

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

U-500 concentrated insulin [human] 500 unit/mL pen (Humulin R U-500 Concentrated Kwikpen)

Notes:

- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- # For patients aged 18-64, recommend A1c goal of < 7.0% unless significant co-morbidities (history of dementia, blindness, lower extremity amputation, CKD 4/5, ESRD, cardiomyopathy/HF, or ASCVD). For patients aged 65 or older, consider A1c goal of < 8.0%
- GMI = Glucose Management Indicator, an estimated A1c level based on continuous glucose monitoring data

Initiation (new start) criteria: Formulary **U-500 concentrated insulin [human] 500 unit/mL pen (Humulin R U-500 Concentrated Kwikpen)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Diagnosis of diabetes mellitus
- On maximally tolerated metformin dose or intolerance* or contraindication to metformin XR
- On a SGLT2 inhibitor (e.g. Jardiance) or intolerance or contraindication to SGLT2 inhibitors
 - SGLT2 inhibitor not required for patients diagnosed with type 1 diabetes
- On a GLP-1 agonist (e.g. liraglutide or semaglutide) or intolerance or contraindication to GLP-1 agonist
 - GLP-1 agonist not required for patients diagnosed with type 1 diabetes
- HbA1c or GMI remains above patient's designated goal# while taking total daily dose (TDD) of insulin greater than or equal to 200 units
- All previous insulin prescriptions have been discontinued

Criteria for members already taking the medication who have not been reviewed previously (e.g., new members): Formulary **U-500 concentrated insulin [human] 500 unit/mL pen (Humulin R U-500 Concentrated Kwikpen)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Diagnosis of diabetes mellitus
- On maximally tolerated metformin dose or intolerance or contraindication to metformin XR
- On SGLT2 inhibitor (e.g. Jardiance) or intolerance or contraindication to SGLT2 inhibitors
 - SGLT2 inhibitor not required for patients diagnosed with type 1 diabetes

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- On GLP-1 agonist (e.g. liraglutide or semaglutide) or intolerance or contraindication to GLP-1 agonists
 - GLP-1 agonist not required for patients diagnosed with type 1 diabetes
- Using total daily dose (TDD) of insulin greater than or equal to 200 units

Continued use criteria for patients stable on the medication: Formulary **U-500 concentrated insulin [human] 500 unit/mL pen (Humulin R U-500 Concentrated Kwikpen)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Using total daily dose (TDD) of insulin greater than or equal to 200 units