Clinical Policy: Inhaled Agents for Asthma and COPD

Reference Number: HIM.PA.153
Effective Date: 03.01.21
Last Review Date: 02.21
Line of Business: HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following are inhaled agents for asthma and/or chronic obstructive pulmonary disease (COPD) requiring prior authorization:

- Short acting beta-2 agonist (SABA): albuterol (ProAir® Digihaler®), levalbuterol (Xopenex® HFA, Xopenex® inhalation solution)
- Inhaled corticosteroid (ICS): budesonide (Pulmicort Respules®)*, ciclesonide (Alvesco®), fluticasone (Armonair® Digihaler™), mometasone (Asmanex® HFA, Asmanex® Twisthaler®)
- Long acting beta-2 agonist (LABA): arformoterol (Brovana®), formoterol (Perforormist)
- Long acting muscarinic antagonist (LAMA): aclidinium bromide (Tudorza® Pressair®), glycopyrrolate (Seebri™ Neohaler®, Lonhala® Magnair®), revefenacin (Yupelri®)
- Combination ICS/LABA: budesonide/formoterol (Symbicort®)*, fluticasone/salmeterol (Advair Diskus®*, AirDuo® Digihaler™, AirDuo® RespiClick®), mometasone/formoterol (Dulera®)
- Combination LABA/LAMA: aclidnium/formoterol (Duaklir® Pressair®), indacaterol/glycopyrrolate (Utibron™ Neohaler®), tiotropium/olodaterol (Stiolto® Respimat®)
- Combination ICS/LAMA/LABA: budesonide/glycopyrrolate/formoterol (Breztri Aerosphere™)

**Generic agents do not require prior authorization.*

FDA Approved Indication(s)

ProAir Digihaler and Xopenex are indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children (ProAir Digihaler/Xopenex HFA: 4 years of age and older; Xopenex inhalation solution: 6 years of age and older) with reversible obstructive airway disease. ProAir Digihaler is also indicated for the prevention of exercise-induced bronchospasm (EIB) in patients 4 years of age and older.

The other inhaled agents are indicated as follows:

Drug Name	Asthma	COPD
ICS		
Alvesco	X (Age ≥ 12 years)	
Armonair Digihaler	X (Age ≥ 12 years)	
Asmanex HFA	X (Age ≥ 5 years)	
Asmanex Twisthaler	X (Age ≥ 4 years)	
Pulmicort Respules	X (Age 1-8 years)	
LABA		
Brovana		X

Drug Name	Asthma	COPD
Perforomist		X
LAMA		
Lonhala Magnair		X
Seebri Neohaler		X
Tudorza Pressair		X
Yupelri		X
ICS/LABA		
Advair Diskus	X (Age ≥ 4 years)	X
AirDuo Digihaler	X (Age ≥ 12 years)	
AirDuo RespiClick	X (Age ≥ 12 years)	
Dulera	X (Age ≥ 5 years)	
Symbicort	X (Age ≥ 6 years)	X
LABA/LAMA		
Duaklir Pressair		X
Stiolto Respimat		X
Utibron Neohaler		X
ICS/LABA/LAMA		
Breztri Aerosphere		X

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that inhaled agents for asthma and COPD are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Requests for Xopenex HFA/Inhalation Solution (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Presence of cardiac disease;
   b. Member experienced clinically significant adverse effects from albuterol use within the last 90 days;
2. Member does NOT have history of allergy or hypersensitivity to albuterol or levalbuterol;
3. Request does not exceed (a or b):
   a. Xopenex HFA: 2 inhalers per 30 days;
   b. Xopenex inhalation solution: 4 vials per day (12 mL per day).

Approval duration: 6 months

B. Requests for All Other Inhaled Agents for Asthma or Chronic Obstructive Pulmonary Disease (must meet all)**:**

1. Diagnosis of asthma or COPD as FDA-approved for the requested agent (*see FDA Approved Indications section*);
2. Age is one of the following (a or b):

a. Asthma: Appropriate per the prescribing information for the requested agent (*see FDA Approved Indications section*);
b. COPD: ≥ 18 years;

