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 **12 months.**

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 **12 months.**

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 **12 months.**

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 **12 months.**

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 **12 months.**

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 **12 months.**

VII. Insulin degludec 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 (Brand only) and Toujeo 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 alternatives Tresiba (Brand only) and Toujeo.

Approval will be for **12 months.**

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 **12 months.**

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 **12 months.**

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 **12 months.**

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 **12 months.**

XII. Bydureon, Bydureon BCise, Byetta, Mounjaro 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 Trulicity **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 Ozempic, Trulicity, **AND** Victoza

Approval will be for **12 months.**
*Excludes off-label use for weight management

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 **12 months.**

XIV. Tyrvaya, 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 **12 months.**

XV. Amitiza (brand only), Ibsrela, Motegrity, 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 the formulary alternative Linzess at an optimal therapeutic dosage; **OR**
  The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying the formulary alternative Linzess

Approval will be for **12 months.**

XVI. Auvi-Q 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 alternatives (EpiPen, EpiPen Jr, epinephrine auto-injector, Symjepi) at an optimal therapeutic dosage; **OR**
  The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying the formulary alternatives (EpiPen, EpiPen Jr, epinephrine auto-injector, Symjepi)

Approval will be for **12 months.**

XVII. Adlyxin, Admelog, AirDuo RespiClick (brand only), AirDuo Digihaler, Alvesco, Amitiza (brand only), Apidra, ArmonAir, Auvi-Q, Breztri Aerosphere, Budesonide/formoterol fumarate inhalation solution (generic Symbicort), Bydureon, Bydureon BCise, Byetta, Cequa, Dulera, Eysuvis, Flovent, Humulin R-100, Humulin N, Humalog, Humalog Mix, Ibsrela, Insulin degludec, Invokana, Invokamet (IR and XR), Jentadueto, Kazano (brand only), Kombiglyze XR, Lantus, Lyumjev, Motegrity, Mounjaro, Nesina (brand only), Onglyza, Oseni (brand only), Pizensy, Pradaxa, Pulmicort Flexhaler, Qtern, Savaysa, Segluromet, Semglee, Steglatro, Steglujan, Tradjenta, Tyrvaya, and generic equivalents are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Quantity Limits Apply

- Trulicity – 4 pens/28 days
- Tyrvaya – 2 nasal spray bottles/30 days
- Ozempic – 1 pen/28 days

- Ibsrela – 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

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- Alvesco. [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc., December 2021.
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- AirDuo Digihaler (fluticasone/salmeterol) [prescribing information]. Research Frazer, PA: Teva Respiratory LLC; November 2020.
- ArmonAir Digihaler (fluticasone propionate inhalation powder) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA Inc; June 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; June 2021.
- Flovent HFA (fluticasone propionate inhalation aerosol) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
- Flovent Diskus (fluticasone propionate inhalation powder) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2022.
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- 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.
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- 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.
- Tyrvaya [prescribing information]. Princeton, NJ: Oyster Point Pharma, Inc,; October 2021.

- Pradaxa (dabigatran etexilate) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; July 2020.
- Savaysa (edoxaban) [prescribing information]. Parsippany, NJ: Daiichi Sankyo; April 2020.
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- 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.
- Lyumjev (insulin lispro-aabc) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; June 2020.
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- Auvi-Q (epinephrine) [prescribing information]. Richmond, VA: Kaleo, Inc; September 2019.
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- Insulin Degludec [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; July 2022.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.81
Policy Creation: June 2015
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