



# Oral Inhalers Step Therapy with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

## POLICY REVIEW CYCLE

**Effective Date**  
03-01-2024

**Date of Origin**  
05-01-2005

## FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
ADVAIR DISKUS®*  (fluticasone propionate and salmeterol)  Inhalation powder	Twice-daily treatment of asthma in patients 4 years of age and older.  Maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD).  <ul style="list-style-type: none"> <li>Limitations of use: not indicated for relief of acute bronchospasm.</li> </ul>		1
Alvesco®  (ciclesonide)  Inhalation aerosol	Maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 12 years of age and older.  <ul style="list-style-type: none"> <li>Limitations of use: not indicated for the relief of acute bronchospasm.</li> </ul>		2
Arnuity Ellipta®  (fluticasone furoate)  Inhalation powder	Maintenance treatment of asthma in adult and pediatric patients aged 5 years and older.  <ul style="list-style-type: none"> <li>Limitations of use: not indicated for the relief of acute bronchospasm.</li> </ul>		3
Asmanex HFA®  (mometasone furoate)  Inhalation aerosol	Maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older.  <ul style="list-style-type: none"> <li>Limitations of use: not indicated for the relief of acute bronchospasm.</li> </ul>		4
Asmanex Twisthaler®  (mometasone furoate)	Maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 4 years of age and older.  <ul style="list-style-type: none"> <li>Limitations of use: not indicated for the relief of acute bronchospasm.</li> </ul>		5

Agent(s)	FDA Indication(s)	Notes	Ref#
Inhalation powder			
Flovent Diskus®  (fluticasone propionate)  Inhalation powder	Maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. <ul style="list-style-type: none"> <li>• Limitations of use: not indicated for the relief of acute bronchospasm.</li> </ul>		6
Flovent HFA®  (fluticasone propionate)  Inhalation aerosol	Maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients aged 4 years and older. <ul style="list-style-type: none"> <li>• Limitations of use: not indicated for the relief of acute bronchospasm.</li> </ul>		7
QVAR RediHaler®  (beclomethasone dipropionate HFA)  Inhalation aerosol	Maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 4 years of age and older. <ul style="list-style-type: none"> <li>• Limitations of use: not indicated for the relief of acute bronchospasm.</li> </ul>		8

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

## CLINICAL RATIONALE

Asthma	<p>Asthma is a respiratory disease of chronic airway inflammation that is characterized by variable symptoms of wheezing, shortness of breath, chest tightness and/or cough, and expiratory airflow due to bronchoconstriction, airway wall thickening, and increased mucus. Asthma affects an estimated 300 million people worldwide of all ages and imposes a substantial burden on patients, their families, the community and on healthcare systems. The long-term goals of asthma management from a clinical perspective are to achieve good symptom control and maintain normal activity levels along with minimizing the risk of asthma-related death, exacerbations, persistent airflow limitation and side-effects. It is also important to determine the patient's own goals regarding their asthma.(9,10)</p> <p>For the best outcomes, inhaled corticosteroid (ICS)-containing treatment should be started as soon as possible after the diagnosis of asthma is made. Current guidelines provide no preference on the specific type of ICS to use and note that recommendations for broad populations will be different compared to individual patients that need to consider their own goals and preferences, characteristics and phenotype, along with practical issues such as cost, adherence, and availability.(9,10)</p>
COPD	<p>Long-term monotherapy with an inhaled corticosteroid (ICS) is not recommended for the treatment of chronic obstructive pulmonary disease (COPD). If there is an indication for an ICS, the preferred combination is long-acting-beta2 agonist (LABA) + long-acting muscarinic antagonist (LAMA) + ICS which can be administered as single or multiple inhaler therapy. If patients with COPD have features of asthma, treatment should always include an ICS. Guidelines do not recommend one type of ICS over another. Guidelines recommend the patient and the prescriber to make the decision</p>

