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, ArmonAir, Flovent (brand and generic), 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 **12 months.**

II. Breztri Aerosphere 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 Trelegy Ellipta; **OR**
- The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying the formulary alternative Trelegy Ellipta

Approval will be for **12 months.**

III. Humulin R-100, Humulin N, Humulin 70/30, Humalog, Humalog Mix, Lyumjev 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 the formulary alternative(s) (Novolin, Novolog, Fiasp, 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 formulary alternative(s) (Novolin, Novolog, Fiasp or Novolog Mix)

Approval will be for **12 months.**

IV. Brenzavvy, 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 **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 Farxiga **AND** Jardiance

Approval will be for **12 months.**

V. Kombiglyze ER and generic equivalents, 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 **12 months.**

VI. Lantus, Rezvoglar, insulin glargine-yfgn, and Semglee 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 **12 months.**

VII. Insulin degludec 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 Tresiba (Brand only) **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 the formulary alternatives Tresiba (Brand only) and Toujeo.

Approval will be for **12 months.**

VIII. Onglyza and generic equivalents, 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 **12 months.**

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 **12 months.**

X. Pradaxa (brand only) 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 **12 months.**

XI. AirDuo RespiClick (brand only), AirDuo Digihaler, , 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 the THREE formulary alternatives fluticasone-salmeterol (generic Advair), Breo Ellipta, **AND** budesonide/formoterol fumarate oral inhalation (generic Symbicort) 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 fluticasone-salmeterol (generic Advair), Breo Ellipta, **AND** budesonide/formoterol fumarate oral inhalation (generic Symbicort)

Approval will be for **12 months.**

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

Approval will be for **12 months.**

XIII. Cequa, Cyclosporine ophthalmic emulsion (excludes Brand Restasis), Eysuvis, Miebo, 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.**

XIV. Amitiza (brand only), Ibsrela, Motegrity, 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. Admelog, AirDuo RespiClick (brand only), AirDuo Digihaler, Alvesco, Amitiza (brand only), Apidra, ArmonAir, Brenzavvy, Breztri Aerosphere, Cequa, Cyclosporine ophthalmic emulsion, Dulera, Eysuvis, Flovent, Humulin R-100, Humulin N, Humalog, Humalog Mix, Ibsrela, Inpefa, Insulin degludec, insulin glargine-yfgn, Invokana, Invokamet (IR and XR), Jentadueto, Kazano (brand only), Kombiglyze XR, Lantus, Lyumjev, Miebo, Motegrity, Nesina (brand only), Onglyza, Oseni (brand only), Pizensy, Pradaxa (brand only), Pulmicort Flexhaler, Qtern, Rezvoglar, Savaysa, Segluromet, Semglee, Steglatro, Steglujan, Tradjenta, Tyrvaya, Vevye, and generic equivalents are considered **not medically necessary** for patients who do not meet the criteria set forth above.

<u>Quantity Limits Apply</u>
- 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

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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POLICY HISTORY

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