3. Failure of the following formulary agent(s) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:

Requested Agent	Required Step Through Agent(s)
ProAir Digihaler	Two generic albuterol sulfate HFA products, each from a different manufacturer
Pulmicort Respules	Age is between 1 to 8 years or documentation supports inability to use inhaler devices *AND* if request is for brand Pulmicort Respules, medical justification supports inability to use generic Pulmicort Respules (e.g., contraindications to excipients)
All other ICS: Alvesco, Armonair Digihaler, Asmanex HFA, Asmanex Twisthaler	Qvar® RediHaler™ *AND* Pulmicort Flexhaler™ *AND* Arnuity® Ellipta® *AND* Flovent® Diskus®/HFA®
LABA: Brovana, Perforomist	Arcapta® Neohaler® *AND* Serevent® Diskus® *AND* Striverdi® Respimat®, unless request is for a nebulized LABA and documentation supports inability to use inhaler devices
LAMA: Lonhala Magnair, Seebri Neohaler, Tudorza Pressair, Yupelri	Incruse® Ellipta® *AND* Spiriva® Handihaler®/ Respimat®, unless request is for a nebulized LAMA and documentation supports inability to use inhaler devices
Brand Advair Diskus	Medical justification supports inability to use generic fluticasone/salmeterol products (generic Advair Diskus, Wixela™ Inhub™) (e.g., contraindications to excipients)
All other ICS/LABA: AirDuo Digihaler, AirDuo RespiClick, Dulera	Advair HFA® *AND* Breo Ellipta® *AND* Symbicort (brand or generic budesonide/formoterol) *AND* fluticasone/salmeterol (generic Advair Diskus or Wixela Inhub)
LABA/LAMA: Duaklir Pressair, Stiolto Respimat, Utibron Neohaler	Anoro® Ellipta® *AND* Bevespi Aerosphere™
ICS/LABA/LAMA: Breztri Aerosphere	Trelegy™ Ellipta®

4. For requests for an agent with a digital component (e.g., Digihaler products): Medical justification supports necessity of the digital component (i.e., rationale why inhaler usage cannot be tracked manually);
5. Request does not exceed one of the following (a or b):
   a. The health plan quantity limit;
   b. The FDA-approved maximum dose for the relevant indication (see *Section V*).

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. All Requests in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for Xopenex HFA/inhalation solution, albuterol has not been used within the past 3 months as evidenced by pharmacy claims history;
4. If request is for a dose increase, request does not exceed one of the following (a or b):
   a. The health plan quantity limit;
   b. The FDA-approved maximum dose for the relevant indication (see *Section V*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease
EIB: exercise-induced bronchospasm
FDA: Food and Drug Administration
ICS: inhaled corticosteroid
GINA: Global Initiative for Asthma
GOLD: Global Initiative for Chronic Obstructive Lung Disease
LABA: long acting beta-2 agonist
LAMA: long acting muscarinic antagonist
SABA: short acting beta-2 agonist

