Formulary Medical Necessity Program

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

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, 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 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. Kazano, 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. Nesina, Onglyza, Oseni, 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. 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.

VIII. 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.

IX. 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 BOTH of the formulary alternatives Bydureon 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.

X. Xigduo XR 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 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

Approval will be for **lifetime**.

XI. Aerospan, Alvesco, Apidra, Flovent, Humulin R-100, Humulin N, Humalog, Humalog Mix, Kombiglyze XR, Kazano, Nesina, Onglyza, Oseni, Pulmicort Flexhaler, Savaysa, 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

**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 HFA.” [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline, January 2012.
• “Symbicort.” [prescribing information]. Wilmington, DE: AstraZeneca LP, August 2013.U.S. Food and
• Bydureon [package insert]. West Chester, OH: Amylin Pharmaceuticals Inc; February 2014
• Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc; April 2013
• Tanzeum [package insert]. Wilmington, De: GlaxoSmithKline LLC; April 2014
• Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2014.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.81
Policy Creation: June 2015
Reviewed: July 2017
Revised: January 2017
Current Effective Date: March 1, 2017