

Pharmacy Medical Necessity Guidelines: Respiratory Inhalers

Effective: February 15, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<p>Fax Numbers: RXUM: 617.673.0988</p>	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Short-Acting Beta-Agonists

- ProAir Digihaler (albuterol) is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease. It is also approved for the prevention of exercise-induced bronchospasm in patients 4 years of age and older. ProAir Digihaler contains a built-in electronic module that detects, records, and stores data on inhaler events for transmission to the mobile application. Use of the mobile application is not required for administration of medication to the patient.
- ProAir RespiClick (albuterol) is indicated for the treatment or prevention of bronchospasm in patients 12 years of age and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 12 years of age and older.
- Xopenex HFA (levalbuterol tartrate) is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.
- Brand name ProAir HFA, brand name Xopenex HFA, ProAir RespiClick, and albuterol nebulizer solution are the preferred short-acting beta-agonists for Tufts Health Together and they are covered without Prior Authorization.**

Inhaled Corticosteroids

- Alvesco (ciclesonide) is indicated for maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older.
- Arnuity Ellipta (fluticasone furoate) is indicated for maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older.
- Asmanex HFA (mometasone furoate) is indicated for maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older.
- Asmanex Twisthaler (mometasone furoate) is indicated for maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. The 110 microgram formulation is indicated for patients 4 through 11 years of age, while the 220 microgram formulation is indicated for patients 12 years of age and older.
- Budesonide inhalation suspension (generic Pulmicort Respules) is indicated for maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.
- Flovent Diskus (fluticasone propionate) is indicated for maintenance of asthma as prophylactic therapy in patients 4 years of age and older.
- Flovent HFA (fluticasone propionate) is indicated for maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older.
- Pulmicort Flexhaler (budesonide) is indicated for maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients six years of age and older.

- Qvar Redihaler (beclomethasone) is indicated for maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older.
- **Asmanex HFA, Asmanex Twisthaler, Flovent Diskus, Flovent HFA, and Pulmicort Flexhaler are the preferred inhaled corticosteroids for Tufts Health Together. Asmanex HFA, Flovent Diskus, Flovent HFA, and Pulmicort Flexhaler are covered without Prior Authorization for all members. Asmanex Twisthaler 110 mcg is covered without PA for members less than 12 years of age while the 220 mcg dose is covered for members 12 years of age and older.**

Inhaled Corticosteroid/Long-Acting Beta-Agonist (ICS/LABA) Inhalers

- Advair HFA (fluticasone propionate/salmeterol) is indicated for treatment of asthma in patients aged 12 years and older.
- Advair Diskus (fluticasone/salmeterol) is indicated for the treatment of asthma in patients 4 years of age and older, as well as for maintenance of treatment in patients with chronic obstructive pulmonary disease (COPD).
- Breo Ellipta (fluticasone furoate/vilanterol) is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with COPD. It is also indicated for once-daily treatment of asthma in patients aged 18 years and older.
- Dulera (mometasone furoate/formoterol fumarate) is indicated for the treatment of asthma in patients 5 years of age and older.
- Fluticasone propionate/salmeterol (generic AirDuo) is indicated for the treatment asthma in patients 12 years of age and older.
- Symbicort (budesonide/formoterol) is indicated for the treatment of asthma in patients 6 years and older. Symbicort (budesonide 160 mcg/formoterol 4.5 mcg) is also indicated for the twice-daily maintenance treatment of airflow obstruction in patients with COPD, including bronchitis and emphysema.
- **Brand name Advair Diskus, Advair HFA, Dulera, and brand name Symbicort are the preferred ICS/LABA inhalers for Tufts Health Together and they are covered without Prior Authorization.**