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Advair HFA	Asthma: 2 inhalations BID (starting dosage is based on asthma severity)	Asthma: 2 inhalations of 230/21 mcg BID
albuterol (ProAir HFA®, Proventil HFA®, Ventolin HFA®)	*Metered-dose inhaler [MDI] (e.g., ProAir HFA)*: 2 puffs every 4 to 6 hours as needed *Nebulization solution:* 2.5 mg via oral inhalation every 6 to 8 hours as needed	*MDI*: 12 puffs/day *Nebulization solution*: 4 doses/day or 10 mg/day Higher maximum dosages for inhalation products have been recommended in National Asthma Education and Prevention Program guidelines for acute exacerbations of asthma.
Anoro Ellipta (umeclidinium/ vilanterol)	COPD: 1 inhalation by mouth QD	COPD: 1 inhalation/day
Arcapta Neohaler (indacaterol)	COPD: 75 mcg inhaled orally QD	COPD: 75 mcg/day
Arnuity Ellipta (fluticasone furoate)	Asthma: ≥ 12 years: 100-200 mcg inhaled QD 5-11 years: 50 mcg inhaled QD	Asthma: ≥ 12 years: 200 mcg/day 5-11 years: 50 mcg/day
Breo Ellipta (fluticasone/ vilanterol)	Asthma: 1 inhalation of 100/25 or 200/25 mcg QD COPD: 1 inhalation of 100/25 mcg QD	Asthma: 200/25 mcg/day COPD: 100/25 mcg/day
Bevespi Aerosphere (glycopyrrolate/ formoterol)	COPD: 2 inhalations BID	COPD: 2 inhalations/day
budesonide/formoterol (Symbicort)	Asthma: 2 inhalations BID COPD: 2 inhalations (160/4.5 mcg) BID	Asthma/COPD: 160/4.5 mcg BID
Flovent Diskus (fluticasone)	Asthma: 1 inhalation BID (starting dosage is based on asthma severity)	Asthma: 2,000 mcg/day
Flovent HFA (fluticasone)	Asthma: 1 inhalation BID	Asthma: 1,760 mcg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
fluticasone/salmeterol (Advair Diskus, Wixela Inhub)	Asthma: 1 inhalation BID (starting dosage is based on asthma severity COPD: 1 inhalation of 250/50 mcg BID	Asthma: 500/50 mcg BID COPD: 250/50 mcg BID
Incruse Ellipta (umeclidinium)	COPD: 1 inhalation (62.5 mcg) QD	COPD: 62.5 mcg/day
Pulmicort Flexhaler (budesonide)	Asthma: Starting dose of 180-360 mcg inhaled BID	Asthma: 720 mcg BID
Qvar RediHaler (beclomethasone)	Asthma: ≥ 12 years: 40 mcg, 80 mcg, 160 mcg, or 320 mcg inhaled BID 4-11 years: 40 mcg or 80 mcg inhaled BID	Asthma: ≥ 12 years: 640 mcg/day 4-11 years: 160 mcg/day
Serevent (salmeterol)	Asthma/COPD: 1 inhalation (50 mcg) BID	Asthma/COPD: 100 mcg/day
Spiriva Handihaler (tiotropium bromide monohydrate)	COPD: 2 inhalations (18 mcg) QD	COPD: 18 mcg/day
Spiriva Respimat (tiotropium bromide monohydrate)	Asthma: 2 inhalations (1.25 mcg) QD COPD: 2 inhalations (2.5 mcg) QD	Asthma: 2.5 mcg/day COPD: 5 mcg/day
Striverdi Respimat (olodaterol)	COPD: 2 inhalations QD	COPD: 5 mcg/day
Trelegy Ellipta (fluticasone/ umeclidinium/ vilanterol)	Asthma: 1 inhalation (100/62.5/26 mcg or 200/62.5/26 mcg) by mouth QD COPD: 1 inhalation (100/62.5/26 mcg) by mouth QD	Asthma: 200/62.5/26 mcg/day COPD: 100/62.5/26 mcg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - All agents: hypersensitivity to any component of the requested agent or the following as additionally specified:
    - Advair Diskus, AirDuo Digihaler/RespiClick, ArmonAir Digihaler, Asmanex Twisthaler, Tudorza Pressair, Trelegy Ellipta: milk proteins
    - Brovana: arformoterol, racemic formoterol
  - Advair Diskus, AirDuo Digihaler/RespiClick, Alvesco, ArmonAir Digihaler, Asmanex HFA/Twisthaler, Dulera, Pulmicort Respules: primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures
  - Brovana, Duaklir Pressair, Stiolto Respimat, Perforomist, Utibron Neohaler: use of a LABA without an ICS in patients with asthma

