient.

6. Governing Bodies Approval
   On November 4, 2015, the U.S. Food and Drug Administration approved mepolizumab (Nucala®) for use with other asthma medicines for the maintenance treatment of asthma in patients aged 12 years and older. Mepolizumab (Nucala®) is approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines.

   Mepolizumab (Nucala®) is administered once every four weeks by subcutaneous injection by a health care professional into the upper arm, thigh, or abdomen. Mepolizumab (Nucala®) is a humanized interleukin-5 antagonist monoclonal antibody produced by recombinant DNA technology in Chinese hamster ovary cells. Mepolizumab reduces severe asthma attacks by reducing the levels of blood eosinophils, a type of white blood cell that contributes to the development of asthma.

   On March 28, 2016, the U.S. Food and Drug Administration approved reslizumab (CINQAIR®) for use with other asthma medicines for the maintenance treatment of asthma in patients aged 18 years and older. Reslizumab (CINQAIR®) is approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines.

Reslizumab (CINQAIR®) is administered once every four weeks by intravenous infusion in a clinical setting prepared to manage anaphylaxis. Reslizumab (CINQAIR®) is a humanized interleukin-5 antagonist monoclonal antibody produced by recombinant DNA technology in murine myeloma non-secreting 0 (NS0) cells. Reslizumab (CINQAIR®) reduces severe asthma attacks by reducing the levels of blood eosinophils, a type of white blood cell that contributes to the development of asthma.

CODING REQUIREMENTS:

Procedure Codes

CPT Code	Description
J3490	Unlisted drugs [when specified as mepolizumab or reslizumab]
J3590	Unclassified biologics [when specified as mepolizumab or reslizumab]
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96401	Chemotherapy administration, subcutaneous or intramuscular
HCPCS	**Description**
C9473	Injection, mepolizumab, 1 mg

Diagnosis Codes

ICD-10 Diagnosis Codes	Description
J45.50	Severe persistent asthma, uncomplicated [add-on maintenance treatment of patients aged 12 years and older]
J45.51	Severe, persistent asthma with (acute) exacerbation [add-on maintenance treatment of patients aged 12 years and older[
J45.52	Severe persistent asthma with status asthmaticus [add-on maintenance treatment of patients aged 12 years and older]
J82	Pulmonary eosinophilia, not elsewhere classified [add-on maintenance treatment of patients aged 12 years and older] [eosinophilic asthma]

REIMBURSEMENT:

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S):

Mepolizumab (Nucala®) Prescribing Information. Accessed on September 13, 2016 from http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125526Orig1s000Lbl.pdf.

American Academy of Allergy Asthma and Immunology (AAAAI). Practice Parameters: Allergy Diagnostic Testing. Available at: http://www.aaaai.org. Accessed on August 25, 2016.

FDA approves Reslizumab (Cinqair) to treat severe asthma [news release]. Silver Spring (MD): U.S. Food and Drug Administration, March 23, 2016. Accessed on April 8, 2016 from: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491980.htm.

Reslizumab (CINQAIR®) Prescribing Information. Accessed on March 28, 2016 from http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761033lbl.pdf.

FDA approves Nucala to treat severe asthma [news release]. Silver Spring (MD): U.S. Food and Drug Administration, November 4, 2015. Accessed on January 7, 2016 from: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm471031.htm.

American Academy of Allergy Asthma and Immunology (AAAAI). Conditions and treatments. Asthma. Available at: http://www.aaaai.org/. Accessed on September 13, 2016.

American Academy of Allergy Asthma and Immunology (AAAAI). AAAAI allergy & asthma medication guide. Available at: http://www.aaaai.org/conditions-and-treatments/treatments/drug-guide/inhaled-corticosteroids.aspx. Accessed on September 13, 2016.