	together based on the patient's abilities, goals, and preferences with an emphasis on adherence to therapy.(11)
Safety	<p>ADV AIR DISKUS is contraindicated in the following:(1)</p> <ul style="list-style-type: none"> <li>• Primary treatment of status asthmaticus or other acute episodes of asthma or COPD where intensive measures are required.</li> <li>• Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone propionate, salmeterol, or any of the excipients.</li> </ul> <p>Alvesco is contraindicated in the following:(2)</p> <ul style="list-style-type: none"> <li>• Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.</li> <li>• Patients with known hypersensitivity to ciclesonide or any of the ingredients of Alvesco. Rare cases of hypersensitivity reactions with manifestations such as angioedema, with swelling of the lips, tongue and pharynx, have been reported.</li> </ul> <p>Arnuity Ellipta is contraindicated in the following:(3)</p> <ul style="list-style-type: none"> <li>• Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.</li> <li>• Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate or any of the excipients.</li> </ul> <p>Asmanex HFA is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.(4)</p> <p>Asmanex Twisthaler is contraindicated in the following:(5)</p> <ul style="list-style-type: none"> <li>• Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.</li> <li>• Patients with known hypersensitivity to milk proteins or any ingredients of Asmanex Twisthalers.</li> </ul> <p>Flovent Diskus is contraindicated in the following:(6)</p> <ul style="list-style-type: none"> <li>• Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.</li> <li>• Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone propionate.</li> </ul> <p>Flovent HFA is contraindicated in the following:(7)</p> <ul style="list-style-type: none"> <li>• Primary treatment of status asthmaticus or acute episodes of asthma requiring intensive measures.</li> <li>• Hypersensitivity to any ingredient.</li> </ul> <p>QVAR RediHaler is contraindicated in the following:(8)</p> <ul style="list-style-type: none"> <li>• Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.</li> <li>• Patients with known hypersensitivity to beclomethasone dipropionate or any of the ingredients in QVAR RediHaler.</li> </ul>

## REFERENCES

Number	Reference
1	ADVAIR DISKUS prescribing information. GlaxoSmithKline. October 2020.
2	Alvesco prescribing information. Covis Pharma. February 2023.
3	Arnuity Ellipta prescribing information. GlaxoSmithKline. March 2023.
4	Asmanex HFA prescribing information. Organon Global Inc. June 2021
5	Asmanex Twisthaler prescribing information. Merck & CO., INC. February 2021.
6	Flovent Diskus prescribing information. GlaxoSmithKline. June 2022.
7	Flovent HFA prescribing information. GlaxoSmithKline. August 2021.
8	QVAR RediHaler prescribing information. Teva Respiratory, LLC. September 2022.
9	Cloutier, M. M., Baptist, A. P., Blake, K. V., Brooks, E. G., Bryant-Stephens, T., DiMango, E., Dixon, A. E., Elward, K. S., Hartert, T., Krishnan, J. A., Lemanske Jr., R. F., Ouellette, D. R., Pace, W. D., Schatz, M., Skolnik, N. S., Stout, J. W., Teach, S. J., Umscheid, C. A., & Walsh, C. G. (2020, December). 2020 Focused updates to the Asthma Management Guidelines. National Heart Lung and Blood Institute (NHLBI). <a href="https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates">https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates</a>
10	Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2023. <a href="http://www.ginasthma.org">www.ginasthma.org</a>
11	Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease, 2023. <a href="https://goldcopd.org">https://goldcopd.org</a>

## POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 100-50 MCG/DOSE	100-50 MCG/ACT	M ; N ; O	O ; Y		
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 250-50 MCG/DOSE	250-50 MCG/ACT	M ; N ; O	O ; Y		
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 500-50 MCG/DOSE	500-50 MCG/ACT	M ; N ; O	O ; Y		
Alvesco	ciclesonide inhal aerosol	160 MCG/ACT ; 80 MCG/ACT	M ; N ; O ; Y	N		
Flovent diskus	fluticasone propionate aer pow ba	100 MCG/ACT ; 100 MCG/BLIST ; 250 MCG/ACT ; 250 MCG/BLIST ; 50 MCG/ACT ; 50 MCG/BLIST	M ; N ; O ; Y	M		
Flovent hfa	fluticasone propionate hfa inhal aer ; fluticasone propionate hfa inhal aereo	110 MCG/ACT ; 220 MCG/ACT ; 44 MCG/ACT	M ; N ; O ; Y	M		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 100-50 MCG/DOSE	100-50 MCG/ACT	1	Inhaler	30	DAYS			
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 250-50 MCG/DOSE	250-50 MCG/ACT	1	Inhaler	30	DAYS			
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 500-50 MCG/DOSE	500-50 MCG/ACT	1	Inhaler	30	DAYS			
Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 115-21 MCG/ACT	115-21 MCG/ACT	1	Inhaler	30	DAYS			
Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 230-21 MCG/ACT	230-21 MCG/ACT	1	Inhaler	30	DAYS			
Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 45-21 MCG/ACT	45-21 MCG/ACT	1	Inhaler	30	DAYS			
Airduo digihaler 113/14	Fluticasone-Salmeterol Aer Powder BA	113-14 MCG/ACT	1	Inhaler	30	DAYS			
Airduo digihaler 232/14	Fluticasone-Salmeterol Aer Powder BA	232-14 MCG/ACT	1	Inhaler	30	DAYS			
Airduo digihaler 55/14	Fluticasone-Salmeterol Aer Powder BA	55-14 MCG/ACT	1	Inhaler	30	DAYS			
Airduo respiclick 113/14	Fluticasone-Salmeterol Aer Powder BA 113-14 MCG/ACT	113-14 MCG/ACT	1	Inhaler	30	DAYS			
Airduo respiclick 232/14	Fluticasone-Salmeterol Aer Powder BA 232-14 MCG/ACT	232-14 MCG/ACT	1	Inhaler	30	DAYS			
Airduo respiclick 55/14	Fluticasone-Salmeterol Aer Powder BA 55-14 MCG/ACT	55-14 MCG/ACT	1	Inhaler	30	DAYS			
Airsupra	albuterol-budesonide inhalation aerosol	90-80 MCG/ACT	3	Inhalers	30	DAYS			
Alvesco	Ciclesonide Inhal Aerosol 160 MCG/ACT	160 MCG/ACT	2	Inhalers	30	DAYS			
Alvesco	Ciclesonide Inhal Aerosol 80 MCG/ACT	80 MCG/ACT	1	Inhaler	30	DAYS			
Anoro ellipta	Umeclidinium-Vilanterol Aero Powd BA 62.5-25 MCG/INH	62.5-25 MCG/ACT	1	Inhaler	30	DAYS			
Armonair digihaler	Fluticasone Propionate Aer Pow BA	55 MCG/ACT	1	Inhaler	30	DAYS			
Armonair digihaler	Fluticasone Propionate Aer Pow BA	113 MCG/ACT	1	Inhaler	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Armonair digihaler	Fluticasone Propionate Aer Pow BA	232 MCG/ACT	1	Inhaler	30	DAYS			
Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 100 MCG/ACT	100 MCG/ACT	1	Inhaler	30	DAYS			
Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 200 MCG/ACT	200 MCG/ACT	1	Inhaler	30	DAYS			
Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 50 MCG/ACT	50 MCG/ACT	1	Inhaler	30	DAYS			
Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 100 MCG/ACT	100 MCG/ACT	1	Inhaler	30	DAYS			
Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 200 MCG/ACT	200 MCG/ACT	1	Inhaler	30	DAYS			
Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 50 MCG/ACT	50 MCG/ACT	1	Inhaler	30	DAYS			
Asmanex twisthaler 120 me ; Asmanex twisthaler 14 met ; Asmanex twisthaler 30 met ; Asmanex twisthaler 60 met	Mometasone Furoate Inhal Powd 220 MCG/INH (Breath Activated)	220 MCG/INH	1	Inhaler	30	DAYS			
Asmanex twisthaler 30 met ; Asmanex twisthaler 7 mete	Mometasone Furoate Inhal Powd 110 MCG/INH (Breath Activated)	110 MCG/INH	1	Inhaler	30	DAYS			
Atrovent hfa	Ipratropium Bromide HFA Inhal Aerosol 17 MCG/ACT	17 MCG/ACT	2	Inhalers	30	DAYS			
Bevespi aerosphere	Glycopyrrolate-Formoterol Fumarate Aerosol 9-4.8 MCG/ACT	9-4.8 MCG/ACT	1	Inhaler	30	DAYS			
Breo ellipta	fluticasone furoate-vilanterol aero powder	50-25 MCG/INH	1	Inhalers	30	DAYS			
Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 100-25 MCG/INH	100-25 MCG/ACT	1	Inhaler	30	DAYS			
Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 200-25 MCG/INH	200-25 MCG/ACT	1	Inhaler	30	DAYS			
Breyna ; Symbicort	Budesonide-Formoterol Fumarate Dihyd Aerosol 160-4.5 MCG/ACT	160-4.5 MCG/ACT	3	Inhalers	30	DAYS			
Breyna ; Symbicort	Budesonide-Formoterol Fumarate Dihyd Aerosol 80-4.5 MCG/ACT	80-4.5 MCG/ACT	3	Inhalers	30	DAYS			
Breztri aerosphere	Budesonide-Glycopyrrolate-Formoterol Aers	160-9-4.8 MCG/ACT	1	Inhaler	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Combivent respimat	Ipratropium-Albuterol Inhal Aerosol Soln 20-100 MCG/ACT	20-100 MCG/ACT	2	Inhalers	30	DAYS			
Duaklir pressair	Acclidinium Br-Formoterol Fum Aero Pow Br Act 400-12 MCG/ACT	400-12 MCG/ACT	1	Inhaler	30	DAYS			
Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 100-5 MCG/ACT	100-5 MCG/ACT	3	Inhalers	30	DAYS			
Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 200-5 MCG/ACT	200-5 MCG/ACT	3	Inhalers	30	DAYS			
Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 50-5 MCG/ACT	50-5 MCG/ACT	3	Inhalers	30	DAYS			
Flovent diskus	Fluticasone Propionate Aer Pow BA 100 MCG/BLISTER	100 MCG/ACT ; 100 MCG/BLISTER	1	Inhaler	30	DAYS			
Flovent diskus	Fluticasone Propionate Aer Pow BA 250 MCG/BLISTER	250 MCG/ACT ; 250 MCG/BLISTER	4	Inhalers	30	DAYS			
Flovent diskus	Fluticasone Propionate Aer Pow BA 50 MCG/BLISTER	50 MCG/ACT ; 50 MCG/BLISTER	1	Inhaler	30	DAYS			
Flovent hfa	Fluticasone Propionate HFA Inhal Aer 110 MCG/ACT (125/Valve)	110 MCG/ACT	1	Inhaler	30	DAYS			
Flovent hfa	Fluticasone Propionate HFA Inhal Aer 220 MCG/ACT (250/Valve)	220 MCG/ACT	2	Inhalers	30	DAYS			
Flovent hfa	Fluticasone Propionate HFA Inhal Aero 44 MCG/ACT (50/Valve)	44 MCG/ACT	1	Inhaler	30	DAYS			
Incruse ellipta	Umeclidinium Br Aero Powd Breath Act 62.5 MCG/INH (Base Eq)	62.5 MCG/INH	1	Inhaler	30	DAYS			
Proair digihaler	Albuterol Sulfate Aer Pow BA	108 MCG/ACT	2	Inhalers	30	DAYS			
Proair hfa ; Proventil hfa ; Ventolin hfa	Albuterol Sulfate Inhal Aero 108 MCG/ACT (90MCG Base Equiv)	108 MCG/ACT	2	Inhalers	30	DAYS			
Proair respiclick	Albuterol Sulfate Aer Pow BA 108 MCG/ACT (90 MCG Base Equiv)	108 MCG/ACT	2	Inhalers	30	DAYS			
Pulmicort flexhaler	Budesonide Inhal Aero Powd 180 MCG/ACT (Breath Activated)	180 MCG/ACT	2	Inhalers	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Pulmicort flexhaler	Budesonide Inhal Aero Powd 90 MCG/ACT (Breath Activated)	90 MCG/ACT	1	Inhaler	30	DAYS			
Qvar redihaler	Beclomethasone Diprop HFA Breath Act Inh Aer 40 MCG/ACT	40 MCG/ACT	1	Inhaler	30	DAYS			
Qvar redihaler	Beclomethasone Diprop HFA Breath Act Inh Aer 80 MCG/ACT	80 MCG/ACT	2	Inhalers	30	DAYS			
Serevent diskus	Salmeterol Xinafoate Aer Pow BA 50 MCG/DOSE (Base Equiv)	50 MCG/DOSE	1	Inhaler	30	DAYS			
Spiriva handihaler	Tiotropium Bromide Monohydrate Inhal Cap 18 MCG (Base Equiv)	18 MCG	30	Capsules	30	DAYS			
Spiriva respimat	Tiotropium Bromide Monohydrate Inhal Aerosol 1.25 MCG/ACT	1.25 MCG/ACT	1	Inhaler	30	DAYS			
Spiriva respimat	Tiotropium Bromide Monohydrate Inhal Aerosol 2.5 MCG/ACT	2.5 MCG/ACT	1	Inhaler	30	DAYS			
Stiolto respimat	Tiotropium Br-Olodaterol Inhal Aero Soln 2.5-2.5 MCG/ACT	2.5-2.5 MCG/ACT	1	Inhaler	30	DAYS			
Striverdi respimat	Olodaterol HCl Inhal Aerosol Soln 2.5 MCG/ACT (Base Equiv)	2.5 MCG/ACT	1	Inhaler	30	DAYS			
Trelegy ellipta	Fluticasone-Umeclidinium-Vilanterol AEPB	200-62.5-25 MCG/ACT	1	Inhaler	30	DAYS			
Trelegy ellipta	Fluticasone-Umeclidinium-Vilanterol AEPB 100-62.5-25 MCG/INH	100-62.5-25 MCG/ACT	1	Inhaler	30	DAYS			
Tudorza pressair	Acclidinium Bromide Aerosol Powd Breath Activated 400 MCG/ACT	400 MCG/ACT	1	Inhaler	30	DAYS			
Xopenex hfa	Levalbuterol Tartrate Inhal Aerosol 45 MCG/ACT (Base Equiv)	45 MCG/ACT	2	Inhalers	30	DAYS			

## CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 100-50 MCG/DOSE	100-50 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 250-50 MCG/DOSE	250-50 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance



Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 500-50 MCG/DOSE	500-50 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Alvesco	ciclesonide inhal aerosol	160 MCG/ACT ; 80 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Flovent diskus	fluticasone propionate aer pow ba	100 MCG/ACT ; 100 MCG/BLIST ; 250 MCG/ACT ; 250 MCG/BLIST ; 50 MCG/ACT ; 50 MCG/BLIST	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Flovent hfa	fluticasone propionate hfa inhal aer ; fluticasone propionate hfa inhal aereo	110 MCG/ACT ; 220 MCG/ACT ; 44 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 100-50 MCG/DOSE	100-50 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 250-50 MCG/DOSE	250-50 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Advair diskus ; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 500-50 MCG/DOSE	500-50 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 115-21 MCG/ACT	115-21 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 230-21 MCG/ACT	230-21 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 45-21 MCG/ACT	45-21 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Airduo digihaler 113/14	Fluticasone-Salmeterol Aer Powder BA	113-14 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Airduo digihaler 232/14	Fluticasone-Salmeterol Aer Powder BA	232-14 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Airduo digihaler 55/14	Fluticasone-Salmeterol Aer Powder BA	55-14 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Airduo respiclick 113/14	Fluticasone-Salmeterol Aer Powder BA 113-14 MCG/ACT	113-14 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Airduo respiclick 232/14	Fluticasone-Salmeterol Aer Powder BA 232-14 MCG/ACT	232-14 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Airduo respiclick 55/14	Fluticasone-Salmeterol Aer Powder BA 55-14 MCG/ACT	55-14 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Airsupra	albuterol-budesonide inhalation aerosol	90-80 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Alvesco	Ciclesonide Inhal Aerosol 160 MCG/ACT	160 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Alvesco	Ciclesonide Inhal Aerosol 80 MCG/ACT	80 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Anoro ellipta	Umeclidinium-Vilanterol Aero Powd BA 62.5-25 MCG/INH	62.5-25 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Armonair digihaler	Fluticasone Propionate Aer Pow BA	232 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Armonair digihaler	Fluticasone Propionate Aer Pow BA	113 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Armonair digihaler	Fluticasone Propionate Aer Pow BA	55 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 100 MCG/ACT	100 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 200 MCG/ACT	200 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 50 MCG/ACT	50 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 100 MCG/ACT	100 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 200 MCG/ACT	200 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 50 MCG/ACT	50 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Asmanex twisthaler 120 me ; Asmanex twisthaler 14 met ; Asmanex twisthaler 30 met ; Asmanex twisthaler 60 met	Mometasone Furoate Inhal Powd 220 MCG/INH (Breath Activated)	220 MCG/INH	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Asmanex twisthaler 30 met ; Asmanex twisthaler 7 mete	Mometasone Furoate Inhal Powd 110 MCG/INH (Breath Activated)	110 MCG/INH	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Atrovent hfa	Ipratropium Bromide HFA Inhal Aerosol 17 MCG/ACT	17 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Bevespi aerosphere	Glycopyrrolate-Formoterol Fumarate Aerosol 9-4.8 MCG/ACT	9-4.8 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Breo ellipta	fluticasone furoate-vilanterol aero powd ba	50-25 MCG/INH	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 100-25 MCG/INH	100-25 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 200-25 MCG/INH	