Anticholinergics

- Atrovent HFA (ipratropium) is indicated for the maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema.
- Incruse Ellipta (umeclidinium) is indicated for the maintenance treatment of patients with COPD.
- Ipratropium nebulizer solution
- Lonhala Magnair (glycopyrrolate) is indicated for long-term, maintenance treatment of airflow obstruction in patients with COPD.
- Seebri Neohaler (glycopyrrolate) is indicated for the long-term, maintenance treatment of airflow obstruction in patients with COPD.
- Spiriva HandiHaler (tiotropium bromide) is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with COPD, and for reducing COPD exacerbations.
- Spiriva Respimat (tiotropium bromide) 1.25 mcg is indicated for the long-term, once-daily, maintenance treatment of asthma in patients 6 years of age and older. The 2.5 mcg strength is indicated for long-term, once-daily maintenance treatment of COPD, and for reducing COPD exacerbations.
- Tudorza Pressair (aclidinium) is indicated for the maintenance treatment of patients with COPD.
- Yupelri (revefenacin) is indicated for the maintenance treatment of patients with COPD.
- **Atrovent HFA, Incruse Ellipta, ipratropium nebulization solution, Seebri Neohaler, Spiriva HandiHaler, Spiriva Respimat, and Tudorza Pressair are the preferred respiratory anticholinergics for Tufts Health Together and they are covered without Prior Authorization.**

Anticholinergic/Long-Acting Beta-Agonist

- Anoro Ellipta (umeclidinium/vilanterol) is indicated for maintenance treatment of COPD.

Medication Name	Coverage
Short-Acting Beta-Agonists	
Albuterol nebulization solution	Covered
ProAir HFA (albuterol sulfate)	Covered;BP
ProAir RespiClick (albuterol sulfate)	Covered
Xopenex HFA (levalbuterol tartrate)	Covered;BP

Albuterol HFA (generic Ventolin HFA, generic Proventil HFA)	PA
Levalbuterol nebulization solution	PA
ProAir Digihaler (albuterol sulfate)	PA
Long-Acting Beta-Agonists	
Striverdi Respimat (olodaterol)	Covered
Arcapta Neohaler (indacaterol)	Not Covered
Serevent Diskus (salmeterol)	Not Covered
Inhaled Corticosteroids	
Asmanex HFA (mometasone)	Covered
Asmanex Twisthaler (mometasone) 110 mcg	< 12 years old: Covered ≥ 12 years old: PA
Asmanex Twishaler (mometasone) 220 mcg	< 12 years old: PA ≥ 12 years old: Covered
Flovent Diskus (fluticasone propionate)	Covered
Flovent HFA (fluticasone propionate)	Covered
Pulmicort Flexhaler (budesonide)	Covered
Alvesco (ciclesonide)	PA
Arnuity Ellipta (fluticasone furoate)	PA
Budesonide inhalation suspension	< 13 years of age: Covered ≥ 13 years of age: PA
Qvar Redihaler (beclomethasone)	PA
Inhaled Corticosteroid/Long-Acting Beta-Agonist Combination Inhalers	
Advair Diskus (fluticasone/salmeterol)	Covered;BP
Advair HFA (fluticasone/salmeterol)	Covered
Dulera (mometasone/formoterol)	Covered
Symbicort (budesonide/formoterol)	Covered;BP
Breo Ellipta (fluticasone/vilanterol)	PA;QL
Fluticasone/salmeterol inhalation powder (generic AirDuo RespiClick)	PA;QL
Anticholinergic Inhalers	
Atrovent HFA (ipratropium)	Covered
Incruse Ellipta (umeclidinium)	Covered
Ipratropium nebulization solution	Covered
Seebri Neohaler (glycopyrrolate)	Covered
Spiriva HandiHaler (tiotropium bromide)	Covered
Spiriva Respimat (tiotropium bromide)	Covered
Tudorza Pressair (aclidinium)	Covered
Lonhala Magnair (glycopyrrolate inhalation solution)	PA;QL
Yupelri (revefenacin inhalation solution)	PA;QL

BP = Brand Preferred; PA = Prior Authorization; QL = Quantity Limit

COVERAGE GUIDELINES

The plan may authorize coverage of a nonpreferred respiratory inhaler for Members when the following criteria for a particular regimen are met and limitations do not apply:

Short-Acting Beta-Agonists

Albuterol HFA (generic Proventil HFA)

1. The Member has a diagnosis of asthma, chronic obstructive pulmonary disease (COPD), or exercise-induced bronchospasm (EIB)

AND

2. The Member has had an inadequate response, adverse reaction, or contraindication to albuterol inhaler (Proair HFA or Proair RespiClick) (note: pharmacy claims are NOT sufficient)