- Boxed warning(s): none reported

Appendix D: General Information

- Although inhaler devices with a digital component may offer increased convenience with tracking of inhaler usage, there is currently no evidence that this leads to improved clinical outcomes, including safety and effectiveness.
- Per the 2020 Global Initiative for Chronic Obstructive Lung Disease (GOLD) COPD guidelines, combination therapy (LAMA + LABA, ICS + LABA, or ICS + LAMA + LABA) is recommended for Group D patients (i.e., those who are very symptomatic and are at high risk of exacerbation). Selection of which combination to use depends on the individual patient:
  - For those with more severe symptoms, LAMA + LABA may be used.
  - For those with a history of asthma or blood eosinophil counts at least 300 cells/uL, LABA + ICS may be used.
  - For those who are inadequately controlled by dual therapy, triple therapy with ICS + LAMA + LABA may be used.
- Historical management of asthma has involved an as-needed short-acting beta agonist for reliever therapy, with stepwise approach to add on controller maintenance therapies such as inhaled corticosteroids and long-acting beta agonists. In 2019, the Global Initiative for Asthma (GINA) guidelines for asthma management and prevention began recommending that inhaled corticosteroids be initiated as soon as possible after diagnosis of asthma, including use as reliever therapy (to be administered as-needed alongside a short-acting beta agonist).
- Alvesco: Use in pediatric patients < 12 years of age: Two identically designed randomized, double-blind, parallel, placebo-controlled clinical trials of 12-weeks treatment duration were conducted in 1,018 patients aged 4 to 11 years with asthma but efficacy was not established. In addition, one randomized, double-blind, parallel, placebo-controlled clinical trial did not establish efficacy in 992 patients aged 2 to 6 years with asthma.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Advair Diskus	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	500/50 mcg BID
	COPD	1 inhalation of 250/50 mcg BID	250/50 mcg BID
AirDuo Digihaler	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	232/14 mcg BID
AirDuo RespiClick	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	232/14 mcg BID
Alvesco	Asthma	Starting dose for patients who received bronchodilators alone: 80 mcg inhaled BID Starting dose for patients who received inhaled corticosteroids: 80 mcg inhaled BID	320 mcg/day 640 mcg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Starting dose for patients who received oral corticosteroids: 320 mcg inhaled BID	640 mcg/day
ArmonAir Digihaler	Asthma	1 inhalation BID (starting dosage is based on asthma severity)	232 mcg BID
Asmanex HFA	Asthma	2 inhalations BID (starting dosage is based on asthma severity)	800 mcg/day
Asmanex Twisthaler	Asthma	Dose varies based on previous therapy and age: 1 inhalation QD-BID	880 mcg/day
Breztri Aerosphere	COPD	2 inhalations by mouth BID	4 inhalations/day
Brovana	COPD	One 15 mcg/2 mL vial inhaled via nebulizer every 12 hours	30 mcg/day
Duaklir Pressair	COPD	One inhalation by mouth BID	2 inhalations/day
Dulera	Asthma	Age 5 to 11 years: 2 inhalations of 50/5 mcg BID Age ≥ 12 years: 2 inhalations of 100/5 mcg or 200/5 mcg BID (starting dosage is based on asthma severity)	200/5 mcg/day 800/20 mcg/day
Lonhala Magnair	COPD	One 25 mcg vial inhaled via nebulizer BID	50 mcg/day
Perforomist	COPD	One 20 mcg/2 mL vial inhaled via nebulizer every 12 hours	40 mcg/day
ProAir Digihaler	Treatment or prevention of bronchospasm	2 inhalations every 4 to 6 hours	12 inhalations/day
	Prevention of EIB	2 inhalations 15 to 30 minutes before exercise	2 inhalations before exercise
Pulmicort Respules	Asthma	Starting dose for patients who received bronchodilators alone or inhaled corticosteroids: 0.5 mg inhaled per day (0.5 mg QD or 0.25 mg BID; for inhaled corticosteroids, may go up to 0.5 mg BID) Starting dose for patients who received oral corticosteroids: 1 mg inhaled per day (1 mg QD or 0.5 mg BID)	Bronchodilator alone: 0.5 mg/day Inhaled or oral corticosteroid: 1 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
Seebri Neohaler	COPD	One inhalation (15.6 mcg) BID	2 inhalations/day
Stiolto Respimat	COPD	Two inhalations by mouth QD at the same time of day	2 inhalations/day
Symbicort	Asthma	2 inhalations BID (starting dosage is based on asthma severity)	160/4.5 mcg BID
	COPD	2 inhalations (160/4.5 mcg) BID	160/4.5 mcg BID
Tudorza Pressair	COPD	1 inhalation (400 mcg) BID	800 mcg/day
Utibron Neohaler	COPD	Inhalation of the contents of one capsule BID	2 capsules/day
Xopenex HFA	Treatment or prevention of bronchospasm	2 puffs every 4 to 6 hours as needed; in some patients, 1 puff every 4 hours may be sufficient	2 puffs every 4 hours; higher doses may be required acutely during severe exacerbations
Xopenex inhalation solution	Treatment or prevention of bronchospasm	0.31 mg to 1.25 mg inhaled via nebulization 3 times per day, given every 6 to 8 hours	1.25 mg/dose 3 times/day
Yupelri	COPD	One 175 mcg mcg vial inhaled via nebulizer QD	175 mcg/day

