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. Proventil and Ventolin may be considered medically necessary for 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, 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 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. 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**.

VII. Onglyza, Tradjenta, 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 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**.

VIII. 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**.

IX. 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**.

X. 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**.

XI. 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**.

XII. 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**.

XIII. 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**.
XIV. Aerospan, Admelog, Alvesco, Apidra, Cequa, Flovent, Humulin R-100, Humulin N, Humalog, Humalog Mix, Jentadueto, Kombiglyze XR, Onglyza, Pulmicort Flexhaler, Savaysa, Segluromet, Steglatro, Steglujan, Symbicort, Tanzeum, Tradjenta, 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
- 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
- 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: January 2019
Revised: December 2018
Current Effective Date: February 9, 2019