Albuterol HFA (generic Ventolin HFA)

1. The Member has a diagnosis of asthma, chronic obstructive pulmonary disease (COPD), or exercise-induced bronchospasm (EIB)

AND

2. The Member has had an inadequate response, adverse reaction, or contraindication to albuterol inhaler (Proair HFA, Proair Respiclick, or Proventil HFA) (note: pharmacy claims are NOT sufficient)

Levalbuterol Nebulization Solution

1. The Member has a diagnosis of asthma, chronic obstructive pulmonary disease (COPD), or exercise-induced bronchospasm (EIB)
AND
2. The Member has had an inadequate response, adverse reaction, or contraindication to inhaled albuterol nebulization solution
AND
3. One of the following:
 - a. The Member is less than 13 years of age
OR
 - b. Provider submits clinical rationale for the nebulized solution

ProAir Digihaler

1. The Member has an appropriate diagnosis
AND
2. The Member has one of the following:
 - a. Inadequate response or adverse reaction to **TWO** albuterol inhalers, one of which must be ProAir HFA or ProAir RespiClick (note: pharmacy claims are NOT sufficient)
OR
 - b. Contraindication to **ALL** albuterol inhalers

Inhaled Corticosteroids

Alvesco (ciclesonide), Arnuity Ellipta (fluticasone furoate), Qvar RediHaler (beclomethasone)

1. The Member has a diagnosis of asthma
AND
2. The Member meets **ONE** of the following:
 - a. The Member has had an inadequate response or adverse reaction to **ONE** inhaled corticosteroid that does not require prior authorization (Asmanex HFA, Asmanex Twisthaler, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler) (note: pharmacy claims are NOT sufficient)
OR
 - b. The Member has a contraindication to **ALL** inhaled corticosteroids that do not require prior authorization (Asmanex HFA, Asmanex Twisthaler, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler)

Asmanex Twisthaler (mometasone furoate) 110 mcg for members ≥ 12 years old

1. The Member has a diagnosis of asthma
AND
2. The prescriber provides a clinical rationale for the use of 110 microgram strength in members 12 years of age or older

Asmanex Twisthaler (mometasone furoate) 220 mcg for members < 12 years old

1. The Member has a diagnosis of asthma
AND
2. The prescriber provides a clinical rationale for the use of 220 microgram strength in members less than 12 years of age

Budesonide Inhalation Suspension (generic Pulmicort Respules) (note: covered within QL for members 0 through 12 years of age)

1. The Member has a diagnosis of asthma
AND
2. The Member meets ONE of the following:
 - a. The Member has a claim for a nebulized respiratory product and no claims for inhalers within the last month
OR
 - b. There is a clinical rationale for nebulized formulation

Inhaled Corticosteroid/Long-Acting Beta-Agonist Inhalers
Breo Ellipta (fluticasone furoate/salmeterol)

For the diagnosis of asthma:

1. The Member has a diagnosis of asthma
AND
2. The Member is 18 years of age or older
AND
3. The Member meets **ONE** of the following:
 - a. The Member has had an inadequate response or adverse reaction to Advair (fluticasone/salmeterol inhalation aerosol, powder) or budesonide/formoterol
OR
 - b. The Member has a contraindication to both Advair (fluticasone/salmeterol inhalation aerosol, powder) and budesonide/formoterol

For the diagnosis of COPD:

1. The Member has a diagnosis of chronic obstructive pulmonary disease (COPD)
AND
2. The Member is 18 years of age or older
AND
3. The Member has had an inadequate response, adverse reaction, or contraindication to budesonide/formoterol (Symbicort)

Fluticasone/Salmeterol Inhalation Powder (generic AirDuo RespiClick)

1. The Member has a diagnosis of asthma
AND
2. The Member has **ONE** of the following:
 - a. The Member has had an inadequate response or adverse reaction to Advair (fluticasone/salmeterol inhalation aerosol, powder) (note: pharmacy claims are not sufficient)
OR
 - b. Clinical rationale for necessity of lower dose of fluticasone/salmeterol
OR
 - c. Member is already receiving another RespiClick formulation

Anticholinergic Inhalers

Lonhala (glycopyrrolate inhalation solution), Yupelri (revefenacin)