VI. Product Availability

Drug Name	Availability
Advair Diskus	Inhalation powder containing fluticasone/salmeterol: 100/50 mcg, 250/50 mcg, 500/50 mcg
AirDuo Digihaler	Inhalation powder: In each actuation: 55/14 contains 55 mcg of fluticasone propionate and 14 mcg of salmeterol; 113/14 contains 113 mcg of fluticasone propionate and 14 mcg of salmeterol; 232/14 contains 232 mcg of fluticasone propionate and 14 mcg of salmeterol (14 mcg). AirDuo Digihaler contains a built-in electronic module
AirDuo RespiClick	Inhalation powder: In each actuation: 55 mcg/14 mcg contains 55 mcg of fluticasone propionate and 14 mcg of salmeterol; 113 mcg/14 mcg contains 113 mcg of fluticasone propionate and 14 mcg of salmeterol; 232 mcg/14 mcg contains 232 mcg of fluticasone propionate and 14 mcg of salmeterol
Alvesco	Inhalation aerosol: 80 mcg/actuation, 160 mcg/actuation
ArmonAir Digihaler	Inhalation powder containing 55 mcg, 113 mcg, or 232 mcg of fluticasone propionate per actuation. ArmonAir Digihaler contains a built-in electronic module
Asmanex HFA	Inhalation aerosol containing 50 mcg, 100 mcg, or 200 mcg of mometasone furoate per actuation

Drug Name	Availability
Asmanex Twisthaler	Inhalation device: 110 mcg/actuation, 220 mcg/actuation
Breztri Aerosphere	Inhalation aerosol: pressurized metered dose inhaler containing a combination of budesonide (160 mcg), glycopyrrolate (9 mcg), and formoterol fumarate (4.8 mcg) per inhalation
Brovana	Inhalation solution (unit-dose vial for nebulization): 15 mcg/2 mL
Duaklir Pressair	Inhalation powder: 30 and 60 metered dose dry powder inhaler metering 400 mcg aclidinium bromide and 12 mcg formoterol fumarate per actuation
Dulera	Inhalation aerosol containing mometasone/formoterol: 50/5 mcg, 100/5 mcg, 200/5 mcg
Lonhala Magnair	Sterile solution for inhalation in a unit-dose vial: 25 mcg/mL
Perforomist	Inhalation solution (unit dose vial for nebulization): 20 mcg/2 mL solution
ProAir Digihaler	Inhalation powder: dry powder inhaler 108 mcg of albuterol sulfate (equivalent to 90 mcg of albuterol base) from the mouthpiece per actuation. The inhaler is supplied for 200 inhalation doses. ProAir Digihaler includes a built-in electronic module
Pulmicort Respules	Inhalation suspension: 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
Seebri Neohaler	Inhalation powder in capsules: 15.6 mcg of glycopyrrolate inhalation powder for use with the Neohaler device
Stiolto Respimat	Inhalation spray: 2.5 mcg tiotropium (equivalent to 3.124 mcg tiotropium bromide monohydrate), and 2.5 mcg olodaterol (equivalent to 2.736 mcg olodaterol hydrochloride) per actuation; two actuations equal one dose
Symbicort	Metered-dose inhaler: budesonide (80 or 160 mcg) and formoterol (4.5 mcg) as an inhalation aerosol
Tudorza Pressair	Inhalation powder in a multi-dose dry powder inhaler: 400 mcg/actuation
Utibron Neohaler	Inhalation powder in capsule, for use with the Neohaler device: 27.5 mcg of indacaterol and 15.6 mcg glycopyrrolate
Xopenex HFA	Inhalation aerosol (15 g pressurized canister containing 200 actuations): 59 mcg of levalbuterol tartrate (equivalent to 45 mcg of levalbuterol free base) per actuation
Xopenex inhalation solution	• Inhalation solution (unit-dose vial for nebulization): 0.31 mg/3 mL, 0.63 mg/3 mL, 1.25 mg/3 mL • Inhalation solution concentrate: 1.25 mg/0.5 mL
Yupelri	Inhalation solution (unit-dose vial for nebulization): 175 mcg/3 mL

VII. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved individual drug policies- CP.PCH.35 Alvesco, CP.PCH.36 Asmanex, HIM.PA.48 Pulmicort Respules, HIM.PA.102 Utibron Neohaler, HIM.PA.150 Breztri Aerosphere, and HIM.PA.151 Duaklir Pressair (all to be retired); added additional agents and revised criteria to reflect SDC CY2021 strategy/prior clinical guidance; added requirement for medical justification for requests for agents with digital component.	10.29.20	02.21
Added option for request to not exceed the health plan quantity limit.	04.23.21	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.