200-25 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Breyna ; Symbicort	Budesonide-Formoterol Fumarate Dihyd Aerosol 160-4.5 MCG/ACT	160-4.5 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Breyna ; Symbicort	Budesonide-Formoterol Fumarate Dihyd Aerosol 80-4.5 MCG/ACT	80-4.5 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Breztri aerosphere	Budesonide-Glycopyrrolate-Formoterol Aers	160-9-4.8 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Combivent respimat	Ipratropium-Albuterol Inhal Aerosol Soln 20-100 MCG/ACT	20-100 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Duaklir pressair	Acidinium Br-Formoterol Fum Aero Pow Br Act 400-12 MCG/ACT	400-12 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 100-5 MCG/ACT	100-5 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 200-5 MCG/ACT	200-5 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 50-5 MCG/ACT	50-5 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Flovent diskus	Fluticasone Propionate Aer Pow BA 100 MCG/BLISTER	100 MCG/ACT ; 100 MCG/BLIST	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Flovent diskus	Fluticasone Propionate Aer Pow BA 250 MCG/BLISTER	250 MCG/ACT ; 250 MCG/BLIST	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Flovent diskus	Fluticasone Propionate Aer Pow BA 50 MCG/BLISTER	50 MCG/ACT ; 50 MCG/BLIST	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Flovent hfa	Fluticasone Propionate HFA Inhal Aer 110 MCG/ACT (125/Valve)	110 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Flovent hfa	Fluticasone Propionate HFA Inhal Aer 220 MCG/ACT (250/Valve)	220 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Flovent hfa	Fluticasone Propionate HFA Inhal Aero 44 MCG/ACT (50/Valve)	44 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Incruse ellipta	Umeclidinium Br Aero Powd Breath Act 62.5 MCG/INH (Base Eq)	62.5 MCG/INH	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Proair digihaler	Albuterol Sulfate Aer Pow BA	108 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Proair hfa ; Proventil hfa ; Ventolin hfa	Albuterol Sulfate Inhal Aero 108 MCG/ACT (90MCG Base Equiv)	108 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Proair respiclick	Albuterol Sulfate Aer Pow BA 108 MCG/ACT (90 MCG Base Equiv)	108 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Pulmicort flexhaler	Budesonide Inhal Aero Powd 180 MCG/ACT (Breath Activated)	180 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Pulmicort flexhaler	Budesonide Inhal Aero Powd 90 MCG/ACT (Breath Activated)	90 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Qvar redihaler	Beclomethasone Diprop HFA Breath Act Inh Aer 40 MCG/ACT	40 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Qvar redihaler	Beclomethasone Diprop HFA Breath Act Inh Aer 80 MCG/ACT	80 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Serevent diskus	Salmeterol Xinafoate Aer Pow BA 50 MCG/DOSE (Base Equiv)	50 MCG/DOSE	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Spiriva handihaler	Tiotropium Bromide Monohydrate Inhal Cap 18 MCG (Base Equiv)	18 MCG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Spiriva respimat	Tiotropium Bromide Monohydrate Inhal Aerosol 1.25 MCG/ACT	1.25 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Spiriva respimat	Tiotropium Bromide Monohydrate Inhal Aerosol 2.5 MCG/ACT	2.5 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Stiolto respimat	Tiotropium Br-Olodaterol Inhal Aero Soln 2.5-2.5 MCG/ACT	2.5-2.5 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Striverdi respimat	Olodaterol HCl Inhal Aerosol Soln 2.5 MCG/ACT (Base Equiv)	2.5 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Trelegy ellipta	Fluticasone-Umeclidinium-Vilanterol AEPB	200-62.5-25 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Trelegy ellipta	Fluticasone-Umeclidinium-Vilanterol AEPB 100-62.5-25 MCG/INH	100-62.5-25 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Tudorza pressair	Acclidinium Bromide Aerosol Powd Breath Activated 400 MCG/ACT	400 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xopenex hfa	Levalbuterol Tartrate Inhal Aerosol 45 MCG/ACT (Base Equiv)	45 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

## STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval	
Advair Diskus	<b>TARGET AGENT(S)</b>	<b>PREREQUISITE AGENT(S)</b>
	Advair Diskus*	fluticasone propionate-salmeterol aerosol powder generic
*generic available		
<p><b>Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>The patient's medication history include ONE prerequisite agent as indicated by: <ol style="list-style-type: none"> <li>Evidence of a paid claim(s) <b>OR</b></li> <li>The prescriber has stated that the patient has tried ONE prerequisite agent AND ONE prerequisite agent was discontinued due to lack of effectiveness or an adverse event <b>OR</b></li> </ol> </li> <li>The patient is currently being treated with the requested agent as indicated by ALL of the following:</li> </ol>		

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> <li>A. A statement by the prescriber that the patient is currently taking the requested agent <b>AND</b></li> <li>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent <b>AND</b></li> <li>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm <b>OR</b></li> </ul> <p>3. The prescriber has provided documentation that ALL prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm</p> <p><b>Length of Approval:</b> 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.</p>

Alvesco, Flovent/fluticasone	<b>TARGET AGENT(S)</b>	<b>PREREQUISITE AGENT(S)</b>	<b>REQUIRED NUMBER OF PREREQUISITES AND LOOK BACK TIMEFRAME</b>
	Alvesco Flovent Diskus Flovent HFA Fluticasone propionate aerosol inhalation	Arnuity Ellipta Asmanex HFA Asmanex Twisthaler Qvar HFA	1 prerequisite within the past 90 days
<p><b>Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ul style="list-style-type: none"> <li>1. The patient’s medication history include ONE prerequisite agent as indicated by: <ul style="list-style-type: none"> <li>A. Evidence of a paid claim(s) <b>OR</b></li> <li>B. The prescriber has stated that the patient has tried ONE prerequisite agent AND ONE prerequisite agent was discontinued due to lack of effectiveness or an adverse event <b>OR</b></li> </ul> </li> <li>2. The patient is currently being treated with the requested agent as indicated by ALL of the following: <ul style="list-style-type: none"> <li>A. A statement by the prescriber that the patient is currently taking the requested agent <b>AND</b></li> <li>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent <b>AND</b></li> <li>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm <b>OR</b></li> </ul> </li> <li>3. The prescriber has provided documentation that ALL prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm</li> </ul> <p><b>Length of Approval:</b> 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.</p>			

### QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	<p><b>Quantity limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ul style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ul style="list-style-type: none"> <li>A. BOTH of the following: <ul style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> </ul> </li> </ul> </li> </ul>

Module	Clinical Criteria for Approval
	<p data-bbox="469 180 1409 268">2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit <b>OR</b></p> <p data-bbox="354 268 695 296">B. BOTH of the following:</p> <ol data-bbox="469 296 1409 415" style="list-style-type: none"> <li data-bbox="469 296 1409 352">1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li data-bbox="469 352 1409 415">2. Information has been provided to support therapy with a higher dose for the requested indication</li> </ol> <p data-bbox="232 449 708 478"><b>Length of Approval:</b> up to 12 months</p>