1. The Member has a diagnosis of chronic obstructive pulmonary disease (COPD)
AND
2. The Member is 18 years of age or older
AND
3. The Member meets **ONE** of the following:
 - a. The Member has a claim for a nebulized respiratory product and no claims for inhalers within the last month
OR
 - b. Clinical rationale for nebulized formulation
AND
4. The Member has had an inadequate response, adverse reaction or contraindication to ipratropium inhalation nebulizer solution

Anticholinergic/Long-Acting Beta-Agonist Combination Inhalers

Anoro Ellipta (umeclidinium/vilanterol)

1. The Member is diagnosed with chronic obstructive pulmonary disease (COPD)
AND
2. The Member has tried and failed or the provider indicates clinical inappropriateness of therapy with either a long-acting anticholinergic or a long-acting beta-agonist

LIMITATIONS

1. Requests for brand-name products, which have therapeutically equivalent generics, will be reviewed according to the Brand Name criteria. In those instances in which the brand name agent is preferred

over the generic, requests for the generic will be reviewed according to the Brand Name criteria from the perspective that the brand is preferred over the generic.

2. Budesonide inhalation suspension is covered without Prior Authorization for members 0 through 12 years of age.
3. Quantity limits apply as follows:

Medication Name	Quantity Limit
Inhaled Corticosteroid/Long-Acting Beta-Agonist Combination Inhalers	
Breo Ellipta (fluticasone/vilanterol)	1 inhaler/month
Fluticasone/salmeterol inhalation powder (generic AirDuo RespiClick)	1 inhaler/month
Anticholinergic Inhalers	
Lonhala Magnair (glycopyrrolate inhalation solution)	60 mL/month
Yupelri (revefenacin inhalation solution)	90 mL/month

CODES

None

REFERENCES

1. Advair Diskus® (fluticasone propionate/salmeterol) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
2. Advair HFA® (fluticasone propionate/salmeterol) [prescribing information.] Research Triangle Park, NC: GlaxoSmithKline; February 2019.
3. AirDuo RespiClick (fluticasone/salmeterol) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals, LLC; February 2020.
4. Alvesco (ciclesonide) [prescribing information]. Zug, Switzerland: Covis Pharma; April 2019.
5. Anoro Ellipta (umeclidinium/vilanterol) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2020.
6. Arnuity Ellipta (fluticasone furoate) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2020.
7. Asmanex HFA (mometasone furoate) [prescribing information]. Whitehouse Station, NJ: Merck & Co; August 2020.
8. Asmanex Twisthaler (mometasone furoate) [prescribing information]. Whitehouse Station, NJ: Merck & Co; December 2019.
9. Atrovent (ipratropium) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; February 2020.
10. Breo Ellipta (fluticasone/vilanterol) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
11. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA*. 2020;324:2301-2317.
12. Dulera (mometasone furoate/formoterol fumarate) [prescribing information]. Whitehouse Station, NJ: Merck and Co Inc; August 2019.
13. Flovent Diskus (fluticasone propionate) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2020.
14. Flovent HFA (fluticasone propionate) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; April 2020.
15. Global Initiative for Asthma. Global strategy for asthma management and prevention, updated 2020. ginasthma.org/wp-content/uploads/2020/06/GINA-2020-report_20_06_04-1-wms.pdf. Accessed 22 January 2021.
16. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2020 report. Available at: goldcopd.org/wp-content/uploads/2019/12/GOLD-2020-FINAL-ver1.2-03Dec19_WMV.pdf. Accessed March 31, 2020. ProAir RespiClick (albuterol) [prescribing information]. Horsham, PA: Teva Respiratory, LLC; April 2018.
17. ProAir DigiHaler (albuterol) [prescribing information]. Parsippany, NJ: Teva Respiratory LLC; September 2020.
18. Pulmicort Flexhaler (budesonide) [prescribing information]. Wilmington, DE: AstraZeneca LP; October 2019.

