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DRUG POLICY

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, beclomethasone dipropionate, Flovent, fluticasone (generic 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** formulary alternatives, Asmanex **AND** QVar

Approval will be for 12 months.

- II. Advair Diskus (brand only), Advair HFA (brand only), AirDuo RespiClick (brand only), Symbicort (brand only), 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 **ALL THREE** formulary alternatives, Breo Ellipta, budesonide-formoterol (generic Symbicort), **AND** fluticasone-salmeterol (generic Advair), 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 THREE** formulary alternatives, Breo Ellipta, budesonide-formoterol (generic Symbicort), **AND** fluticasone-salmeterol (generic Advair)

Approval will be for 12 months.

- III. Umeclidinium-vilanterol (authorized generic of Anoro Ellipta) 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, Anoro Ellipta at 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, Anoro Ellipta

Approval will be for 12 months.

- IV. Admelog, Apidra, Humalog, Humalog Mix, Humulin 70/30, Humulin N, Humulin R 100, Humulin N, Kirsty, Lyumjev, and Merilog 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 **ALL** the formulary alternatives, Fiasp, 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 **ALL** the formulary alternatives, Fiasp, Novolin, Novolog, or Novolog Mix,

Approval will be for 12 months.

- V. Lantus, Levemir, Rezvoglar, and Semglee (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 **BOTH** formulary alternatives Basaglar **AND** insulin glargine-yfgn 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 Basaglar and insulin glargine-yfgn

Approval will be for 12 months.

VI. Insulin degludec (generic Tresiba) and insulin glargine U-300 (generic 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); **AND**
- The patient tried and had an inadequate treatment response or intolerance to **BOTH** formulary alternatives Tresiba (brand only) **AND** Toujeo (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 **BOTH** formulary alternatives Tresiba (brand only) and Toujeo (brand only)

Approval will be for 12 months.

VII. Brenzavvy and generic equivalents, dapagliflozin (generic Farxiga), Inpefa, 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 (brand only) **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** formulary alternatives Farxiga (brand only) **AND** Jardiance

Approval will be for 12 months.

VIII. Dapagliflozin-Metformin (generic Xigduo XR), 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 (brand only) **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** formulary alternatives Xigduo XR (brand only) **AND** Synjardy (IR or XR)

Approval will be for 12 months.

IX. Brynovin (oral solution), Nesina (brand only), Onglyza and generic equivalents, Oseni (brand only), Tradjenta, and Zituvio 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, alogliptin (generic Nesina) **AND** sitagliptin (generic 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 **BOTH** formulary alternatives, alogliptin (generic Nesina) **AND** sitagliptin (generic Januvia)

Approval will be for 12 months.

X. Jentadueto (IR and XR), Kazano (brand only), Kombiglyze ER and generic equivalents, and Zituvimet (IR and 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 alogliptin-metformin (generic Kazano) **AND** sitagliptin-metformin (generic 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 **BOTH** formulary alternatives alogliptin-metformin (generic Kazano) **AND** sitagliptin-metformin (generic Janumet (IR or XR))

Approval will be for 12 months.

XI. Qtern and Steglujan 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.

XII. Pradaxa (brand only), Savaysa, rivaroxaban (generic Xarelto) oral tablet 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 (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 **BOTH** formulary alternatives, Eliquis **AND** Xarelto (brand only)

Approval will be for 12 months.

XIII. Rivaroxaban (generic Xarelto) oral suspension 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, Xarelto (brand only) oral suspension, 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, Xarelto (brand only) oral suspension

Approval will be for 12 months.

XIV. Amitiza (brand only), Ibsrela, Motegrity (brand only), 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.

XV. Cequa, Cyclosporine ophthalmic emulsion (excludes Brand Restasis), Eysuvis, Miebo, Tryptyr, Tyrvaya, and Vevye 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 (brand only) **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 (brand only) **AND** Xiidra

Approval will be for 12 months.

XVI. Admelog, Advair Diskus (brand only), Advair HFA (brand only), AirDuo RespiClick (brand only), Alvesco, Amitiza (brand only), Apidra, Brenzavvy and generic equivalents, Cequa, Cyclosporine ophthalmic emulsion, Dapagliflozin (generic Farxiga), Dapagliflozin-Metformin (generic Xigduo XR), Dulera, Eysuvis, Flovent, Fluticasone (generic Flovent), Humulin 70/30, Humulin N, Humulin R-100, Humalog, Humalog Mix, Ibsrela, Inpefa, Insulin degludec (generic Tresiba), insulin glargine U-300 (generic Toujeo), Inpefa, Invokana, Invokamet (IR

and XR), Jentaduetto (IR and XR), Kazano (brand only), Kombiglyze ER, Lantus, Levemir, Lyumjev, Merilog, Miebo, Mirabegron (generic Myrbetriq), Motegrity (brand only), Nesina (brand only), Onglyza and generic equivalents, Oseni (brand only), Pizensy, Pradaxa (brand only), Pulmicort Flexhaler, Qtern, Rezvoglar, Savaysa, Segluromet, Semglee (brand only), Steglatro, Steglujan, Symbicort (brand only), Tradjenta, Tryptyr, Tyrvaya, Umeclidinium-vilanterol, Vevye, Zituvio and generic equivalents, and Zituvimet are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Quantity Limits Apply

- Tyrvaya – 2 nasal spray bottles/30 days
- Ibsrela – 60 tablets/30 days
- Brenzavvy – 30 tablets per 30 days
- Inpefa – 30 tablets per 30 days
- Miebo – 12mL per 30 days
- Brynovin – 120 mL per 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.

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- Humulin N (human insulin isophane [rDNA origin]) suspension injection [prescribing information]. Indianapolis, IN: Eli Lilly; November 2019.
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- 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.
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- Miebo (perfluorohexyloctane) [prescribing information]. Bridgewater, NJ: Bausch & Lomb, Inc; May 2023.
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- Xarelto [prescribing information]. Leverkusen, Germany: Bayer HealthCare AG, Inc; June 2025

*Some content reprinted from CVSHealth

POLICY HISTORY

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