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. Proventil HFA, Ventolin HFA, and generic albuterol sulfate HFA 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 ProAir 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 ProAir

Approval will be for lifetime.
II. Aerospan, Alvesco, 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.

III. Humulin R-100, Humulin N, Humulin 70/30, Humalog, Humalog Mix, 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, 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, or Novolog Mix)

Approval will be for lifetime.

IV. Farxiga 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 Invokana 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 Invokana 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 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);
- 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) and Symbicort (brand and generic) 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** Dulera 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** Dulera

**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. Xigduo 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 Invokamet (IR or 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 Invokamet (IR or XR) AND Synjardy (IR or XR)

Approval will be for lifetime.

XIV. Cequa 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. Motegritory and Zelnorm 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. Aerospan, Adlyxin, Admelog, AirDuo RespiClick (brand only), Alvesco, Apida, Cequa, Farxiga, Flovent, generic albuterol sulfate HFA, Humulin R-100, Humulin N, Humalog, Humalog Mix, Jentadueto, Kazano (brand only), Kombiglyze XR, Lantus, Motegritory, Nesina (brand only), Onglyza, Oseni (brand only), Proventil HFA, Pulmicort Flexhaler, Qtern, Savaysa, Segluromet, Steglatro, Steglujan, Symbicort, Tanzeum, Tradjenta, Toujeo, Trulicity, Ventolin HFA, Xigduo XR, Zelnorm, and generic equivalents are considered not medically necessary for patients who do not meet the criteria set forth above.

Quantity Limits Apply
- 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

- AirDuo Respliclick. [prescribing information]. Frazer, PA: Teva Respiratory, LLC; March 2018.
- Flovent Diskus (fluticasone propionate inhalation powder) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
- Pulmicort Flexhaler. [prescribing information]. Wilmington, DE: AstraZeneca LP, July 2010.
- 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.
- Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; November 2019
- Tanzeum. [prescribing information]. Wilmington, De: GlaxoSmithKline LLC; December 2017.
- Segluromet. [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2018.
- Xigduo XR (dapagliflozin/metformin) [prescribing information]. Wilmington, DE: AstraZeneca; October 2019.
- Pradaxa (dabigatran etexilate) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; March 2018.
• Savaysa (edoxaban) [prescribing information]. Parsippany, NJ: Daiichi Sankyo; November 2017.
• Farxiga (dapagliflozin) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.
• 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 RespClick (albuterol) [prescribing information]. Horsham, PA: Teva Respiratory; August 2018.
• Proventil HFA (albuterol) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; July 2018.
• 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.
• Toujeo Solostar (insulin glargine) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; November 2018.

*Some content reprinted from CVSHealth

**POLICY HISTORY**

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