Formulary Medical Necessity Program

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization. The intent of this Formulary Medical Necessity program is to confirm the appropriate coverage of the target drugs when evidence is provided documenting a trial and failure of the preferred formulary alternatives or a clinical reason such as expected adverse reaction or contraindication that prevents the patient from trying the formulary alternatives. These criteria apply to all medications subject to formulary medical necessity not otherwise managed through drug specific criteria.

POLICY

Criteria for Initial Approval

I. Alvesco, ArmonAir, Flovent, and Pulmicort Flexhaler may be considered **medically necessary** when the following criteria are met:
   - The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
   - The patient tried and had an inadequate treatment response or intolerance to **BOTH** formulary alternatives Asmanex **AND** QVar at optimal therapeutic dosages; **OR**
   - The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying BOTH of the formulary alternatives Asmanex **AND** QVar

Approval will be for **lifetime.**

II. Breztri Aerosphere may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to the formulary alternative Trelegy Ellipta; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying the formulary alternative Trelegy Ellipta

Approval will be for **lifetime.**

III. Humulin R-100, Humulin N, Humulin 70/30, Humalog, Humalog Mix, Lyumjev Admelog and Apidra may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to equivalent formulary alternative(s) (Novolin, Novolog, Fiasp, or Novolog Mix) at optimal therapeutic dosages; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying the equivalent formulary alternative(s) (Novolin, Novolog, Fiasp or Novolog Mix)

Approval will be for **lifetime.**

IV. Invokana and Steglatro may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to **BOTH** formulary alternatives Farxiga **AND** Jardiance at optimal therapeutic dosages; **OR**
  The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying BOTH of the formulary alternatives Farxiga **AND** Jardiance

Approval will be for **lifetime.**

V. Kombiglyze ER, Jentadueto (IR and XR), and Kazano (brand only) may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to formulary alternative Janumet (IR or XR) at optimal therapeutic dosages; **OR**
  The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying the formulary alternative Janumet (IR or XR)

Approval will be for **lifetime.**

VI. Lantus and Semglee may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to **BOTH** formulary alternatives Basaglar and Levemir at optimal therapeutic dosages; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying BOTH of the formulary alternatives Basaglar and Levemir.

Approval will be for **lifetime.**

VII. Toujeo may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to the formulary alternative Tresiba at optimal therapeutic dosages; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying the formulary alternative Tresiba.

VIII. Onglyza, Tradjenta, Nesina (brand only) and Oseni (brand only) may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to formulary alternative Januvia at optimal therapeutic dosages; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying the formulary alternative Januvia

Approval will be for **lifetime.**

IX. Qtern, Steglujan, and generic equivalents may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to formulary alternative Glyxambi at optimal therapeutic dosages; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying formulary alternative Glyxambi

Approval will be for **lifetime.**

X. Pradaxa and Savaysa may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to **BOTH** formulary alternatives, Eliquis and Xarelto, at optimal therapeutic dosages; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying BOTH formulary alternatives, Eliquis **AND** Xarelto

Approval will be for **lifetime.**

XI. AirDuo RespiClick (brand only), AirDuo Digihaler, Budesonide/formoterol fumarate oral inhalation (generic Symbicort), and Dulera may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to the THREE formulary alternatives Advair, Breo Ellipta, **AND** Symbicort (Brand only) at optimal therapeutic dosages; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying the THREE formulary alternatives Advair, Breo Ellipta, **AND** Symbicort (Brand only)

Approval will be for **lifetime.**

XII. Tanzeum, Trulicity, and Adlyxin may be considered **medically necessary** for the treatment of diabetes when all of the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to **ALL** of the formulary alternatives Bydureon or Bydureon BCise **AND** Ozempic **AND** Victoza at optimal therapeutic dosages; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying ALL of the formulary alternatives Bydureon or Bydureon BCise **AND** Ozempic **AND** Victoza

Approval will be for **lifetime.**

XIII. Invokamet (IR or XR) and Segluromet may be considered **medically necessary** when the following criteria are met:
- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to **BOTH** formulary alternatives Xigduo XR **AND** Synjardy (IR or XR) at optimal therapeutic dosages; **OR**

The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying BOTH of the formulary alternatives Xigduo XR **AND** Synjardy (IR or XR)

Approval will be for **lifetime.**

XIV. Cequa and Eysuvis may be considered **medically necessary** when the following criteria are met:

- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to **BOTH** formulary alternatives Restasis **AND** Xiidra at optimal therapeutic dosages; **OR**
  The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying BOTH of the formulary alternatives Restasis **AND** Xiidra

Approval will be for **lifetime.**

XV. Motegrity, Zelnorm, and Pizensy may be considered **medically necessary** when the following criteria are met:

- The requested drug is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines); **AND**
- The patient tried and had an inadequate treatment response or intolerance to **BOTH** formulary alternatives Amitiza **AND** Linzess at optimal therapeutic dosages; **OR**
  The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying BOTH of the formulary alternatives Amitiza **AND** Linzess

Approval will be for **lifetime.**

XVI. Adlyxin, Admelog, AirDuo RespiClick (brand only), AirDuo Digihaler, Alvesco, Apidra, ArmonAir, Breztri Aerosphere, Budesonide/formoterol fumarate inhalation solution (generic Symbicort), Cequa, Dulera, Eysuvis, Flovent, generic albuterol sulfate HFA, Humulin R-100, Humulin N, Humalog, Humalog Mix, Invokana, Invokamet (IR and XR), Jentadueto, Kazano (brand only), Kombiglyze XR, Lantus, Lyumjev, Motegrity, Nesina (brand only), Onglyza, Oseni (brand only), Pizensy, Pradaxa, Proventil HFA, Pulmicort Flexhaler, Qtern, Savaysa, Segluromet, Semglee, Steglatro, Steglujan, Tanzeum, Tradjenta, Toujeo, Trulicity, Ventolin HFA, Zelnorm, and generic equivalents are considered **not medically necessary** for patients who do not meet the criteria set forth above.