19. Pulmicort Respules (budesonide) [prescribing information]. Wilmington, DE: AstraZeneca LP; October 2019.
20. Qvar Redihaler (beclomethasone) [prescribing information]. Frazer, PA: Teva Respiratory; March 2018.
21. Seebri Neohaler (glycopyrrolate) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; January 2018.
22. Spiriva HandiHaler (tiotropium bromide) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; February 2018.
23. Spiriva Respimat (tiotropium bromide) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; August 2020.
24. Symbicort (budesonide/formoterol fumarate) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2019.
25. Tudorza Pressair (aclidinium bromide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2019.
26. Xopenex HFA (levalbuterol tartrate) inhalation aerosol [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; February 2017.
27. Yupelri (revefenacin) [prescribing information]. Morgantown, WV: Mylan Specialty, LP; May 2019.

APPROVAL HISTORY

January 13, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. March 10, 2015: Added Anoro Ellipta and Breo Ellipta.
2. August 11, 2015: Modified to include ProAir RespiClick; approval duration modified to life of plan.
3. December 8, 2015: Modified to accommodate the diagnosis of asthma for Breo Ellipta.
4. January 1, 2016: Administrative change to rebranded template.
5. November 15, 2016: Reflected generic availability of levalbuterol inhaler. Added "requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria" to the limitations section.
6. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
7. October 18, 2017: Effective 1/1/2018, added approval criteria for Symbicort and Dulera. Updated criteria for Advair and Breo Ellipta. Added generic fluticasone/salmeterol Respiclick as a preferred respiratory inhaler.
8. December 12, 2017: Effective 12/18/17, updated Advair and Breo Ellipta criteria to allow trial and failure with generic fluticasone/salmeterol for the treatment of COPD. Effective 4/1/18, updated Anoro Ellipta criteria to require a trial and failure with Spiriva Respimat or a long-acting beta-agonist (LABA).
9. May 8, 2018: Effective 5/30/18, Symbicort 80/4.5 will be available without restriction for members who are 6 through 11 years of age.
10. December 11, 2018: Effective 12/17/18, updated criteria for Anoro Ellipta to require trial and failure with either a long-acting anticholinergic or a long-acting beta-agonist. Administrative changes made to template.
11. August 13, 2019: Updated MNG to indicate that generic Advair Diskus is covered. Updated criteria for Advair HFA, Breo Ellipta, Dulera, and Symbicort to include generic Advair Diskus as an example of a preferred generic fluticasone/salmeterol formulation. Updated the MNG to reflect that generic Ventolin HFA and generic Proair HFA are preferred.
12. October 15, 2019: Effective 1/1/2020, updated COPD criteria for Advair HFA to remove AirDuo as a trial option and require trial and failure with both Symbicort and generic fluticasone/salmeterol (Advair Diskus). Updated COPD criteria for Symbicort to require trial and failure with generic fluticasone/salmeterol (Advair Diskus). Specified that Proair criteria applies to Proair Respiclick.
13. November 12, 2019: Added criteria for Proair Digihaler to the MNG.
14. April 14, 2020: Effective 4/20/20, removed generic Proventil HFA and levalbuterol HFA from the MNG, as they are now covered. Updated the MNG to reflect that Symbicort is available generically.
15. November 24, 2020: Effective January 1, 2021, added criteria for generic albuterol (Ventolin, Proventil), levalbuterol nebulizer solution, Lonhala, Yupelri, and generic AirDuo Respiclick. Updated criteria for ProAir Digihaler and Breo Ellipta. Removed criteria for Proair RespiClick, generic Advair Diskus, Advair HFA, generic Symbicort, and Dulera. Updated limitations section of the MNG to indicate that requests for generics with preferred brand names will be reviewed according to the Brand Name criteria from the perspective that the brand is preferred over the generic.
16. January 12, 2021: Effective February 1, 2021, updated MNG to indicate that budesonide nebulizer solution is covered without PA for members 0 through 12 years of age.

17. February 9, 2021: Effective February 15, 2021, updated MNG to remove quantity limits for Incruse Ellipta, Seebri Neohaler, Spiriva HandiHaler, Spiriva Respimat, Tudorza Pressair, Advair Diskus, Advair HFA, Symbicort, Dulera, Alvesco, Arnuity Ellipta, Qvar Redihaler, and budesonide nebulizer solution. Updated criteria for budesonide nebulizer to remove requirement that the member is less than 13 years of age, as the agent is covered without PA for members 0-12 years of age.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.