Formulary Medical Necessity Program

**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. 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**.

II. 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.

III. 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.

IV. Kombiglyze ER 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 BOTH formulary alternatives Janumet (IR or XR) AND Jentadueto 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 Janumet (IR or XR) AND Jentadueto

 Approval will be for lifetime.

V. Basaglar, Levemir, and Tresiba 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 Lantus 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 BOTH of the formulary alternatives Lantus AND Toujeo

 Approval will be for lifetime.
VI. Onglyza 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 **BOTH** formulary alternatives Januvia **AND** Tradjenta 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 Januvia **AND** Tradjenta

**Approval** will be for **lifetime**.

VII. Qtern 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**.

VIII. 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**.

IX. AirDuo RespiClick (brand only) and Symbicort 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**.
Approval will be for lifetime.

X. 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 BOTH of the formulary alternatives Bydureon AND Victoza

Approval will be for lifetime.

XI. 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.

XII. Aerospan, Admelog, Alvesco, Apidra, Flovent, Humulin R-100, Humulin N, Humalog, Humalog Mix, Kombiglyze XR, Onglyza, Pulmicort Flexhaler, Savaysa, Segluromet, Steglatro, Symbicort, Tanzeum, Trulicity, 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

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, September 2011.
• Advair HFA. [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline, March 2013.
• AirDuo Respliclick. [prescribing information]. Frazer, PA: Teva Respiratory, LLC; January 2017.
• Flovent Diskus. [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline, September 2011.
• Flovent HFA. [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline, January 2012.
• Pulmicort Flexhaler. [prescribing information]. Wilmington, DE: AstraZeneca LP, July 2010.
• Symbicort. [prescribing information]. Wilmington, DE: AstraZeneca LP, August 2013. U.S. Food and
• Byetta. [prescribing information]. San Diego, CA: Amylin Pharmaceuticals Inc; October. 2011.
• Bydureon. [prescribing information]. West Chester, OH: Amylin Pharmaceuticals Inc; February 2014
• Victoza. [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; April 2013
• Tanzeum. [prescribing information]. Wilmington, De: GlaxoSmithKline LLC; April 2014
• Trulicity. [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2014.
• Admelog. [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2017.
• Steglatro. [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2017.
• Segluromet. [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2017.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.81
Policy Creation: June 2015
Reviewed: April 2018

Wellmark Blue Cross and Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association.

© 2018 Wellmark, Inc.