<u>Quantity Limits Apply</u>

- Tanzeum 4 pens/28 days
- Trulicity 4 pens/28 days
- Ozempic (0.25mg/dose or 0.5mg/dose) 1 pen/28 days
- Ozempic (1mg/dose) 2 pens/28 days
- Zelnorm 60 tablets/30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable.

REFERENCES

- Advair Diskus. [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
- Advair HFA. [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2019.
- Alvesco. [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc., December 2019.
- AirDuo Respiclick. [prescribing information]. Frazer, PA: Teva Respiratory, LLC; February 2020.
- AirDuo Digihaler (fluticasone/salmeterol) [prescribing information]. Research Frazer, PA: Teva Respiratory LLC; July 2019.
- ArmonAir Digihaler (fluticasone propionate inhalation powder) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA Inc; February 2020.
- Dellon ES; Gonsalves N; Hirano I; Furuta GT; et al. ACG Clinical Guideline: Evidence Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE). Am J Gastroenterol 2013; 108(5):679-692.
- Dulera. [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; August 2019.
- Flovent HFA (fluticasone propionate inhalation aerosol) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
- Flovent Diskus (fluticasone propionate inhalation powder) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019..
- Pulmicort Flexhaler. [prescribing information]. Wilmington, DE: AstraZeneca LP, October 2019.
- Symbicort (budesonide/formoterol) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2019.
- Byetta (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2018.
- Bydureon (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; February 2019.
- Victoza (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; June 2019.
- Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; November 2019
- Tanzeum. [prescribing information]. Wilmington, De: GlaxoSmithKline LLC; December 2017.
- Trulicity. [prescribing information]. Indianapolis, IN: Eli Lilly and Company; January 2019.
- Adlyxin. [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; January 2019.
- Qtern. [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2019.
- Admelog. [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2019.
- Humalog (insulin lispro injection [rDNA origin] solution) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; November 2019.
- Steglatro. [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; November 2019.
- Steglujan. [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2019.
- Segluromet. [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2018.

- Xigduo XR (dapagliflozin/metformin) [prescribing information]. Wilmington, DE: AstraZeneca; October 2019.
- Cequa [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; October 2019.
- Motegrity [prescribing information]. Lexington, MA: Shire US, Inc. December 2019.
- Pizensy [prescribing information]. Braintree, MA: Braintree Laboratories, Inc.; February 2020.
- Zelnorm [package insert]. Louisville, KY: US WorldMeds, LLC; June 2020.
- Pradaxa (dabigatran etexilate) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; July 2020.
- Savaysa (edoxaban) [prescribing information]. Parsippany, NJ: Daiichi Sankyo; April 2020.
- Farxiga (dapagliflozin) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2020.
- Steglatro (ertugliflozin) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme; November 2019.
- ProAir HFA (albuterol) [prescribing information]. Frazer, PA: Teva Respiratory LLC; June 2019.
- ProAir RespiClick (albuterol) [prescribing information]. Horsham, PA: Teva Respiratory; December 2018.
- Proventil HFA (albuterol) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; October 2019.
- Ventolin HFA (albuterol) [prescribing information]. Research Triangle Park, NC GlaxoSmithKline; December 2019.
- Humulin N (human insulin isophane [rDNA origin]) suspension injection [prescribing information]. Indianapolis, IN: Eli Lilly; November 2019.
- Humulin 70/30 (70% human insulin isophane suspension and 30% human insulin injection [rDNA origin] suspension) [prescribing information]. Indianapolis, IN; Eli Lilly and Company; November 2019.
- Humalog Mix 50/50 (50% insulin lispro protamine suspension and 50% insulin lispro injection [rDNA origin] solution) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2019.
- Humalog Mix 75/25 (75% insulin lispro protamine suspension and 25% insulin lispro injection [rDNA origin] suspension) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; November 2019.
- Onglyza (saxagliptin) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; June 2019.
- Nesina (alogliptin) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America Inc; June 2019.
- Oseni (alogliptin and pioglitazone) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc; June 2019.
- Lantus (insulin glargine) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; November 2019.
- Toujeo Solostar (insulin glargine) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; November 2018.
- Lyumjev (insulin lispro-aabc) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; June 2020.
- Breztri Aerosphere (budesonide, glycopyrrolate, and formoterol) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2020.
- Semglee (insulin glargine) [prescribing information]. Morgantown, WV: Mylan Specialty LP; June 2020.
- Eysuvis (loteprednol) [prescribing information]. Watertown, MA: Kala Pharmaceuticals, Inc; October 2020.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.81
Policy Creation: June 2015
Reviewed: January 2021
Revised: January 2021
Current Effective Date: February 23, 2021